

# AMWA

## *Indiana Chapter Newsletter*

July 2016



# American Medical Writers Association Indiana Chapter

## Executive Committee 2014-2015

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President-Elect	Esther Brooks-Asplund, PhD
Secretary	Rachael Mann
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Member Resources	Esther Brooks-Asplund, PhD
Program	Barbara Lightfoot, BS, CCRP
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Social Media & Marketing	Linda Hughes, MA

## Newsletter

<b>Editor</b>	David Caldwell, PhD
<b>Assistant Editor</b>	Alyssa Garrelts, PhD
<b>Section Editor</b>	
Freelance	Esther Brooks-Asplund, PhD

### *Coming Attractions*

**October 5-8, 2016**

**AMWA 2016 Medical Writing & Communication Conference**

**Sheraton Denver Downtown Hotel**

**Denver, CO 80202**

### Links

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[AMWA Indiana Chapter](#) [Indiana Chapter LinkedIn](#)

[Global English Blog](#)

[Health Care Brand Journalism Blog](#)

[WilliamsTown Communication Blog](#)

### Please let us hear your voice!

Let us know if there is anything we can do to help you benefit professionally from your AMWA membership. Volunteering to help our chapter or national association is a great way to have fun while meeting some wonderful people, improving yourself and the profession, and becoming and being the leader you were meant to be. Join our LinkedIn group, come to the chapter events, or click on the name of a chapter officer or committee chair above to join the conversation about medical communication and our chapter.

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## Cover

Find AMWA members near you by searching the AMWA member directory by city or zip code.

This map of the locations of our 84 chapter members was created with [BatchGeo](#).



Dear AMWA members:

I'd like to begin this letter with gratitude. First, I want to thank all of you for honoring me with the opportunity to serve as your President. The lessons I have learned and the friendships I have made within this organization are ones that I will always treasure. I also want to thank Bill Pietrzak and the Education Committee for another wonderful annual conference. I found the networking session on Friday to be fun and invaluable, even despite my natural aversion towards networking. And the Saturday speakers were informative, inspirational, and entertaining. Kathy Spiegel led the workshop and, as always, she did a fantastic job.

The AMWA Indiana chapter has a bright future ahead. I am thrilled that Esther Asplund will serve as President next year. The Nominating Committee is proposing a strong team to support her: David Caldwell (who has countless hours to this organization) for President-Elect, Nico Bivi (who has performed admirably as Treasurer this year and has taken on additional duties as we have taken steps to incorporate) for Treasurer, and Angela Beeler (past president of the AMWA Southwest chapter) for Secretary.

As you know, we sent out a survey some months ago asking whether the chapter should incorporate, stay as is, or dissolve. The feedback, both in terms of comments and volume, was loud and clear. You love this chapter and you want to support this chapter. The Executive Committee then took the steps to incorporate and we are officially a nonprofit organization that is an entity separate from, but related to, the national AMWA organization. We also applied for and received 501c3 tax-exempt status that will allow us greater flexibility in receiving and making donations, greater legal protection in terms of liability, and greater stability for the future. We are excited to have a firm foundation so that we can continue to deliver strong educational programs and networking events.

In closing, I urge all of you to become involved in the chapter. We can remain strong and provide top-notch programming only if we have volunteers willing to put in the time. As the new

administration takes over for the 2016-2017 year, ask yourself what you can do to make this upcoming year the best in AMWA Indiana history.

