Tuesday, October 20, 10:00 to 11:00 AM

US FDA Real Time Oncology Review Program and FDA Assessment Aid: Early Provision of Data Authoring of a New Summary Document for Efficient FDA Review (Regulatory Writing)
David Sorscher, PhD, RAC, Merck & Co., Inc.
Norman Heyden RPh, MS, Merck & Co., Inc.
John Busillo, PhD, Merck & Co., Inc.
The Real Time Oncology Review (RTOR) and Assessment Aid (AAid) are FDA pilot programs to facilitate review of oncology submissions. The RTOR involves early submission of data prior to a submission. The AAid is jointly authored by the applicant and FDA reviewers, thereby providing a chance to present critical results in an FDA review template. Medical writers play an important role in writing the AAid. Best practices, experiences, and tools will be shared for medical writers to author an effective AAid, including instructions and examples from previous AAids and direct transference and reuse of text/data from submission documents. Both pilots have reduced the time to approval of new therapies.

Target Audience: All levels

Knowing Which Button to Push: Communicating the Value Proposition of Medical Writing (Career Development)
Robin Whitsell, Whitsell Innovations
As medical writers, we intersect with a wide variety of potential stakeholders within and across our organizations. Some of our team members value our contributions and understand the expertise, quality, and soft skills we use to author-by-committee. On the flip side, some team members consider medical writers to be scribes or typing trolls and have minimal understanding of our contributions, the demands on our time, or, possibly, the physical and mental limitations of the human body. In this session, we’ll momentarily acknowledge those collaborative colleagues and then discuss ways to mitigate less helpful team behaviors. This session will focus on strategies for providing respectful disagreement, defusing combative coworkers, and, importantly, asserting the medical writer value proposition.

Target Audience: 2 to 5 years’ experience
Collaborative Writing: Ensure Success with an Effective Strategy (Core Knowledge/Skills)
Crystal Herron, PhD, ELS, Redwood Ink, LLC
Writing with your colleagues can be an efficient and valuable process. But collaborative writing can also be cumbersome and frustrating. You need to find common ground among different writing styles, working practices, and personality traits. Whether you’re working with writers across the hall or the globe, you can set your team up for success. Learn valuable strategies that can guide your team in completing a writing project collaboratively and efficiently. You can then focus on blending complementary strengths, generating new ideas, sharing the workload, and building trust—all while working toward the same goal.

Target Audience: All levels

Navigating Potential Ethical Pitfalls in Research Publications (Scientific Publications)
Anne Murray, PhD, Methodist Health System
Damiana Chiavolini, MS, PhD, UT Southwestern Medical Center
Researchers, publishers, and medical communicators are responsible for ensuring that dissemination occurs in an ethical manner. However, in an effort to rapidly produce manuscripts, some aspects of publication ethics (eg, data manipulation, reporting guidelines, regulatory approvals, predatory publishers, multiple submissions) may be overlooked, leading to the publication of subpar and/or incorrect information. Alternatively, authors may not be aware of some ethical aspects of publishing. What ethical issues do we need to inform our colleagues about to ensure successful publication? Learn about potential ethical obstacles that medical communicators encounter during the publication process and how to overcome these obstacles.

Target Audience: All levels

Tuesday, October 20 2:15 to 3:15 PM
Umbrella Protocol Toolkit for Early Drug Development (Regulatory Writing)
Shawn Watson, PharmD, PhD, BCPS, Bicycle Therapeutics
Umbrella protocols include multiple studies in a single protocol and provide a great deal of leverage because they allow different cohorts to run concurrently, accelerate overall clinical development, and reduce development costs. Nonetheless, their designs are complicated and present unique challenges to a regulatory writer. This session focuses on these challenges, with an emphasis on single-ascending dose-escalation (SAD) and multiple-ascending dose-escalation (MAD), drug-drug interaction (DDI), pharmacokinetic lead-in, bioavailability, and thorough QT studies. The discussion includes what information these studies provide, the rationale for combining these studies into a single protocol in early development, strategic consideration for combining these studies, and tactical guidance for writing these protocols.
Low-Cost and Low-Effort Ways to Create Infographics and Visually Appealing Slides  
Kelly Schrank, MA, ELS, Bookworm Editing Services LLC  
Many clients and employers are ramping up expectations for slide design and many are requesting infographics. Are you ready to move past words in a Word document to presenting concepts in a more visually appealing manner in PowerPoint or PDF? Many people still think you need to be a graphic designer to create infographics or visually appealing slides, but apps such as Canva and templates in PowerPoint can move you forward. Exposing yourself to new ideas and good design can go a long way. Come to this session for resources and ideas for how to get started!  

