

Luminary Hotel & Co., Autograph Collection  
Fort Myers, Florida

# 2022 SOUTHEAST REGIONAL CONFERENCE

JUNE 13-14



[www.amwa.org/southeast\\_regional](http://www.amwa.org/southeast_regional)

# SCHEDULE & PROGRAM

## SUNDAY, JUNE 12

5:00 – 6:30 PM Informal gathering at Hotel Lobby or Rooftop Bar, Dinner on own

## MONDAY, JUNE 13

8:00 – 8:50 AM Networking Breakfast with AMWA Welcome

### 9:00-10:30 AM **Educational Sessions**

#### **Regulations: Developing a Clinical Evaluation Strategy with an Eye to Regulatory and Quality Requirements**

**Karen Bannick McQuoid, MA, FRAPS, RAC**

*Audience: Entry to Mid-career (1-8 years)*

“We need clinical data, STAT!” In decades past, it was very common that a manufacturer needed clinical data for the US and not necessarily elsewhere. Manufacturers often conducted clinical studies in those “elsewhere” countries and then submitted to the US. In the past decade, this has changed dramatically. Clinical evidence is now needed to gain CE mark for devices in the EU and other countries. This presentation will review these changed requirements and discuss strategies to obtain the right data efficiently and to avoid unnecessary duplication of efforts in multiple geographies. After participating in this session, participants should be able to

- Identify key regulatory reasons for clinical data
- Understand basic elements of clinical evaluation
- Understand opportunities to build global evaluation strategies

#### **Jam Session for Early to Mid-career Freelancers**

**Brian Bass, MWC**

*Audience: Early to Mid-career (1-5 years as a freelancer)*

Launching a freelance business is a big step. Whether you're currently contemplating the leap to independence or are already a few years into the adventure, every freelancer has questions. This jam session will provide a supportive space for early to mid-career freelancers to share their concerns, fears, and apprehensions; to get their questions out onto the table, discover they're not alone, and get answers; to share experiences; and to develop a valuable support network. The session is lightly structured to permit a free flow of discussion without getting stuck on a single topic and moderated by a seasoned freelancer with more than 3 decades of experience. At the end of this session, attendees will be able to:

- Recognize common issues that arise among beginner freelancers
- Formulate solutions to shared freelance issues
- Use feedback from peers to validate freelance concerns and experiences

### 9:00 AM-12:00 PM **Workshop (additional fee)**

#### **Strategies for Persuasive Writing**

**Susan Aiello, DVM, ELS**

*Audience: Entry to Mid-career (1-8 years)*

Did you know there is an entire science behind persuasion and influence? In this session, we will explore the principles of persuasion and examine how to achieve the building blocks of credibility and logic in written materials. Participants will learn a writing framework that begins with setting a goal and ends with gaining commitment, considering the audience and the environment. Specific writing techniques will be shared for improving clarity, building an argument, and telling a persuasive story.

## MONDAY, JUNE 13 (continued)

10:30–11:00 AM Beverage Break

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### 11:00 AM – 12:00 PM Educational Sessions

#### **Leveraging Public Relations in Medical Communications**

**Katrina Burton, BS**

*Audience: All levels*

Public Relations (PR) plays a crucial role in healthcare communications. Healthcare institutions and organizations are investing more time and money in PR to educate, raise awareness and build public trust about vital medical topics, health initiatives and patient programs designed to help people live healthier and more fulfilling lives. As medical communicators, it is important to understand the dynamics of how PR can leverage a relationship between medical institutions and the public. Attendees will learn:

- Best practices for developing a strategic PR plan
  - The who and how of engaging stakeholders
  - The components to building strong media relationships
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#### **Resources for Researching Medical Devices Using Publicly Available Databases**

**Sara VanWyk, MPH, CCRP, RAC, MWC**

*Audience: New/Entry level (0 to 5 years)*

The MEDDEV 2.7/1 Rev 4 (June 2016) and European Union (EU) Regulation 2017/745 (2017) have placed a new or renewed focus on the aggregation of data about subject and similar medical devices marketed in the EU, including characteristics, suspected device-associated incidents, clinical trials, and evaluations. The MDCG 2019-9 guidance has further directed the presentation, content, and validation of the summary of safety and clinical performance (SSCP) of such implantable and Class III devices in the EU. Ms. VanWyk will address resources for researching medical devices using databases maintained by US, EU, and other health authorities. She will additionally provide a brief overview of content and anticipated release information for SSCPs. At the end of the presentation, attendees should be able to identify the relevant guidance documents for clinical evaluation, list publicly available databases for literature search, and describe the content of an SSCP.