Best,

*Laura Town*

Laura Town  
President  
AMWA Indiana chapter  
[ltown@willtown.com](mailto:ltown@willtown.com)

*Laura is the 2015-2016 president of the AMWA Indiana chapter and owns WilliamsTown Communications, a publishing and e-learning firm. WilliamsTown specializes in producing healthcare content for nursing and allied health professionals.*

2016  
AMWA

Medical Writing &  
Communication  
Conference

OCTOBER 6-8 | DENVER, CO

Find updates to chapter and community events on our [Web site](#)



## The Work (and Writing) Life of a Laboratory Animal Veterinarian

Lynn Wachtman, DVM, MPH ([lwachtman96@yahoo.com](mailto:lwachtman96@yahoo.com))

Much has changed in the veterinary landscape since James Herriot roamed the English countryside treating milk fever and birthing calves. Modern veterinarians demonstrate an increasing level of specialization including concentrations in animal behavior, cardiology, and neurology. General practitioners are using modern technologies such as ultrasound imaging, digital radiology, laparoscopic and laser surgical techniques, and telemedicine. Veterinarians are embedded in the government and work within the FDA, USDA, CDC, NIH, and most branches of the military. Last, but not least, any organization using animals for a research purpose is required to have a veterinarian in its employ.

### *REGULATIONS*

The regulations that establish the veterinary role within research organizations originated in the late 1960's with the "Laboratory Animal Welfare Act", amended and renamed in 1970 to the "Animal Welfare Act" (1). This act, administered through the USDA, regulates commercial traffic of research animal species, establishes standards for housing and transportation, and ensures the provision of "adequate" veterinary care to these animals.

The "Health Research Extension Act" of 1985 additionally requires that any institution receiving PHS research funding provide a written assurance of compliance with the "Public Health Service Policy on the Humane Care and Use of Laboratory Animals" (2). This policy requires that a veterinarian with training or experience in laboratory animal medicine have authority and responsibility for activities involving animals at a given institution. Furthermore, this policy requires that institutions design their animal care programs based on the "Guide for the Care and Use of Laboratory Animals" which further describes components of an acceptable veterinary care program (3).

Much has changed in the veterinary landscape since James Herriot roamed the English countryside

### *CERTIFICATION AND ROLES*

Although the regulatory requirement is for the provision of “adequate” veterinary care, veterinarians who work in the preclinical research realm often seek additional training and complete a rigorous certification process through the American College of Laboratory Animal Medicine.

The role of a laboratory animal veterinarian is complex and broad based. These veterinarians ensure the health and welfare of the animals housed within the research colony, design and manage animal facilities, supervise the technical staff working within these facilities, develop policy based on regulatory guidance, monitor the execution of research projects, and assist with implementation of occupational health and safety programs. These veterinarians may also participate in collaborative and independent biomedical research and often make valued contributions to animal model development and refinement. There is also no shortage of involvement in medical writing for the laboratory animal veterinarian.

### *WRITING PROTOCOLS*

There are a number of documents that veterinarians write. One of the most important is the Institutional Animal Care and Use Committee (IACUC) study protocol. Any research project employing animals must have an approved study protocol on file with the local IACUC. This protocol is subject to renewal on an annual basis and a detailed review at 3 year intervals. This document describes the details of the research project and serves as the outline for the execution of the project. Any proposed deviation from what is set forth in the IACUC protocol must be resubmitted as an amendment and subjected to additional review and approval. Descriptions of the components of the IACUC protocol are described in the “Institutional Animal Care and Use Committee Guidebook” (4).

One of the most important documents a veterinarian writes is a study protocol

Because the veterinarian is an expert on animal physiology and clinical care, he or she often serves as a valuable resource to investigators in the design and writing of the IACUC protocol.

## An IACUC protocol has three major components

Three major components of an IACUC protocol are described here.

The first is the lay summary. This section, which describes the aims and significance of the research project, should be written in plain language that is easily comprehended by members of the public.

The second major component is a detailed description of all procedures that will be performed during the execution of the project. This section includes an accounting of the species and numbers of animals required, narratives describing all surgical and interventional procedures, an inventory of the anesthetics or analgesics to be used, a description of any euthanasia methods, and a timeline detailing the flow of work. It is critical that the text of this section be written to maintain experimental flexibility but yet provide sufficient detail to ensure that animals will be handled humanely. Institutional veterinarians may be involved in generating standardized descriptions of the most commonly utilized procedures. This standardized text can be populated into the draft of an IACUC protocol. Not only does this reduce the work load of the investigators when writing these lengthy documents but also ensures that procedures will be executed with a superior standard of care.

