Delawriter

Summer 2009

The Quarterly Newsletter of the American Medical Writers Association–Delaware Valley Chapter (AMWA-DVC)

Message From Your President and President-Elect

I am proud to announce the 2009-2010 slate of officers for AMWA-DVC and to introduce a new group of core volunteers. What's more, I'd like to invite YOU to step up and volunteer your time—for just an hour or for longer. We have options to fit all sizes!

Jen and I have been members of AMWA-DVC for about 5 years—that may seem short to many of you long-timers—but in that time, we've volunteered at every opportunity, met the members of this chapter and the national group, and listened to the needs of our membership. What is clear is that economic conditions are affecting all of us in medical writing—some of those conditions positively affect us, some negatively. How can we work together in the coming year as an organization of professionals to meet our challenges and discover OPPORTUNITIES?

Let's stay positive as professional medical writers and editors in the coming year and educate ourselves in ways that will give us new skills and enable us to put our best foot forward. Let's find ways to collaborate to benefit not only ourselves but the greater health care community of providers and patients.

Offer your ideas at every opportunity. Let us know what is important to you professionally and personally. Let's build a community of achievers who move forward as professionals and advocates dedicated to health care for all.

Lisa P. Breck
AMWA-DVC President
president@amwa-dvc.org

Jennifer Maybin
AMWA-DVC President-Elect
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AMWA-DVC New Officers

By Lisa P. Breck and Barbara Rinehart

At the June 30 chapter meeting, the following new officers were elected by unanimous vote of the general membership:

President-Elect/Chapter Delegate: Jennifer Maybin, MA, ELS (term 2009–2010)

Treasurer: Alan M. Struthers, PhD (term 2009–2011)

Their biographies were published in the Spring 2009 *Delawriter*. We are grateful to the nominating committee who presented an excellent slate and extend our best wishes to these incoming officers, who will be working with President Lisa P. Breck (term 2009–2010); Secretary Cyndy L. Kryder (term 2008–2010); and Immediate Past President Barbara Rinehart, MS (term 2009–2010).

Nominating Committee

Lisa P. Breck, Chair
Brian Bass
Lori De Milto, MJ
John A. Smith, BS, PhD

Other New Positions for 2009-2010:

Chair, *Delawriter*: Eileen Girten, MS

Volunteer Coordinator: Linda Felcone, MA

Inside

AMERICAN MEDICAL WRITERS ASSOCIATION

Regulatory Writing: A Different Breed of Writer

By Michelle Dalton

Linda Felcone, MA, a freelance medical writer, presented an overview of regulatory writing at the AMWA-DVC Seventh Annual Freelance Workshop on April 25, 2009, in Blue Bell, Pennsylvania. Regulatory writing is "definitely not for everyone," said Ms Felcone; however, she said it is nice to "balance it with other types of writing."

First and foremost, she said, do not think of regulatory writing as anything except compiling information and processing it through various documents with an enormous amount of data per study. "It's extremely deadline-driven. You are the bottleneck between the pharmaceutical company's spending money on developing the drug and making money once it's marketed," she explained.

Breaking In

Although there seems to be an emphasis on writers with advanced degrees (PhD, PharmD, or MD), there are ways for people without an advanced degree to break into the field. For example, Ms Felcone recommended focusing on a specialized niche, such as preparing narratives for serious adverse events during clinical trials. She also suggested working for a clinical research organization, applying for entry-level positions in the regulatory department of large pharmaceutical companies, or subcontracting for an experienced regulatory writer.

To be successful as a regulatory writer, Ms Felcone stressed "diplomacy is the key. You must make the various departments at a company want to give you the information you need to complete the various sections. This is usually not as easy as it sounds. You have to be a 'people person' who also pays strict attention to detail."

Other areas regulatory writers need to know include the drug development process, the structure of an International Conference on Harmonisation submission, a basic grasp of statistics, current regulations and issues at the U.S. Food and Drug Administration (FDA), and a general knowledge of using the Web to find information. For those completely new to medical and regulatory writing, she recommends reading fellow AMWA member Tom Lang's *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors and Reviewers* and *Medical Statistics Made Easy* by Michael Harris and Gordon Taylor.

Learn Your Field, or Any Field

"You need to treat learning this field like a job," she said. Volunteering at organizations such as

See Regulatory on 5.

Hiring Freelance Medical Writers: The Good, The Bad, and The Ugly from the Agency Perspective

By Mary Howe

On April 25, 2009, at the Freelance Workshop held in Blue Bell, Pennsylvania, Mary Dominiecki, PhD, Medical Director at AOI Communications, explained what medical communications agencies value in freelance writers. The bottom line, from the agency perspective, is that freelance writers must meet deadlines and deliver high-quality products.