Target Audience: 5 to 8 years’ experience

**Bridging the Gap: Best-Evidence Strategies for Health Literate, Public-Facing Clinical Trial Materials**  
Catina O’Leary, PhD, LMSW, Health Literacy Media  
Engagement in clinical research relies on patient access to and understanding of the processes and materials connected to clinical trials. Until very recently, most clinical trial materials were developed without meaningful consideration of patient preferences. Recent regulatory guidance mandates communication of clinical trial results to participants in plain language. This provides an impetus for development of participant-friendly materials across the clinical trial process. Operationalizing the processes to develop public-facing materials between study sponsors and medical writers is a challenge and opportunity. Learn to bridge the gap between science writing and medical writing to produce health literate public-facing clinical trial materials.  

Target Audience: All levels
Wednesday, October 21, 10:00 to 11:00 AM

What the Best Medical Writers Know About Nonclinical Data (Regulatory Writing)
Beth Krause, MS, MBA, RRD International, LLC
The nonclinical realm is often unfamiliar territory for medical writers, despite being an integral component of drug development. Essentially all drugs are supported by some nonclinical studies, the results of which will follow the compound through to the product label. Learn about the types of nonclinical data included in an initial investigational new drug submission and how these data influence clinical development; the impact of nonclinical information in common clinical documents, such as protocols, clinical study reports, and investigator’s brochures; and the importance of nonclinical studies beyond the initial investigational new drug application and how they impact drug development through approval.

Target Audience: All levels

Mentoring Programs: One Size May Not Fit All
Mary Burder, PhD, Parexel International
Mentoring programs have become a best practice, as they promote the sharing of knowledge and experience and facilitate growth and development. However, one size may not fit all, as each mentee may be in a different stage of career and/or development at the onset of mentoring. Thus, mentoring programs should be tailored to the mentees’ needs and career objectives. Three different mentoring programs will be discussed: new-hire mentoring, which facilitates transition into a new company/new position; project mentoring, for acquisition of client/project-specific skills and processes; and role shadowing, which enables exposure to new roles and skills for career development.

Target Audience: All levels

Roll-out of a Medical Writing Artificial Intelligence Tool: The Future is Here (Core Knowledge/Skills)
Julia Forjanic Klapproth, Trilogy Writing & Consulting
Artificial intelligence will be the future of generating initial drafts of documents by pulling raw material together from various sources. This session provides an overview of what artificial intelligence can and cannot do in the context of medical writing to set expectations for what we can hope to get from such a system. Also described are the steps involved in developing such a tool: who was involved, how long it took, what kinds of set-backs were encountered, and how the technology actually guided where it was taken. The session will include a live demo of what the system is now able to do: what you put in, how you interact with the tool, and how it helps the writer. Participants will see in real time how long this process takes and, ultimately, what it generates as a product for the medical writer to work with.

Target Audience: All levels
Addressing Legislative Efforts to Limit the Livelihood of Freelance Medical Communicators
(Freelance)
Tim Day, Innovative Strategic Communications, LLC
Agnella Matic, PhD, CMPP, AIM Biomedical, LLC
Carol Keys, PhD, CMPP, Thinking Cap Medical Communications, LLC
Recent activities by state and federal legislative bodies (eg, California AB5) will have an adverse impact on the livelihood of freelance writers. Although the specific impact of each legislative activity will vary, these actions will have the effect of imposing limits on the amount and type of work freelancers can do. The nature of these legislative efforts has caught many by surprise. The ripple effects of the resulting limitations will affect an expansive swath within the publications sector, including writers, publishers, and medical communication agencies, as well as pharmaceutical, biotech, and medical device firms. The fluid nature of the situation will be addressed, and an interim status of legislative activities will be presented.

