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# EXPLORING TRENDS & OPPORTUNITIES IN MEDICAL COMMUNICATION





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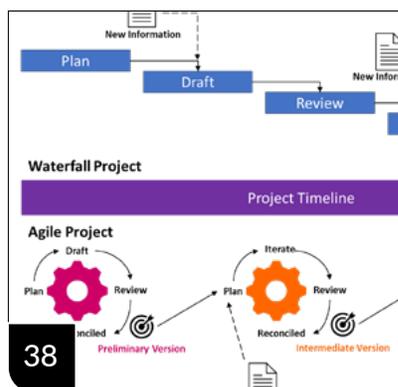
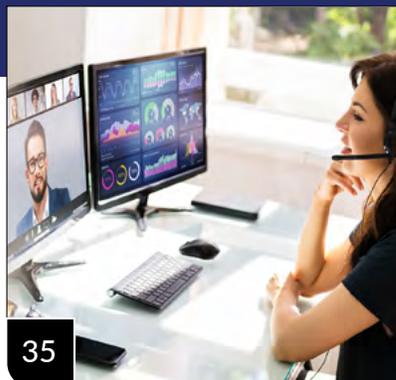
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**SUBSCRIPTION:** The *AMWA Journal* is published quarterly. Subscription is included with AMWA membership. Nonmember subscriptions cost is \$75 per year.

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The *AMWA Journal* is in the MLA International Bibliography and selectively indexed in the Cumulative Index to Nursing and Allied Health Literature (CINAHL) print index and the CINAHL database.

The opinions expressed by authors contributing to the *Journal* do not necessarily reflect the opinions of AMWA or the institutions with which the authors are affiliated. The association accepts no responsibility for the opinions expressed by contributors to the *Journal*.

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ISSN 2163-5315

### AMWA JOURNAL MISSION STATEMENT

In support of the mission of the American Medical Writers Association (AMWA) and to advance the broader profession, the *AMWA Journal* publishes content that reflects the interests, concerns, and expertise of medical communicators. Its purpose is to inform, inspire, and motivate medical communicators.

**FROM THE EDITOR & GUEST EDITOR**

## AMWA Journal on Open Journal Systems



**Michael G Baker, PhD**  
Editor-in-Chief

We hope you share our excitement that the *American Medical Writers Association (AMWA) Journal* has gone digital on the Open Journal Systems (OJS) platform. OJS is cloud hosted, community-led open-source software that allows us to provide the journal in an enhanced format, with features that include

- direct access to subscriber-only content via your AMWA member login,
- easy indexing and discoverability, as recommended by Google Scholar,
- article abstracts in HTML format, which is ideal for search engine crawlers (keywords), and
- DOI indexing (forthcoming).

A full PDF version each issue of the *AMWA Journal* will continue to be available to you via download from the *AMWA Journal* site on OJS. Archive issues will be debuted on the site as we continue to build up our presence online.

Our initial online issue is dedicated to exploring trends and opportunities in medical communication, the theme of the 2021 AMWA Annual Conference. Our transition to a digital platform is in keeping with trends in our field, with other medical communication trends to be explored in future theme-based that will be announced on the *AMWA Journal* site. We encourage you to write for the *Journal* on a topic for an upcoming theme or for any of our regular sections.

*AMWA Journal* will continue to bring you great content every quarter and we welcome your input on the digital format.



**Shari Rager, MS, CAE**  
2021-2022 Staff Liaison

CONFERENCE

## 2021 Swanberg Award Tribute Lori L. Alexander, MTPW, ELS, MWC—A Tribute

Compiled by Susan Krug, MS, CAE, and Cynthia L. Kryder, MS, MWC



### ABSTRACT

Lori L. Alexander is the 2021 recipient of American Medical Writers Association’s (AMWA) Harold Swanberg Distinguished Service Award, which is given to an active member who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession. Sadly, Lori lost a brief but courageous battle with cancer in June 2021. In the following pages, you’ll hear from Lori Alexander’s colleagues, friends, and her wife, Deb. We hope you’ll gain insight into who Lori was as a person, her passions, her professional accomplishments, and the immense mark she made on the field of medical communication.

Lori L. Alexander was one of America’s most influential medical communicators. Her work in medical communication, extensive service as a volunteer leader of the American Medical Writers Association (AMWA), experience as an educator within the field, and passion for health literacy and creating clear medical information empowered thousands of medical writers and editors, whose work in turn has touched the lives of millions of people.

Clear communication is essential to scientific research, meaningful patient-physician interactions, and better health outcomes. When the resources produced by medical communicators enable people to better understand their treatment options, it helps them make more informed health care decisions. Medical writers engage in developing the required documentation for clinical trials and approvals of new drugs and medical devices, as well as with writing reports on trial results and implications. Medical writers and editors also help prepare the millions of science, health, and medicine articles published each year.

Lori’s work in medical communication spanned a variety of settings and she was a master at editing, writing, and developing educational resources for health care professionals and lay audiences. She began her medical

communication career as an assistant editor in the editorial department of Lahey Clinical Medical Center and later became a senior copyeditor of the *Journal of Bone and Joint Surgery*. In 1998 Lori became assistant director of the Publications Department of the American Society of Clinical Oncology (ASCO). In 2004 Lori and Deb founded Editorial Rx, Inc, specializing in medical writing and editing, and publications development and management. In this capacity Lori worked with medical and health-related associations, advocacy groups, research foundations, medical institutions, medical publishers, government agencies, and physician-authors.

Lori’s contribution to the field includes service both within and outside of AMWA. She was also an active member of the Editorial Freelancers Association and the Center for Plain Language. The University of California San Diego (UCSD) Extension recruited Lori to help set up and develop a Medical Writing and Editing Certificate Program on regulatory writing, journal publications, continuing education, and grant writing. She was also an instructor of Medical Terminology and Business Communication at Newbury College and she developed and led several AMWA Workshops, including “Medical Terminology” and “Using Principles of Classical Rhetoric to Enhance Medical Communication.”

Lori joined the AMWA staff after 6 years of service on the AMWA Board. Lori understood the roles of volunteer leader and staff and the important synergy of the relationship in achieving organization goals. She called the opportunity to guide and manage the educational program at the association that had been “my professional home for nearly 20 years” an “opportunity of a lifetime.” Working with her in both capacities was an exciting and enriching opportunity of my lifetime. The AMWA staff enjoyed working with Lori in both capacities, and we are incredibly grateful for her leadership, mentorship, and friendship.

—Susan Krug, MS, CAE, AMWA Executive Director

Lori wore many hats at AMWA: Journal Editor, Chair of the Annual Conference Programming Committee and the Education Committee, workshop leader, head of the strategic planning initiative, President of the Board of Directors (BOD), and most recently, AMWA Education Director. I don't know which hat was her favorite, but I do know she was thrilled and honored to be able to use her vision to propel AMWA Education into the future.

I got to know Lori after she invited me to join the *AMWA Journal* Editorial Board. Her passion for AMWA was obvious, and she was never shy about reminding us that we needed to create content for medical writers AND editors in all work settings.

Lori was a masterful communicator. She loved words, and she loved to write, and she loved inspiring that same passion in others.

Among Lori's many gifts was her unique ability to recognize leadership skills in others. And once she got you to say "yes" the first time, she wouldn't let go. Many of you know what I'm talking about. Lori was a quiet but forceful leader who encouraged people to use their talents, to move outside of their comfort zones, and to aspire to be more. She inspired us by her example.

Lori was first my colleague, but she quickly became my friend. I was inspired by her ability to always look forward—to that next webinar, to the next workshop, to the next conference, to the next trip to Broadway. Lori had a deep passion for giving and doing for others, and she did more than simply write a check. She regularly prepared meals for residents of a local shelter, and each year she bought Christmas gifts for needy families. She was a remarkable, generous woman who found joy in sharing her gifts. The medical writing and editing community—and the world—is richer for having had Lori in it.

—**Cyndy Kryder, MS, MWC**, AMWA President 2018–2019

Lori would laugh at me for starting this with a quote from the Dalai Lama, but it seems so true to her and her legacy: "Just as ripples spread out when a single pebble is dropped into water, the actions of individuals can have far-reaching effects." — Dalai Lama XIV

This tribute to Lori reflects the effect of her life on us. Obviously as her wife, friend, and collaborator, Lori's effect on me is profound.

Lori first turned my head in the late 1990s when she synthesized a complicated abstract into clear, understandable English. She was one of those rare people who can flow from copyediting to structural editing to document design and



Lori Alexander with Susan Krug, Brian Bass, and Cynthia L. Kryder

back. Her elegant tables, nonredundant prose, and realistic timelines brought rigor and simplicity to work and life that was often messy and complicated.

Lori understood firsthand the need to integrate proven research results into patient care. Two of her siblings were allied health professionals and her mother did triage admitting work at a local emergency room. Like me, her passion at its core was writing. She wrote television screenplays in her 20s, had an agent who brought her promising close calls, and lived with a cat named Malibu. But Hollywood was not meant to be for Lori, which was our gain in the field of medical communication.

Lori and I are essentially the same age, 2 months apart, and we are Boston girls; we experienced the transition from paper to computers in medical literature in parallel time. In the 80s you would have found each of us wandering the stacks of the Harvard Medical Library several days a month, checking references for our respective journals. We ate at the same Lebanese-American food truck, went to the Harvard Coop for supplies, and drove up and down Storrow Drive to and from our respective homes.

Flash forward 10 years later and Lori and I finally are working together and soon thereafter, become a couple after studiously not dating for a year as professional colleagues. We loved each other that much. By this time, I had joined AMWA. I attended my first meeting in 1987 in Boston and was hooked. I took to heart that to make medical writing a profession, you have to treat it as a profession. Lori joined in the 90s, and, similar to her approach to everything she enjoyed and thought important, she was all in. And she had the skills, the vision, the camaraderie, and the humor to take us all along with her.

Flash forward to the future—which was Lori’s specialty as a leader—she was committed to creating and delivering AMWA programs to meet the needs of medical communicators tomorrow as well as today.

Lori was a builder—of sentences, articles, daily meeting newspapers, departments, your member magazine, her own business, a life of travel, and community including the AMWA community. She was a family woman and loved to see the world firsthand. She had actionable bucket lists. She took risks and had managerial courage. She was a powerful example of what you can do when you share your strengths with others.

Lori would want all of you to be successful, to make a difference, and to have fun doing it. For a small person, Lori had huge footsteps and an even bigger heart. We all stand on her shoulders as we face the future without her.

—**Deb Whippen**, AMWA Board of Directors 2012–2014,  
Editor and Publisher, Editorial Rx, Inc.



Deb Whippen and Lori Alexander

Those reading these words know that AMWA’s mission is to promote excellence in medical communication and to provide educational resources in support of that goal. I have never known a person who exemplifies that mission more than Lori Alexander. Rather than talk about what Lori accomplished, I’d like to reflect on why and how I think she was able to achieve so much.

Lori had a deep love of language. Not just words but all aspects: how words fit together, the structure of a paragraph, the nuance of verb tenses, how punctuation enhances clarity—don’t misuse a colon! Seriously. Lori’s love of language wasn’t based on a love of rules, being the smartest person in the room (even when she was), or detail obsession. It was

grounded in shaping communication so that the intended recipient could receive the best understanding, period. Whether writing or editing, every detail of every communication was under scrutiny. Lori left no stone unturned to deliver her aim.

And that brings me to the second part, the real magic of her work. That’s Lori’s love of her fellow person. Lori devoted both her career and her personal life to the pursuits that would bring the greatest benefit to others. I think this is why she and Deb had such a perfect partnership—kindred spirits in the kindness and wisdom of their hearts.

It pleases me to know that truly, it is Lori’s work in the field of medical communication—through her legacy of mentees and the improvements she has made in the field—that will help future physicians and patients learn how to adapt to the advancements that are coming in care for brain tumors, other cancers, and other diseases. As a cancer survivor and a professional working in the field of medical education, I will continue to be inspired by my colleague and friend, and I know that is true of countless others.

—**Lisa Greaves**, Division Director, Educational Meetings  
at American Society of Clinical Oncology

I still remember that first conversation I had with Lori Alexander in the early aughts roughly 20 years ago. She was interviewing as a candidate for editor of the *AMWA Journal* and I was leading the search committee. As impressive as Lori’s experience and qualifications were on paper, meeting her by telephone that first time we spoke was unforgettable. Lori was sharp, creative, innovative, and enthusiastic—not only about the journal, but about the medical communication profession itself. She embodied the collaborative spirit of AMWA so completely that it was easy to get lost in all the ideas she proposed and directions she envisioned. However, it was her solitary strength and depth of purpose that kept you grounded and focused.

Lori went on to lead the journal to unprecedented heights, and she continued her leadership and service to AMWA well beyond her 10 year editorial tenure. I always enjoyed hearing her speak, whether giving workshops or attending committee and board meetings. Lori had the knack to bring people and ideas together, interwoven with the spark of creativity and a genuineness of mutual care and appreciation. Lori left us far too soon. She made an indelible impression on me, both as a friend and a colleague in the organization we all love and support.

—**Tom Gegeny, MS, ELS, MWC, CMPP**  
AMWA President 2009–2010

Lori gave me the big break I needed when I was beginning my freelance graphic design and medical illustration business. Early in my career, my work consisted of mostly small jobs with medical organizations in Boston. I met Deb and Lori while they were both working at the Boston area office of ASCO, a global oncology organization, in the late 1990s. I really wanted to take on larger publication projects and Lori offered me the opportunity to be the designer on the quarterly *ASCO News* publication. We worked well together, and with her recommendation and support, I went on to do many other ASCO publications, print collateral, and conference work, which was a huge boost to my career. When Lori became Editor for the *AMWA Journal* in 2003, she once again offered me a fantastic opportunity. That began my wonderful relationship with AMWA, which has continued to the present. Our close work together on many types of projects continued when she and Deb started Editorial Rx.

Professionally, I was awed by her skills at planning, organizing, and executing projects. She had a strong vision for the *AMWA Journal* and we worked together with the leadership on a redesign. Her attention to detail as an editor was top of the line and I learned so much from her. I am so grateful to have had Lori in my professional life, but after working so closely together for so many years, we also became great friends, always sharing with each other what was happening in our lives day to day.

Personally, I admired what a beautiful adventurous person she was—always planning out her next bucket-list trip. She was warm and welcoming and had a wicked sense of humor. She loved to decorate for every holiday, which I loved to kid her about. I will miss her so much, but know she positively impacted not only my life but many others.

—Amy Boches, graphic designer, *AMWA Journal*



Lori receiving an award in 2012 for 10 years as Editor of the *AMWA Journal*.

Lori Alexander was one of a kind and in many ways her contributions to AMWA and the field of medical writing were immeasurable. She was never one to brag, or even talk about, her accomplishments. She just went about doing her job and finding ways to contribute her time and her wonderfully creative ideas, wherever needed.

I had been an AMWA member for more than 10 years before I met Lori, and it wasn't at AMWA. I met her when, at the suggestion of a fellow AMWA member, she offered me a freelance job working at the ASCO annual meeting as a reporter for the daily newspaper that they published during the meeting. It didn't take long for me to see what a consummate professional Lori was. Working for the *ASCO Daily News* was one of the most challenging and fulfilling freelance jobs I ever had; and when Lori asked me back the next year, and the next, and the next, I knew I had finally made it as a freelance medical writer.

I couldn't have been happier when I learned that Lori had accepted the position as Editor of the *AMWA Journal*. Based on my experience working with her at the ASCO Conferences, I knew that AMWA was about to benefit in ways we couldn't imagine. And we did...

I am grateful to have had the opportunity to both work for Lori—through ASCO and her business, Editorial Rx, Inc.—and with Lori on the *AMWA Journal* and many of the projects she chaired. I could never say “no” to my dear friend Lori, and every time we worked together, I learned something new. Lori Alexander made me a better medical writer, and her many contributions to the field of medical writing and AMWA are truly immeasurable.

—Donna Miceli, DLM Writing Services, Retired  
Freelance Writer, Editor & PR Consultant

Lori was the consummate penguin fan. She loved everything about them. It was a highlight of her life to travel to Antarctica to see them in their natural habitat. But I'll get back to that in a moment.

The Swanberg Award is such a fitting tribute to Lori in recognition of her amazing career and innumerable accomplishments. Like Dr Swanberg, Lori was also a transformational leader of AMWA. There was no role Lori held that didn't result in major change for the better. Lori brought skill, expertise, and, importantly, a talent for uniting others to the table.

There is a picture of Lori in the photo gallery of her Facebook page in which she's sporting a mask that says, “Less me and more we.” That singlehandedly describes Lori's leadership. Ever self-effacing, she truly looked for ways to build bridges with others and to generate such enthusiasm for an initiative that many already-very-busy

people willingly jumped in to give of their time and talents. Lori allowed people to be at their best—to offer their best ideas and their best work.

And, like her beloved penguins, she overlooked difficulties and instead focused on what could be achieved, not on what couldn't. You see, penguins don't spend time worrying about not being able to fly, but they are excellent swimmers and effortlessly fly through the water. And one species uses the sun to navigate from land to sea, adjusting for the sun's changing position in the sky throughout the day. In all these ways, penguins have adapted to the challenges their environment poses. Lori did the same, but she also mobilized our profession to move in new and even better directions. Lori set an incredible example for others, and she did so with a fair dose of good humor. I can't think of anyone more deserving of AMWA's highest honor.

—**Melanie Fridl Ross, MSJ, ELS**, AMWA President 2010-2011



Lori and Scooter.

I was fortunate to meet Lori early in her AMWA career. She told me that she wanted to get more involved in AMWA and *that* she did. Once Lori set her mind to something, nothing stopped her—thus her lengthy list of AMWA accomplishments. She had an affinity for education, and her contributions to AMWA's education program, in my opinion, will never be equaled and will live on through the many medical writers she influenced.

I worked with her on multiple education initiatives, including the Certification Commission, in which she made major contributions as a subject-matter expert, including in item development. Lori always said “yes” whenever someone asked her to help. When she became the AMWA Education Director, for the first time, we had someone at headquarters who was an actual medical writer and who readily understood members' needs. Lori charted a new course to expand AMWA's educational offerings. Her legacy to that program will continue, and we members will continue to be the beneficiaries.

When I think of Lori, I hear her infectious laugh and remember her stories. Lori always had a story. In her work-

shop on classical rhetoric, she promoted the use of stories in scientific publications. That workshop caused me to rethink scientific writing, and I teach her philosophy to my students. Lori said, “A story engages you. It taps into your imagination. It connects you with others. Medical writing lacks stories.” She was correct, of course, and gave us simple guidelines for adding story to manuscripts—if only by just switching to first person or giving patients a voice.

When I think of Lori, I also hear her say, “If you have a minute, I'd like to run this idea I have by you.” That was the hook, and I was always honored to be part of Team Lori for whatever new idea she envisioned. Lori often said how grateful she was for the opportunities AMWA gave her to help do her job better, to network with colleagues, and to grow as a leader. What Lori gave back, however, was legion. If every medical writer who benefited from Lori's wisdom planted a seed in her memory, a vast wilderness of flowers would be the result.

The Nobel Laureate Anatole France said, “To accomplish great things, we must dream as well as act.” Lori did both, and she will be greatly missed...

—**Marianne Mallia, ELS, MWC**, AMWA President 2002-2003, 2010  
AMWA Swanberg Award Recipient

In an organization with more than its share of brilliant, talented, and generous members, Lori quite simply was a rockstar. Her commitment and passion for the mission of AMWA were unrivaled. Her imprint will be lasting.

—**Victoria White**, Former Editor-in-Chief, *AMWA Journal*

I have long felt that Lori was a natural choice to receive the Swanberg Award. Anytime AMWA is mentioned, it is Lori who pops into my mind. You would be hard-pressed to find another member who has devoted more time and energy to helping AMWA live up to its mission.

I first met Lori when I was at a crossroads in my professional life. I had just left industry and entered the freelance life. At the 2011 AMWA Conference in Jacksonville, I met Deb Whippen and she immediately got me involved in AMWA Florida and turned me over to Lori who realized she had some “fresh volunteer material” to develop. She wasted no time talking me into volunteering on my first of many “Lori-run projects.” Lori was the mentor I had no idea I had always been searching for, but I am just happy I realized what I gift the universe had presented me when I needed it most.

A project or team led by Lori was sure to accomplish its goals and it was always rewarding to be a part of them. Lori led with kindness and was always inclusive long before it

was in vogue. She had a knack for taking you out of your comfort zone and getting you involved in areas that didn't just get the job done for the organization, but left you rewarded with new skills for future use. You wanted to do more because she inspired you with all the confidence you needed to get the job done.

Lori was a naturally curious soul with a thirst for learning and a drive for teaching and sharing what she knew. She was passionate about storytelling as a vehicle for medical communication and as the master communicator, she was every bit the skilled listener as she was the gifted storyteller.

It was always exciting to get one of those calls, "Hi Larry, this is what we are thinking about doing, and I think you would be a great fit." I am grateful for each of those experiences. Lori did a solid for our founder and award namesake, Harold Swanberg. We are so lucky for the legacy Lori has left for us as a guide for the next leg of the AMWA journey.

—**Larry Lynam**, Annual Conference Committee 2012–2018, 2018 President's Award recipient



Lori with her gavel for starting her term as AMWA President 2016-2017.

I can think of no one more deserving to receive the Harold Swanberg Distinguished Service Award. Lori Alexander's contributions to AMWA vastly exceed the criteria of distinguished contributions to medical communication. I first met Lori while attending an AMWA BOD meeting as a chapter delegate and later, I had the honor of joining the BOD

and serving alongside Lori. I am just one of many that Lori brought into her network, and I am honored.

Lori and I also worked together with UCSD to create and grow an educational program for new medical writers and editors. It leverages the multifaceted expertise of several AMWA members including Yeshi Mikyas, Donna Simcoe, Dikran Toroser, Noelle Demas, and Lynne Friedmann. Since its launch in 2016, the program has continued to expand and grew stronger. Much of its success is attributed to Lori, who in 2017 took a leadership role in the program and served as the program's consulting director. On monthly faculty calls, she pushed each of us to continuously improve our courses, and she was a favorite of the students. Lori brought leadership, grace, and a strong understanding of our field to the program. When she took the position of Education Director at AMWA, Lori ensured that she could continue to serve as the director of the UCSD program, and for that, we are all eternally grateful. The program itself has certified over 50 students. When she stepped away earlier this year, it took 2 folks to fill her shoes. Her presence is and will be missed.