The third major component of the IACUC protocol is the justifications for the use of animals, the use of a particular species of animal, and the use of the designated number of animals. This section must include a written consideration of alternative methods (the Three R's first described by Russell and Burch in 1959) for meeting the research goals. These methods include strategies that Reduce the numbers of animals used, Replace animals with in silico or in vitro models, and Refine the procedures employed to minimize pain and distress experienced by the animals (5).

### *OTHER MEDICAL AND SCIENTIFIC WRITING*

Veterinarians also contribute to grant submissions and research manuscripts. With the increased focus on reproducibility and rigor of preclinical research findings, veterinarians are frequently consulted and asked to assist in writing the Materials and Methods section of scientific manuscripts and Vertebrate Animals section of grant proposals.

Many journals have adopted the Animals in Research: Reporting of In Vivo Experiments (ARRIVE) guidelines as a resource for authors (6). These guidelines detail the information required for a complete and transparent reporting of a preclinical study in a 20-item checklist. Details requested for adequate reporting include information on the species, strain, and genetic background of the animals used, as well as housing and husbandry parameters such as cage design, bedding material, light/dark cycle, room temperature, room humidity, and types of environmental enrichment provided. Investigators recognize the importance of these parameters as factors that may affect the design of their projects. Facility veterinarians are often the most knowledgeable about these parameters and serve as a valuable resource for investigators both in the design and reporting of their research projects.

Veterinarians participate in many other writing activities. These include writing Standard Operating Procedures (SOPs), policy statements, white papers, and components of preclinical submissions such as INDs and 510Ks. They also write articles for AMWA chapter newsletters!

I hope that you have found this brief description of the work (and writing) life of a laboratory animal veterinarian interesting and informative.

### *REFERENCES*

1. The Animal Welfare Act and subsequent amendments, 7 U.S.C. § 2131-2159 (1966).
2. Public Health Service Policy on Humane Care and Use of Laboratory Animals

**Veterinarians  
participate in  
many writing  
activities**

(Revised 2015). Office of Laboratory Animal Welfare, National Institutes of Health.

3. Guide for the Care and Use of Laboratory Animals, Eighth Edition (2011). Institute for Laboratory Animal Research, National Research Council.

4. Institutional Animal Care and Use Committee Guidebook (2002). Applied Research Ethics National Association, Office of Laboratory Animal Welfare, National Institutes of Health.

5. The Principles of Humane Experimental Technique (1959). Russell WMS and Burch RL. Methuen and Company, London.

6. Improving bioscience research reporting: the ARRIVE guidelines for reporting animal research (2010). Kilkeny C, Browne WJ, Cuthill IC, Emerson M, and Altman DG. PLoS Biology.

*Lynn Wachtman is an ACLAM boarded veterinarian and independent consultant.*



## Make a Difference: AMWA Indiana's Mentoring Program

**Esther Brooks-Asplund, PhD** ([esther.asplund@att.net](mailto:esther.asplund@att.net))

Mentoring is an old tradition rooted in Greek mythology. Just as Mentor provided guidance and advice to Odysseus's son Telemachus, professional organizations and institutions use mentoring to accelerate organizational learning, facilitate and transfer knowledge among members, and improve the morale and cohesion of the organization.

When I first transitioned from basic science to a career in the pharmaceutical industry, my employer (a contract research organization) had instituted a 1-year fellowship program that involved mentoring. For one year, I met weekly with my mentor, a senior scientist, who provided guidance and advice to assist me with the transition into the industry. This advice covered a range

of topics to help me meet corporate and sponsor obligations, ranging from hosting sponsor meetings to resources for writing a clinical study report. This program benefited the Mentees, Mentors, and the organization. My mentor was recognized by the organization for his leadership and loyalty. We developed a good working relationship and his advice helped me do my job more efficiently. Over time, my self-confidence and self-reliance increased, and my project success reflected positively on his mentoring skills. Overall, the company benefited because the program fostered communication, cohesion, and accelerated learning across the organization.