Target Audience: All levels

Wednesday, October 21, 2:15 to 3:15 PM

A Powerful Combination: The Value of the Writer-Editor Partnership
Crystal Herron, PhD, ELS, Redwood Ink, LLC
Every writer can benefit from partnering with a good editor. Even the best writers. A good editor will dive deep into your writing, tear it apart objectively, and then help you put it back together in a clear and compelling way. They will invest time in refining your writing to elevate it to a higher standard than you thought possible. They will become your partner, teacher, and collaborator. Learn the benefits of partnering with a professional editor and how you can find the best editor to complement your writing skills and style.

Target Audience: All levels

3 Easy Steps to Get More Freelance Clients on LinkedIn (Freelance)
Lori DeMilton, MJ, Lori De Milto Writer for Rent LLC
JoAnna Pendergrass, DVM, JPen Communications LLC
Kelly Schrank, MA, ELS, Bookworm Editing Services LLC
More and more clients are using LinkedIn to find freelance medical writers and editors and to check them out before deciding whether to contact one. But many freelancers don’t know what to do on LinkedIn to get found by clients and impress them. Once you know the three easy steps to success on LinkedIn, attracting more clients will be easier and less time-consuming. Learn how to get found and impress clients with a complete profile focused on their needs and rank higher in search results by building a big, relevant network and being active (posting and commenting on other people’s posts).

Target Audience: All levels
Tricks and Tips for Time Management (Core Knowledge/Skills)
*Melissa Christianson, PhD, Whitsell Innovations*
Time is one of a writer’s most valuable resources, and managing this resource in the face of competing challenges can be among the most complex parts of a writer’s job. However, most writers receive little or no training on effective time management skills and, consequently, lose a sizable fraction of their working time to inefficiency. Fortunately, making purposeful changes in working habits can help writers improve their time management skills. This session will address 6 common time management problems and explore specific solutions for each one. Participants will learn actionable strategies for improving their time management skills and increasing productivity.

**Target Audience:** All levels

Beyond the Needs Assessment: Creative Perspectives on Continuing Medical Education Content Development (Education for Professionals)
*Don Harting, MA, MS, ELS, CHCP, Harting Communications*
This session offers an advanced look into writing for accredited continuing medical education (CME). The session begins with a discussion of a few key industry trends that are driving greater creativity in CME writing. After a brief mention of the needs assessment, which is considered a basic assignment, we’ll delve into how to work with clients and faculty to develop more advanced assignments, including digital monographs, polling questions, test questions, interactive case studies, outcome reports, meeting posters, and peer-reviewed journal articles. The session will end with a look ahead at additional types of CME writing assignments that may become common in the future, including software and games.

**Target Audience:** 5 to 8 years’ experience

*Thursday, October 22, 10:00 to 11:00 AM*

Clinical Evaluation Reports: Requirements, Recommendations, and Reality (Medical Devices)
*Karen Bannick McQuoid, Bannick LLC  
Denise King, Medtronic*
Clinical Evaluation Reports (CERs) are recognized as an invaluable element of any European medical device submission, especially in light of quickly evolving interpretations of the European Medical Device Regulations (EU MDRs). The reality is that there is a science and an art to the preparation of CERs. The bar for the CER content and expectations for the analysis of all clinical evidence available on the device continues to be raised in any unpredictable trajectory. This session will provide a brief overview of key elements of the requirements and hone in on recommendations for avoiding common pitfalls seen during Notified Body Review. A panel of key experts will engage the audience in a discussion of current audit findings and recommended solutions. Discussion will address some related documents, including Clinical
Evaluation Plans, Post Market Clinical Follow-Up Plans, and Reports and Summaries of Safety and Performance, as time allows.

**Target Audience:** All levels

**Regulatory Chemistry, Manufacturing, and Controls Submissions: Lifecycle Decisions**
*(Regulatory Writing)*

*Nellie Waterland Forwood, MS, RAC, CQE, Synchrogenix*

The chemistry, manufacturing, and controls (CMC) information in an initial marketing application needs to be a balance between current manufacturing and testing practices, requirements in the various guidance documents, and the need for some flexibility in the lifecycle management of the marketed product. Learn about the CMC detail necessary in an initial marketing application balanced against the postapproval ramifications of including too much detail in certain aspects of the application.