No one could say no when Lori asked, no one. What I recall is her sense of humor. If ever we were sitting next to each other, I knew I would be stifling laughter. I will always be most grateful for her friendship. Her authenticity was rare, and her example will serve as guidance for me and so many others. May we honor her today and always with our work, with our welcoming community, and with authenticity.

—**R. Michelle Sauer Gehring, PhD, ELS**, Instructor, UCSD Extension, AMWA Secretary 2020–2022

I was surprised when Lori Alexander asked me to join the AMWA board during her year as president. I was also nervous and quite honored. I soon learned that Lori had a gift for including others. Many may shy away from inclusion, but Lori embraced it. She always made room for others to contribute in their own way, all while providing support and lighting the path.

I also learned that Lori was highly productive on her own. She literally performed the work of many and made it look easy. I think this combination—including others and high productivity—is what allowed her to accomplish so much.

I was able to witness Lori's craft up close, and I was astonished by her drive, compassion, and commitment to medical writing. She truly loved what she did, and this made work feel like play.

AMWA is blessed to have had Lori leading on multiple fronts over the years, from the *AMWA Journal* to conference planning and education initiatives, to name a few.

Undoubtedly, her departure leaves a void that cannot be easily filled, but her leadership is an inspiration that endures.

It's truly fitting for Lori to be honored with AMWA's highest award. Lori, thank you for being a wonderful mentor and friend. Although you are greatly missed, it lightens my heart to think that you are spending time with penguins.

—**Theresa Singleton, PhD**, AMWA Board of Directors 2016–2019

I first “met” Lori when she emailed me in 2016 suggesting I submit an interest form for the AMWA Executive Committee (EC) as she was starting her AMWA Presidency. The email ended with the postscript: “I noticed on your LinkedIn profile that you’re looking for an opportunity to join a nonprofit board—I hope AMWA fits that!”—which I now know is so Lori. I first met her in person in an elevator. I was so nervous, because she was and always will be a giant in our field (those who know us might chuckle, I’m almost a foot taller than Lori). But Lori was so genuine, warm, and caring that I quickly felt comfortable, and it wasn’t soon after that we became friends. Just last week I found a card from a gift she gave my daughter who had a brain tumor in 2018—tears came to my eyes but smiles also came to my face. Because she was President when I joined the EC, I’ll always think of her as the model AMWA President; never did I imagine that we’d lose her during my presidency. Lori will be so missed, but she will always be with us.

—**Gail V. Flores, PhD**, AMWA President 2020–2021

I first met Lori years ago when I was a delegate to the AMWA board, and I must say I was instantly comforted by her warmth and inclusiveness. Over the years, I’ve had a chance to work with Lori on several initiatives while she was President of AMWA and later as Education Director. Each experience was not only an opportunity for me to learn something new and to grow my professional expertise, but also gave me the chance to inform others about the role public relations and marketing plays in the field of medical communication. Lori understood that medical communicators work in a variety of settings and across multiple areas. She had the desire to develop educational resources to support members that work in the different niches within medical communication.

When I think of an inclusive and servant leader for AMWA, I think of Lori. We as an organization are now reaping the benefits of Lori’s passion and commitment to

AMWA. I can’t think of anyone more deserving to receive the 2021 Swanberg Award. I am comforted to know that her legacy will live on through AMWA and will inspire many medical communicators along the way.

—**Katrina R. Burton**, AMWA President 2021–2022

Lori was so many things to so many people. To me she was a dear friend, a valued colleague, a trusted leader, a generous resource, a joyful spirit, and a kind heart. But I think there’s one way to sum her up—Lori was an accelerant. She always set my mind on fire with her energy and enthusiasm.

Working with Lori when she was Editor of the *AMWA Journal*, she brought so many innovative ideas to the table. Nothing was impossible. She would light a match with a simple thought or suggestion that would ignite collaboration as it spread across the room. During her AMWA presidency, Lori fused the organization together behind a new governance structure that strengthened AMWA while bringing it into compliance with evolving guidelines. As Director of Education, Lori’s passion for teaching others fueled an explosion of new educational products and programs that will continue to serve AMWA and the medical writing profession for years to come.

Receiving the 2021 Harold Swanberg Distinguished Service Award for Lori’s contributions to the medical communication profession is a great and well-deserved honor. The honor of knowing Lori, working with her, and learning from her, is all ours.

—**Brian Bass, MWC**, AMWA President 2013–2014, 2017 AMWA Swanberg Award Recipient



Lori teaching at the 2018 AMWA Medical Writing & Communication Conference.

CONFERENCE

## 2021 John P. McGovern Award Address Style and Substance

Stacy L. Christiansen, MA / Managing Editor, *JAMA*, and Chair, *AMA Manual of Style* Committee, Chicago, IL



*The John P. McGovern Award is named in honor of John P. McGovern and is presented to a member or nonmember of AMWA to recognize a preeminent contribution to any of the various modes of medical communication. The McGovern Award is presented during AMWA's Medical Writing & Communication Conference.*

Hello, AMWA attendees. I'm Stacy Christiansen, and I am incredibly humbled to be talking to you as the 2021 John P. McGovern Award winner. Looking through the list of previous winners leaves me a little starstruck; I am in incredibly good company.

I have been very fortunate to spend my medical communication career at one organization, the American Medical Association (AMA). I was hired in the last century (but very, very late in the last century) as a copy editor for the specialty journals published by the AMA. Their names at the time were *Archives of Dermatology*, *Archives of Internal Medicine*, and a handful of others. They have been successfully rebranded as *JAMA Dermatology*, *JAMA Internal Medicine*, etc.

After a few incredibly instructive years as a copy editor, I had the opportunity to move over to the flagship journal, *JAMA*. One of the main differences with *JAMA* was applying all of the skills and knowledge I had gained, but faster. I was up for the challenge and the rest is history. I moved from copy editing manager to managing editor of *JAMA*.

I've also been a member of the committee that produces the *AMA Manual of Style* since 2002. I worked on the 10th edition, and then became the co-chair for the eleventh, just published last year.

Before I dive in, I just want to take a brief minute to give thanks where it's due—to acknowledge the people who have mentored me, educated me, and supported me along the way. The person who fills all of these roles is *JAMA* Network Executive Managing Editor Annette Flanagin, who, by the way, won this award in 2009. Annette is a manager, educator, problem-solver, and cheerleader all in one, and she has

set the bar high at *JAMA*, but is always willing to give me a boost to reach it.

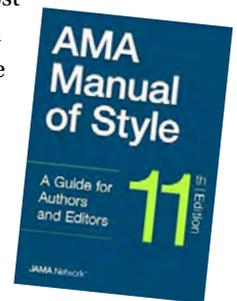
Another McGovern award winner has also been a huge influence on me, and that's Cheryl Iverson, the previous chair of the *AMA Manual of Style* committee. She won the award back in 2004. Cheryl is one of the most upbeat, can-do people I have ever met, and her support and encouragement helped me believe I could wrangle this stylebook, no problem.

There are a host of others who have been instrumental, including all sorts of folks at *JAMA*, from editors in chief to all of the amazing manuscript editors, systems administrators, editorial assistants, and production staff. Also, AMWA and Council of Science Editors (CSE) colleagues, a number of people at Oxford University Press, and even authors, readers, and tweeters who share their experience and feedback. I owe a debt of gratitude to a host of individuals for helping me along this path.

So, in thinking about this talk, I settled on *Style and Substance* as the title, because that's one phrase I feel sums up a lot of our work in medical communication. And then, I struggled with a subtitle.

My first idea was "But What Do You DO?" I'm sure I'm not alone in this scenario. You're at a gathering with people you're meeting for the first time, and they inevitably ask what you do for a living. And you reply, "medical writer," or worse, "medical editor." Medical writer at least is sort of clear: you write about medical stuff. But medical editor? One well-meaning older man asked if that meant I was a secretary—his word. Other times I've been met with a blank stare and the question, "Yeah, but what do you DO?"

So, I thought about that. What do we do? My personal philosophy can be summed up as ACC. That's an acronym I coined for accuracy, clarity, and consistency. As an editor, those are the paramount goals of anything I work on, from



a brief news item to a large groundbreaking clinical trial. A good editor should be behind the scenes helping an author ensure that the science is communicated accurately, clearly, and consistently.

There are varying perspectives about what editors actually do, from people who aren't sure, to those who are as invested in the product as editors are—namely writers—and, of course, the “track changes” reality.

There have been some attempts to place value on editorial work, such as a comparison of unedited papers with final publication. In this study from 2015,<sup>1</sup> readers were asked to read 4 articles in their unedited and edited versions. While these articles were principally news stories and not trial reports, I think the findings are relatable. Readers preferred the edited versions, and felt the quality was worth the cost.

Two papers published in 2007 in *Learned Publishing* also investigated the changes between author manuscripts and final published versions.<sup>2,3</sup> In the first study, a review of 189 articles published in science, technology, engineering, and mathematics journals or humanities publications compared the author's version with the final article. A substantial amount of edits worked to correct citation errors, a third of the edits fixed grammatical or stylistic problems, and nearly 14% of the edits queried missing data. The authors concluded that editing contributes substantially to the accuracy of the paper and is therefore an important function for the integrity of the article of record.<sup>2</sup>

The second paper in *Learned Publishing* was by Goodman and colleagues, and it compared self-archived manuscripts with the published versions. This study looked at 24 papers in biochemistry or social sciences, and the results were similar to the first study. In general, the editing helped improve the readability of the paper, although no errors were serious enough to invalidate significant data, conclusions, or the overall validity of the findings, and none of them would warrant a correction or a retraction.<sup>3</sup>

A slightly older study was presented at the Peer Review Congress in 2001.<sup>4</sup>

This was a systematic review of the literature on technical editing, which has been posited to improve accuracy and clarity—2 of my ACC words. The authors found 11 studies of technical editing that concluded that editing improves readability, may improve quality, and increases the accuracy of references and quotations. It also elevates the accuracy of abstracts.<sup>4</sup>

*The Ninth International Congress on Peer Review and Scientific Publication is set to meet in September 2022. Get your research done! Abstracts can be submitted now.*

There have been some other efforts to validate the contributions of communication professionals, but I have yet to see any study that says, “nah, don't bother.”

As I mentioned earlier, I was hired at the turn of the century, and we still did a lot of things on paper. We were just learning how to edit in Microsoft Word, and some of us learned to write custom scripts. My first script removed the 0 before the decimal point in *P* values. I am still super proud of that very basic script that no one uses.

Among editorial staff, there was some general fear as technology evolved that editors might be replaced. Spellcheck and grammar checking in Word were the first software-based features that took on some of an editor's responsibilities, followed by more sophisticated programs such as software that autocorrects errors, or that fixes terminology based on preselected rules (for example, changing British spelling to US spelling).

Technology can be incredibly helpful to improve quality by spotting errors, but we've all had a good laugh over auto-correct or spell Czech. I get really tired of spellcheck's shirt; that process can go to he'll. I realize that correct spelling is impotent, but sometimes the corrected words aren't write.

And sometimes it's not individual words but sentence construction that editors need to fix. For example:

The patient has chest pain when lying on her right side for over a year.



The patient lives at home with his mother, father, and pet turtle, who is presently enrolled in daycare.

Editors work to preserve the credibility of a paper and of a journal or other publication as a whole. While I know we've all had a good chuckle about menu gaffes and not worried too much about how the food would be, the same is not true of more serious communication.

As the patient, if you were provided a document intended to address your concerns about a new medication or a diagnosis, what would your confidence be if it were riddled with errors? We might assume anyone or any company that did not take the time to do something as straightforward as proofreading might not have done the necessary quality checks on the product or information itself.

And although technology might be able to assist with some functions of a writer or editor’s job, it simply will never replace the judgment a human brings to the work. There is nothing misspelled or grammatically wrong with the sentence, “This medication is for diabetics.” But a well-trained writer or editor will tell you that it’s best to use patient-first language to avoid labeling people with a disease or a condition. Microsoft Word would pass over that sentence with nary a red squiggly line, but the editor would recast it as “This medication is for patients with diabetes.”

The same is true for language addressing people’s sex or gender, age, socioeconomic status, race and ethnicity, or disabilities. Writers and editors are in tune with inclusive language in a way that even the most sophisticated software cannot replicate, so clearly human editors are important. And as advanced as technology becomes, medical writers and editors will always be needed if the desired result is clear, accurate, and valid content.

Editors’ work with references is particularly important—ensuring that references are cited, are associated with the right content in the text, and are complete enough that they can link to the original source, allowing readers to access the primary information. Knowing when citations are needed, which citations are appropriate vis-à-vis the reference list, and ensuring citation accuracy really rely on well-trained medical writers and editors.

I realize some of you are saying, “Stacy, you’re preaching to the choir.” And I know that, but it doesn’t hurt to hear evidence to validate our work. Consider this your affirmation. Your work matters *tremendously* in helping communicate science clearly and accurately, with the ultimate goal of advancing science and helping patients.

You may remember that I mentioned earlier that I was toying with several subtitles for this talk. My second idea was along the lines of “Who Cares About Style?” or “Why Is It Important to Use a Stylebook?” Although we all carry knowledge in our heads, it’s much more efficient and consistent to share it. With the pace of information sharing continually accelerating, it’s inefficient to have to ask around if something is hyphenated. And of course, depending on who you ask or where you look, you might get different answers. Having one place to look up guidance will help establish consistent decision-making.

I would never ask anyone to read the *AMA Manual of Style* cover to cover—or any stylebook for that matter—unless you can’t fall asleep. A stylebook is a reference tool, like the dictionary.

Now, there are definitely sections of a style manual that lend themselves to narrative, and perhaps certain chapters

should be must-reads, like those that provide the history of certain policies to give you some context. But essentially, a stylebook is a resource for consultation and guidance.

So why should you use a stylebook? Because they provide guidance on how to handle small details, substantive issues, and even major problems. For example, you may not remember the rule for using en dashes with compound terms. Where does the hyphen go? When do you really need to use the en dash? Give me some examples! A style manual is happy to oblige.

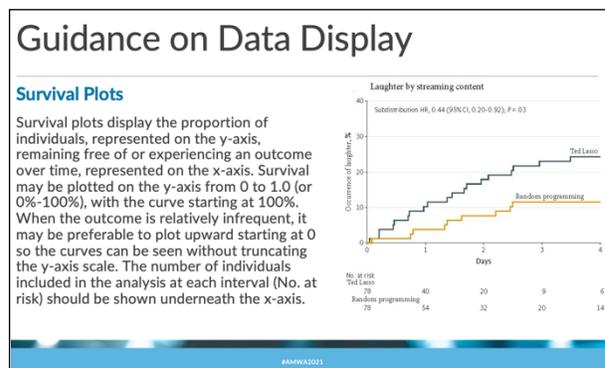
Same thing with comma use. Most style guides will share a preference for using the serial comma or not, and it’s important to use (or not use) it consistently. Following one main guide or adopting a house style on this point will ensure that all content is in agreement.



A collection of commonly used manuals.

Another guidance point a manual will assist with is what is capitalized in a title, especially if you don’t encounter terms such as *in situ* or *mendelian* very often.

Stylebooks also provide guidance on substantive issues such as data display, for example, the basic formatting of what should be included in a survival curve. The example here provides the general expectations for formatting, like using a nonbreaking scale starting at 0, or, alternatively, at 100. The guide also explains what elements need to be included to interpret the figure, such as the number of patients in follow-up and plotting the progression of time on the x-axis.



Other substantive guidance a manual will offer might involve language use, in this case guidance on inclusive language. Stylebook authors will have done their

homework on wording to be used in certain disciplines or in certain situations. In the examples here, there are specific recommendations for how to report on race and ethnicity, as well as disabilities and diseases. Note the theme here, which is asking authors and editors to use person-first language.

### Guidance on Inclusive Language

- Racial and ethnic terms should not be used in noun form (eg, avoid *Asians*, *Blacks*, *Hispanics*, or *Whites*); the adjectival form is preferred (eg, *Asian women*, *Black patients*, *Hispanic children*, or *White participants*) because this follows AMA style regarding person-first language.
- Avoid labeling (and thus equating) people with their disabilities or diseases (eg, the blind, schizophrenics, epileptics). Instead, put the person first. Avoid describing persons as *victims* or with other emotional terms that suggest helplessness (*afflicted with*, *suffering from*, *stricken with*, *maimed*). Avoid euphemistic descriptors, such as *physically challenged*, *special*, or *special needs*.

#AMWA2021

Finally, a style guide should also provide guidance on major issues, for example in medical articles what to do when an identifiable image of a patient is included with a document for publication. You can see here the manual provides a list of options for how to legally and ethically handle this situation.

### Guidance on Major Issues

How do you handle a photograph of a patient?

- Written informed consent for publication (patient permission)
- Editing/deleting details
  - However, *altering* descriptive characteristics is not appropriate as it is a form of falsification and may be misunderstood by readers and others conducting secondary analyses of published reports.
- Cropping
- Omitting image altogether

#AMWA2021

Another major issue that might arise in a writer or editor's work is dealing with authorship issues. A style manual will likely offer guidance on how to navigate authorship, or at least suggest resources for assistance.

### Guidance on Major Issues

Resolving authorship concerns

1. Only those individuals who meet the criteria for authorship may be listed as authors.
2. The first author has contributed the most to the work, with other authors listed in descending order according to their levels of contribution. Note: Some groups choose to list the most senior author(s) last.
3. Decisions about the order of authors should be made as early as possible (eg, before the manuscript is written) and reevaluated later if needed by consensus.
4. Disagreement about order should be resolved by the authors, not the editor.
5. Authors may provide a publishable footnote explaining the order of authorship, if there is a compelling reason.
6. Editors may request documentation of authors' specific contributions.

#AMWA2021

This can be very helpful for writers or editors because it provides an authoritative guidance to cite. I can't tell you how many times I've copied and pasted from the *AMA Manual* online to help explain what our policy is, or why it is.

Stylebooks usually also offer guidance on how to organize information, which helps readers digest the information. For example, readers expect an abstract in a clinical trial report, and some even expect that they can skip reading the whole thing, just reading the last paragraph (the conclusions). When the document is organized, ideas flow logically, tables and figures present data efficiently and in a logical order, and readers can skim the paper but still find what they're looking for, and come away with at least a basic understanding of the study.

### Guidance on Organization

- Titles and Subtitles
- Author Bylines and End-of-Text Signatures
- Author Footnotes
- Abstract
- Parts of a Manuscript, Headings, Subheadings, and Side Headings
  - Introduction
  - Methods
  - Results
  - Discussion
  - Conclusions
- Data Display (Figures, Tables)
- Acknowledgments (Article Information)
- References

#AMWA2021

You don't have to use the *AMA Manual*—although it would be great if you did! The important thing is to have a resource available that will provide guidance in your work, whether it's a question on comma use, or help with serious issues like conflicts of interest or handling retractions.

These are the tools medical writers and editors need to practice their craft: reference tools; software programs for word processing, data display, and reference management; and most importantly, your brains, skills, and experience. The end result is a well-equipped communicator whose work helps the science shine.

Remember, ACC (accuracy, clarity, and consistency) never go out of style.

Thank you, everyone, for your time and attention, and thank you, colleagues, for the McGovern Award.

#### Acknowledgment

I thank Jodie Rothschild, Principal Medical Writer at Rothschild Medical Communications, for her help in bringing the transcript to the page.

**Author declaration and disclosures:** *The author notes that she is employed by the American Medical Association, which publishes the AMA Manual of Style. No other disclosures were reported.*

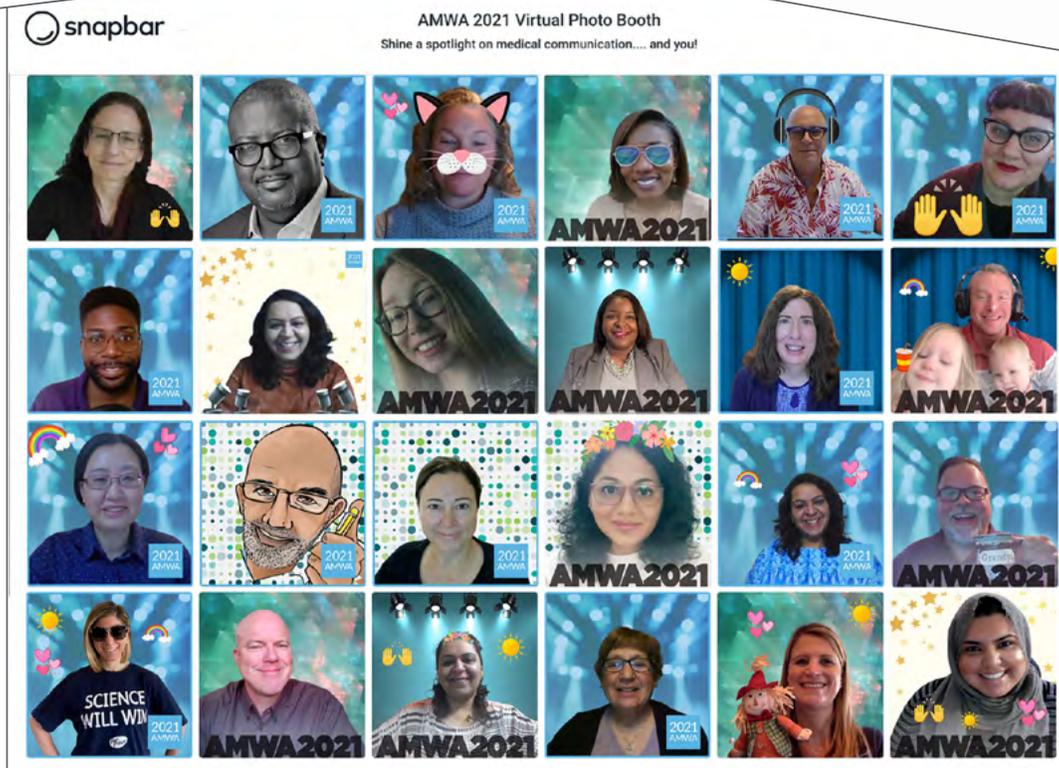
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The 2021 Alvarez Award address by recipient Harriet A. Washington will be published in a future issue of *AMWA Journal*.