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12:15 – 1:45 PM Networking Luncheon

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### 2:00 – 3:30 PM Educational Sessions

#### **Communicating Science to the Public**

**Susan Aiello, DVM, ELS**

*Audience: All levels*

In this session, we will consider best practices and strategies for communicating science to the public, both for written pieces and for in-person or virtual presentations. Individual topics include understanding the audience, determining the message, and effectively using language and visuals. Challenges and potential pitfalls to be avoided will be described. Time will be devoted to handling scientific uncertainty and managing crisis communications, as well as dealing with journalists and the media. This usually makes for a lively discussion, so come prepared to share!

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## MONDAY, JUNE 13 (continued)

2:00 – 3:30 PM **Jam Session for Seasoned Freelancers**

**Brian Bass, MWC**

*Audience: Advanced (more than 8 years as a freelancer)*

When accomplished musicians jam, their combined talent, energy, and experience make a special kind of synergy. A similar kind of magic happens when seasoned freelancers get together to discuss their ideas, concerns, and challenges with peers who have the same or more experience. These rare gems of collegial conversation and commiseration happen spontaneously and usually unpredictably. This discussion will provide a supportive space for experienced freelancers to wrestle their demons and share their experiences. Whether you emerged bloodied and bruised, valiant, or victorious, we all have stories to tell, and we can all learn from and teach each other. This session is lightly structured to permit a free flow of discussion without getting stuck for too long on a single topic. At the end of this session, attendees will be able to:

- Recognize common issues that arise among experienced freelancers
- Formulate solutions to shared freelance issues
- Use feedback from peers to validate freelance concerns and experiences

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3:30 – 4:00 PM **Beverage Break**

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4:00 – 5:00 PM **MedWrite Talks (8-10 minutes each)**

**Best Practices for Client Interaction**

**Sara VanWyk, MPH, CCRP, RAC, MWC**

In an era of electronic communication, when writer-client relationships can be exclusively forged online, consulting success relies on the maintenance of a professional brand that projects competence. In this session, we will discuss best practices for client interaction by electronic resources, including review of virtual meeting, email, and report communication case studies that are based on real-world experiences.

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**Small Business Survival Skills: Your Way to Success**

**Queen Buyalos, PharmD**

Over 20% of new businesses fail in their first year, and 50% close within five years. When starting their businesses, freelance medical writers face many difficulties and barriers, especially if breaking into the field. Some are held back by challenging personal and work situations. As time passes, some begin to believe and accept that they will not succeed. Hence, they decide to shut down and stop writing. Pulling from my personal experience as an immigrant, the mom of a childhood cancer survivor, pharmacist, and a medical writer, I not only pushed through adversities but stayed focused. I developed skills that propelled my business and myself forward. This presentation will teach freelance medical writers small business survival skills that will encourage them to keep pushing through, stay focused and not give up on their business prematurely.

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**It's All In How You Pivot**

**Brian Bass, MWC**

Every day brings challenges and choices, opportunities to decide whether to stay the course or head in a new direction. How you pivot can make all the difference. In this MedWrite talk, Brian Bass, MWC, will reveal some of the best, and the worst, decisions he's made in his career as an employee and as a freelancer, and how choosing to make a choice has propelled him along the path to success.

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## MONDAY, JUNE 13 (continued)

4:00 – 5:00 PM **Reminders of Life Lessons from the Barnyard**  
**Susan Aiello, DVM, ELS**

Let's take a lighthearted look at a few life lessons seen through the lens of working with our animal friends.

5:00 – 6:00 PM Happy Hour (cash bar) Lobby or Rooftop Bar, Dinner on own

## TUESDAY, JUNE 14

9:00 AM-12:00 PM **AMWA Workshops (additional fee)**

**Advanced Writing**  
**Susan Aiello, DVM, ELS**

*Audience: For participants with 2 or more years of experience in editing or writing*

This workshop is geared toward exploring the cognitive processes involved in approaching and working through a writing project, either as a sole undertaking or with others. We'll compare outlining and mind mapping and discuss how to leverage each technique for best results for specific writing projects. We'll examine the importance of rewriting and editing to the writing process, and the principles of enlivening our use of language to make it more engaging and accessible to readers. Finally, let's unblock writer's block!

