

DELAWRITER

The quarterly newsletter of AMWA-DVC

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August 2011

Delawriter Goes Electronic

New Format for DVC Newsletter

This issue marks the first electronic *Delawriter*! AMWA-DVC is now publishing our newsletter electronically and will be using professional e-mail marketing to produce and distribute program announcements and other e-mails to members. We hope that you enjoy the new electronic format, which is designed to let you easily read each issue and quickly identify and access articles of interest. The electronic format also enables us to provide you with links to lots of other information and resources on the AMWA-DVC, AMWA national, and other Web sites.

We welcome your feedback! Please send comments about the e-*Delawriter* to: Delawriter@amwa-dvc.org.

Publication Considerations

Impact Factors and Reporting Standards

By Elizabeth Manning Duus

The 2011 International Symposium for the Multinational Association of Supportive Care in Cancer was held in Athens, Greece, from June 23 to 25, 2011. In addition to scientific seminars and poster sessions, a relevant education session on publishing journal articles was also held.

Publishing Journal Articles

Fredrick D. Ashbury, PhD, editor-in-chief of the journal *Supportive Care in Cancer*, began the session with his presentation entitled "Submitting Manuscripts for Publication Consideration: Key Issues and Lessons Learned." During this talk, he described the procedures for the peer-review of manuscripts submitted to journals. Dr Ashbury also suggested that when determining where to submit a manuscript, one should take into account a journal's impact factor (IF). The IF is commonly used as a measure of the importance and value of a journal to its field, and it should be considered in relation to the findings/implications of a proposed manuscript to determine if a journal may be a good fit. A journal's IF is calculated as the ratio of A/B, where B = the total number of "citable items" published by that journal from the 2 to 3 years prior, and A = the total number of citations to those articles from 1 year prior.

The next presentation was "Pitfalls of Writing for Journals," given by Ian Olver, MD, PhD, Clinical Professor, Department of Medicine, University of Sydney. Dr. Olver stressed that authors must understand and comply with multiple reporting standards

when preparing manuscripts for publication. Aside from the given journal's formatting requirements, two other such general reporting standards include the International Committee of Medical Journal Editors (ISJME), which provides uniform requirements for manuscripts submitted to biomedical journals (http://www.icmje.org/urm_main.html) and Good Publication Practices (GPP), which describe how company-sponsored medical research should be communicated (<http://www.gpp-guidelines.org>). Dr. Olver also provided some examples of reporting standards that pertain to different types of manuscripts:

- [CONSORT](#): Consolidated Standards of Reporting (randomized controlled) Trials
- [PRISMA](#): Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- [STARD](#): Standards for the Reporting of Diagnostic Accuracy Studies
- [STROBE](#): Strengthening the Reporting of Observational Studies in Epidemiology

The Web sites for these reporting standards contain information such as checklists and flow-diagrams to provide guidance to authors about what information is expected within a journal article to ensure "transparent and complete reporting" of study data.

The presentations by both Drs. Ashbury and Olver drove home two key points when considering manuscript publication:

1. Understand how to select the appropriate journal for a manuscript
2. Review not only journal specifications, but also relevant reporting standards specific to the manuscript type.

Elizabeth Manning Duus, PhD, is an Associate Director, Clinical Research, at Helsinn Therapeutics in Bridgewater, NJ.

AMWA-DVC Program Preview: 2011-2012

The Delaware Valley Chapter's first dinner meeting of the year is scheduled for September 21, 2011, at the Sheraton Bucks County in Langhorne, Pennsylvania:

Identifying and Responding to Conflicts of Interest:

Our profession's ethics are under fire. What is required to comply with current guidance? What is a well-intentioned medical writer to do? Our panel of experts (representing freelance medical writers, the pharmaceutical industry, and medical communications agencies or CROs) will discuss the basic rules of the game. Bring your questions.

Details are posted to the AMWA-DVC [Web site](#).

We vary the location of our events, holding some in New Jersey and some in Pennsylvania, to make them accessible to the whole chapter. Upcoming meetings and events include a continuation of last year's series on certifications of interest to medical writers, the annual freelance workshop in April, and the annual Princeton conference on May 12.

Suggestions for meeting topics are always welcome and can be e-mailed to the program chairs (programs@amwa-dvc.org).