## SCREENS FROM THE VIRTUAL CONFERENCE



**CONFERENCE**

## Session Reports

### BEST PRACTICES FOR MEDICAL WRITING WITH A DISCLOSURE MINDSET

**Speaker**

**Thomas Wicks, MBA**, *Chief Strategy Officer, TrialScope/Informa, Jersey City, NY*

**By Nisreen Shumayrikh, PhD**

Clinical trials are conducted almost everywhere worldwide, and trial disclosure requirements continue to expand, with an average of 2 new trial registries going live every year. This global expansion can lead to inconsistent public disclosure of study protocols, trial results, and associated documents.

The inconsistency becomes apparent when the information is disclosed through various registries, company trial websites, and publications and then assessed by recruiters, industry and financial analysts, and patient advocacy groups.

Regulators in various countries have started to include disclosure compliance in their inspection regime, whereas industry critics and transparency advocates continue their detailed assessments of transparency practices. Beyond these regulatory inspections and assessments, sponsors face additional risks if the disclosure decisions are not well harmonized.

In his presentation at AMWA's 2021 conference, Thomas Wicks, Chief Strategy Officer at TrialScope/Informa, suggested best practices to regulatory medical writers for authoring source documents such as protocols and clinical study reports (CSRs) with disclosure requirements in mind.

**Efficient Disclosure**

To support disclosure, Mr Wicks suggested creating a protocol "disclosure template" that includes the main registration data, including the trial identification number, public and scientific titles, brief description, eligibility criteria, and others. A good starting point is adopting the registration data set developed by the World Health Organization and providing the protocol registration information from [clinicaltrials.gov](https://clinicaltrials.gov) or [EudraCT](https://eudract.europa.eu) (if available) to local affiliates, partners, and contract research organizations (CROs) to use as their source data for registration to local registries.

Mr Wicks then discussed some disclosure considerations regarding study endpoints.

These include

- alignment: explain clearly how each endpoint aligns with objectives,
- measure: document how each endpoint will be measured,
- scales: explain scales and indicate the best and worst scores,
- objective: include measurement objective,
- classification: classify endpoints and structure them (eg, primary, exploratory, secondary),
- templates: ensure that objective has one or more endpoints,
- definitions: define study process (eg, study dates, enrollment), and
- summaries: summarize all nonserious adverse events in a test.

"Each study objective has to be backed up with an endpoint," Mr Wicks said.

**Incorporating Plain Language**

When preparing source documents such as the clinical trial protocol or CSR, consider the information needs of patients and potential trial participants.

The information relevant to patients and participants should be written in plain language as part of the protocol, including

- the study title and a brief description,
- the description of the health condition,
- the product description,
- the key inclusion/exclusion criteria,
- description of study procedures/assessments,
- primary and, possibly, key secondary outcome measures,
- additional context around age range and sex of the participants, and
- length of participation.

The advantage is that submitting these plain language elements to trial registries improves patient communication and benefits users like recruiters and patient advocates. Regarding the source documents, Mr Wicks emphasized integrating plain language elements in the protocol, CSR, and even the informed consent form, which is often not

a clear as could it be. Additionally, he suggested adding a plain language abstract to the study synopsis, especially when the sponsor does not plan to provide a separate plain language summary. Other handy tools include developing a plain language glossary and templates.

### Prepare for Redaction and Anonymization

*For participant information, AVOID the following:*

- using pronouns in patient narratives; consider using “the patient” instead,
- using “verbatim” with quotes by the investigator, as these may include unique circumstances that could describe a patient, or
- including patient IDs in images of tables. If patient IDs are required, then either include tables with selectable text (instead of copied as an image) or keep table formatting consistent across all images to ease redaction.

*For study or sponsor staff information and other identifiers, AVOID the following:*

- adding names of the study staff with their organizational titles; instead, use only their study role,
- including contact information such as fax, phone, or email,
- incorporating CVs or certificates or adding them to an appendix,
- adding personal identifiers to bookmarks (such as patient IDs, names, study admin), or
- providing treatment allocation and group information throughout the document.

Other final considerations:

- Limit duplication that requires duplicate redactions, for example, providing a table with patient narrative information followed by text with some of the same information.
- In the sample Case Study Report Case Report Form (CRF), use a clearly fake patient ID like XXXX or 0000 (not even “1234”).
- Aim to keep page numbering consistent between the CSR and the PDF copy to help remove out-of-scope information.
- Because foreign language pages are out of scope, you may keep these in an appendix or remove them.

These are some best practices for medical writing with a disclosure mindset. It is part of your job as a regulatory medical writer to have a basic knowledge of disclosure regulations and support trial transparency.

*Nisreen Shumayrikh is a medical writer and scientific communicator at Guanine Medical in Vancouver, BC, Canada*

**Author declaration and disclosures:** *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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## BRIDGING THE GAP: TRANSITIONING INTO REGULATORY MEDICAL WRITING

### Speakers

**Amber Carr, PhD**, *Medical Writer, Merck, Rahway, NJ*

**Savannah Mageau, PharmD**, *Medical Writer, Merck, Rahway, NJ*

**Shengjie Xu, PhD**, *Medical Writer, Merck, Rahway, NJ*

### By Stephany Panlilio, MS

The role of a medical writer is everchanging and requires a range of technical knowledge and soft skills to create cohesive documents in preparation for submission to regulatory health authorities. Medical writers come from a variety of different backgrounds with varying levels of experience. For those looking to enter the field, there are a number of transferable skills from previous experiences, training opportunities, and techniques to bridge knowledge gaps in preparation for transitioning into a regulatory medical writing role. This article summarizes the experiences of Dr Carr, Dr Mageau, and Dr Xu as they each transitioned into regulatory medical writing.

### Skills Leveraged from Previous Experiences

In their presentation, Dr Carr, Dr Mageau, and Dr Xu shared their previous roles in experimental research, pharmacy practice, computational research, and teaching and medical communication and the skills they gained from each that were transferable to their role as medical writers. The skills they found most applicable to medical writing are summarized into the following 3 categories: soft skills, technical skills, and core knowledge.

#### Soft Skills

The soft skills of self-management and project management that Dr Xu gained from her time in experimental research have helped in her medical writing role. Managing time, setting priorities, and working independently are critical as a medical writer, and developing these skills can increase productivity. Medical writers must be able to manage multiple project timelines and have the flexibility to adjust when something unexpected arises (eg, shifting research

direction, delays at clinical sites, etc.). In addition to managing timelines, managing resources is important for a successful submission, as is continuously reassessing those resources as the project develops.

Dr Mageau was able to apply the leadership skills she developed from her previous experience in pharmacy practice. In medical writing, leadership is important because writers coordinate with several functional areas to produce documents, which includes coordinating meetings and leading presentations.

### ***Technical Skills***

Dr Carr found that her experiences in computational research and teaching and medical communication developed her technical skills for process proficiency and scientific communication, which in turn proved to be applicable to her role in medical writing. As a medical writer, the ability to manage and organize multiple projects concurrently and keep a process-driven approach saves time and can lead to streamlining processes in the future. As medical writing becomes more dependent on technology, it is important to have medical writers who are proficient in different software and who are willing to troubleshoot or test software as needed.

Scientific communication is another soft skill Dr Carr was able to bring from her previous experience to medical writing. Having a background in scientific communication taught her how to write for her audience by ensuring that the appropriate level of detail is included for the intended audience as well as modelling scientific thinking while keeping the audience engaged. Lastly, being able to communicate scientific information includes using evidence to craft a coherent story and to support the conclusions, as is done when writing clinical study reports and other regulatory documents.

### ***Core Knowledge***

In her pharmacy practice experience, Dr Mageau was able to gain real-world experience in several therapeutic areas, which helped to develop her core knowledge of different disease states, which is especially helpful when writing clinical regulatory documents. She was also able to utilize her experience collaborating with multidisciplinary teams as well as leading discussion and presentations, as medical writers build documents with several cross-functional teams.

### **Training Opportunities**

Numerous opportunities to further develop knowledge and understanding of the drug development process, clinical

research, and medical writing are available to those looking to enter the field. Training courses recommended by Dr Carr, Dr Mageau, and Dr Xu included the Introduction to the Principles and Practice of Clinical Research offered by the National Institutes of Health (NIH), the Regulatory Affairs Certification Preparation Program offered by the North Carolina Regulatory Affairs Forum, and Making Medicines: The Process of Drug Development certificate program offered by Eli Lilly.

In addition to training courses, Dr Xu had the opportunity to serve on an Institutional Review Board (IRB) where she gained hands-on experience. When serving on the IRB, Dr Xu learned local and international regulations, including good clinical practice, as well as ethical principles for clinical research. This experience also gave her the opportunity to review clinical study protocols and Investigator's Brochures (IBs), which is applicable to her role as a medical writer.

Dr Mageau participated in an internship at GlaxoSmithKline, where she gained experience in the Global Medical Sciences and Clinical Pharmacology groups. From this experience, she compiled data and used source documents, such as clinical study reports and IBs, to write manuscripts, abstracts, and presentations.

Another opportunity to expand knowledge and gain experience in the industry is by networking, as suggested by Dr Carr. Joining local and national chapters of organizations like AMWA provides opportunities for communicating and creating relationships with others in the field and learning from their experiences, finding training recommendations, and attending conferences to learn what is new in the industry.

### **Bridging Knowledge Gaps**

All 3 presenters shared their experiences bridging the gaps in their knowledge in their training course at Merck, which follows the AMWA Recommended Training Outline and focuses on 3 key areas: core knowledge and skills, documents, and soft skills.

### ***Core Knowledge and Skills***

Dr Mageau recommended the AMWA Essential Skills Certificate Program, which provides a background for the core knowledge in medical communication. In addition, taking this course also shows a commitment to developing professionally, further enhancing credibility as a medical writer.

Development of technical aptitude as a medical writer is important to enhance productivity and efficiency in writing documents. As regulatory documents are now primarily digital, Microsoft Word is a helpful authoring tool. In

addition, utilizing a collaborative authoring platform, such as SharePoint, enables multiple writers to work on a document concurrently. As documents are further developed, tools such as table, listing, and figure tools are available to help format and present data clearly to reviewers. Lastly, as a large amount of data are presented in regulatory documents, it is essential to have a quality control tool in place to ensure a document is ready for submission.

### **Documents**

In the rotational training program at Merck, Drs Carr, Mageau, and Xu were able to gain hands-on experience and participate in shadowing opportunities to develop an understanding of the types of documents that medical writers author. During that time, they learned how documents were built during the authoring process, shadowed the Quality Control group, attended consensus meetings, and eventually transitioned to being lead authors.

### **Soft Skills**

Lastly, further developing self-management and people skills helps to strengthen a medical writer's ability to work collaboratively even while remote, build connections, and maintain high productivity. Medical writers are responsible for leading meetings and managing a team to build a cohesive document. Having strong people skills is critical to achieving this goal.

When transitioning into a regulatory medical writing role, there are several transferrable skills that can be utilized from previous experiences, including soft skills, technical skills, and core knowledge. To further prepare new writers, numerous training opportunities are offered through organizations such as NIH, local regulatory affairs forums, and more. Lastly, AMWA provides a recommended training outline focusing on core knowledge and skills, documents, and soft skills that further helps to bridge any knowledge gaps for new writers entering the everchanging field.

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## **GROWING YOUR CAREER AS AN EDITOR**

### **Speakers**

**Crystal Herron, PhD, ELS**, *Redwood Ink, San Francisco Bay Area, CA*

**Loretta Bohn, ELS**, *RTI International, Research Triangle Park, NC*

**Erica Goodoff, ELS(D)**, *The University of Texas MD Anderson Cancer Center, Houston, TX*

### **By Angela Trenkle, BS**

Being a strong editor is a skill set that can open many doors in the medical writing field. In this panel session, three editors discussed some of their tips and tricks for navigating the world of editors.

### **How Editing and Writing Differ**

Ms Goodoff began by explaining that writing is almost like a brain dump; you are just writing everything that is in your mind with regard to the topic. Editing requires more of a critical thinking piece: I have content, but how do I shape it? Dr Herron added that emotional intelligence is also an important skill to have for editing so that you can eloquently explain your proposed changes to authors. Ms Bohn also emphasized that editing is not personal and that editors are looking at the writing from a different perspective—advocating for readers. All three of these editors mentioned that it was important to explain why you're recommending the changes and to back up your suggestions with data and resources.

### **Key Skills for Editing Grant Proposals**

Ms Goodoff began by stating that a key skill for editing grant proposals is to find ways to make it as effortless as possible to read the text and to make sure that the logic flows and ties back to the main objective. Dr Herron emphasized that the storytelling element of the research project is important, which includes how the research project is expected to end. Ms Bohn pointed out the navigation pane in Word, which is a good way to look at pieces of a grant for consistency. All three mentioned the importance of cutting down the length and wording and ensuring that the entire document is consistent in flow.

### **Teaching/Mentoring Editors**

Ms Goodoff began by discussing how coaching new colleagues in editing differs from editing when the client is the only one who will see your edits. It can be helpful to teach new editors because it helps you to become a better editor, but you must find that balance between fixing the problems and teaching the new editor to do it themselves. With

colleagues, it can be complicated because you're editing someone else's editing, so it's important to check your ego at the door. Dr Herron suggested specifically that freelancers try to find another editor that they can trust and learn from because, most of the time, freelancers are working alone. Ms Bohn also added to this by emphasizing the importance of having a more organized approach when meeting with someone and suggested cross-teaching so you can learn from each other.

### Working Remotely

Ms Bohn began by mentioning that the skills are the same, but mentoring someone that you aren't in the same room with requires a unique approach. Ms Goodoff chimed in and agreed that the core editing skills are the same, but the presentation of the information is different when working remotely. She had to learn a lot of new technology and noted that you don't get the same chance to rely on audience reactions, but you can write a tentative script while presenting on Zoom. Dr Herron added the suggestion that you can post a sticky note with a person drawn on it near your camera; that way you have "someone" to talk to and look at near the camera, which will help your audience connect with you. Ms Bohn closed by suggesting a fake commute at home, something that signifies the beginning and the end of your workday.

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## REMOTE BUT NOT ALONE: NAVIGATING DIFFICULT PERSONALITIES WHEN YOU WORK FROM HOME

### Speaker

**Melissa Christianson, PhD**, *Whitsell Innovations, Inc., Chapel Hill, NC*

### By Stacie Marsh, MPA, CPH, GPC

Collaborative medical writing requires leadership from professional medical writers to guide teams of people toward the common goal of completing documents with clarity, precision, and adherence to third party guidelines, often within challenging timeframes. Medical writing teams typically include groups of individuals from widely varying backgrounds, areas of expertise, priorities, pressures, and

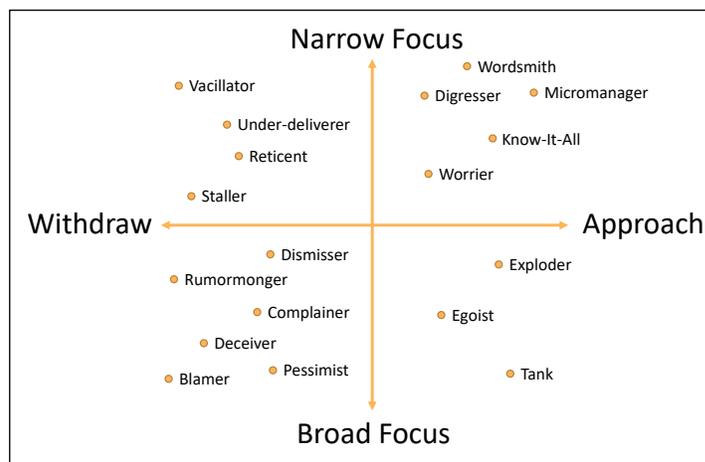
communication styles. Medical writers must foster effective teamwork in order to successfully lead their teams toward achieving their common goal.

The pandemic has forced more writing teams to collaborate in a virtual environment, requiring medical writers to recognize and navigate team dynamics and interpersonal intricacies in creative ways. Dr Christianson's presentation at the American Medical Writers Association (AMWA)'s 2021 Medical Writing and Communication conference identified the most common personality types among difficult members of medical writing teams and provided specific strategies for navigating these traits in a virtual environment.

### Defining and Recognizing Difficult Behaviors

The first step in dealing with difficult behaviors is recognizing that they exist. Although perceptions of difficult behaviors vary by the individual assessing the behavior, difficult behaviors and attitudes typically refer to those that are misaligned with the expectations of the writer and the team.

Dr Christianson illustrated the most common types of difficult behaviors in a behavior categories axis (Figure). Group 1 includes those who are narrowly focused with tendencies to approach a project in a way that mismanages the writers time, attention, and processes, and ultimately impedes the writer's ability to move a project forward in an optimal timeframe. Examples of Group 1 traits include micromanagers, digressers, know-it-alls, worriers, and wordsmiths. Those in Group 1 may be concerned about proving their own worth or getting blamed for less-than-optimal outcomes for reasons such as job vulnerability or being new in a position with perhaps lesser credentials than other team members.



**Figure.** Top left (Group 3); top right (Group 1); bottom left (Group 4); bottom right (Group 2).

Group 2 includes those who are more broadly focused but aggressively approach projects. These behaviors conjure

an elephant barreling through a meeting, causing chaos in their wake. Examples include those with strong egos, often short tempers, and who are prone to derail a team's progress in unpredictable ways. Individuals displaying these tendencies may not realize the value of writers in handling important team functions.

Group 3 includes those who are more narrowly focused on a project yet withdrawn or disengaged from specific tasks at hand. These individuals tend to be reticent to voice their opinion or make an important contribution until a problem arises, vacillate, and fail to provide clarity to move forward, stall a meeting's progress, and generally under-deliver on their intended roles and contributions. Reasons for these behaviors can be attributed to cultural complexities, competing priorities, and simple unawareness of what is expected of them as part of the medical writing team, among others.

Finally, Group 4 includes those who approach a project from a broad perspective but whose actions withdraw from the functions or goals of the team. Individuals displaying these characteristics tend to be pessimists, complainers, rumormongers, blamers, deceivers, and dismissers. Unfortunately, these are often the most common types of difficult behaviors and influence the tone and dynamic of entire teams in a negative manner. These behaviors are often exacerbated by—and sometimes a result of—ineffective communication from project leaders, including medical writers leading cross-functional teams.

### Dealing With Difficult Behaviors

Learning to proactively identify potentially challenging team dynamics and communication styles—and the context in which these behaviors may be based—can help writers anticipate and prevent problems before they arise, or at least limit their impact.

Dr Christianson suggested early actions, ongoing strategies, and meeting solutions for each of the 4 groups. Following these practical tips will ensure that cross-functional teams collectively and efficiently achieve their common goal of producing a clear, compelling, and compliant final product. The presentation included practical strategies to assert writers' leadership roles and assess team member characteristics in order to identify potentially difficult behaviors and mitigate their impact early in a project. For example, writers should confidently

articulate their qualifications and their roles as writers and project managers at the outset of a project, followed by detailing the roles, expected contributions, and associated timeframes for all other team members.

Writers may want to consider holding a pre-kickoff meeting with a team representative prior to the formal kickoff in order to get a feel for team dynamics and personality traits. During the kickoff, writers should encourage team members to turn their cameras on in order to match voices/behaviors/tones with names and visibly monitor problematic behavior. The kickoff meeting should establish ground rules and timelines expected of all team members for the project duration. Writers may also want to consider assigning a note taker for meetings so they can focus on the task at hand as they tune in to team dynamics.

**Medical writers have immense power to lead writing teams in a way that fosters productive, collegial behavior.**

Clear and consistent communication is paramount. Writers should be very clear about what they need from individual team members and communicate with them directly if needed. Timed agendas sent in advance of each meeting, as well as emails using the “bottom-line-up-front” approach are also helpful in keeping difficult behaviors in check.

Medical writers have immense power to lead writing teams in a way that fosters productive, collegial behavior. If difficult behaviors arise despite adherence to these proactive strategies, writers should remain professional, positive, solutions-oriented, firm, and confident in their leadership to keep teams moving forward toward their common goal.

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## SALES TRAINING AND BEYOND: DEVELOPING EDUCATIONAL CONTENT ACROSS THE PHARMA/ BIOTECH LANDSCAPE

### Speakers

**Gail V. Flores, PhD**, *Medical Writer, Encore Biomedical Communications LLC, Encinitas, CA*

**Lauren Mays Weddle, PhD**, *Learning Strategist and Senior Medical Director, Curtis Learning LLC, Philadelphia, PA*

**Julie Munden, BA**, *Director of Editorial Services, Curtis Learning LLC, Philadelphia, PA*

### By Kavita Garg, MPharm

*Gail V. Flores, Lauren Mays Weddle, and Julie Munden*, speakers at the 2021 American Medical Writers Association (AMWA) Medical Writing & Communication Conference, discussed the elements (*who, what, and how*) of sales training materials, debunked some misconceptions about them, and revealed insights into what it's like to work in this field. Their goal was to bring awareness to an unmet need in the AMWA community by providing medical communicators with the skills required to work in sales training for the biotech and pharma industries.

### Busting Common Myths

Dr Flores described the field of sales training as being a black box that remains unopened. She addressed some misconceptions about what developing sales training materials entails.

### Who (Key Stakeholders, Their Roles, and Processes Involved)

Dr Mays Weddle introduced the key players for the sales education and training materials that medical writers

(MWs) create (from both the client and agency sides).

The procedures involved in developing collaborative concepts for a variety of target audiences with different learning needs are discussed below. The key role players are project leads, writers, and editors.