Dr Dominiecki suggested that, given these priorities, short writing tests or paid, trial projects may be better tools for screening potential writers than supplied writing samples because tests and projects involve deadlines and primary work products, whereas writing samples may not. Moreover, asking high-quality questions about source material, formatting, project requirements, and deadlines are signs that the writer is professional and competent. Conversely, typos in résumés, tests, or work products, and questions that are off-topic or irrelevant can send a strong, negative signal.

Dr Dominiecki pointed out that a single writer does not need to be an expert in everything to be valuable. For example, she relayed the story of "Bob," a fantastic, but technically challenged, writer who had difficulty creating data tables. She found a simple solution: Bob writes for her, but he doesn't build data tables.

For writers who want to develop strong working relationships with medical communications agencies, Dr Dominiecki provided the following recommendations: (1) develop expertise in a small number of subject areas, (2) work on projects within your comfort zone, and (3) communicate clearly and honestly about your strengths. Writers who follow these suggestions are more likely to complete quality projects on time and become valuable resources to people within the agency.

Mary Howe, PhD, is a freelance medical writer specializing in pharmaceutical research and development.

DVC Volunteer Corner

Many thanks to the volunteers who worked so hard to bring all of us programming, Web resources, and the *Delawriter* during our 2008-2009 program year. We look forward to working with more of you this coming year.

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Elizabeth A. Manning, PhD
Nikki Manno
Jennifer Maybin, MA, ELS
Monica Nicosia, PhD

DVC Toolkit
Mary Howe, PhD

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Lisa Vawter, PhD

Celebrating Long-term Members

Congratulations to 41 AMWA-DVC members who have achieved 10 or more years of AMWA membership and who this year celebrate AMWA anniversaries divisible by five:

45 years—since 1964
Edith Schwager, Philadelphia, PA

25 years—since 1984
Susan E. Dalton, ELS, Newtown, PA

20 years—since 1989
Thomas Cannon, Pottstown, PA
Karen L. Zimmermann, Mount Laurel, NJ
Lew Pinsker, Flemington, NJ
Sandra C. Cottrell, PhD, MS, Doylestown, PA
Gary Dorrell, MS, ELS, West Chester, PA
Linda Seligman, Belle Mead, NJ
Carole Kantor, Highland Park, NJ

15 years—since 1994
Brian Bass, Robbinsville, NJ
Charlene B. Powell, ELS, Trenton, NJ
Danita Bagaglio Sutton, PhD, West Amwell, NJ
Alice J. West, Glen Mills, PA
Mary Ann F. Wojcik, MS, Bridgewater, NJ
John R. Parker, Princeton, NJ

10 years—since 1999
Karen D. Dougherty, PhD, East Stroudsburg, PA
Anna J. Hagen, PhD, ELS, Doylestown, PA
Isabelle E. Darnis-Wilhelm, MD, Princeton, NJ
Janet K. Stoltenborg, MS, MBA, Wilmington, DE

See Celebrating on 4.

Pricing Strategies for Success

By Julie Munden

At the AMWA-DVC Seventh Annual Freelance Workshop held on April 25, 2009, at Normandy Farms in Blue Bell, Pennsylvania, Brian Bass, president of Bass Advertising, Inc., began his presentation, "Pricing Strategies for Success," with the following question: "How many people want to be successful?" As expected, nearly everyone raised their hand. But, Bass explained, being successful is more than just good business acumen, discipline, and hard work. Bass revealed that pricing your services right is really the way to achieve success. Although setting fees may be daunting and stressful for some, Bass presented his plan for pricing using 3 rules:

1. Decide *how* to charge. Do you charge by the hour, job, unit of work, or retainer? To reap the financial benefits of a project, Bass recommends charging by the project. "Charging by the hour punishes the proficient and rewards the inefficient," said Bass. For example, a new freelance writer charging $85 per hour would earn $4,250 for a project that required 50 hours. However, over time and with better skills, the same type of project may take 30 hours and the writer would earn $2,550. Thus, the writer's hourly rate would decrease with better proficiency. Charging by the project is a win-win situation according to Bass.

2. Decide *what* to charge. A writer can use resources such as the AMWA 2007 Salary Survey available on AMWA's Web site, www.amwa.org. However, Bass does point out that in the 2007 survey, two-thirds of AMWA's freelance writers still charged hourly rates. In deciding what to charge, he suggests contacting AMWA colleagues, looking at your past projects, and ultimately, listening to your gut instincts. Bass states, "I work out 3 to 4 estimates and then make my decision based on past experience, the experience of others, and by computing the value of what the project is really worth. Looking at all of these different ways and what your gut tells you will help with your decision." However, he cautioned attendees to be aware that no two projects are ever alike. It is important, Bass stressed, to remember the nuances and subtleties of projects, such as the number of drafts when deciding what to charge.

