

AMWA MID-AMERICA

Fall 2017



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A Note from the Editor

Magdalena Berry, MA

Dear Chapter Members,

The **2017 AMWA Medical Writing and Communication Conference** is rapidly approaching. It'll be in Orlando, FL, November 1-4. These annual conferences are wonderful opportunities for you to learn about the profession, broaden your skill set, and share your expertise. I've included in this newsletter a list of chapter members who are on this year's program. AMWA has a robust educational component, and the Conference offerings cover a wide range of topics. In addition, this is a chance to meet and network with other AMWA members (a very nice bunch of folks, indeed).

You can still register! Here are the deadlines:

Regular registration rates: July 1 – September 30

On-site registration rates apply October 1

Last day to cancel conference registration and receive a partial refund: October 11

AMWA Workshop homework is due to the leader by October 11

Our **annual chapter dinner** is a highlight! Information about it from Joanne McAndrews, who organizes these dinners for us, can be found on page 3.

You can find more information about the chapter and some other resources for writers at our chapter web site: www.amwa-midamerica.org

As always, feel free to send me any suggestions or contributions for this newsletter.

Magdalena Berry

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Chapter Officers

President: Rona Clair Grunspan, MD

Treasurer: Leslie Neistadt, ELS

Secretary: Linda Landon, PhD

Membership chair: Heather McNeill, MA

Kansas City events coordinator: Laura Long,

MA

Newsletter chair: Magdalena Berry, MA

Webmaster: Lisa M. Balbes, PhD

St. Louis Freelance Luncheon Coordinators:

Lisa M. Balbes, PhD, Joanne M. McAndrews,

PhD

St. Louis-area Freelance Luncheon Series: TechWrite STL

Joanne McAndrews, PhD
Lisa Balbes, PhD



The TechWrite STL group continues to hold bi-monthly meetings. At most meetings, a topic of interest to freelance medical and technical writers is presented by a member and discussed by the group, usually over lunch at a local restaurant.

In July, Jo Seltzer discussed her experiences writing and producing segments for the “Innovations” programming, which airs on the St. Louis Higher Education Television (HEC-TV) channel. Jo described the step-by-step process involved in writing for television, including script writing, integrating content with photographs and video, interviewing subject matter experts, and editing video to assemble the final product. Attendees learned that a just how much time, effort and planning is required to produce just a few minutes of quality video.

Dr. Anu French was the guest speaker at our annual dinner, held on August 29th. AMWA

members and guests were treated to a presentation about Mindfulness Meditation, specifically mindfulness as a tool in self care, and current research on its role in wellness. French lead the group through some experiential mindful practices, and closed the evening with a sound healing experience using her own healing bowls and harmonium.

Upcoming events include “Best (and Worst) Books of 2017” in November, and “Business Travel Tips” in January 2018.

Lisa Balbes and Joanne McAndrews have been co-organizing the group since September 2006, when it was formed as a merger of the local AMWA and STC-CIC groups. A schedule of upcoming luncheons can be found on our chapter website (<http://www.amwa-midamerica.org/index.html>). A complete list of past topics, as well as handouts, is available on the History tab on that website.

AMWA Mid-America Chapter Dinner

By Joanne M. McAndrews, PhD and Leslie E. Neistadt, ELS

For the past twelve years, Mid-America chapter members have gathered for dinner on Thursday evenings during the AMWA Medical Writing & Communication Conference. We always enjoy meeting each other and learning about members' different backgrounds and work environments. This year's dinner is planned for Thursday November 2nd in Orlando, FL. We will dine at Frontera Cocina in the Disney

Springs area. There is a free shuttle bus that runs from the Walt Disney World Swan and Dolphin to the Disney Springs area.

Please email

joanne@joannemcandrews.com by Friday October 20th if you plan to attend. Hope to see you there!



*Join us in Orlando
November 1 - 4, 2017*

Chapter Members Presenting in Orlando

The Mid America Chapter is well-represented by members leading Sessions and Roundtables at this year's Conference!

Session: *Crib Notes for CMC Module 3: Content, Organization, and Post-Approval Impact*

The Evolving Regulatory Landscape

Mary Ellis Bogden, BA, Senior CMC Regulatory Consultant, Whitsell Innovations, Inc., Chapel Hill, NC **Karry Smith, PhD, MPH, Medical Writer and Consultant, Whitsell Innovations, Inc., Des Moines, IA**

Module 3 (Quality) of the Common Technical Document (CTD) includes the Chemistry, Manufacturing, and Controls (CMC) information for the intended marketed drug product. Information about development, characteristics, standards, and packaging for the drug substance(s) and product are contained in this module. Module 3 is present in the IND and the content is initially developed and managed by subject matter experts or CMC functional area heads in the early stages of development. As development of a drug moves through Phase 3, a higher level of collaboration between CMC experts and regulatory writers is required to prepare the NDA submission. Familiarity with the source documentation on supporting Module 3 enables the regulatory writer to be efficient and strategic when compiling an NDA, as many sections in other modules cross-reference data contained within Module 3. Understanding the location of content and life-cycle strategy for Module 3 during NDA compilation is essential for managing the dossier

Roundtables

Expectations and Reflections of a New Regulatory Medical Writer

Jenny Cochran, PharmD, MBA, Medical Writer, Cardinal Health Regulatory Services, Overland Park, KS

This discussion will provide an overview of regulatory medical writing requirements, conveyed by a new writer. We will discuss the expectations of a new writer and how to leverage group collaboration to ensure successful completion of regulatory documents. We will also reflect on examples of writing requests and lessons learned during the first years of medical writing.

Grow your Own Local Network of Communication Professionals **Joanne M. McAndrews, PhD, Freelance, St. Louis, MO**

Online networking (LinkedIn, Twitter, Facebook, AMWA Engage, etc.) is wonderful, but nothing really beats face-to-face interaction with colleagues. This roundtable will cover the how-tos of starting and maintaining a local network of writers, editors, and other communication professionals in your area. We'll discuss recruiting members, finding a place to meet, meeting formats, meeting topics, maintaining a membership list, and the many benefits of connecting in person on a regular basis with professionals in your field.

Chapter Members Present in Orlando

Ideal Situations and Challenges Facing a New Regulatory Medical Writer

Kevin Farmer, PhD, Medical Writer, Cardinal Health Regulatory Services, Overland Park, KS

This discussion will provide an overview of regulatory medical writing requirements, from a new writer's perspective. We will discuss ideal situations and particular challenges faced by a new writer and illustrate examples of successfully completed regulatory documents within a real-life context.

Sitting is the New Smoking: Increasing the Longevity of You and Your Medical Writing Career

Meg Robison, Chief Executive Officer, Signa Medical Writing, Lincoln, NE

Strict timelines, urgent needs, multiple projects and deadlines, and often unrealistic expectations result in medical writers spending many hours sitting in front of a computer screen every day. The effects are not only poor posture and eye strain, but potentially brain, spine, and heart strain that can shorten a writer's career. Research shows that we sit an average of 9.3 hours per day, and medical writers are at particular risk for this habit because of the nature of our profession and the particular personality traits that led us to this exciting profession in the first place. Longevity in medical writing isn't just about ergonomics, it is about recognizing changes that are needed in both working environment and attitude to focus

Events in Kansas City

by **Laura Long**

AMWA's Kansas City-area members are planning a networking event for mid-November. There will be drinks, appetizers and an opportunity to chat with fellow current and prospective members. Stay tuned for an email with more details!