### Key Stakeholders

<b>Audience</b>
<ul style="list-style-type: none"> <li>• Medical affairs, sales, clinical nurse educators, patient services, patients, health care providers</li> </ul>
<i>Training for commercial sales representatives</i> <ul style="list-style-type: none"> <li>• Adult learners</li> <li>• Educational background varies</li> <li>• Years of commercial sales experience varies</li> </ul>
<b>Client Team</b>
<i>Main point of contact</i> <ul style="list-style-type: none"> <li>• Commercial training manager or director</li> <li>• Lead initiatives</li> </ul> <i>Team involved in reviewing materials</i> <ul style="list-style-type: none"> <li>• Marketing</li> <li>• Medical</li> <li>• Legal</li> <li>• Regulatory</li> </ul>
<b>Sales Training Team (Curtis Learning LLC)</b>
<i>Main point of contact</i> <ul style="list-style-type: none"> <li>• Learning Strategist</li> <li>• Medical Director</li> <li>• Project Manager</li> </ul> <i>Content development team</i> <ul style="list-style-type: none"> <li>• Medical writer</li> <li>• Medical editor</li> <li>• Content manager</li> <li>• Medical illustrator</li> <li>• Graphic designer</li> <li>• Fact-checkers</li> <li>• Technical team</li> </ul>

Developing Sales Training Materials Is NOT	What Medical Communicators DO
Writing materials that teach selling skills	 <ul style="list-style-type: none"> <li>• Focus primarily on science and clinical education</li> </ul>
Writing marketing or promotional materials	 <ul style="list-style-type: none"> <li>• Write <b>educational</b> materials</li> </ul> <p><i>A disclaimer is included in the footer of every page or slide of every deliverable, stating that these materials are not to be used for promotional purposes.</i></p>
Writing materials with “spin”	 <ul style="list-style-type: none"> <li>• Follow the same ethical standards as all other medical communicators, and they can only develop documents that are accurate and completely referenced to high-quality resources</li> </ul>

## Curriculum Design and Development

Bringing therapy to market is a multi-year process around United States Food and Drug Administration (FDA) approval, so the training materials in the curriculum supporting the product (client's drug) launch typically cover a range of topics.

1. Prelaunch
  - a. Foundational training
  - b. Disease state, treatment landscape, and product knowledge
2. Launch
  - a. Launch training/workshops
  - b. Certification
3. Postlaunch
  - a. Ongoing support for existing indication
  - b. New foundational and launch curriculum for additional indications

## What (Types of Deliverables For Sales Training)

Dr Flores also highlighted becoming familiar with a variety of print and digital deliverables that includes medical illustrations for their sales-trained clientele.

1. Prelaunch (print or digital modules, assessments, patient cases, quick reference cards, interactive deep dives, subject matter expert-facilitated sessions)
2. Launch
  - a. Launch training/workshops
  - b. Annotated package inserts
  - c. Certification
3. Postlaunch
  - a. Update of previous materials
  - b. Resources to address knowledge or skill gaps

Dr Flores contrasted and explained how sales training in medical writing differs from other types of medical writing.

**Similarities:** Deliverables most commonly include an outline and 3 drafts, working templates, medical editing, and graphic design, elements of storytelling, and adherence to strict citation guidelines, and referencing of every statement to the publication page. Although not ideal, many projects also have some out-of-scope work due to late reviews and changing therapeutic landscapes.

**Differences:** For sales training materials, the MW decides how to present content (bulleted lists, tables,

medical illustrations, graphics, or infographics), collaborates with medical illustrators and artists, writes customized glossary definitions for terms the learner may not be familiar with, and writes for real-world application.

## How (Key Steps in Deliverable Development)

Munden summarized the key steps in the deliverable development process. It's important to understand them to grasp their significance and what happens when these deliverables are used in the field.

1. Content outline (MW, client)
2. Draft 1 (MW)
3. Draft 2 (MW, review, edited, and fact-checked by medical editor; uploaded into client's content management system by a content manager)
4. Medical/Legal/Regulatory (MLR) reviews all deliverables for approvals and resolves comments
5. Additional drafts—resolve MLR comments, layout finalization, re-upload by content manager
6. Document approval—incorporate any changes in the layout, comments resolution, deliverables ready for use

All documents—outline and all drafts—are fully annotated and internally edited and reviewed before submitting to the client.

## Key Takeaways

Knowing the essential people and processes involved in sales training content development, as well as how to collaborate effectively throughout content development, is necessary when writing for sales training audiences. Medical writing for sales training focuses on scientific and clinical education. From early conception through final approval and dissemination, generating sales training materials requires various key steps.

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## TEACHING THE NEXT GENERATION OF REGULATORY MEDICAL WRITERS

### Speakers

**Kim Jochman, PhD, RAC**, Director, Medical Writing, Merck & Co., Inc, Rahway, NJ

**Marsha Caton-Faustin, PhD**, Director, Oncology Medical Writing, Merck & Co., Inc, Rahway, NJ

**By Kavita Garg, MPharm**

### General Session Overview

The speakers at the 2021 American Medical Writers Association (AMWA) Medical Writing and Communication Conference, *Kim Jochman* and *Marsha Caton-Faustin*, discussed the importance of having standardized regulatory medical writing (MW) training programs, with a focus on the need for structured training programs for entry-level and early-career regulatory MWs. The speakers also discussed how their organization adapted and implemented industry-level guidelines to develop training programs for new regulatory writers. Sharing this approach can help other organizations train new regulatory MWs and provide them with all of the essential skills required for performing this job.

### Why Do We Need A Training Program For Regulatory Writers?

Caton-Faustin explained why organizations need a standardized training program for regulatory writers. People generally envision writers sitting at their desks, pounding

away at the keyboard, and completing writing chores, especially in a regulatory or scientific writing career. Most people with scientific degrees know how to write and present scientific data, but how many of them have had one-on-one coaching from a mentor or coach to bridge the gap between academic writing and regulatory writing? How many writers were given no guidance at all and learned to write regulatory documents by trial and error or by sink or swim?

A regulatory or scientific writer, whether working for a sponsor organization, a contract research organization, or a medical agency, works with cross-functional teams, manages multiple projects, and juggles a lot on daily basis, all while completing their writing tasks. Many organizations do not provide formal training to their writers, and experienced writers have a varied baseline experience. Looking at the landscape of regulatory writing, it is important to provide MWs with thorough training so that they understand what they're entering into and what they'll be required to do in this dynamic profession. Developing skills in regulatory writing takes a long time. It's tough to create a training program that fits all writers because of the wide range of regulatory documents and leadership skills.

### Developing a Structured Training Program

Jochman shared some of the resources that can be used to provide some guidance—the DIA's Medical Writing Competency Model and the AMWA Recommended Training Outline for Regulatory Writers (Table 1).

**Table 1.** Brief Overview of Industry-Level Guidance

Available Industry-Level Guidance	
DIA Medical Writing Competency Model (2018) <sup>1,2</sup>	AMWA Recommended Training Outline for Regulatory Writers (2020) <sup>3</sup>
<ul style="list-style-type: none"> <li>• Focuses on professional medical writing within the life sciences industry.</li> <li>• The working group consisted of experts from multiple companies, medical writing specialties, and industry sectors.</li> </ul>	<ul style="list-style-type: none"> <li>• Based on DIA Competency Model (especially Section 2) and experience of AMWA Workforce Training Committee.</li> </ul>
<p><b>Consists of 2 sections</b></p> <ol style="list-style-type: none"> <li>1) Core work functions divided into functions, tasks, and activities:               <ol style="list-style-type: none"> <li>a) Core role delivery eg, document preparation, development, and finalization</li> </ol> </li> <li>2) Knowledge and skills to successfully perform these functions for all MWs, regulatory MWs, and MW managers               <ol style="list-style-type: none"> <li>a) Knowledge at different levels</li> <li>b) Skills and abilities</li> <li>c) Behaviors</li> </ol> </li> <li>3) Does not distinguish competencies of novice MWs from experienced MWs</li> </ol>	<p><b>Consists of</b></p> <ol style="list-style-type: none"> <li>1) List of recommended training topics and priorities for training, from entry-level to more advanced levels               <ol style="list-style-type: none"> <li>a) Core knowledge and skills                   <ol style="list-style-type: none"> <li>i) Drug development process</li> <li>ii) Medical writing skills</li> <li>iii) Technical aptitude</li> <li>iv) Analytical skills</li> </ol> </li> <li>b) Documents (3 levels)</li> <li>c) Soft skills                   <ol style="list-style-type: none"> <li>i) Management skills</li> <li>ii) Personal development</li> </ol> </li> </ol> </li> <li>2) List of independent reading for regulatory MWs</li> <li>3) Customizable training checklist template</li> </ol>

Jochman also talked about how their company used these guidelines to develop rotational training programs for entry-level MWs (Table 2).

Caton-Faustin discussed their early-career development program, designed for employees from varied backgrounds, including those who have finished the entry-level MW program as well as those who have come in from other organizations or even different departments within their own company (Figure).

### Key Takeaways

In summary, a MW training program provides the foundation for entry-level and early-career writers to succeed in their careers. In a nutshell, the mentoring program may include

1. preparing a coaching framework and a partnership between the coach and manager,
2. rotations across several specialty groups within the MW department,
3. hands-on activities and shadowing experiences,
4. lecture-type training sessions, and
5. on-the-job training with careful coaching.

The training program helps novice regulatory writers gain document-specific knowledge, general MW skills, a strong regulatory foundation using industry-standard resources such as AMWA and DIA guidance, statistical understanding, data interpretation ability, and leadership skills.

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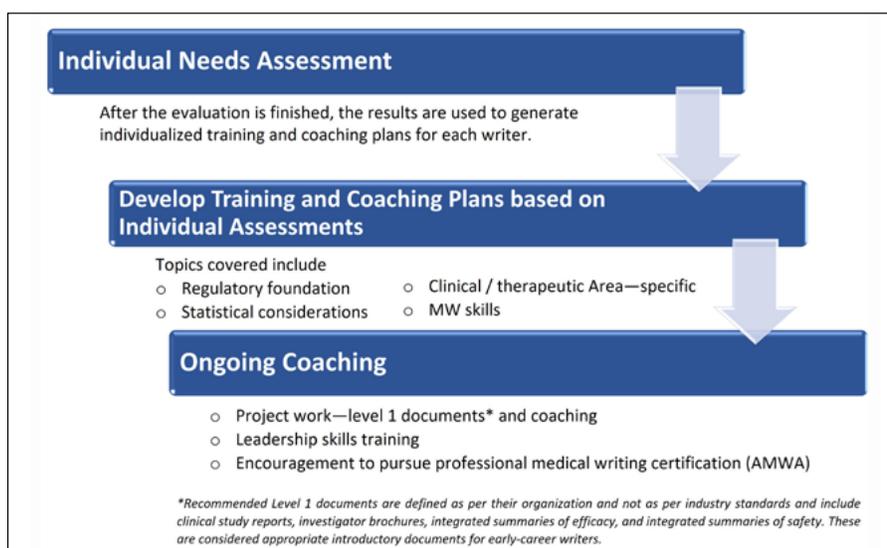
### Resources

1. Clemow DB, Wagner B, Marshallsay C, et al. Medical writing competency model – section 1: functions, tasks, and activities. *Ther Innov Regul Sci.* 2018;52(1):70-77.
2. Clemow DB, Wagner B, Marshallsay C, et al. Medical writing competency model – section 2: knowledge, skills, abilities, and behaviors. *Ther Innov Regul Sci.* 2018;52(1):78-88.
3. Yih L, Alexander L. *AMWA Recommended Training Outline for Regulatory Writers.* American Medical Writers Association; 2020. Accessed October 2021, <https://info.amwa.org/hubfs/Offer/Regulatory-writer-training%20ebook/regulatory-writer-training.pdf>.

**Table 2.** Case Study of Rotational Program for Entry-level MWs (<1-year experience)

Month 1	General orientation	
Months 2-4	Rotation with assigned document* team	Hands-on training, writing style, clinical trial data
Months 5-7	Rotation with clinical technical editing team	Quality control review; clinical study report trainings and shadowing experiences also begin
Months 8-9 (6 weeks)	Rotation with clinical content standards team	Technical aptitude
Months 9-10 (3 weeks)	Rotation with the document* team	Health literacy concepts
Month 11+	End rotations; begin supporting MW team on regulatory documents	Hands-on training

\*The first rotation is with the narrative team—narratives are the brief, participant-level documents that they learn at the beginning of the training program. The next rotation is with the teams writing informed consent documents. Shadowing opportunities for more complex documents, such as clinical study reports, are also provided throughout the rotational program. Overall, the training program includes core knowledge, soft skills, networking, and corporate culture.



**Figure.** Overview of training programs for early-career MWs (1-2 years' experience). AMWA, American Medical Writers Association; MW, medical writer.

## THE QUICK AND THE DIRTY: BEST PRACTICES FOR WRITING AND EDITING UNDER TIGHT TIMELINES

### Speakers

**J. Kelly Byram, MS, MBA, ELS**, *Immediate Past President and Director-at-Large for New Mexico, AMWA Southwest Chapter, Freelance Editor and Writer, Owner of Duke City Consulting, LLC, Albuquerque, NM*

**Theresa E. Singleton, PhD**, *2021 AMWA Fellow, Freelance Scientific Writer, Owner of Singleton Science, LLC, Beverly, MA*

**Damiana Chiavolini, MS, PhD**, *President-Elect of AMWA Southwest Chapter, Academic Writer, Editor, and Instructor, Richardson, TX*

### By Stephany Panlilio, MS

In medical writing, the scope and timeline for documents varies, depending on the type of document and the client for which the document is being prepared. However, these 2 aspects determine a medical writer's ability to take on a new project. This article summarizes the experiences of Ms Byram and Dr Singleton as freelance medical writers and editors, and Dr Chiavolini as a medical writer and editor in academia, and their best practices for writing and editing under tight timelines.

### Tight Timelines Versus Short Notice

It is important to first differentiate between a tight timeline and short notice. In some cases, a client can reach out requesting help with a project, but the expectation is the project starts right away. This is short notice. On the other hand, a client may reach out ahead of time, but provide only a short amount of time to prepare a document, hence, a tight timeline. In either instance, the first step would be to identify the scope of the project and define expectations of the medical writer/editor and the client.

For freelance medical writers/editors, other considerations may include if this is a new client or an established client and the time needed to educate on the process. Taking on a rush project from a new client is riskier because the client may be new to the process in general or may not have worked on a given document type. Dr Singleton emphasized, "As a freelance medical writer, the best asset I have to offer is my word," and taking on a project that could potentially compromise quality could impact a writer's reputation. There is a lot of value added in taking the time to educate a new client on how the process might look, setting expectations, and establishing a schedule. If the timeline does not account for this, the client may not be a good fit.

In academia, there is more flexibility in timelines for many documents, with the exception of grant proposals.

However, it is still important to set expectations and educate stakeholders on the process and typical turnaround times.

### Advice for New Writers and Editors

The first piece of advice given by Ms Byram, Dr Singleton, and Dr Chiavolini to new writers when working on a document with a tight timeline was to ask questions. Asking questions may slow down the process, but it is imperative to get as much information as needed upfront from the client and to fully understand the agreements being made and to clarify deliverables.

Another critical piece of advice is to set boundaries. Freelance writers are typically hired to solve problems that a client may not have the experience or expertise to solve. Establishing boundaries (eg, typical turnaround times and exceptions) and expectations from both the writer and the client early in the process is important. Boundaries are not meant to create barriers and hinder progress, instead they strengthen collaboration between the writer and client, keeping the project focused and on target.

### Strategies Used When a Project Is Not on Schedule

When working on a tight timeline, every minute matters. If a risk arises that could potentially cause a project timeline to not be met, the best strategy is communication. Reaching out to the project team as soon as possible is critical. It also provides the opportunity to ask questions. Is the scope of the work negotiable? Is it possible to focus on the key messages of the document rather than the language? If the project team is not providing the information needed to author pertinent sections of the document, reach out to the principal investigator for assistance; for example, ask whether there is a possibility for timeline extension.

Proactively setting expectations and maintaining clear communication throughout a project can help to keep the project on schedule.

### Tools

A variety of tools are available to assist with authoring, editing, and composing documents of all types, and ensuring timelines are met. Examples of tools utilized by Ms Byram, Dr Singleton, and Dr Chiavolini for different documents are provided below.

- CONSORT (Consolidated Standards of Reporting Trials) guidelines and extensions for writing manuscripts
- Plain language guidelines (eg, Multi-Regional Clinical Trials Center's Clinical Research Glossary, released in June 2021)
- Client-specific style guide cheat sheets

- Second (or even third) computer monitor
- Printouts of grant request for proposals and request for applications
- Templates for writers
- Glossaries from cancer centers or other stakeholders
- Digitally curating information
- Time tracking/management tools
- Optimizing software already in use
- Checklists and detailed project notetaking

A medical writer's ability to take on new projects depends on the scope and timeline for a given document. Clear communication, educating the client, and setting expectations and boundaries upfront are needed to ensure the project is completed according to the timeline, without compromising quality. In their presentation, Ms Byram, Dr Singleton, and Dr Chiavolini provided several strategies for assessing the ability to take on a project with a tight timeline, as well as several tools for creating high-quality documents within that timeline.

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## TIME TO CLOCK IN: APPLYING MANUFACTURING BEST PRACTICES TO CONSISTENTLY AND EFFICIENTLY PRODUCE HIGH-QUALITY DOCUMENTS

### Speaker

**Jenni Pickett, PhD**, *Whitsell Innovations, Inc., Chapel Hill, NC*

**Mary Ellis Bogden, BA**, *Whitsell Innovations, Inc., Chapel Hill, NC*

### By Stephany Panlilio, MS

Regulatory writing and manufacturing have many commonalities. As with manufactured products, regulatory documents should be produced at a reasonable cost, completed per an agreed upon timeline, be fit for intended purpose, and should meet a set of corporate, legal, and customer standards. What can regulatory writers learn from advances in manufacturing processes?

## Manufacturing Best Practice Philosophies

Many modern manufacturing processes and principles came from the car manufacturer, Toyota. The Toyota Way operates under 4 driving principles.<sup>1</sup> These principles can also be applied to medical writing, as described below.

- **Long-term Philosophy – Forward Thinking.**  
Focusing on the processes used to create products or documents can help improve efficiency over time.
- **Add Value to the Organization by Developing Your People and Partners.**  
In manufacturing and regulatory writing, ensuring that team members have the right skills is essential.
- **The Right Process Will Produce the Right Results.**  
A robust process will ensure a high-quality product.
- **Continuously Solving Root Problems Drives Organizational Learning.**  
Manufacturers and regulatory writers should develop and maintain a system to identify root causes and quickly address issues.

## Good Regulatory Writing Practice

Manufacturers of pharmaceutical products must adhere to Good Manufacturing Practice (GMP) to mitigate risk. A robust GMP quality system includes training people; controlling starting materials and equipment; clearly defining manufacturing, packaging, and storage processes; testing for quality; and documenting each step.

To produce high-quality documents, the following are necessary: trained people, correct source materials that are up-to-date and easy to use, defined processes for the writing and review cycles, a quality control review process, and documenting each step (Figure). So, what would a theoretical good regulatory writing practice include?

- Developing the team by ensuring team members have the proper education, relevant experience, and knowledge of regulations and company policies can help to reduce the risk of human error. Specific risks to your team can be evaluated by a gap analysis of critical skills. Cultivating a growth mindset culture in which employees feel comfortable being noisy in their ignorance helps identify critical training needs.
- Creating a Quality Document Profile, similar to the Quality Target Product Profile used in GMP, verifies the correct template, sources, interpretation, and team expectations are used for the document. Using a storage management system prevents errors due to use of incorrect templates, outdated data, or irrelevant sources.

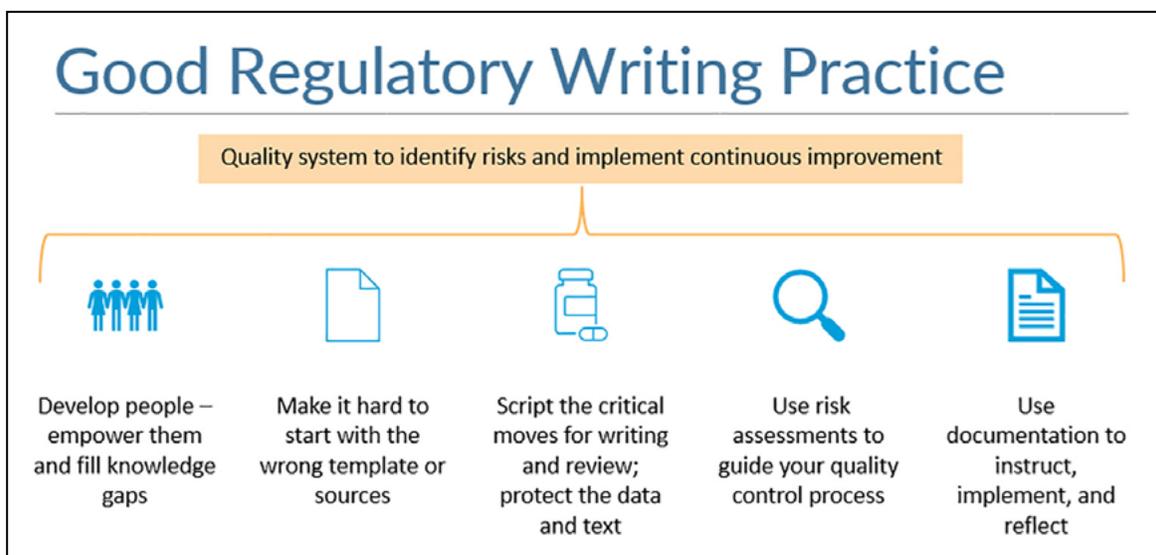


Figure. Elements of a theoretical good regulatory writing practice.

- Protecting the data and text by using good data hygiene and limiting review cycles prevents transcription errors, incorrect data interpretation, and inconsistent text or messages within the document. Reviewer fatigue and consistency errors can be reduced by waiting until the last review to write certain sections, such as the executive summary, synopsis, list of abbreviations, and summary of changes.
- Using risk-based quality control techniques can improve efficiency and ensure the most important areas in the document are correct. In GMP, Critical Quality Attributes (CQAs) are factors which would impact the overall quality of the product. Identifying CQAs in your document (ie, new data in an investigator brochure) can help your reviewer prioritize where to start.
- Recording the document development process in a tracker allows you to confirm you have followed all the key steps above and also see where improvements can be made.
- Reviewing your document development process periodically will allow you to address new risks as you discover them and improve efficiency and quality over

time. GMP uses Corrective Action Preventative Action, a system in which root causes are identified, and solutions are proposed, verified, and implemented.