#### *NEW AMWA INDIANA CHAPTER MENTORING PROGRAM*

AMWA Indiana is now offering a mentoring program as a benefit to its chapter members to advance and enhance the careers of both mentees and mentors. This program is a collaborative, confidential, reciprocal, and voluntary relationship between a Mentee and Mentor in which both persons are mutually accountable for: a) helping the Mentee achieve and apply clear and mutually defined learning goals designed to develop and grow the Mentee's career; and b) critically reflecting on that particular mentoring relationship. Not only is it expected that this program will benefit both Mentors and Mentees, but AMWA Indiana will also benefit by transferring and broadening the knowledge base of its membership and facilitating communication, cohesion, and collaboration among members.

Mentors should be willing to serve as a professional role model and counselor to a Mentee; facilitate trustful communications with the Mentee; introduce the Mentee to new, and reinforce existing, practice skills that increase the probability of the Mentee's career advancement; and encourage and help the Mentee to actively participate in a set of career advancing professional experiences, including AMWA events and activities. If you are concerned that serving as a Mentor would require too much time, please know that participation in the program only requires that you commit 1 uninterrupted hour per quarter per year! This means 4 hours of one-on-one discussion, and possibly

**AMWA  
Indiana is now  
offering a  
mentoring  
program**

an additional 4-6 hours for email with the Mentee, preparing some background information for the Mentee, or reviewing a writing sample for the Mentee. The program is not meant to be overly burdensome for Mentors or Mentees.

Mentees should, with the Mentor, set mutually agreeable learning objectives. Mentees should receive in good spirit the advice and guidance offered by the Mentor. If you are new to medical writing or an experienced medical writer wanting to learn more about other opportunities in the medical communication field, this is an opportunity to get a head start. As this is a mentoring program, it is expected that Mentees may have little to no knowledge about a given field of medical communication. If you are interested in participating as a Mentee, you should not be embarrassed by lack of knowledge or experience in a given area. For example, while I have worked within the pharmaceutical industry for more than 15 years now, I have very limited knowledge about the structure and content of medical device submissions. After listening to Christa Goode speak at our annual conference in June, I am interested in learning more about writing a Clinical Evaluation Report or other medical device submission.

If you are concerned about confidentiality, please know that it is expected that both Mentor and Mentee will maintain confidentiality of all communications and avoid disclosing any client's confidential information.

The requirements for participating in the program are few. Mentors and Mentees should both be members in good standing with AMWA and its Indiana chapter and be willing to meet in person or electronically for at least 1 uninterrupted hour per quarter. Additionally, Mentors should have:

- At least 3 years' experience in a medical communication specialty; and
- A desire to share their experience with a Mentee to achieve his/her professional objectives.

**Requirements  
for  
participating  
in the  
program are  
few**

If you are interested in participating in the AMWA Indiana mentoring program or have any questions, please email our chapter's Member Resources Chair (Esther Brooks-Asplund) at [esther.asplund@att.net](mailto:esther.asplund@att.net). We will then try to pair you on the basis of shared interests and objectives in August/September 2016. Enrollment will continue biannually thereafter.

I hope you will consider participating in this program so that we can all reach the common goal of achieving excellence in medical communication!

