

DELAWRITER

The quarterly newsletter of AMWA-DVC

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Summer 2014

June Networking Dinner and Business Meeting

Join us on June 10 for dinner at the elegant Chimney Hill Estate Inn (Lambertville, N.J.) as we honor the volunteers who make AMWA-DVC possible and highlight opportunities for you to become more involved. DVC's Brian Bass, president of AMWA (National), will also update us on what's new at AMWA, including ways you can become involved at the national level. There will also be plenty of time to network with colleagues and stroll the grounds, with alpacas for petting and gardens in bloom.

Registration starts at 5:30 PM, a buffet dinner at 6:15 PM, and the speaker program at 7:00 PM.

To register, [click here](#).

Vote in this Year's AMWA-DVC Elections

This year AMWA-DVC will run its first-ever fully electronic election for chapter officers. Members in good standing will receive an email before June 1 with a link for voting. Thanks to President-elect Eileen McCaffrey for helping us modernize this process.

Annual Conference Preview

AMWA's Annual Conference, to be held October 8-11, 2014, in Memphis, Tenn., will be packed with educational and networking opportunities. Each day has networking events, plentiful and diverse educational offerings, and award-winning speakers.

Look for the registration brochure in mid-June. In the meantime, AMWA's Annual Conference [webpage](#) has some information, such as the preliminary Schedule at a Glance.

Medical, Regulatory, and Legal Review: Can you choose the approved claims of the lowly egg?

By Kathy Molnar-Kimber

Sarah Zimov, PhD, an independent medical communications professional, gave an interactive seminar at the AMWA-DVC meeting on February 26 in Lahaska, Pa., that highlighted 10 tips for navigating medical, regulatory and legal (MRL) review. Several of those tips are presented here.

Many of these tips apply to all writing assignments, such as Tip #1: Know the lingo..., and use it properly. Numerous document review systems have distinct acronyms associated with them. Furthermore, acronyms and names vary at different companies. Or Tip #3: Solidify your scope of work so you can meet the expected goals of not only the agency, but also the end client. Many writers, even experienced writers, often ask for a template or an example of the document from the particular company to help expedite the project.

Be Respectful

Zimov's Tip #6 is to treat trade names and competitors fairly and with respect. For example, a document can provide the results and safety of two competing compounds in a given disease or assay. However, unless the two compounds were tested in the same assay at the same time by the same principal investigators (in other words, in a head-to-head comparison), the text should not directly compare the results or safety of the two compounds.

Understand Medical, Regulatory, and Legal Review

Each specialty contributes its expertise to the documents. Medical department personnel reviews ensure medical accuracy; while regulatory department personnel reviews maintain compliance with the myriad of government agencies, especially the US Food and Drug Administration. Several recent extremely high-cost lawsuits or penalties alleging false advertising claims have led to the legal department personnel review taking a more heavy-handed approach. Interestingly, often the three reviewers will disagree among themselves.

Zimov illustrated her points on how the identification of acceptable claims can be very challenging by using the "lowly, delicious egg." The American Egg Board had

submitted the following 11 claims to the US Department of Agriculture. Which of the following words and phrases are "approvable" advertising claims?

- a) Rich source of protein
- b) Healthy
- c) Satisfying
- d) Relatively low calories
- e) Diet food
- f) Nutrient-dense
- g) Nutritious
- h) Relatively low fat
- i) Safe
- j) Recognizable
- k) Can relieve hunger

See the answer at the end of this article.

Choose Resources and References Carefully

Zimov's Tip #7 reminds us all to choose resources or references carefully. In most cases, current-edition textbooks, product information, and recent (less than 5 years old) primary journal articles from well-respected journals are acceptable to the MRL review team. The National Institutes of Health websites, recognizable medical dictionaries, and medical advocacy groups also usually provide acceptable resource literature.

Because the MRL team will want to confirm accurate paraphrasing, annotating the references for each section or paragraph can speed up their review and is usually essential. Note that reference files without annotations may also be requested for uploading into electronic submission systems, so keep a set of "clean" references, Zimov advised.

[Quiz answers: c, f, j, k]

Kathy Molnar-Kimber, PhD, is President of Kimnar Group LLC.

News from National

AMWA's Board of Directors met in April in Bethesda, Md. DVC President-Elect Eileen McCaffrey, MA, and Immediate Past President Jennifer Maybin, MA, ELS, were our chapter delegates. Our own Brian Bass is now AMWA president, and the Executive Committee includes other DVC-ers: Scott Kober, MBA, CCMEP, education; Cyndy Kryder, MS, member resources; and Nick Sidorovich, MSED, chapter relations.

Upcoming Planned Actions

- Increase educational/product offerings:
 - During 2014, AMWA's education team is aiming to host 3 Google Hangouts and 3 webinars using GoToWebinar.
 - Attendance at the annual conference has been flat, and with contracts set through 2017, AMWA has paid penalties in recent years for not meeting conference contractual obligations (ie, hotel rooms, food/beverage funds). National respectfully requests that members who attend the annual conference use AMWA-negotiated room blocks to ensure the organization can meet its contract obligations.
 - While in-person education through the annual conference and chapter conferences has its place, it's a relatively expensive way to deliver education. AMWA plans to implement multiple forms of online learning and increase content development.
- Enhance member resources and expand membership.
- Improve infrastructure to increase resources and organizational capacity, such as new software and webinar technology, and recruiting and developing new workshop leaders.
- Improve communication to internal and external stakeholders.
- Define the profession by implementing a medical writing certification program. The group hopes to have its first exam at the 2015 annual conference.