Identifying risks throughout regulatory document processes and finding ways to proactively mitigate them are imperative steps to creating high-quality documents. As regulations evolve and processes increase in complexity, implementing elements of a good regulatory writing practice provides a framework to focus on long-term investments in efficiency and quality of your documents by continually improving your people and processes.

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**Author declaration and disclosures:** *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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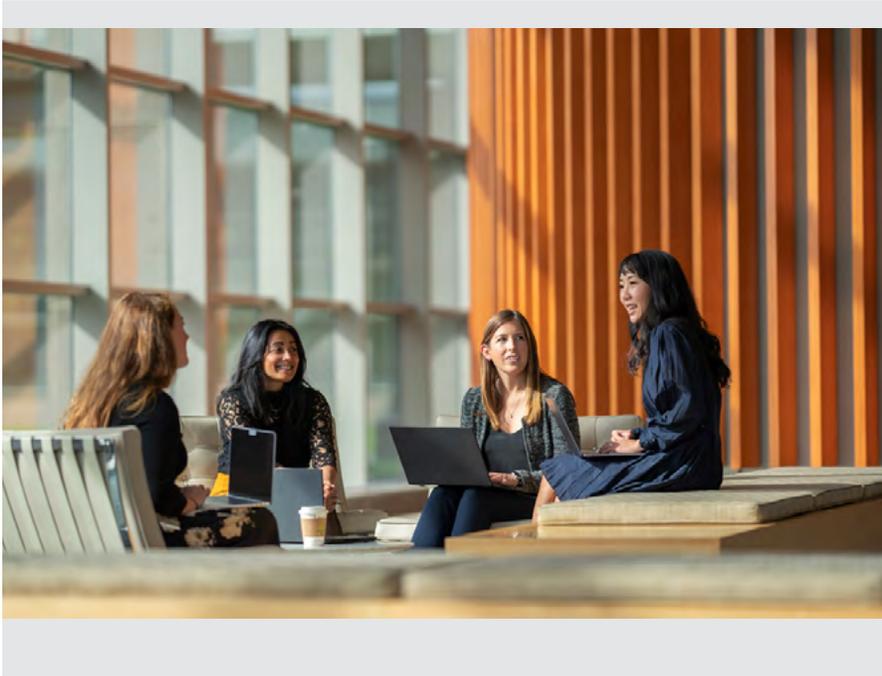


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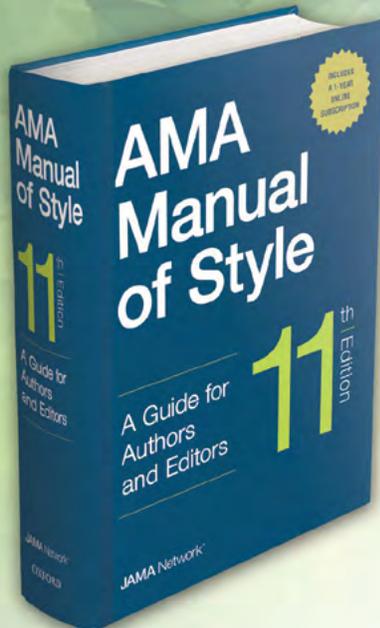
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FEATURE

## Digital Enhancements of Scientific Content at Virtual and Hybrid Conferences

Qing Zhou, PhD, ELS / Regeneron Pharmaceuticals Inc, Tarrytown, NY

### ABSTRACT

Since the beginning of 2020, scientific conferences around the globe have evolved quickly to adapt to a virtual or hybrid format when in-person meetings were disrupted by the COVID-19 pandemic. With the digital platforms now in place to enable virtual participation, interaction with scientific content in a digital format will likely become a new norm of the scientific conference experience. Digital enhancements of scientific presentations and posters may help bridge the gap of communication in a virtual format and may extend the reach of scientific content. This article provides a brief overview of common types of digital enhancements and summarizes insights from two conference organizers from their conversations at the “InformED” podcast. Researchers, conference organizers, and medical communication and publishing professionals will continue to optimize the digital enhancements and explore innovations to maximize the value of scientific content disseminated at virtual and hybrid scientific conferences.

At traditional in-person scientific conferences, scientific content is typically delivered through oral presentations to a live audience in meeting rooms or through display of posters in large exhibition halls. In the last decade or so, even before the coronavirus disease 2019 (COVID-19) pandemic, a trend toward the use of digital content had already started among many scientific conferences in which e-posters were displayed on large screens instead of on poster boards and recorded oral presentations and e-posters were made available on demand to meeting attendees after the conference.

The arrival of the COVID-19 pandemic in early 2020 put an abrupt stop to in-person meetings and forced all scientific conferences to quickly adapt to either an entirely virtual format in which all participants joined online, or a hybrid format that combined some on-site participation elements with virtual participation of those who were unable to travel on-site due to travel or quarantine restrictions, or who



preferred to attend remotely for other reasons.<sup>1-7</sup> With the emergence of multiple variants of (SARS-COV-2), much uncertainty remains as to when the world will ever return to a pre-COVID-19 state in which fully in-person conferences will resume. Virtual and hybrid conference formats also opened unprecedented opportunities of wider outreach to members and audiences around the globe. As meeting organizers have already invested in and developed online platforms, these digital infrastructures will likely stay to enable hybrid conferences even after the COVID-19 pandemic is over.<sup>5-7</sup> Therefore, interaction with scientific content in a digital format will likely become a new norm of the scientific conference experience.

### DIGITAL ENHANCEMENTS OF SCIENTIFIC CONTENT AT VIRTUAL AND HYBRID CONFERENCES

What are the digital enhancements in the era of virtual and hybrid conferences? How do conference attendees interact and consume these digital enhancements? The answers to these questions are slightly different for the 2 main types of conference content, oral presentations and posters.

For oral presentations, a prerecorded video of the oral presentation is usually required ahead of the conference. If a discussant is assigned to moderate a session with several talks, the discussant’s presentation that summarizes different talks may also be prerecorded. In a hybrid meeting,

even when most presentations are delivered live on-site, prerecorded presentations may still be required as backup in case a presenter is unable to travel on-site.

During a virtual or hybrid conference, live broadcasting of oral presentations is either delivered live, prerecorded, or a mix of both is essential to create a “live” experience for meeting attendees to listen and watch these talks for the first time. To add to the live interactions, presenters and moderators typically join live either onstage (for live presentations) or on screen (by applications such as Zoom) for discussions and Q&A. Virtual participants can typically submit text-based questions by a chat function on the meeting platform which are then selected by the moderator for answering and discussion.

For scientific posters, digital enhancements refer to additional materials beside the poster file itself on the virtual meeting platform. In the absence of face-to-face interactions between presenters and poster viewers, these digital enhancements may help bridge the gap of communication. Common digital enhancements include

- QR codes embedded in posters. These QR codes can link to supplementary materials such as methodological details, additional results, and additional resources.
- Poster slides. These slides, usually brief (eg, 5-10 content slides, as specified by the conference), provide a succinct summary of the poster, thus offering a quicker and easier read, especially on smaller screens of hand-held devices.
- Audio or video recording of the poster. In these recordings, the presenter can give an overview of the poster and explain certain key points of the research work. In the absence of face-to-face interactions, these recordings offer a personal touch to the virtual posters.

In addition, for both oral presentations and posters, the conference platform may enable additional enhancements such as auto-generated captions or transcripts accompanying audio and video recordings. The conference platform may also allow a meeting attendee to reach out to a presenter to ask questions, thus providing an opportunity of developing professional connections that may translate into future collaborations.

## INSIGHTS FROM MEDICAL SOCIETIES AND CONFERENCE ORGANIZERS

Several episodes on the InformED podcast offered interesting insights on digital enhancements from the perspective of medical societies and conference organizers. InformED

is a podcast series created by the International Society for Medical Publication Professionals (ISMPP), in which the host interviews different guests in episodes to talk about key trends and issues facing medical communication and publication professionals in an ever-evolving field.

In episode 4 of the 2020 season,<sup>8</sup> the podcast host Rob Matheis, ISMPP President and CEO, interviewed Travis Hicks, the Director of Web Operations at American Society of Clinical Oncology (ASCO). The 2020 ASCO conference took place entirely in a virtual format at the end of May 2020. An important insight by Hicks is that consumption of scientific content becomes the “primary focal point” of the virtual meeting experience.<sup>8</sup> The amount of content consumed over 3 days of the virtual ASCO conference was impressive: 2.5 million pageviews in 2 days; and at one point 16,000 individuals were watching live, with 30,000 more viewing on-demand content. In the absence of the other social aspects of a traditional conference, attendees naturally focused on content, and many discussed the content online through social media. For digital enhancements, a big difference from previous in-person meetings is the incorporation of the poster video on the platform. It turned out that videos were the most consumed pieces, although other enhancements were also valuable such as slides for download and links to additional resources. ASCO also developed homegrown applications to allow meeting attendees to ask questions to presenters, which helped with building professional rapport and connections.

In 2 more recent episodes in the 2021 season (episodes 3 and 4),<sup>9,10</sup> Matheis talked to David Barrett, the CEO of the American Society of Gene and Cell Therapy (ASGCT), on navigating the changing medical conferences. In part 1 of the conversation, Barrett reflected on recent experiences from virtual ASGCT meetings and pointed out that the aspect valued the most by attendees was the access to live meeting content (eg, live presentations or prerecorded materials) as they are being presented.<sup>9</sup> Although some technical difficulties caused temporary interruptions of content broadcasting, the meeting organizers were able to fix the problems and restore content streaming. Another important aspect valued by meeting attendees was engagement with speakers during the live sessions. Attendees could submit questions that were monitored by the session chair and “upvote” certain questions to the front of the line for answering. In addition, Barrett reflected that the virtual format made it possible for attendees to switch from one talk to another quickly among different sessions (or “talk surfing”), which might not have been possible during conventional meetings.

In part 2 of the conversation that focuses on virtual display of scientific posters, Barrett also emphasized the importance of poster slides and prerecorded content that can enhance the reach of virtual posters.<sup>10</sup> The built-in feature for contacting poster authors also allowed for connections between the attendees and the presenters. Initial metrics from the virtual conferences suggested that about 50% of meeting attendees visited the digital poster halls, with varied view counts of individual digital posters (ranging from low dozens to several hundreds of views per poster). Although no comparison can be made due to lack of similar metrics for traditional conferences, these numbers may suggest a more active engagement with poster materials by conference attendees. Looking ahead, Barrett mentioned that the hybrid meeting model would likely stay, as the meeting organizers are trying to “marry” the 2 approaches of live engagement and enduring the sharing of digital contents to maximize the value of scientific conferences.<sup>10</sup>

## SUMMARY AND OUTLOOK

Scientific conferences around the globe have quickly evolved to embrace virtual and hybrid meetings in the last 2 years. The hybrid meeting approach will likely stay even after the COVID pandemic and become a new norm for scientific conferences. Digital enhancements of scientific presentations and posters are therefore important to bridge the gap of communication in a virtual format and may extend the reach of scientific content. Still, virtual interactions may not fully achieve the effect of in-person interactions, and there are still drawbacks of digital content such as technical difficulties affecting live streaming and the need for additional resources and IT capabilities to effectively manage and maintain all digital content by the meeting organizer. Researchers, conference organizers, medical communicators and publishing professionals will continue to optimize the digital enhancements and explore innovations to maximize the value of scientific content disseminated at virtual or hybrid scientific conferences.

**Author declaration and disclosures:** *The author notes no commercial association that may pose a conflict of interest in relation to this article. The views and opinions expressed in this article are those of the author and do not necessarily reflect the views of Regeneron or its employees.*

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## RESEARCH

## Agile Strategies in the Rigid Regulatory Environment

Jeanette M. Towles and Jason S. Casavant / Synterex Inc, Boston, MA

### ABSTRACT

This article will discuss the real-world application of agile project strategies to expedite the development of high-quality deliverables that satisfy the structure and rigor of the regulatory environment. The coronavirus disease 2019 (COVID-19) pandemic challenged regulatory writers not just to rethink the structure of their workdays and the nature of their interactions with their colleagues but to leverage technology and adopt strategic project thinking to help their teams meet aggressive timelines while working in the virtual workspace. Scenarios will include the application of agile project strategies to working on COVID-19 programs or programs heavily impacted by COVID-19, from expedited submission processes to rapid responses to regulatory authority requests for information. This assessment will include what strategies worked well, what strategies did not, and what an agile project should look like within the regulatory writing space.

Across industries, different methodologies for project management are used. The most popular include the waterfall, Kanban, adaptive project framework, lean, and critical path methodologies.<sup>1</sup> The reason for the variety in project management styles is simple—optimal delivery of a product in any industry requires processing of multiple intrinsic and extrinsic variables. In our experience in the biotech and pharmaceutical space, most regulatory writing deliverables have been planned by using the waterfall methodology; but the current space has become more dynamic, influenced almost daily by decisions made by regulators, research committees, health care professionals, venture capitalists, and—most importantly—the scientific method itself. Delivering quality regulatory documents in the current space requires methodology adaptation to an evolving landscape. As the discipline of project management in other industries has evolved to account for ever-increasing change, with project lifecycles now ranging from the very plan-driven to the iterative to the highly adaptive,<sup>1</sup> the authors considered whether non-waterfall methodologies could be adapted to regulatory writing.

This article briefly describes the *waterfall approach* historically used in medical writing and discusses the application of alternative project management methodologies to achieve quick, adaptive, and controlled regulatory document development.

### THE WATERFALL APPROACH AND ITS PITFALLS

Regulatory writing project management typically has followed the waterfall method, which aligns with document development in an environment requiring sponsors to implement and maintain quality systems. The standard operating procedures (SOPs) that underpin these systems are often prescriptive, delineating steps that can be documented, thereby demonstrating compliance. Project timelines tend to mirror these SOPs in their fixed, stepwise progression toward controlled content creation. Project management software uses predecessor/successor inputs to capture this progression and can leverage this information to generate understandable outputs for coauthors and non-medical writing stakeholders. The benefits of the methodology include ample time for both the regulatory writer and coauthors to think, research, and then write and align reviewer comments and changes across the document before the next iteration.

This project management methodology is ideal for projects with a predictable path.<sup>1</sup> The format and content of nonpivotal clinical study reports (CSRs), annual investigator brochure updates, or developmental safety update reports (DSURs) are well described in the regulations, generally limiting stakeholder impact on document structure, and the timelines may be defined by regulation (eg, DSURs) or may be driven by fewer extrinsic factors (eg, a competitive landscape).

Whereas the waterfall methodology relies on predictability, the regulatory writing environment has changed dramatically since the pandemic began. Regulations regarding coronavirus disease 2019 (COVID-19) and non-COVID-19 studies, contract research organization (CRO) and site procedures, and sponsor priorities shifted to enable accel-

erated clinical evaluation of diagnostic, therapeutic, and preventive products to address the pandemic. Regulatory writing projects have been initiated without an assessment of requirements (eg, initiation of a full protocol without identified study endpoints due to an evolving understanding of the clinical course of the disease), well-vetted concepts, or access to real-time investigator clinical observations.<sup>2</sup> Consequently, regulatory writers have been asked to coauthor in real time in a manner significantly divergent from the stepwise collaboration afforded by the traditional waterfall methodology.

## ALTERNATIVE PROJECT MANAGEMENT STRATEGIES

During the first half of 2021, our operational and executive teams reviewed opportunities for continuous improvement. We focused on several COVID-19-related regulatory writing projects because of a recent uptick in requests for supporting projects with accelerated timelines and imperfectly defined parameters similar to what we had observed with COVID-19-related projects, leading us to wonder if a linear way of working might become a relic and if we might need to adapt all or part of our business model. The scenarios we selected for review included the following elements:

- Required multiple resources within the company (eg, regulatory writer and operations support).
- Required >50% resource utilization for the regulatory writer for a discrete period.
- Timelines did not follow a sequential pattern (ie, one or more authoring steps were concurrent), so the writer was unavailable for other projects.
- Coauthoring with the client was done by using collaborative technology.

The selected projects had a timeline that was prospectively created and/or maintained by the regulatory writer and that was available for resourcing manager review.

### Scenario 1

At the time of project initiation, just shortly before the pandemic was declared, one could count on both hands the number of COVID-19-related studies in [clinicaltrials.gov](https://clinicaltrials.gov). The regulatory writer used relevant software and searches of [clinicaltrials.gov](https://clinicaltrials.gov) for recruiting COVID-19 treatment studies to collect clinical intelligence and develop a protocol synopsis, which was then used to facilitate regulatory agency, CRO, and site interactions (Table 1). After receipt of Food and Drug Administration (FDA) feedback on the pre-investigational new drug application (IND) package and about 2 weeks before IND submission, the

**Table 1.** Scenario 1: Medium-Sized Pharmaceutical Company Filing an IND in a COVID-19-Related Indication

<b>Type of Product</b>	Treatment (COVID-19)
<b>Requirements</b>	File IND
<b>Systems</b>	Teams, PleaseReview (sponsor owned)
<b>Regulatory Writing Resources</b>	External consultants (no established MW department)
<b>Timelines</b>	Pre-IND meeting request package 3 weeks IND (2 weeks from pre-IND feedback)
<b>Stakeholders</b>	US regulators; later in the process, global regulators IRB/IEC Internal team Internal management Study sites External philanthropy groups (funding) CRO
<b>Regulatory Landscape</b>	Guidance still being drafted, no guidance available on endpoints and objectives yet; heavy cross-referencing to an existing IND in another indication
<b>Risks</b>	Proceeded with protocol and informed consent form writing at risk ahead of pre-IND feedback to meet timelines; defer many of the details on testing and analysis to ancillary documents (eg, Pharmacy Manual) because details not available yet (EUA for diagnostics had occurred only a few weeks previously <sup>2</sup> )
<b>Project Management Strategies</b>	Communication phone tree Stand-up meetings every other day between work sprints Resource layering for ancillary writing tasks Small core team Cloud-based authoring and review

COVID-19, coronavirus disease 2019; CRO, contract research organization; EUA, emergency use authorization; IEC, independent ethics committee; IND, investigational new drug application; IRB, institutional review board; MW, medical writing.

FDA issued guidance on COVID-19-related study conduct.<sup>3-5</sup> Given that the protocol was nearly finalized, the team had to quickly interpret the guidance, implement any changes addressing conflicts with prior clinical intelligence and an evolving standard of care, and confirm those changes with internal and external stakeholders (eg, confirm that the FDA's oxygenation cutoff for disease severity matched the site's cutoff).

Traditional stepwise project management methodologies were recognized as being too rigid for this dynamic environment, so the team incorporated strategies used in more adaptive methodologies. Change was rapidly communicated through a phone tree and scheduled check-ins every other day, with ad hoc meetings called for specific topics or live edits. The core authoring team was limited to the regulatory writer, clinician, and clinical trial manager,

with supplemental members reviewing specific language in the protocol, which enabled efficient and focused authoring during short work sprints. All authoring was done in Teams, with access managed by a dedicated information technology (IT) professional who was part of the phone tree. A regulatory writing operations associate supported the writer by formatting, locating references, and managing citations. The document underwent a single round of management review in PleaseReview, during which most of the reviewers used the software's commenting feature to provide substantive feedback. The team vetted management comments together, and the core authors discussed any outstanding issues with their line management outside of the review and reported back the results of the conversation. Roundtables attended by all core and supplemental authors as well as the management reviewers were used to efficiently align on resolution of any pending comments.

Structured communication and cloud-based tools were leveraged by the small core team, enabling them to efficiently respond to shifts in the regulatory landscape while also permitting team members to author, consult with management and subject matter experts, and achieve consensus. The team successfully provided a quality deliverable during an uncertain time in drug development and advanced an important potential treatment for COVID-19.

## Scenario 2

This project proceeded in the context of hyper-compressed timelines and the need to look at not only new interim data but also cumulative data (Table 2).

While the CRO was pulling the marketing application documents together and facilitating the various reviews, full-time employees (FTEs) and consultants provided oversight and management of timelines and risks and facilitated interactions with multiple internal and external stakeholders. Because of the time constraints on the project, live data reviews were employed, during which the CRO regulatory writer engaged directly with stakeholders early in the drafting process, allowing for real-time drafting, consensus building, and a reduction in draft cycles. The success of this approach was contingent upon the availability of the correct attendees and their endorsement of this adaptation over more traditional iterative authoring and review processes.

Although Scenario 1 used a small core team with targeted reviewers to achieve consensus, this scenario used a larger review team, which included team members and management, to increase functional alignment at approval, which worked in large part because of the team trust at all levels. In this scenario, the use of PleaseReview followed

**Table 2.** Scenario 2: Medium-Sized Pharmaceutical Company Filing a Marketing Application in a COVID-19–Related Indication

<b>Type of Product</b>	Preventive (COVID-19)
<b>Requirements</b>	File a marketing application
<b>Systems</b>	Teams, PleaseReview (CRO owned), Veeva
<b>Regulatory Writing Resources</b>	CRO writers Internal FTE External consultants functioning as embedded FSP (established MW department)
<b>Timelines</b>	12 weeks (changed to 8 weeks)—critical/ASAP
<b>Stakeholders</b>	Global regulators, including multiple US bodies IRB/IEC Internal team Internal management Study sites CRO
<b>Regulatory Landscape</b>	Rapidly evolving; constant feedback from multiple agencies and the need to resolve divergent feedback; prior EUA and global conditional approvals
<b>Risks</b>	Competitive landscape is a significant concern Multiple overlapping documents to meet timeline Sponsor exponential growth in a short timeframe
<b>Project Management Strategies</b>	Communication phone tree Stand-up meetings every other day between work sprints Resource layering for ancillary writing tasks Small core team Cloud-based authoring and review

ASAP, as soon as possible; COVID-19, coronavirus disease 2019; CRO, contract research organization; EUA, emergency use authorization; FSP, full-service provider; FTE, full-time employee; IEC, independent ethics committee; IRB, institutional review board; MW, medical writing; SME, subject matter expert.

highly prescriptive SOPs that did not enable the internal regulatory writers and the consultants (who only had reviewer licenses) to review live copies of fundamentally relevant documents (eg, parallel review of in-development CSRs or summary modules and in-development clinical overview). The system was used for a stepwise review, comment reconciliation, and closeout workflow. Although PleaseReview allows for the attachment of reference documents to the review, those documents were changing concurrently, rendering this option ineffective. Ultimately, a system was needed to facilitate document finalization with the key subject matter experts after team review. An initial attempt to use SharePoint for this activity failed because of a lack of prospective access management as well as restrictions on the use of guest accounts (for external consultants and regulatory writers) for internal SharePoint sites; the writer and subject matter expert resolved outstanding issues via email.