*Esther Brooks-Asplund is the 2015-2016 president-elect and member resources chair of our chapter and owner of Hoosier Medical Communication Services in Bloomington, IN.*

**We will pair  
Mentors and  
Mentees in  
August/  
September**

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## Report: AMWA Indiana 2016 Chapter Conference

David Caldwell, PhD ([davidccaldwell@att.net](mailto:davidccaldwell@att.net))

*Asterisks indicate photographs by **Elaine Crabtree, MA, ELS***  
([elacrabtree@earthlink.net](mailto:elacrabtree@earthlink.net))

Our AMWA Indiana chapter (founded in 1996) celebrated its 20th year with a spectacular conference in downtown Indianapolis on June 10 & 11.

### Networking

Thirty two medical communicators (mostly AMWA members) from four states (IL, IN, MI, OH) met old and new friends for a fun round-robin speed-networking session and dinner roundtable discussions at The Rathskeller restaurant and for breakfast and lunch at The Columbia Club. The roundtables were moderated by

Bill Pietrzak, PhD (*Working Remotely as a Contract Medical Writer*), Laura Town (*Table's Choice*), Esther Brooks-Asplund, PhD, RAC (*Achieving Regulatory Affairs Certification: The What, Why, and How*), and David Caldwell, PhD (*Mentoring for Medical Communicators*).

## Education

Participants also learned more about our profession from true experts during seven career enhancing open sessions and one AMWA workshop, briefly summarized here.

### MANAGING THE AGONY AND THE ECSTASY OF FREELANCING: THE CHALLENGES OF FREELANCE WRITING Eric Metcalf, MPH, *HealthWrite, Inc.*

The legend of the freelance—happy, free, the boss, large income, unlimited potential—doesn't always match life. In his own personable and entertaining style, Mr. Metcalf offered tips on how to survive and thrive as a freelance by practicing positive psychology, owning the process and not the results (eg, setting controllable goals and appropriate client fees, socializing professionally, steadying work flow), and selecting a protected market niche.

### A PERSPECTIVE ON MANUSCRIPT WRITING Joseph Giaconia, MS, *INC Research*

What is consistently true of manuscripts accepted for publication? Mr. Giaconia helped us gain confidence in writing successfully by sharing best practices that he discovered empirically. These include: managing the perceptions of authors and reviewers; focusing on a single primary question about one unmet medical need; and writing clearly, correctly, concisely, specifically, and with balance.

### HOW TO BE A SUCCESSFUL CONTRACT WRITER FOR THE MEDICAL DEVICE INDUSTRY: AN INDUSTRY PERSPECTIVE Christa Goode, MPH, *Depuy-Synthes\**

Now is the time for hiring writers in the medical device industry. Ms. Goode gave us an edge on our competition by telling us what device companies look for in an employee,



including: initiative; common sense and intuition; efficiency; ability to think through complex information, meet expectations, and establish trust; knowledge of device terminology and of how to write a systematic literature review; scientific knowledge; and writing skills.

## BIOLOGICS IN ORTHOPEDICS

William King, PhD, *Zimmer-Biomet* and *Clemson University\**

The once and future regenerative medicine inspires Mr. King's orthopedic research. From the time of Hesiod's tale of Prometheus' regenerative liver to now, the goal of this field has been to utilize the body's limited ability to self-repair. Despite the field's tendency to over-promise and under-deliver (eg, no stem cell product is marketed to the public today), researchers continue to strive for profitable regenerative treatments that are less expensive and invasive than organ transplants and that can intervene before a patient becomes critically ill.



## DOCUMENTING AND REPORTING ADAPTIVE CLINICAL TRIALS

Brenda L. Gaydos, PhD, *Eli Lilly and Company* and *Indiana University School of Medicine*

The frequency of adaptive clinical trials is increasing because they are often more efficient, effective, and informative than traditional trials. But best practices for reporting them have not been developed. Ms. Gaydos treated us to her industry-leading thoughts on how to report these trials for various adaptive designs, trial phases, and audiences (such as regulatory reviewers, Investigational Review Boards, and the general scientific community).