Other Upcoming Events

- Join writers from all over the country at AMWA's 71st Annual Conference, being held in Jacksonville, Florida, from October 20 to 22. Speakers, workshops, networking - this conference has it all. The full brochure and registration form are [online](#) (scroll down to Annual Conference Planning, Registration Brochure).
- Look for announcements about our chapter Holiday Cheer event in December or January and other networking and dinner meetings during the year.

Ninth Annual Freelance Workshop

AMWA-DVC's Ninth Annual Freelance Workshop was held on April 2, 2011, in King of Prussia, PA. The following three articles report some highlights of the presentations. Additional articles will appear in the next issue of the *Delawriter*.

Freelance Workshop

My Day at the 2011 AMWA-DVC Freelance Workshop

By Jason Vian

For me, the 2011 AMWA-DVC Freelance Workshop was filled with excitement as this marked the first anniversary of my fascination with the profession of medical writing. This was my second DVC Freelance Conference and it proved to be just as fascinating as last year's.

The day began with lectures for the entire group. Debra Gordon, MS, kicked things off by speaking about "The 10 Hottest Skills for a Freelance Medical Writer in 2011." Among the skills highlighted were the abilities to be flexible, listen to your intuition, and keep your sense of humor. She also touched on an important question: "Do you know how long it takes you to complete a certain type of project?" According to Ms Gordon, if a writer knows the answer to that question, he/she may begin to quote prospective clients the total cost of a project and not present them with figures that could change even if the project remains unchanged. Billing on a project basis, she explained, "allows someone who can work quickly and efficiently to earn more profit on a job and stay within the expected market price for a piece of work."

The conference topics then turned from general to specific when Brian Bass spoke about "Risk Evaluation and Mitigation Strategies (REMS)" and Cindy Van Dijk discussed working for contract research organizations. Both offer a range of options for writers to find work.

The final morning session offered some smaller group talks. Lisa Breck drove home the message that freelance medical writers are business owners and need to plan accordingly. She covered topics such as the types of insurance coverages necessary for a small business and the tools that are essential for success.

The afternoon roundtables offered 3 opportunities to gain insight on a particular topic in a small group setting. These were open forums where participants could share their experiences relative to the topic being discussed. Regulatory writing, "jump-starting your career," and sales training were on the agenda for me that day.

Linda Felcone, MA, hosted two roundtables: one on jump-starting a career as a freelance and one on regulatory writing. She suggested being able to understand the medical writing industry from the inside. She emphasized: "This will give you a true understanding of the needs that clients have. Without that experience, a person trying to break into this career will really struggle."

Regulatory writing is a difficult field to break into, but one that can provide a great many opportunities to a writer. "Experience really plays a key role in getting jobs as a regulatory writer", Ms Felcone explained. She added, "Once you get that first job and complete it well, then finding work becomes easier. It is very template driven because of the formats that need to be followed, but a person who can understand the science and data that are being used may have an easier time with this type of work."

The third roundtable for the day was on sales training. Ms Breck utilized her experience in this area to give several examples of the complexity that these types of project can take on. Ms Breck stated, "It is easy to get run over if you are not careful during these types of projects." She added that one "must have the confidence to advise the client as to the best way to craft the project based on the goals of the training."

All in all, the 2011 Freelance Conference was a great way to learn something new and meet new people. Those two things are always a recipe for a worthwhile experience.

Jason Vian, MS, MBA, is a Certified Athletic Trainer/ Medical Writer who enjoys a career as an allied healthcare professional in outpatient physical rehabilitation and sports medicine. 3 V Medical Communication, LLC, utilizes his over 15 years of experience in healthcare, which includes clinical practice, writing, and teaching.

Freelance Workshop

Risk Evaluation and Mitigation Strategies

By Ilsa Gomez-Curet

Brian Bass, an award-winning writer, introduced attendees to the history of drug safety and the development of Risk Evaluation and Mitigation Strategies (REMS). The US Food and Drug Administration (FDA) requires REMS for many new, and some existing, pharmaceutical products, and these REMS may provide new business opportunities for freelance medical writers.

Before the Era of Risk Management

Although REMS is the latest step in risk management, the concept of risk management and drug safety dates back to the 1840s. In 1938, the Food, Drug, and Cosmetic Act (FD&C Act) addressed fraudulent claims for medicines and introduced the new drug application (NDA) process.

After the passage of the FD&C Act, a number of amendments were issued to close the loopholes of previous legislation. For example, the Kefauver-Harris Amendment of 1962 required that manufacturers demonstrate the efficacy of their drug in addition to its safety. This amendment resulted in development of the investigational new drug application (INDA) process.