**Target Audience:** All levels

**Strategies for Effective Risk Communication**
*(Health Communication)*

*Melissa Christianson, PhD, Whitsell Innovations*

The rise of patient-centered care and shared decision-making models has created a crucial role for risk communication in health care. Effective risk communication occurs when physicians and other medical communicators share clear and accurate information about health-related risks in a way patients can understand. Failure of this process compromises patient involvement in care decisions. However, obstacles such as variable health literacy rates, attitudes toward science, and data complexity make risk communication difficult. This session outlines both barriers to and strategies for successfully communicating risk information to nonexpert audiences. Participants will learn proactive methods for clearly and effectively communicating about health-related risks.

**Target Audience:** All levels

**Editing: Hard Knowledge, Soft Skills**
*(Career Development)*

*Loretta Bohn, ELS, RTI International*

*Erica Goodoff, ELS, The University of Texas MD Anderson Cancer Center*

*Crystal Herron, PhD, ELS, Redwood Ink*

The skills and tasks of writers and editors, though they may overlap, are distinct. If you’ve been doing editing tasks for more than a couple of years, either as a freelancer or an employee, you know this, and you seek out other members of your tribe. AMWA is a home for anyone in health or scientific communication, so whether you’re a “real” medical writer who also edits your peers’ work or you work full-time at any form of editing, you belong here! Join us—two
staff editors and a freelance editor—for a panel discussion on how to maintain our mental health as editors, how to manage expectations and conflict, and what new trends or new trends or challenges we’re seeing.

**Target Audience:** 5 to 8 years’ medical editing experience

**Thursday, October 22, 2:15 to 3:15 PM**

**Enforcing House Style: Customizing PerfectIt for Client, Agency, or Publication Preferences**  
*Daniel Heuman, Intelligent Editing Ltd*

Checking that every detail conforms to a house style is time-consuming and it can distract you from ensuring that science is presented correctly. There is an easier way! This session will show how you can use PerfectIt to build a custom style sheet and check your preferences. It will show how you can set up a different style sheet for each agency, client, or publication that you work with; and it will describe show you can share that with colleagues.

**Target Audience:** Some experience with PerfectIt on a PC with Windows

**Communication Is a Key Success Factor in Gene Therapy** *(Core Knowledge/Skills)*  
*Angela Johnson, MSE, PMP, RAC, Sigilon Therapeutics, Inc.*

With more than 800 cell and gene therapy (CGT) products in development, the US FDA has announced that by 2025, as many as 20 new CGT products will enter the market annually. This influx of CGT products triggers paradigm shifts in industry, including small-batch manufacturing, novel clinical trials for rare diseases, and treatments geared for individual patient genetics, often with use of newly available biomarkers and data insights. For medical communicators, this situation creates a landscape of opportunities in regulatory document development, communicating complex trial information, and effectively reaching patients and clinicians. This session will provide an overview of terminology and concepts in GCT; writing strategies for key regulatory documents (eg, Regenerative Medicine Advanced Therapy Designation (RMAT) and GCT clinical trial documents); and strategies to engage clinicians, patients, and advocacy groups through clear communication of CGT research and will help prepare medical communicators to effectively frame concepts in CGT for wide audiences.

**Target Audience:** All levels

**Foundation Grants 101** *(Grantsmanship)*  
*Madison Hedrick, MA, US Medical Research Services, LLC*

Federal government awards are considered big money, but private foundations are more frequent funders. When an organization wins foundation grant money, it often becomes their largest funding source and award. Unfortunately, instructions on foundation grants are sparse, despite their usefulness in the medical writing career skillset. Learn how foundation grants are define, what subtypes there are, and how to determine the best grant for each situation.
Target Audience: All levels

Analysis of Mentoring: From Marginal to Maximal

Susan Morris, MEd, CPCC, ACC, Susan Morris Coaching

In today’s life sciences industry, technical professionals are rewarded for their deep expertise, sometimes at the expense of an equivalent excellence in building and maintaining one important business relationship. This important business relationship is the mentoring relationship. This session will provide an analysis of the benefits of mentoring for the mentee and mentor. Learn about a 4-step mentoring process that, when followed, takes mentoring from marginal to maximum rewards.

Target Audience: All levels