## GOOD PUBLICATION PRACTICES (GPP3) FOR COMPANY-SPONSORED RESEARCH: A GENERAL OVERVIEW

Carol Sanes-Miller, MS, ISMPP CMPP, *Shire*

Ethical, accurate, complete, transparent. Medical writers and editors can make their manuscripts and presentations sparkle



by following the broadly applicable [GPP3 guidelines](#) issued in 2015. Ms. Sanes-Miller explained the principles addressing three concerns of these guidelines, which she coauthored: authorship, what and when to publish, and disclosing a conflict of interest.



### PERSONALIZED HEALTHCARE: THE EVOLUTION OF MEDICINE

Jingzi Sherman, MD, MS, *Roche Diagnostics Corp.\**

Like 501 Levi jeans, personalized health care fits the treatment to the patient. All stakeholders win: patient, physician, regulators, and 3<sup>rd</sup> party payers. Dr. Sherman shared exciting examples of companion diagnostics (devices that provide information needed for the safe and effective use of a therapeutic product) and complementary diagnostics (devices that identify a subset of patients who respond well to a drug or devices that provide information that aids in risk/benefit assessments of treatment but is not needed for using a drug) that herald increasing cooperation among the pharmaceutical, biologics, and medical device industries.



### WORKSHOP

#### CLINICAL STUDY REPORT WRITING: FROM TABLES, LISTINGS, AND GRAPHS TO TEXT

Kathy Spiegel, PhD, *Amgen*

This AMWA workshop, led by AMWA Secretary Kathy Spiegel, gave participants a practical sense of how to best summarize clearly and concisely information from statistical tables, listings, and graphs for a Clinical Study Report.

### Other Conference Highlights

#### TWITTER HASHTAG CONTEST

Elizabeth Rowe, PhD, a scientist who specializes in manuscript and grant writing and data analysis, will receive a \$30 Amazon gift card for winning our chapter conference Twitter Hashtag Contest. Six conference participants helped

our chapter get the word out on Twitter with 12 tweets that included educational tips from the sessions, links to educational references, and photos.

## SPONSOR

We are most grateful to [Pearl Pathways](#) for publicizing and sponsoring our conference. Even though none of its employees are AMWA members, the company sent two to our conference: Gretchen Parker, PhD, RAC (regulatory compliance advisor; co-chair, Pearl IRB board) and Chad Pannucci (director, business development; member, Indiana Center for Biomedical Innovation advisory council).

## Thank you

To all conference participants: THANK YOU for making this 20th year celebration a success!

Our deep gratitude goes to work shop leader Kathy Spiegel, PhD and to all of the open session speakers and roundtable discussion moderators who donated their travel, time, and exceptional talent to our conference.

We sincerely thank our energetic Education Committee members for the many hours of personal time they donated during the last year to organizing this conference: William Pietrzak, PhD (chair), Laura Town; Ellen Stoltzfus, PhD; Kathleen Solotkin, MSN; Elaine Lipscomb, PhD; Elaine Crabtree, MA, ELS; Linda Hughes, MS; and David Caldwell, PhD.

Special thanks go to Bill for leading the committee and persuading Pearl Pathways to sponsor our conference, Laura for hosting the conference at The Columbia Club and (with Sarah Felde) developing the conference brochure, Ellen for planning the events at The Rathskeller restaurant, Elaine L. for publicizing the conference, Elaine C. for taking photographs of the conference, Linda for publicizing the conference and developing and implementing the Twitter Hashtag Contest, and Barbara Lightfoot for providing projection equipment.



William Pietrzak, PhD  
Chair, Education Committee



Speed networking at The Rathskeller restaurant\*



Networking lunch at The Columbia Club\*



Chad Pannucci exhibiting for our conference sponsor, Pearl Pathways\*



Workshop *Clinical Study Report Writing: From Tables, Listings, and Graphs to Text\**



Open Session Audience\*  
(l to r) Joseph Giaconia,  
Eimile Oakes, Ellen  
Stoltzfus, Angela Beeler



Open Session Audience\*