Communicating with Other Communicators

The first Medical Communications Inter-Organizational Summit was held prior to the delegates' meeting. It included AMWA, the Drug Information Association, the International Society for Medical Publications Professionals, and the Society for Technical Communication. Attendees discussed member education as well as opportunities for collaboration. Bass reported that summit participants were particularly interested in exploring how to share educational resources, capitalize on the use of social media to further their missions, and advocate for best practices and industry. Participants agreed to reconvene via scheduled teleconferences to continue the discussions, Bass said.

AMWA's 75th Birthday

Planning is under way for AMWA's 75th birthday, to be celebrated in 2015.

Flexibility Drives Desire to Freelance

Three leaders offer advice to the novice and experienced freelancers alike.

By Michelle Dalton

A panel of experienced freelancers shared their cumulative 60+ years' worth of advice with attendees of AMWA-DVC's 12th Annual Freelance Conference held on March 22, 2014, in Philadelphia. Long-time AMWA-DVC members Brian Bass, Linda Felcone, and Amy Rovi, introduced by moderator Don Harting, each shared why they became full-time freelancers during their panel, "Freelancing and Beyond: Panel Discussion with Veteran Writers."

Strategic Partners

Rovi launched her freelance career once she realized she needed more flexibility than a bricks-and-mortar establishment could provide. "Using the term 'freelance' is a medieval connotation," she said. "We're strategic partners and communicators."

When she was first starting her freelance career, "one of the first things I did was join AMWA, and I haven't looked back. It was my springboard for success." She networked with everyone, and rarely said 'No' to attempting something new. "Be flexible and open to what will work for you and your clients," she said.

Like the other panelists, Rovi said riding the "ebb and flow of work" was her greatest challenge initially-especially since she had been at "the top of my game" when she left a corporate environment. Her advice to those who are not yet sure if being a full-time freelance is going to bring steady income to replace what the traditional job provided-continually prospect, even when you're working on a project.

Love What You Do

Felcone has spent the majority of her career as a regulatory writer, and told attendees, "Don't go into this for the money. Don't think about this as a lucrative profession. My first year, I made \$12,000. I love what I do, and I do it for the patient." She opted to concentrate on limiting the number of clients and maximize being a partner with those clients from the preclinical to the post-marketing stage.

"The biggest problem for me was a crisis in conscience in medical writing because of the negative press it got," she said. "AMWA showed me that pharma is not the dark side."

Being passionate about the type of writing/editing a freelance does is mandatory, she said.

"If you want to save millions of lives, do this professionally for the rest of your life." Felcone may take a week or more to read up on a topic to try to understand it before putting pen to paper. "Work smarter, not harder," she said.

Problem Solver

Bass broke into being a freelance "by accident. I jumped out of an airplane without a parachute and I needed to learn how to fly." Among the things his naiveté brought was "a lack of appreciation for why not having advanced degrees might set me back. Ignorance is bliss-the biggest thing that holds you back is you," he said.

He positions himself not as a particular type of writer or as one with a particular area of expertise, but "as a strategic business partner. I'm a problem solver for my clients."

The key to being a success may sound simple-"don't make simple mistakes," Bass said, but that's often difficult to achieve. "A large reason why I've managed to build a good business is because I haven't shot myself in the foot." He quickly added he "made a lot of mistakes along the way," but that he always tries to learn something from each new assignment or client.

For experienced freelancers, he suggested subcontracting. "I didn't do it for the longest time, but I finally realized the reason subcontracting wasn't working is because I wasn't letting it work," he said. "Hire people who are better than you and pay them every penny they're worth."

Michelle Dalton, ELS, is an award-winning writer with more than 25 years of publishing experience. She is the founder of Dalton & Associates.

Be Your Own Boss and Succeed

By Amy Rovi

Key considerations for building and maintaining a successful freelance business were the focus of "The Boss of Me: The Business of Freelance," a presentation by Kristen Phiel, PhD, during AMWA-DVC's 12th Annual Freelance Conference held on March 22, 2014, in Philadelphia. Phiel probed the audience with essential business questions based on a model that places the business at the center, like the hub of a wheel, with the following questions serving as the supportive spokes:

- Who?
- What?
- When?
- Where?
- How?
- Why?

She elaborated on these essential questions with more specific questions including:

- Who are you?
- Who do you want to work with/for?
- Why do you want to be a freelance?
- When should you become a freelance?
- Where should you conduct business?
- Where can your clients find you?
- How do you conduct your business?

Phiel explored various answers to these questions to help the audience ponder the business possibilities. But Phiel's take-home point remained: only the freelance him/herself can answer those questions. Only after having the answers will a freelance begin to succeed.

First-time attendee Stephanie Vargas, MD, recently started freelance medical writing and editing. "I thoroughly enjoyed Kristen's talk and learned a ton. Prior to the conference, I thought this talk would be over my head as a newbie to the field. However, once she began, I realized that this was the perfect time for me to hear what she had to say," she said.

Phiel also discussed ways to market your business and tools of the trade for writers and editors, as well as her personal business evolution (through snapshots of her website over time). She described her current business structure as a limited liability company (LLC) and further reviewed the legal and tax implications for other business structures including partnerships and corporations. "Her overview of the various business types helped cement my goal of creating an LLC," Vargas said.

Amy Rovi is a medical communications business owner and treasurer of AMWA-DVC.

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