**Regulations: What Does a Medical Writer Need to Know?**

**Karen Bannick McQuoid, MA, RAC, FRAPS**

*Audience: For participants with 2 or more years of experience in editing or writing*

Global medical device companies are seeking European market authorization under the new EU Medical Device Regulations, in force as of May 2021. As medical writers, there is an urgent opportunity to contribute to ensuring that important medical devices remain available to the European patients. There are major differences between the review and approval processes for medical devices in the European Union and the United States. In particular, a clinical evaluation plan (CEP) and report (CER) are required for all European medical devices (except diagnostic tools). This workshop provides practical advice for gathering and reporting valid clinical evidence in compliance with European Directive 2007/47/EC. In-workshop activities: participants will engage in interactive discussion and hands-on exercises. *Note: experience with critical appraisal of the scientific literature and knowledge of medical device development are helpful.*



# FACULTY

## **Susan Aiello, DVM, ELS**

Susan Aiello, DVM, ELS, has 35+ years of experience in editorial, training, and publication services. She is a former Editor-in-Chief of The Merck Veterinary Manual and has edited numerous other medical reference works and health-related nonfiction trade books. Susan is a proud recipient of AMWA's Golden Apple Award and the Swanberg Award. Dr. Aiello is also guest faculty for the Harvard Medical School CME course on writing and publishing for healthcare professionals. In her spare time, Susan mostly plays with animals of all species.

## **Brian Bass, MWC**

Brian Bass, MWC, is an award-winning freelance medical writer and an avid speaker and presenter on the business of freelancing. He is President of Bass Global, Inc., a company that provides medical writing solutions in the areas of pharmaceuticals, biotechnology, devices, and diagnostics for healthcare professional, consumer, and business audiences in a wide range of therapeutic areas and media. Brian is also co-author of The Accidental Medical Writer® series of books, resources, information, and inspiration for freelance medical writers.

## **Karen Bannick McQuoid, MA, RAC, FRAPS**

Karen Bannick McQuoid is the owner and CEO of Bannick LLC where she leads a team of medical device experts that provide clinical, medical writing, quality, regulatory, and auditing guidance to medical device companies. Bannick helps clients get their new medical devices to market and provides guidance to keep the devices on the market.

## **Katrina Burton, BS**

Katrina Burton, BS is a program manager in the Public Relations Office at The University of Texas MD Anderson Cancer Center, currently managing communications and media relations for the MD Anderson Children's Cancer Hospital, the Adolescent and Young Adult Oncology Program and the Children's Art Project. With more than 18 years of experience in health care marketing, communications and public relations, she enjoys writing stories about research, clinical programs, and support services. Burton shares health care and human-interest stories through her own writing and in coordination with media outlets across the country.

## **Queen Buyalos, PharmD**

Queen is a motivational speaker and medical writer who values determination, focus, and mindset. Queen earned her Doctor of Pharmacy (PharmD) degree from Massachusetts College of Pharmacy and Health Sciences in Worcester, MA. Pulling from personal experience as an immigrant, the mom of a childhood cancer survivor, pharmacist, and a medical writer, Queen not only pushed through adversities but used her struggles as fuel to propel her business and herself forward.

## **Sara VanWyk, MPH, CCRP, RAC, MWC**

Sara is a Principal Regulatory Scientist at RQM+, where she performs, writes, and edits clinical evaluation reports. She is currently certified as a clinical research professional (CCRP) by the Society of Clinical Research Associates (SoCRA), in regulatory affairs (RAC-Devices) by the Regulatory Affairs Professionals Society (RAPS), and as a medical writer (MWC) by the American Medical Writers Association (AMWA).



# REGISTRATION RATES AND POLICIES

	Early Rates - April 1-30		Regular Rates - May 1-31	
	Member	Non-Member	Member	Non-Member
Conference Registration Fee	\$225	\$275	\$275	\$325
AMWA Workshop Fee	\$250	\$300	\$300	\$350



## Cancellation Policy

AMWA Regional Conference registration cancellation requests must be sent to [conference@amwa.org](mailto:conference@amwa.org), to be eligible for a refund. Refunds will be issued through your method of payment, less a \$75 cancellation fee. A cancellation fee of \$50 will be charged for workshop cancellations. No refunds or credits will be given for failure to attend, late arrival, unattended events, or early departure. Registration fees are not transferable to another person.