As a lesson learned from other submissions on the same program and aligned with sprint-style project management methodologies, the regulatory writing team attended specific key meetings, communicating about the submission and permitting the team more time to complete action items. The sponsor's Head of Medical Writing attended general meetings and CRO meetings, and the external consultants divided up CRO meetings and other internal meetings; all external consultants and CRO writers attended most document roundtables and stand-up meetings. Those who did not attend could access meeting information via a Teams chat, email, or a OneNote summary.

Overall, although there were observations for future process improvement, the regulatory and quality requirements of this dynamic submission were met, and a submission was filed on time for approval of a groundbreaking regulatory document.

### Scenario 3

The work for this early-phase protocol began as sites across the United States began restricting access because of infectious disease procedures.<sup>2</sup> The protocol for this critical disease had been finalized around the same time the first COVID-19 cases were reported in the United States, and the study was in start-up (Table 3). As COVID-19 cases began to rise globally, the sponsor's concerns mounted regarding the likely impact on study enrollment as well as the ability to ensure proper safety follow-up if patients were enrolled. A protocol amendment was planned to allow for alternate assessments and to reduce the overall travel burden and the chance for COVID-19 exposure for the patient, with the amendment including home collection of samples, select phone visits, alternative media for patient-reported outcomes and informed consent, and home nursing for safety assessments and drug accountability and dispensation (as a last resort due to high cost). Guidance from the FDA on the conduct of studies during COVID-19 was issued several weeks into protocol development and informed several key mitigations that were planned<sup>6</sup>; however, at the time the guidance was issued, the pandemic was evolving, and the agency determined that prior public participation for the guidance was not feasible or appropriate, so early guidance was open to some interpretation.<sup>7</sup>

The core authoring team was limited to the regulatory writer, regulatory writing operations associate, clinician, clinical trial manager, regulatory strategist, program manager, and drug supply/ Chemistry, Manufacturing, and Controls manager. Involvement of each function in this group assured that the protocol was updated efficiently and

**Table 3.** Scenario 3: Medium-Sized Pharmaceutical Company Amending a Protocol in a Non-COVID-19 Indication During the COVID-19 Pandemic

<b>Type of Product</b>	Treatment (non-COVID-19)
<b>Requirements</b>	Team was tasked with finding a way to add necessary flexibility to the study due to the evolving COVID-19 closures in H1 2020
<b>Systems</b>	Teams, PleaseReview (sponsor owned)
<b>Regulatory Writing Resources</b>	External consultants (no established MW department)
<b>Timelines</b>	2 weeks
<b>Stakeholders</b>	Global regulators, including multiple US bodies IRB/IEC Internal team Internal management Study sites CRO
<b>Regulatory Landscape</b>	Guidance on the conduct of studies during COVID-19 newly issued; IND had been open for some time, with one other completed early-phase study
<b>Risks</b>	Q&A on FDA guidance on the conduct of studies during COVID-19 issued and updated during amendment authoring; implementation required active discussion with CRO partners and subcontracted vendors to ensure proper description and execution; mitigations might not be successful and came with a high price tag; small company with limited resources
<b>Project Management Strategies</b>	Resource layering for ancillary writing tasks Core authoring team representing each function Cloud-based authoring and review

COVID-19, coronavirus disease 2019; CRO, contract research organization; FDA, Food and Drug Administration; H, half (of the year); IEC, independent ethics committee; IND, investigational new drug application; IRB, institutional review board; MW, medical writing; Q&A, Questions & Answers.

accurately as conversations progressed with the CRO and other vendors in daily, 1-hour, focused working meetings. Authoring was done in Teams, with access managed by an FTE on the core authoring team. The document underwent a single round of management review using the sponsor-owned PleaseReview platform, with the regulatory writer initiating and managing the review. Similar to reviewers in Scenario 1, reviewers in this scenario mostly utilized the commenting feature. The team vetted management comments together, and the core authors gained alignment with their line management outside of the review. All authors as well as the management reviewers attended the roundtables.

By limiting the team to line-function representatives, employing regular meetings, and using authoring and review tools that promote transparency, the team effectively

used multiple minor draft sprints to implement information and gain consensus as it became available in between meetings with stakeholders and partners. The project aligned with emerging regulatory guidance while mitigating the impact of COVID-19 on enrollment, study feasibility, and participant safety.

## DISCUSSION

Each regulatory writing project has a unique budget and unique collaborators, timelines, risks, and gaps. The regulatory writer and regulatory project manager must discuss the linkages of a project with department and company goals and determine the project management principles to apply; gathering the project requirements should be a deliberate process even in the face of urgent issues or tight timelines.

In consideration of the scenarios described in this article, we determined that the strategies that best balanced a controlled process with adaptability were derived from the agile project management method (Figure 1), particularly the scrum framework. This method, often used in software development, is employed when the “requirements,” or specifications the software needs to meet, change over time as a result of competitive intelligence or other factors; this method uses continuous planning to rapidly identify and implement change.<sup>8</sup> In all 3 of our scenarios, microdrafts were produced in short bursts, or “sprints,” in between other milestones (eg, internal meetings, stakeholder meetings), continuously delivering a work product informed by feedback at all stages (Figure 2). Early and frequent delivery of microdrafts maintains project

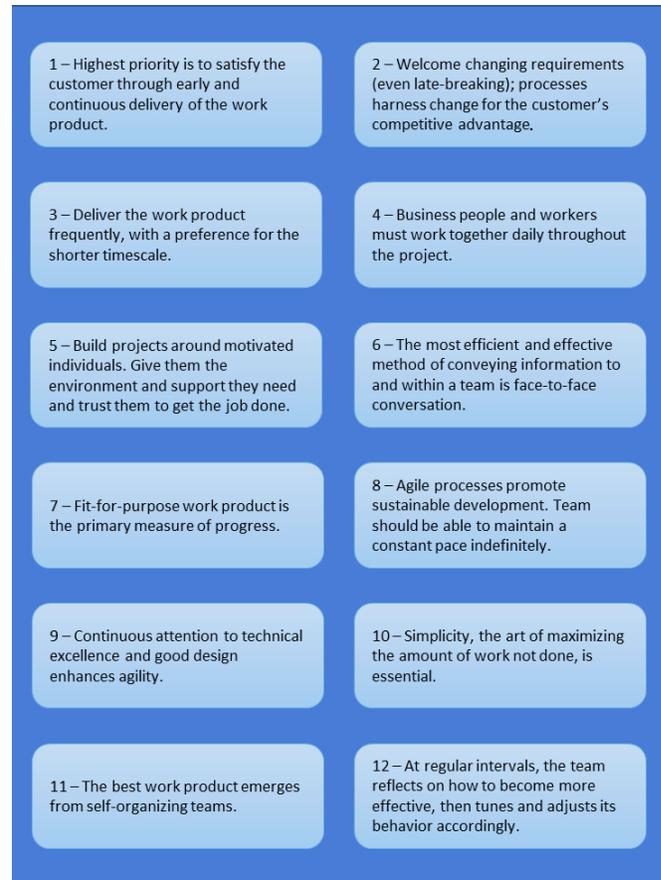


Figure 1. Principles of agile project management. Source: Rigby et al.<sup>8</sup>

momentum and reduces the overall amount of work being done later in the process as well as the potential that late-breaking information could jeopardize quality or

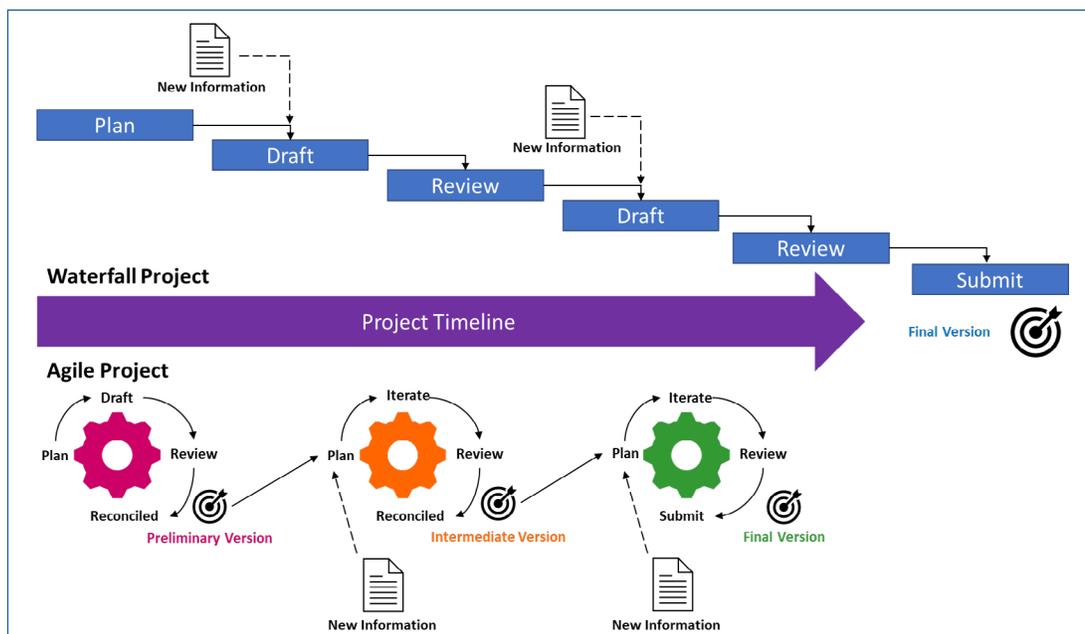


Figure 2. Waterfall compared with Agile methodology for document production. Adapted with permission from Kissflow.<sup>10</sup>

on-time delivery. Regulatory writers often leverage relationships to deliver quality documents on time, but the commitment in these scenarios to produce high-quality microdrafts required the authoring team to be in regular contact to self-regulate and agree on the tasks to be completed, check on progress, and course correct as needed. The focus on optimal technical quality and design in this method is inherently aligned with the rigor required for regulatory documentation as well as the need to position regulatory documentation for the intended audience, and the method's approach to simplicity is also aligned with the latest "lean authoring" trends in regulatory writing.<sup>9</sup>

Any methodology must be paired with the best tools, systems, and practices. Setting expectations for how the team will work together and outlining roles and responsibilities, as well as scheduling regular checkpoints, were critical success factors in each scenario. In addition, proactively managing systems access and education as well as the availability of a dedicated IT business partner to triage technical issues led to a more efficient authoring experience in some of the scenarios, even in a remote environment. It is also worth noting that no system is perfect; informing reviewers of any system limitations may help avoid pitfalls (eg, sponsor's SharePoint is only set up to retain a certain number of versions, or contractors may not have compatible versions of Microsoft Office for coauthoring). Lastly, archiving comments and decisions produced within any system requires regulatory writer discipline and should follow best practices and sponsor procedures to ensure that the rigor of regulatory documentation is met.

Project management software was critical to the success of each of these projects, but we also concluded that certain software features not often used by regulatory writers have become critical in assessing the available resource pool. For example, we had underutilized the project utilization feature to show the exact number of hours that a writer would be dedicated to a project within the start and stop dates for a task.<sup>11,12</sup> As the pandemic progressed and project complexity increased, we implemented the software's enterprise resourcing function, thereby enabling automatic initial notifications of project plan updates in between regular checkpoints.

As a result of our analysis, we also invested in Power BI business intelligence software to visualize data from multiple enterprise applications, including project management and customer relationship management software. Implementation of this analytical tool empowered our leadership team to efficiently track resource allocation and other details, including funds remaining on work orders at both the client and contractor level.<sup>13</sup>

Communication was paramount in the completion of each document in the scenarios. Although the teams came to different conclusions about meetings, they each decided proactively how often and how to interact. Setting such expectations up front in a project both increases the odds of the project's technical success and manages the potential for over-accessibility and burnout. If the team cannot pull away from these digital tools because of an inundation of competing requests, they cannot get the work done. In one of these scenarios, the sponsor acknowledged that they historically had this exact issue and successfully addressed the feedback by dividing and conquering meeting attendance. Thus, several of the principles within the agile method, including the preference for face-to-face interaction, maintaining a sustainable pace, and permitting the team to produce the deliverable, need to be balanced.

The limitations of this review are that the assessments were retrospective (as necessitated by the level of engagement required during the pandemic to complete the above projects) and that the number of projects sampled was small. The types of projects sampled met specific criteria, and any projects that meet some but not all criteria (eg, COVID-19 impact assessment for a CSR) may require a combination of strategies depending on the context. In addition, in Scenario 2, we were engaged as a resource late in the project planning phase and may have been able to influence the project management approach had we been involved earlier.

As we further consider implementation of agile methodology in whole or in part, we acknowledge that the agile method of project management assumes that the workers' time is retained, mostly available, and free of other distractions to be able to pivot. Within regulatory writing departments, resources often cover multiple deliverables over multiple programs, so a shift to properly resource agile projects may lead to a higher overall departmental budget. The ability to potentially get to market sooner, however, may outweigh this burden. This concept also may not be representative of the way that all regulatory writers want to work and in fact will work best when the team wants to rapidly innovate in a unique way<sup>8</sup>; commoditization of this way of working could increase the risk for burnout and cause workers to lose faith in the principles of prioritization, trust, teamwork, and problem-solving that are core to this project management method. Furthermore, this method may require writers with a requisite level of experience to be able to pivot as needed. Considering that experienced writers represent a finite portion of the workforce and given that the demand for this style of working may increase, this could

leave a large gap in the available resource pool that needs to be urgently addressed by leadership in the regulatory writing field.

### Acknowledgement

Synterex would like to thank Fulcrum Therapeutics, Goldfinch Bio, and Moderna, Inc. for their support in writing this article.

### Editorial credit

Jordan Sedlacek, Synterex Inc.

**Author declaration and disclosures:** Jeanette M. Towles and Jason S. Casavant receive funds from several biotech and pharmaceutical companies for regulatory writing services.

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BIOGRAPHY

## John P. McGovern, MD – Physician, Entrepreneur, Philanthropist

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### ABSTRACT

For much of its history, the American Medical Writers Association (AMWA) bestowed 4 awards in honor of 4 of its members: Harold Swanberg, MD, the founder of the Association; Walter Alvarez, MD, in retirement, a nationally syndicated health columnist; Eric Martin, PhD, a pharmacist instrumental in professionalizing regulatory writing; and John P. McGovern, MD, a philanthropist who supported initiatives in biomedical communication. However, the details of the lives of these men are unknown to most AMWA members. Accordingly, this biography describes the life and accomplishments of John P. McGovern, to recognize his achievements and to contribute to the history of the profession and of the Association.

John Phillip McGovern, MD (1921-2007), was a physician, teacher, researcher, humanitarian, businessman, investor, and philanthropist who contributed to the fields of allergy and immunology, widely promoted Sir William Osler’s principles of humanistic medicine, added to the size and scope of Houston’s Texas Medical Center, and enhanced the quality of life in Houston through several major gifts to the city.<sup>1</sup>



John P. McGovern, MD.

The McGovern Allergy Clinic was at one time the largest private allergy clinic in the country.<sup>1</sup> Its success and McGovern’s astute investments in stocks and real estate made him enormously wealthy, wealth that he then donated liberally to support dozens of projects that furthered the advancement of medicine and community life. The John P. McGovern Foundation, now headed by his wife, Kathy, continues to support several worthwhile projects.

In the American Medical Writers Association, the John

P. McGovern Award, funded in 1985 by a grant from the McGovern Foundation, “is presented to a member or non-member of AMWA to recognize a preeminent contribution to any of the various modes of medical communication.”<sup>2</sup> The range of candidates and the nature of the contributions suitable for this award is consistent with John’s own wide range of interests and causes.

(From the author: unless otherwise noted, all information here comes from *John P. McGovern, MD*,<sup>1</sup> a definitive biography written by his friend, Bryant Boutwell, DrPH. This biography is the source of many other accounts of his life.)

### GROWING UP IN WASHINGTON, D.C.

John (Jack, to his friends and family) was born in Washington, DC in 1921, the only child of Francis Xavier McGovern, a surgeon in the US Public Health Service, and Lotti Brown McGovern, a most competent housekeeper and gracious hostess. He was also very close with his maternal grandmother, “Granny Brown,” the kind of woman who would (and did) open her kitchen during the Republican Great Depression to feed families in need. In addition, his second cousin, the actress Helen Hayes, seemed to have been both a confidant and an inspiration to him. The close and supportive nature of the McGovern, Brown, and Hayes families provided several role models of nurturing, hard work, enjoyment, and caring for others.

Even in childhood, John was unusually deliberate, careful, perfectionistic, and above all, driven. As a boy, he liked baseball, football, soccer, stamp collecting (he eventually sold his collection to pay for college expenses), fishing, camping (he was a Boy Scout), and playing marbles. Not the informal play that many children enjoy from time to time, but, as he told his biographer, the “real game of marbles—ringer. A 10-foot circle with 13 marbles in a cross at its center. I’m talking lag lines, pitch lines, and knuckling down to knock the most marbles at center from the ring.”

In fact, his approach to marbles is telling. At age 9, John spent long hours shooting marbles until he was very skilled.

He, like most boys, played with marbles made of cheap glass. However, some marbles are made of quartz—the prized agates—and John was set on collecting agates. He hit on a strategy that involved an attractive challenge. He would bet a bottle of glass marbles against 1 or 2 agates. Few boys could resist the possibility of winning so many marbles, even if they were glass. John's strategy worked—within a year, he owned most of the agates in the neighborhood. The story illustrates the traits he would carry into adulthood: competitiveness and confidence, thoughtful and careful planning, hard work and discipline, and collecting and preserving things of value.

## MEDICAL TRAINING

After graduating high school in 1939, John matriculated into Duke University in Durham, North Carolina. He began medical school in 1942, after completing 3 years of pre-med courses. Duke did not require a bachelor's degree for admission to medical school, but students could earn a bachelor's degree in medicine en route to the doctorate in medicine if they conducted research while in medical school, an option John would take.

Entrance to medical school, of course, involved an interview. In this case, John's interviewer was Wilburt Davison, MD, the founding dean of the medical school and a Rhodes scholar. For John, the interview marked the beginning of medical school and of an important and lifelong friendship. At Oxford, Dr Davison had studied with Sir William Osler, considered by many to be the founder of modern medicine. The mentorship of Dr Davison and the legacy of Sir William Osler would profoundly affect John throughout his life.

John loved medical school. The intensity of an accelerated program, the complexity of the topics, and the long days and short nights challenged him intellectually and physically. He was also becoming interested in research, and not just because it would complete his bachelor's degree. Duke was one of many universities that offered the Borden Prize for Medical Research, which was awarded to medical students with the best original research project completed in the final year of study. (The award was created by *the* Borden, the one who developed condensed milk just before the Civil War and started what became the Borden Food Company. The company ceased operations in 2001.) The \$500 prize (about \$7,500 today) was actually less important than the prestige of winning the award.

John, who was becoming interested in pediatrics, decided to study a particular aspect of pertussis. Before bacteriologists Pearl Kendrick, ScD and Grace Eldering, PhD developed a vaccine, pertussis was the deadliest childhood

disease at the time. However, in the early 1940s, the vaccine was given only to children older than 6 years. John helped develop a test to determine whether infants 3 to 6 months old would produce antibodies to the *Bordetella pertussis* bacterium and thus be eligible for the vaccination.<sup>3</sup> This award made John Duke University's first recipient of the Borden Award. From then on, he always found time to conduct his own research as part of his practice of medicine.

## POSTGRADUATE TRAINING AND TEACHING

From Duke, John—now John P. McGovern, MD—began an internship in pediatrics at Yale-New Haven General Hospital in 1945. After the first year, however, he was called for active duty in the US Army and served in veterans' hospitals from 1946 through 1948. During this time, he worked in rehabilitation medicine during the day and worked at night helping 2 local pediatricians in private practice, an experience he enjoyed and would come back to later in life.

After leaving the Army in 1948, John returned to Duke to complete a residency in pediatrics. Eventually, Dean Davison offered him a fellowship that included a year of study in Europe, first at Guy's Hospital in London, then at the *Hôpital des Enfants Malades* in Paris. During this year, he developed a strong interest in the history of medicine, which in 1996 would result in a bequest that established the John P. McGovern Historical Collections and Research Center at the Texas Medical Center Library.

When John returned from his year abroad, he had received probably the best training in pediatrics at the time. In 1949, he accepted a position at the George Washington University School of Medicine. A year later, he was an Assistant Professor and Chief of Pediatrics at the university's affiliated hospital, the Children's Hospital of the District of Columbia.

In 1951, he received a rare and coveted John and Mary R. Markle Scholar Award. In its 22 year history, the award was given to only 500 physicians. The 5 year, \$30,000 award covered research expenses for talented young physicians who wished to stay in academic medicine rather than move into private practice. However, his increasing workload at the hospital and especially administrative tasks meant less time for research and more time completing paperwork. It took the threat of a promotion that would mean even more paperwork to persuade him to take his award and move on.

Once again, Dr Davison worked the networks and discovered an allergist at Tulane University in New Orleans who was looking for someone with John's training. So, in 1954, John took a position as assistant professor at Tulane University and went to work in Charity Hospital.

Charity Hospital had been providing indigent care in New Orleans since 1736. Moved and rebuilt several times, it was chronically underfunded. The situation was made worse in the 1930s when the governor decreed that the hospital would serve *all* of the state's indigent patients. In 1936, the hospital logged almost 75,000 admissions, making it the busiest hospital in the country with some of the most challenging patients.