In the Era of Risk Management

The Controlled Substances Act (CSA) of 1970 is the first effort in modern risk management, Mr Bass said. The CSA regulates manufacturers, prescribers, and drug dispensers and sets guidelines for patient access to certain drug classes. Other acts that strengthened early risk management processes were issued in the 1990s. In particular, the FDA Modernization Act (FDAMA) of 1997 increased patient access to experimental drugs and devices, and accelerated the review of new, clinically important medications.

The New Era of Risk Management

After several products were removed from the market because of safety concerns, the FDA developed Risk Minimization Action Plans (RiskMAPS) in 2005. RiskMAPS introduced the first plan to monitor a drug throughout its entire life cycle. These action plans provided pharmaceutical manufacturers with tools to address product risk and to develop interventions to mitigate those risks. However, RiskMAPS did not have the power to obligate drug manufacturers to adhere to the guidelines. When the Food and Drug Administration Amendments Act (FDAAA) of 2007 was implemented, RiskMAPs were transformed into a mandatory and enforceable program known as REMS.

REMS Requirements

Specific components that may be included in a REMS include the following:

- Medication Guide and Patient Package Inserts (PPI) - These documents are written for patients. They address important safety information about the drug including drug/class specific issues, dosage, safe administration, side effects, and precautions.
- Communication Plan - This should educate healthcare professionals on drug safety. It consists of tools and materials that educate healthcare providers on drug risks and REMS implementation.
- Elements to Assure Safe Use (EASU) - These systems enforce the appropriate use of a drug. EASUs may include specialized training, continual medical education (CME), patient registries, and certifications provided to health care professionals and facilities.

The FDA's original September 2009 draft guidance on REMS is available [online](#).

Opportunities for Medical Writers

According to Mr Bass, REMS offers multiple opportunities for medical writers. From medication guides and PPIs that may appeal to medical writers with a regulatory focus, to professional communication pieces that may appeal to writers of branded and unbranded educational materials, there are multiple avenues for medical writers to get involved in the implementation of REMS programs. Medical writers are also needed to write postmarketing study reports and publications, communication plans, and other educational support materials that are part of EASUs.

Ilisa Gomez-Curet, PhD, is a freelance biomedical consultant and medical writer. She has over 10 years of experience in biomedical research and writing and editing scientific and technical documents for the academic, hospital, and industry settings.

Freelance Workshop

Opening Industry's Doors

By Jannette Morrow

"Opening Industry's Door: Critical Knowledge and Value-Added Skills You Need Before You Knock," was presented by John Smith, PhD, of Novo Nordisk. "Getting in the door is challenging," Dr. Smith said, "but writers need to start somewhere." He offered the following suggestions:

- Start with networking, developing contacts (including AMWA), volunteering, and accepting entry-level positions.
- Know if there is a market for your services.
- Be prepared to answer why a company should hire you.
- Make companies aware of any special skills that you have.

Dr. Smith says freelancers often have limited access to pharmaceutical companies, but medical communication companies may have more opportunities. Understand the company and make sure your resume or CV is specific to the job. He recommended reading the company Web site. For example, learn a pharmaceutical company's main therapeutic interest, and familiarize yourself with the literature. Know what their unmet needs are, think strategically, and think compliance. Interpersonal skills are also important. "Relationships will take you further than knowledge and skills," Dr. Smith said.

Industry clients are looking for writers with postgraduate degrees in life sciences, health, or medicine. Writers must understand scientific method and reporting. However, it's possible to get hired without a degree. Useful sources for courses and certifications include AMWA and the International Society for Medical Publication Professionals. Companies will want to know if you are knowledgeable about their core business, and the types of projects you have written. Include in your CV any of your publications that are relevant to the position. Industry clients are also looking for good technical skills, regulatory experience, and attention to detail and quality.

Dr. Smith also said to understand that your real client may be another medical writer, a project manager, or an account director. Be aware of client challenges, such as limited budgets, tight timelines, and delays. Clients may have limited experience in the area or may have unrealistic expectations. However, clients should be professional and respectful, know the overall vision and strategy, and provide constructive feedback.

Dr. Smith reminded the audience that freelancers should know both their strengths and the market. "Knock at the door at the right time, continue to develop skills, and know the client's goals and challenges," he said, "and remember that good work sells itself."

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