## Participants with Special Needs

If you have a special need that may affect your participation in the conference, contact [conference@amwa.org](mailto:conference@amwa.org) before May 17 to indicate requirements and/or request accommodations.

## Children

Children under the age of 18 are not permitted in AMWA meeting spaces. No one under 21 years of age is permitted at events where alcohol is served.

## Name Badges

All registered attendees will receive a conference name badge, which must be always worn during the event and within the meeting space for access programs and group meals. AMWA will offer color-coded stickers for attendee badges:

- **Green:** indicates you are comfortable with close contact (i.e. hugs are acceptable)
- **Yellow:** indicates limited contact (i.e. fist or elbow bumps only)
- **Red:** indicates no contact (i.e. wave hello)

## Health & Safety Protocols

AMWA may change, update, or add to these requirements at any time as it deems prudent to best protect the health and safety of attendees and others, and attendees must comply with relevant policies and requirements as communicated by AMWA.

- AMWA requires proof of vaccination status, or proof of a negative COVID-19 test (PCR or rapid test; home tests do not qualify) within 72 hours prior to the first day of attendance.
- Anyone who registers for the in-person event agrees to a COVID-19 Personal Responsibility Statement/Liability Waiver
- All event attendees, regardless of vaccination status, agree not to attend any events if they have an active case of COVID-19. All attendees also agree not to attend any events if they are experiencing possible symptoms of COVID-19 unless and until they receive a negative COVID-19 test.

Attendees will be expected to take common actions to reduce the risk of COVID transmission and to behave responsibly (including leaving the event area) in case of exposure to a COVID case or experiencing symptoms. In such case, attendees should seek appropriate medical attention, including a COVID-19 test, and must immediately inform AMWA should a COVID-19 test be positive during the event or in the 14 days following the event.

Failure to comply with all safety protocols and requirements as listed above or related directions from AMWA representatives on-site may result in the loss of the right to attend or participate in AMWA events, including forfeiting any registration fees paid.

# HOTEL INFORMATION

## Luminary Hotel & Co., Autograph Collection

<https://www.luminaryhotel.com/>

AMWA Southeast Regional Conference Hotel

Room Rate: \$169 + tax per night

Check-in: 4:00 PM, Check-out: 11:00 AM

After registering for the conference, you will be sent a link to reserve your room in the AMWA hotel block. All reservations must be guaranteed with a major credit card or accompanied by a first night room deposit. Reservations must be made no later than May 20, 2022, to receive AMWA's discounted rate, however, the AMWA room block may fill before this date, so register and book your room as soon as possible to avoid disappointment! If you have questions or need assistance with hotel reservations, contact [conference@amwa.org](mailto:conference@amwa.org).

### Parking

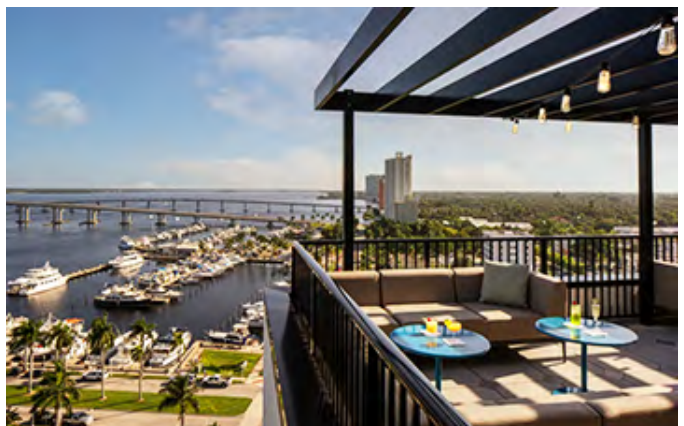
On-site parking, fee: 1 USD hourly, 15 USD daily

Valet parking, fee: 23 USD daily

Off-site parking, fee: 1 USD hourly, 5 USD daily

### Hotel Services & Amenities

- Evening turndown service
- Housekeeping service daily
- Fitness center on, outdoor pool
- Sundry/Convenience store
- Full business center



We look forward  
to seeing you in  
Fort Myers!

If you have questions about the AMWA Conference,  
please contact AMWA staff at [conference@amwa.org](mailto:conference@amwa.org).