Some 20 years later, in the mid-1950s, the workload was better but remained heavy. The hospital had 3,300 beds but treated as many as 4,500 patients on a given day. Children were put 2 to a bed, and adults were put on gurneys between standard beds, so a 20-bed ward functionally became a 40-bed ward. The outpatient clinic saw 5,000 patients a day.

Still, John was able to conduct his Markle-related research after hours, although it made the days much longer, and he enjoyed his colleagues, who were dedicated physicians carrying the same workload. During this period, he decided to become an allergist and passed the American Medical Association's board examination without any advanced training in the field—then and now, a rare accomplishment—making him board-certified in both pediatrics and allergy. He remained at Tulane until 1956, when a favorite professor from medical school asked him to come to Houston where the potential for patient care, teaching, and research was good and getting better. So, at age 35, John moved to Houston.

### THE MCGOVERN ALLERGY AND ASTHMA CLINIC

In the 1950s, flush with oil money, Houston was a rapidly growing city that attracted talented people from several fields, especially medicine. The M. D. Anderson Hospital and Tumor Center (now the University of Texas M. D. Anderson Cancer Center), the Baylor College of Medicine, the University of Texas Dental School at Houston, Baylor St. Luke's Medical Center, Rice University, and Texas Children's Hospital, among other institutions, were in various stages of development.

When John bought the practice of a retiring allergist, the McGovern Allergy Clinic was born. The practice flourished. Soon, the increased number of patients required hiring additional physicians. Their job interviews, all conducted by John himself, often went for 2 hours or more, and some applicants had 2 or even more interviews. During these interviews, they learned about John, Dr Davison, Duke University, and Osler's approach to medicine, among other things. The result of this hiring process was a close-knit staff of pediatric allergists who shared Osler's approach to

medicine and John's work ethic. During this period, he also formed the Texas Allergy Research Foundation.

One new employee caught John's attention. Hired as an office manager, Kathy Galbreath proved a most capable worker who could also cope with her employer's perfectionism and work schedule. The 2 were married in 1961. When asked to name the highlights of his life, John would provide a standard answer: his friendship with Dean Davison, the



John P. (1921-2007) and Kathrine G. McGovern. (Used with permission from the John P. McGovern Foundation.)

influence of Osler, the day he quit smoking in 1963, the day he quit drinking in 1984, and his marriage to Kathy. But, he always added, "not necessarily in that order."

John initially held faculty appointments at Baylor College of Medicine and at the University of Texas Postgraduate School of Medicine. He eventually served for 22 years as Chief of the pediatrics department's allergy section at Baylor and for 16 years as Chief of Allergy Services at Texas Children's Hospital. He was also a professor at the University of Texas at Houston and Chair of the University's Department of the History of Medicine.

After 15 years, thanks to quality care and good business practices, the McGovern clinic had become the largest private allergy clinic in the country.<sup>4</sup> John also shrewdly invested in real estate, at one time owning much of the land that would eventually be occupied by the world's largest medical complex, The Texas Medical Center. (Today, the center occupies nearly 2 square miles, is home to some 60 institutions, and employs more than 100,000 people.)<sup>5</sup> In addition, he also successfully invested in stocks, eventually becoming quite wealthy. In 1961, he had created what would become the John P. McGovern Foundation with \$10,000. At the time of his death, the foundation had \$180 million in assets.

### PROFESSIONAL CONTRIBUTIONS

In addition to practicing medicine, John remained a committed educator and researcher throughout his career. He wrote more than 250 articles and 26 books in the medical sciences and humanities, was president or chief elected

officer of 15 professional medical societies,<sup>6</sup> served on the editorial boards of numerous journals, and received dozens of awards.

**Box. Prestigious Awards Received by John During His 43 Year Career<sup>1,6</sup>**

- The American Medical Association's Special Award for Meritorious Service.
- The William A. Howe Award, the highest honor given by the American School Health Association
- A Private Sector Initiative Commendation, bestowed by President Ronald Reagan, for his lifetime of service in medicine and philanthropy
- The Outstanding Scholarship in Health Care Award from the American Association of Colleges of Nurses
- The Surgeon General's Medal for his lifetime of service, bestowed by Dr C. Everett Koop, at the time, the Surgeon General of the United States
- The R. Brinkly Smithers Gold Medal Award for outstanding work and support in the field of alcoholism and drug abuse, from the National Council on Alcoholism and Drug Dependence
- The Maurice Hirsch Award for Philanthropy
- The Royal Medallion of the Polar Star from Sweden
- L'Ordre National du Mérite from France
- The Kemal Atatürk Gold Medal Distinguished Service Award bestowed by the Government of Turkey, and the first received by an American citizen
- Houston's 2001 Distinguished Citizen of the Year
- The Distinguished Alumnus Award from Duke University
- Fellow, American Association for the Advancement of Science
- Fellow, American College of Physicians
- Honorary Fellow, Royal College of Physicians
- Distinguished Fellow, American Association of Allergy, Asthma, and Immunology
- Fellow, American Society of Addiction Medicine

A member of AMWA's Southwest Chapter since 1961, John became an AMWA Fellow in 1967 and received the Association's highest honor, the Harold Swanberg Distinguished Service Award, in 1988.

During 1968 to 1969, John was president of the American College of Allergists (now the American College of Allergy, Asthma, and Immunology) and was Editor-in-Chief of the college's journals. During his presidency, the college was struggling to achieve a new status as an independent medical specialty, with its own special training requirements and board-certification process. John was instrumental in directing the development of the college's application to American Medical Association's Advisory Board for Medical Specialties. The field became a certified specialty in 1974.

In the late 1960s, John and a Washington, DC physician named Alfred Henderson independently became concerned that the emphasis on science in medical education would supplant the study of the humanities. When Dr Davison brought the 2 men together, they founded The American Osler Society in 1970 to memorialize Osler's life and teachings. The John P. McGovern Academy of Oslerian Medicine was created in 2001 with a \$5 million gift to provide endowments for 5 William Osler Scholars, an amount later augmented with a second gift of \$2.5 million.

Also, in the tradition of Sir William Osler, John worked to support medical libraries. In 1970, he was appointed by President Richard Nixon to the board of the National Library of Medicine. He was Chairman of the Board of Regents of the Library from 1970 to 1974 and chaired the external grants program after leaving the board. He also served on the National Advisory Council of the National Institute of Alcohol Abuse and Alcoholism from 1987 to 1991.

Several awards have been established in his name, among them, The Houston Academy of Medicine's John P. McGovern Compleat Physician Award and from the Office of the President of The University of Texas Medical Branch, the annual John P. McGovern Lifetime Achievement Award in Oslerian Medicine.

## PHILANTHROPIC ACTIVITIES

John was as skillful in giving money away as he was in making it. The John P. McGovern Foundation continues to fund scholarships, lectureships, endowed professorships, distinguished faculty awards, and buildings to advance medical science throughout the country. It donated \$6.5 million to create a new McGovern-Davison Children's Center at Duke University and \$75 million to the University of Texas Health Science Center at Houston (UTHealth) and its medical school, which was renamed the John P. and Kathrine G. McGovern Medical School.<sup>7</sup> The foundation funded UTHealth's McGovern Center for Humanities and Ethics and the McGovern Historical Center, which houses collections on the history of medical specialties, Texas medicine, North American public health, the development of the institutions and hospitals in the Texas Medical Center in Houston, and biographical information on Texas physicians. The foundation has also endowed 26 annual Award Lectureships at universities in Texas and elsewhere, including Duke, Harvard, Yale, the C. Everett Koop Institute at Dartmouth College, and Green College at Oxford University.

The foundation has also established several public Houston landmarks, including McGovern Lake and the John P. McGovern Children's Zoo in Hermann Park, and

was a major donor in the early days of what became the McGovern Museum of Health and Medical Science. In 2017, a \$20 million endowment created the Kathrine G. McGovern College of the Arts at the University of Houston,<sup>8</sup> the first college in the university to be named after a former student and also the first to be named after a woman.

## CLOSING

By all accounts, John was a talented physician, teacher, and researcher. He was also personable, foresighted, deliberate, driven, and above all, generous with his time as well as with his fortune.<sup>9</sup> He made life better for hundreds of thousands of children, medical students, patients, colleagues, and members of the public. In so doing, he, as always, was taking one of Osler's principles to heart, "we are here to add what we can to life, not to get what we can from life."<sup>10</sup>

**Author declaration and disclosures:** *The author reports no commercial associations that may pose a conflict of interest in relation to this article.*

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**FREELANCE FOCUS**



Brian Bass



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Gail V. Flores



Ruwaida Wakil

**Q1: In the new digital age, what are some of the changes you have been making as a medical writer?**

One of the keys to freelancing success is adaptability, and nowhere is that more important than in the area of technology. My goals are to optimize my productivity and to stay at least 1 step ahead of my clients.

These are a few of my most recent advancements to keep up with or ahead of the curve:

- **Online software:** I get about 5 years out of a computer. When it's time for a new one, I have to upgrade most of my software as well. Getting used to new hardware and software at the same time is a nightmare! In 2019 I subscribed to Office 365, and last year I upgraded to Microsoft 365. I also switched to the online version of my bookkeeping software, QuickBooks. Online software upgrades continuously so the changes are incremental instead of sweeping. It also ensures I'm always working with the latest versions.
- **Cloud backup:** About 3 years ago, I switched from a local backup for my computer files to a cloud backup system. I did my research, consulted with my computer guru, and went with Carbonite. It offers 128-bit encryption, world-class security, and Health Insurance Portability and Accountability Act compliance support. It saved my life! During the summer, my computer system had a bit of a hiccup and I lost everything. Within 24 hours, I had it all back.
- **Password manager:** I'm overwhelmed with passwords. Recently I began researching password managers and questioning why I've been so hesitant to use one. The answer is fear of the unknown. Now that I have a better understanding of their security and potential benefits, I'm getting closer to switching over from my current archaic method.
- **Multiple monitors:** I've always docked my laptop to an external monitor. About 7 years ago I added a

second external monitor and immediately wondered why I waited so long! Today I use 3 external monitors and could easily justify more. Not only has it made me more efficient, but it has also saved me a ton of money on printer supplies.

— **Brian Bass**

Naturally, we all try new programs to keep up—but I try to avoid spending money unless something is truly essential for me (eg, Microsoft Word). Having worked with many new small programs that I found unhelpful and too glitchy (eg, EndNote, Grammarly), I stopped using them. I use the spellcheck and grammar check in the Word program. Because I have been a medical writer for more than 25 years now, I trust my English usage without adding yet another electronic helper. Of course, newer people with little hands-on writing experience who are trying to enter the field of medical writing likely need the grammar check programs more than those with years of experience. I do feel that new graduates, or those switching from other professions to medical writing, should *practice* writing on their own so they are more skilled at writing better and faster—this skill comes solely from practice, not from reading about it. But almost everything can be obtained online now.

Because of the annoying (to me) practice of having to subscribe to programs on a monthly basis rather than purchasing them outright and owning the program, I have stopped using certain programs—eg, QuarkXPress, Adobe Illustrator, Adobe InDesign, and Adobe Photoshop. This means that I also have stopped taking on projects that require these programs; I do not regret it, although I was once reasonably proficient with Quark and Illustrator. To me, the editing function in Adobe Acrobat is far more cumbersome and less efficient than editing in Word, so I also no longer take on projects that require *heavy editing* in that program. I prefer now to focus on medical writing, editing,

editorial review and critique, format correction, template creation, and quality assurance for regulatory documents.

Today, almost everything is now done via the Internet and social media, and we all have gradually adjusted to this. No longer is it so easy to call a client or consultant on the telephone; now it is either email or text messaging. Nonetheless, I always speak to a new client by phone before accepting a new project; it is simply more efficient. Today most pharmaceutical/contact research organization clients use shareware programs such as DropBox or GoogleDocs rather than attaching the files to an email; this change has been required for several years now. Because of poor project management on the part of too many clients, this process is frequently more cumbersome than receiving the required materials via email, but one has to *ride the horse in the direction he's going* so I accept this. Once in a while (not often), I encounter a good project manager, and materials are well organized, clearly labeled, and easy to grab.

One can obtain templates and samples of most regulatory reports in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use format online as necessary—but I have all that already from having written so many throughout my career. Likewise, today it is easy to download sample articles from a specific journal (in addition to the Instructions for Authors) to ensure using the proper formats and editorial styles.

On the whole, over the last many years, clients expect medical writers to have a strong facility with technology; often they care more about the tech aspects than the actual writing and the skill of good communication. Equally often, they do not seem to recognize the difference between clear communication/decent writing and the kind of rote things that less experienced people produce. So, I think the horse will continue galloping in this direction and all of us must adapt. If there is too much technology involved and too much unclear data provided, one may opt not to accept that particular project.

— **Cathryn D. Evans**

In the last 1-2 years, I've made changes enabling me to become increasingly less reliant on paper. To proofread my own work, I now save my Word or PowerPoint documents as Portable Document Format files (PDF), which differentiates them enough that I spot errors I wouldn't have noticed in the native files. I review the PDFs on one monitor and enter edits directly into the native files on my other monitor instead of printing the document, proofreading with a red pen, and entering edits into the native files. Not only am I saving paper, but I'm also saving time.

To reduce my use of notepads and sticky notes, I've started using OneNote (part of the Microsoft Office suite). I have various notebooks for meeting notes, invoices, and to-do lists, with tabs for different clients. I particularly like being able to take meeting notes in calendar invites imported from Outlook, so I can capture the date/time of the meeting and the attendees.

I recently started using the scheduling feature of the online time-tracking platform I've been using for years (PayMo). I can see my entire week and month at a glance, including the due dates for each deliverable for each project. It had made scheduling so much easier that I no longer need a physical planner.

Overarching these individual changes is my move to 100% cloud storage. I'm a Mac and iPhone user, and everything on my computer is backed up to my iCloud account. I didn't realize how useful this was until one day last year when my Mac completely died, late in the afternoon, when my first deliverable was due to a new client. I was able to log on to my iCloud account from another computer in the house and was up and running in the same Word file and could access the same highlighted references, bookmarked websites, and emails within 20 minutes.

As medical communicators, I believe we should continue to learn about new programs, platforms, and technologies to increase our value to clients. For those of us who don't have tech support, so many issues can be solved through a simple Google search or YouTube video, empowering us to approach our clients with solutions rather than problems.

— **Gail V. Flores**

The primary change is that I now have a cloud backup system in place. In June, I bought a new computer. I thought my external 1-TB backup drive with nightly backups would work seamlessly to transfer all my data to the new computer in case the Geek Squad had trouble with the computer's hard drive.

The day I gave my computer to the Geek Squad the external backup drive said it was full. Because of the proprietary backup software, the files could not be dragged and dropped off the drive, and I had trouble clearing space. Nevertheless, I thought I had managed to do a full backup that day.

My computer's hard drive had been working fine, but the Geek Squad said the hard drive failed during the data transfer, so they used the external backup drive to transfer data. Unfortunately, something must have gone awry with the backup and many of my Word files were missing.

Another American Medical Writers Association (AMWA) colleague suggested using a cloud back-up system. Many such systems are available. I chose Carbonite Safe Basic (<https://www.carbonite.com/>). Usually \$84/year but now on sale at about \$60/year, the service includes automatic unlimited backup and remote access from any device. The files can be accessed individually by drag and drop or restored as a group. Now I no longer worry about my backup. Another bonus: I can access my complete hard drive remotely, so I don't have to copy files to Dropbox to transfer them to my laptop.

— **Melissa L. Bogen**

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## **Q2: What software do you recommend to a new freelancer?**

Microsoft Office is of course a must for any new freelancer for creating and working in Word, PowerPoint, and Excel documents; other features such as Outlook and OneNote are optional, but I prefer using them as they work well with my other Office products (for example, my customized spellcheck and autocorrect settings are automatically incorporated across all products in the Microsoft suite). Adobe Acrobat Pro DC is critical for highlighting and annotating journal articles and other references. Finally, an accounting program is key for submitting and tracking invoices.

In addition to software housed on a computer, I recommend that new freelancers subscribe to an online time-tracking platform, a medical dictionary, and a cloud storage system, such as Dropbox. I resisted investing in such tools for years because I didn't want to spend additional funds, but once I got them I couldn't believe I ever functioned without them, as they have both increased my efficiency and let clients know that I take my work seriously and have more than paid for themselves over the years.

— **Gail V. Flores**

Go to [https://www.amwa.org/page/Partner\\_Discounts](https://www.amwa.org/page/Partner_Discounts) to find discounts for AMWA members on some of these software programs:

- *AMA Manual of Style* (20% off for AMWA members): I bought the hardcover edition with one year of the online subscription so I can look things up quickly while I'm working. The online version has automatic updates. However, the online version is not as clearly set up as the hardcopy, so I often consult my hard copy

once I know where to look.

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- Stedman's Plus 2022 Medical/Pharmaceutical Spellchecker: This software works seamlessly in Microsoft Office programs (Word, PowerPoint, etc) and contains all the latest medical and pharmaceutical terms. USD \$99.95.  
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<https://intelligentediting.com>
- Jack Lyon's Editor's ToolKit Plus and List Fixer, among others. You can strip footnotes to the end of a file, change automatically numbered lists to fixed numbers, and automate many repetitive tasks to free up your brain for the more substantive edits.  
<https://www.editorium.com>

— **Melissa L. Bogen**

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## **Q3: What are the pros/cons of using grammar or proofreading software such as Grammarly or PerfectIt?**

I have only used PerfectIt, which has been essential for my work as a medical editor. PerfectIt automatically runs some standard consistency checks (eg, compound adjectives before a noun, hyphen or no hyphen, common typos). When an inconsistency is found, it shows the 2 variations and the user chooses the preferred form. The program will stop at each instance to let you decide how and whether to fix the inconsistency. PerfectIt cannot replace an editor. It handles mechanical aspects of job, leaving the editor to make substantive edits.

The Table of Abbreviations that PerfectIt creates at the end is worth the price of the program. The Table that is created must be double-checked because, for example, abbreviations in square brackets are not found and it "thinks" author initials are abbreviations, but the Table easily compiles the vast majority of the abbreviations in a file that can be saved as a separate document.

Versions

- PerfectIt 5 (standalone) is the latest version
- PerfectIt Cloud (is Mac compatible)
  - Secure connection does not send data anywhere
  - Files are confidential

Tutorial: <https://intelligentediting.com/product/introduction/>

Tips for editing in PerfectIt: <https://intelligentediting.com/support/faqs/categories/tips-for-editing-with-perfectit/>

— **Melissa L. Bogen**

As a writer, I have not invested PerfectIt primarily because I use a Mac, and PerfectIt only has cloud support on Macs. Many of PerfectIt's functions are limited while using a Mac,

so I have not found it worth the investment. I would consider it if they offered a Mac version that is as good as the PC version. However, I have used Grammarly. I found it very helpful for doing grammar and language checks that Word will often miss. It is like a second set of eyes for me and is very valuable when working on the same document for too long. On Mac, Grammarly is also cloud-based and is not integrated with Word. But it seems to have all the features that the PC Word-integrated version has. Therefore, I have found it to be a good investment.

— **Ruwaida Vakil**



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**EVERYDAY ETHICS**

## Legal and Ethical Issues in Technical Content Marketing

Scott A. Mogull, PhD / Texas State University, San Marcos, TX

### ABSTRACT

Writers working in industry and contracting are often involved in the writing of technical content marketing for products, services, and personal freelance businesses. In this article, writers in technical industries are introduced to the legal and ethical issues of technical content marketing and advertising, which covers intellectual property, truth in advertising, comparative and competitive advertising, and customer reach. The goal of this article is to provide writers with a better understanding of these legal terms and concepts as well as ethical issues that influence technical content marketing strategy and practice.

Marketing copywriters in technical industries create technical content marketing for the commercialization of technology and for promoting personal freelance businesses. As Rebecca Geier states, “Content is the heart of your inbound marketing program. It’s how new people find your company from searches, it educates prospects and...ultimately it builds trust between your business and your prospects and customers.”<sup>1</sup> Although the writing of marketing copy, marketing genres, tactics, and communication technologies are familiar to copywriters in technical industries, many of the legal and ethical issues and restrictions that influence the decision process are less familiar and often based on word-of-mouth advice from others in these fields. Technical content marketing writers and strategists often encounter internally and externally written marketing copy that may cause liability for the writer or organization and may be considered unethical practice.

This article examines 4 categories of legal and ethical issues in technical content marketing—with many issues also of concern to freelance writers managing their own business. The 4 categories of legal and ethical issues in technical content marketing, which encompasses content creation and distribution include

- intellectual property,
- truth in advertising,

- comparative and competitive advertising, and
- customer reach.

The goal of this article is to examine these 4 categories of legal and ethical issues that influence content marketing practice in the commercialization of technical products and services.

### INTELLECTUAL PROPERTY

One of the pivotal cultural differences between business executives and medical/technical (or scientific) experts is the practice and attitudes associated with information sharing about technology. Specifically, science and technology have a 350-year-old philosophical and ethical tradition of “open science,” which is the free exchange of information for the improvement of society.<sup>2-5</sup> Notably, Robert Merton describes the culture by stating, “The pursuit of science is culturally defined as being primarily a disinterested search for truth and only secondarily, a means of earning a livelihood.”<sup>6</sup> However in the context of marketing copywriting, the technology becomes the product rather than medical, scientific, or technical knowledge and this shift transforms the cultural norms associated with the sharing of information and protection of intellectual property.<sup>7</sup>

Often the scientific and technical information is concealed or selectively disclosed by companies in order to maintain a competitive advantage over competing organizations.<sup>4,7-10</sup> Organizations protect their technology or intellectual property through use of patents and trade secrets. A technology *patent* allows commercial organizations to be the sole commercial provider of an innovative technology (a monopoly) for a period of time in the jurisdiction covered by the granting office. For example, in the United States and Europe, most patents are granted for 20 years, which is considered sufficient time for organizations to recoup the costs of research, development, and commercialization.<sup>11,12</sup> For many medical, scientific, and technical fields, 20 years is generally longer than the market lifetime of most new products. The intent of patent protection is to enable companies to disclose detailed information about a

technology for customer use while protecting sales of novel technologies. Although technical content marketing writers often avoid revealing detailed information about novel technology, much of this technical information is publicly available in US patents, which are typically published and available 18 months after the filing date. Thus, withholding technical information in technical content marketing generally imposes a greater hinderance and annoyance to technical consumers (for example, physicians or patients) than competitors who are familiar with researching patents as well as the scientific literature to understand patented or researched innovations.

The second form of protection, *trade secret*, is information about a technology or manufacturing process that has been developed by an organization and is protected through withholding proprietary information from individuals outside of an organization. In general, trade secrets worth protecting are those that have some commercial value, which may include an innovative process manufacturing process a technical product rather than the technical product itself. Many trade secrets are not eligible for patent protection, so, in contrast to patented technologies, trade secrets inadvertently divulged technical content marketing would undermine this competitive advantage. Many organizations require employees and contractors to sign a nondisclosure agreement (NDA) or a confidentiality agreement that places an individual personally liable for information divulged.

Aside from trade secrets, marketing copywriters in technical fields may find that sharing technical product information in technical content marketing helps construct the ethos of an organization and create a positive brand image. In particular, this sharing of information is most important to technical consumers in the early market, who have a strong curiosity and interest to understand technical innovations.<sup>13</sup> This sharing of technical information is often a concern for marketing copywriters in technical industries who typically provide relevant details, such as detailed understanding of molecular actions and results from clinical trials in patient communication. Apart from Aristotelian persuasion strategies and consumer needs for information, copywriters of technical content marketing also need to consider the legal obligations of providing information that is necessary for the safe use of a product.

## TRUTH IN ADVERTISING

In the United States, as well as the European Union and many other regions, advertising (as well as all forms of marketing or advertising) is legally required to<sup>14-16</sup>

- Be truthful and nondeceptive (in any part or as a whole) and
- Have evidence to support objective statements of fact (using appropriate and widely accepted methods of collecting such evidence).

Any marketing content that is inaccurate, misleading, or unproven is considered false (or deceptive) advertising and is subject to legal action against an organization or freelancer.

In technical content marketing, the most relevant considerations are to ensure the truth and accuracy of all content. As mentioned previously, both the expressed and implied claims (or factual, objective statements) in marketing must be accurate and supported by evidence. Furthermore, the overall context of the text and document (including visuals) must not be misleading to a “reasonable consumer” as interpreted by regulators.<sup>15</sup>

At the simplest level, any expressed claim, or one that is explicitly stated, must be accurate and truthful. For example, the United States Federal Trade Commission (FTC), the governmental organization that monitors most forms of advertising in the United States, provides the following example of expressed claim, “ABC Refrigerators will reduce your energy costs by 25%.”<sup>15</sup>

In contrast, an implied claim is made indirectly or by inference, such as, “ABC Mouthwash kills the germs that cause colds.”<sup>15</sup> According to the FTC, a “reasonable consumer” could make a logical connection between these 2 statements in an implied claim and conclude that the mouthwash will prevent colds.<sup>15</sup> In this example provided by the FTC, the writer’s intent is to mislead readers and imply the use of a particular product (mouthwash) would be a useful product for treating colds. By law, both expressed and implied claims must be verified by scientific evidence using appropriate investigation methods. Another realm of concern is personal experience or customer anecdotes (especially for health-related claims), which are not considered appropriate evidence to support these types of claims.<sup>15,16</sup>

Subjective claims made by a company are more difficult for the FTC to evaluate and often receive less scrutiny.<sup>14,16,17</sup> Thus, overstated subjective claims, or “puffery”, are relatively prominent in consumer advertising.<sup>16</sup> In many cases, simply stating that a product is “the best” is typically ignored by the FTC.<sup>16,17</sup> Yet subjective claims also may be subject to penalty depending on the claim and the impact that such statements have on the overall impression of the communication. For example, a statement would be false advertising if it contains any unsubstantiated, objective element, such as “most consumers prefer XYZ.”<sup>16</sup> Subjective statements are evaluated in context and technical content marketing would

be considered false advertising if such statements contributed to an overall misleading impression in the mind of the consumer.

Another form of subjective claims is those from individuals rather than claims from a commercial organization. Subjective claims from individuals, called endorsements or testimonials, must be an honest opinion and detail the actual experience of the individual. Additionally, endorsements must reflect the typical customer experience rather than unusual cases. The FTC emphasizes that simply stating “results may vary” for an atypical case is not considered sufficient disclosure to avoid legal penalty for misleading advertising.<sup>15,16</sup> Furthermore, an individual providing an expert endorsement must have appropriate qualifications to be considered an expert in an appropriate field and provide a relevant opinion focusing on the key applications of the product. In many regions (including the United States), testimonials must be clearly qualified with a statement of disclosure if provided from any individual that has a personal or financial relationship with an organization. Such disclosure, as well as any disclaimer that qualifies a claim, must be presented in plain language and displayed conspicuously to avoid misleading readers.

Despite these legal requirements, marketing and advertising have long been pushing the boundaries of truthful statements and are generally perceived cynically, fairly or unfairly, as persuasive and deceptive communication with exaggerated claims that are designed to mislead naïve consumers.<sup>18-23</sup> Furthermore, marketing content is prohibited, by law, from deceiving or misleading customers through the omission of relevant (or “material”) information that is important for influencing a “reasonable consumer” to purchase or use a product.<sup>16</sup> Furthermore, ethical technical content marketing includes completeness, so claims are not misrepresented or misinterpreted by the omission of relevant detail.<sup>23</sup> Such perceptions and unethical practice undermine consumer trust and confidence in all forms of marketing communication and organizations. Therefore, to compensate for inherent audience skepticism and distrust, content writers should prioritize direct (explicit), objective, accurate claims and provide complete evidence and description of methods used to collect for the determination of each claim. Ultimately, a detailed and honest independent expert analysis may be particularly persuasive for technical consumers.

## COMPARATIVE AND COMPETITIVE ADVERTISING

In addition to providing accurate and honest information about a product, technical content marketing—particu-

larly for pharmaceuticals and medical products—is often responsive to competitors’ generic drugs or treatments.<sup>24</sup> Comparative advertising is technical content marketing that compares a company’s product to another product—often one from a competitor—either explicitly by stating the brand name of a competing product, or implicitly through reference (such as “Brand X”). Despite common misconceptions about comparative advertising that have arisen from outdated laws and industry norms, both explicit and implicit competitive advertising are legal in the United States, the United Kingdom, and the European Union.<sup>25-27</sup> In fact, the FTC encourages comparative advertising because it provides “important information to consumers” by helping them distinguish between product features and also encourages product improvement and innovation.<sup>25</sup> Comparative advertising is legal as long as it adheres to the following conditions:<sup>25,26,28</sup>

- It provides truthful information that is not misleading in part or in whole.
- It compares equivalent products that meet the same customer need or are intended for the same purpose.
- It objectively compares one or more relevant product performance features that can be scientifically verified with appropriate evidence.
- It excludes any other distortion or misleading information.
- If explicit, it properly identifies competitor(s) by using the exact trade name, trademark, or other distinguishing branding marks so the trademarks (not the products) are not denigrated or discredited.

Under these conditions, comparative advertising is legal and the courts have consistently denied any claims of defamation (or libel) by competitors.<sup>26,29</sup> Comparative advertising is an effective strategy for introducing new products, distinguishing similar products, and establishing a niche in the market.<sup>30-32</sup> Yet some advertisers consider comparative advertising to be unethical and risky, as it may increase the likelihood of complaints about a company’s advertising to the FTC (or other regulatory organizations) as a punitive response by competitors.<sup>29</sup>

## CUSTOMER REACH

Much of marketing strategy is driven by profit rather than the effects that it has on individuals and particular groups. Of particular concern, content writers should be conscious of development and delivery of information to specific, overly narrow target consumers at the exclusion of other consumer groups.<sup>33-35</sup> Particularly in business-to-consumer (B2C) advertising, a historical bias has been writing,

designing, and delivering marketing communication disproportionately toward affluent target markets in industrialized Western countries.<sup>34-36</sup> However, a contrasting situation may also be the case as some B2C advertising has been criticized for specifically targeting economically disadvantaged groups and developing nations with advertisements for harmful products such as cigarettes or infant formula instead of breastmilk.<sup>37-39</sup> Aside from the numerous examples and case studies of biased B2C marketing practices that tend to reduce the market and prevent a product from achieving full market potential, the focus of this discussion is to identify ethical marketing practices so writers can avoid such problems and maximize connection with customers within legal and ethical customer reach.

The most effective strategy for identifying target consumer audiences or a specific market is to characterize potential consumers by providing technical marketing communication focusing on the relevant needs or wants that are addressed by the product.<sup>40</sup> Such an audience analysis should downplay or exclude personal attributes that are unrelated to the product need, which would create a distorted or biased characterization of a target audience that would unnecessarily influence marketing communication strategy. In technical content marketing, different groups of audiences (or buyer personas) are identified and served through a collection of content that is targeted to their specific (often differing) needs or wants.<sup>41</sup> Buyer personas may not specifically be a direct “buyer” or purchaser of a product or service, but each group contributes to the business model of the organization. A common example are company

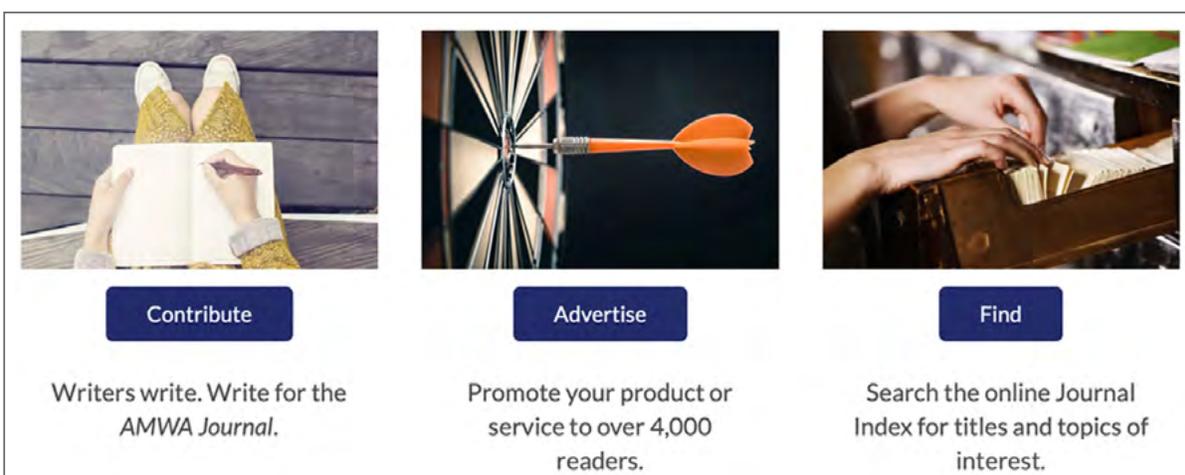
websites, which are organized into sections around the needs of different groups providing resources to address their specific need for information. With a buyer persona strategy, the first layer for organizing a website is to direct individuals from different groups into the proper section of resources. In particular, consider the *American Medical Writers Association (AMWA) Journal’s* homepage (Figure), which provides links to buyer personas to

- “Contribute,” for writers to prepare manuscripts for the journal,
- “Advertise,” for advertisers to promote a product or service to the readers, or
- “Find,” for readers to search a database of articles within the journal.

In this example, specific content of each section of the website provides relevant information that supports the informational needs of these different groups in order to support the publication of the journal.

Additionally, technical markets are international—both as global markets as well as domestic markets with many customers originally from other nations. From a writing and accessibility perspective, the most effective technical content marketing is designed for global audiences. From a communication lens apart from country-specific content regulation, technical content marketing writers can improve communication effectiveness with non-native English speakers by adhering to the following guidelines<sup>42-44</sup>

- Use deductive organization with topic sentences and important information at the beginning of each document, section, and paragraph,



**Figure.** Example of buyer personas (or target audiences) of common visitor categories to the *AMWA Journal’s* home page. Sections of the Journal website are targeted to specific audiences, such as “Contribute” for individuals interested in writing an article for the journal, “Advertise,” for individuals seeking to advertise within the journal, and “Find,” for individuals seeking to find and read an article published by the journal. Collectively, these buyer personas represent the major constituents of the publication. This figure has been reprinted with permission from AMWA.

- Use plain language, concise phrases, short sentences, and the active voice; limit the use of long, complex sentences and avoid negative constructions,
- Use international measurements (the metric system),
- Use a consistent (or controlled) and precise vocabulary based on word denotation and concrete language rather than colloquial words and phrases with embedded connotations (eg, change the colloquial verb phrase “looking into” to the single verb “investigate,” which expresses the intended concept clearly and translates directly), and
- Use clear and specific statements rather than using culturally specific metaphors or figurative language (eg, change the US-centric baseball reference “home run” to “success”).

Not only will these strategies increase the effectiveness of communication to global audiences in English, but these techniques will also facilitate accurate translation into other languages.

Finally, although customer reach is also achieved through the use of technology to deliver technical content marketing, the latest technology may impose communication barriers to some audiences, particularly individuals with disabilities as well as those with older technology or low-bandwidth connections.<sup>45-48</sup> For many technologies, using the latest communication platforms to communicate with affluent, able-bodied, mainstream consumers may prevent communication to a target audience and individuals from other groups. Particularly in regards to accessibility, or inclusion of alternative communication formats for individuals set apart by the digital divide, such communication may be a legal consideration in the United States, Europe, and many other countries.<sup>49</sup> Yet, technology does not always prevent access but, in many cases, also facilitates communication to these groups (for example, YouTube will close caption videos by default for the hearing impaired). The challenge with using the latest communication technology is that the barriers and adaptations are technology specific and constantly shifting. The important point for marketing writers is to provide content in appropriate formats for the widest coverage of potential customers.

## CONCLUSION

In this literature review, the goal has been to introduce medical writers to the legal and ethical issues of marketing in which additional caution is needed. As a review, this article is designed to serve as a foundational resource with reference to sources for further information and clarification of individual issues. The importance of further

researching additional issues depends on the nature of each situation. In particular, the ethical practices of technical content marketing writing and the commercialization of technology are developed from legal and academic sources, which advocate for communicating content rather than rhetorically persuasive strategies. Much of this discussion touches on legal issues and interpretations, which are constantly in flux. In regard to issues with legal implications, specific laws and regulations vary by geographic region and change as new technologies enable novel marketing practices and lawmakers make changes to prior regulations. Thus, specific marketing and advertising copywriting encroaching on legal issues presented within this article require consultation of the latest legal postings and review by attorneys familiar with the jurisdiction in order to evaluate the appropriateness of decisions made by the technical content marketing writer or strategist.

**Author declaration and disclosures:** *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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**AMWA NEWS**

**FROM THE PRESIDENT**

**Building Leaders One Volunteer at a Time**

Katrina R. Burton, BS / 2021–2022 AMWA President

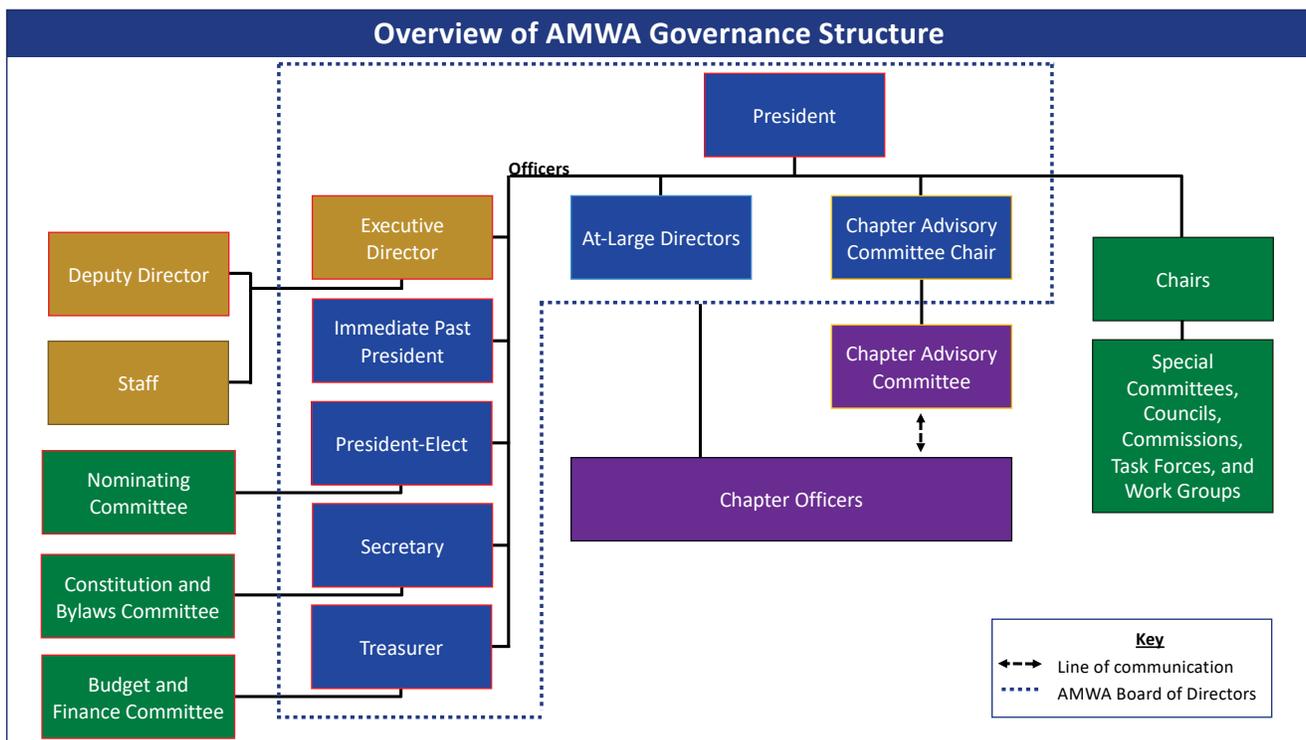


What an exciting time for the American Medical Writers Association (AMWA) as we make the 2022 Spring issue of the *AMWA Journal* accessible on the new digital platform! My sincere appreciation goes to the *AMWA Journal* Editorial Team, AMWA Staff, and the volunteers who put in countless hours to help deliver such an outstanding publication. Congratulations on your efforts in helping the organization to continue to evolve.

As I think about volunteers and how they impact organizations like AMWA, I can't help but reflect on my own trajectory as a volunteer. Looking back on my life experiences, I've always had the desire to help others and to do good. Over the years I've volunteered for causes I was passionate about: children, education, health advocacy, communication, and so much more.

As I grew in my field and more career opportunities became available, AMWA seemed like the perfect fit to hone my leadership skills. It wasn't long after I started dedicating time at the chapter level that I recognized this to be true. My passion grew, and I knew that I needed to do my part in "promoting excellence in medical communication," and contributing to the development of educational resources. I soon began serving in various capacities throughout the organization, recruiting members to AMWA, and encouraging others to volunteer within the organization. The more I served, the more my leadership skills grew.

One key takeaway that has resonated with me over the years, is that leadership and volunteerism are connected. Many people develop leadership skills through volunteering, and good leaders recognize the value of volunteers.



AMWA's governance structure highlights the strategic alignment of AMWA volunteers and staff.

According to a 2016 study surveying the impact that volunteerism has on the success of individuals in the workplace, 80% of hiring managers and those who have influence over hiring managers, indicated that those with volunteer experience move more easily into leadership roles.

For the past 2 years, AMWA, similarly to other organizations and associations, had to pivot to ensure we continued to deliver on our mission, vision, and priorities. We held virtual conferences in 2020 and 2021, continued to provide excellent educational resources, supported chapters and the important work generated by our committees throughout the pandemic, and grew our membership. This would not have been possible without the positive and hard work of our volunteers.

Volunteers help deliver vital programs and services while supporting the overall functionality of the organization. AMWA volunteers are the heart and soul of this

organization, and we are always looking for great leaders to grow with AMWA.

I know you recognize the value that you bring to the field as a medical communicator. I also hope that you understand what you can bring to the organization as a volunteer. The chapter level is a great place to break ground and help build your leadership skills. It also can be a pathway to leadership at the national level. Whatever you do outside of your busy and productive schedules, I hope that you will consider becoming an AMWA volunteer. After all, we are meant to leave organizations such as AMWA better off than how we found them.

➤ If you are interested in becoming an AMWA volunteer, please contact your local chapter or the AMWA membership team at [membership@amwa.org](mailto:membership@amwa.org).

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## CALENDAR OF MEETINGS



### Medical Writing & Communication Conference

NOVEMBER 2-5, 2022  
DENVER, CO

*Trends and Opportunities for Medical Communicators*

#### American Copy Editors Society

March 31 – April 2, 2022

San Antonio, TX

<https://aceseditors.org/conference>

#### International Society for Medical Publication Professionals

April 9-11, 2022

Washington, DC

<https://www.ismpp.org/annual-meeting>

#### Association of Independent Information Professionals

April 27-29, 2022

Virtual

<https://www.aiip.org/conference>

#### American Society for Indexing

Dates and location: TBD

<https://www.asindexing.org/conferences/future-annual-conferences/>

#### Association of Health Care Journalists

April 28 – May 1, 2022

Austin, TX

<https://healthjournalism.org/calendar-details.php?id=2423>

#### Council of Science Editors

April 30 – May 3, 2022

Phoenix, AZ

<https://www.councilscienceeditors.org/events/annual-meeting/cse-2022-annual-meeting/>

#### European Medical Writers Association

May 3-7, 2022

Berlin, Germany

<https://www.emwa.org/conferences/future-conferences>

#### Society for Technical Communication

May 15 – 18, 2022

Chicago, IL

<https://summit.stc.org>

#### Society for Scholarly Publishing

June 1-3, 2022

Chicago, IL

<https://customer.sspnet.org/SSP/Events/2022-Annual-Meeting/ssp/AM22/Home.aspx>

#### Society for Health Communication

June 14, 2022

Austin, TX

<https://www.societyforhealthcommunication.org/national-summit>

#### DIA

June 19 – 23, 2022

Chicago, IL

<https://www.diaglobal.org/Flagship/DIA-2022>