3. Respond to estimate rejections. Bass not only expects this; he honestly invites it. "Rejection is a good sign that your client wants to work with you and that they just need an explanation," says Bass. To estimate a project fee you need to ask as many questions as you can, make assumptions and plan on them, and put everything in writing so there are no surprises.

Bass concluded his presentation with this statement: "Never negotiate your fee, always negotiate the deliverable." For example, you can change the parameters on the deliverable. Bass explained that if you choose to stand your ground, you may lose the project, but if you give in, you will lose yourself. You need to negotiate to win. "It's what makes you a successful business person and a successful medical writer."

Julie Munden has been a freelance medical editor and writer for over 6 years. Her company, Blue Ink Editor, provides editorial and writing services to various medical communications agencies.

Did You Know?

AMWA-DVC now has 867 members! We're the largest chapter of AMWA.

Celebrating . . . from 3

Bradford Challis, PhD, MBA, Ambler, PA

Ann N. Garvey, PhD, Princeton, NJ

Debra M. Milak, Egg Harbor Twp, NJ

Dirdrah Watson, BA, Philadelphia, PA

Curt B. Johnson, MS, MBA, Wilmington, DE

Brenda Smith Meyer, DVM, Collegeville, PA

Richard P. McCabe, PhD, West Conshohocken, PA

Diane Berkstresser, MA, Reading, PA

Susanna J. Dodgson, BSc(Hons), PhD, Haddonfield, NJ

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Gloria Ann Ringel, BA, Fort Washington, PA

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Joanna Shields, Mechanicsburg, PA

Jean B. Kuhl, Lanoka Harbor, NJ

Kathleen Peeples-Lamirande, PharmD, Collegeville, PA

Want to Write for the *Delawriter*?

Send us your ideas and stories or volunteer to cover an AMWA-DVC meeting:

delawriter@amwa-dvc.org

Helping People Sell Can Be Good Business

By Joseph Breck

Medical writers enjoy covering all ends of the communications field, from cutting-edge science articles to regulatory affairs documents. A large part of the mix is also writing pharmaceutical sales training materials—the things that help the sellers sell.

At the Seventh Annual AMWA-DVC Freelance Workshop on April 25, 2009 in Blue Bell, Pennsylvania, freelance medical writer Lynne Lederman, PhD, presented opportunities in pharmaceutical sales training for medical writers.

The first thing Dr Lederman stressed is that sales training is education and not sales. From the writer's perspective, it can cover anything from medicine and science to pharmacology, treatment guidelines, competitive therapies, or managed care. The challenge is effectively communicating a message to the various audiences that may be targeted—some with little or no science background.

While the ultimate customer may consist of pharmaceutical companies, most writers work for or through a medical education or medical communications agency. The agency's task is to build a program to educate various audiences. The writers' titles vary from company to company, but the aim is the same—to help people persuade clients to use their company's therapies on an ongoing basis.

This goal often requires a team approach to reach the desired outcome. Writers can expect to work with editors, illustrators, project managers, subject matter experts, workshop leaders, and desktop publishing experts. It is important to understand the contribution each team member makes, and how the various inputs gel into a compelling training program. The individual pieces of any program can include self-study modules, on-line learning, audio and video scripts, workshops, games, role-playing, etc.

What the "learners" expect out of all this is product knowledge, working information on disease states, current therapy information, and competitive therapy data—information on any or all of the factors that go into an effective sales process and a solid working relationship with a client.

The learning modules that are produced for the client are subject to regulatory, legal, and medical review, meaning that writers should have a good grasp of the product fundamentals. Writers also need to know the learning objectives of the program. They need to structure their writing to help the audience gain knowledge and skills that meet the objectives.

In order to do all of this, you, as a medical writer, must be able to draw on any number of background resources, such as medical and nursing texts, patient advocacy Web sites, peer-reviewed literature, product information, and company Web sites. As in all assignments, what goes without saying is that you need to write well, have product knowledge or be a quick study, understand the industry and the U.S. Food and Drug Administration, and stay current with communications technology.

For more information on opportunities in the medical sales training field, you can visit the Society of Pharmaceutical and Biotech Trainers's Web site at www.spbt.org/en/home.

Joseph Breck is a member of AMWA and a principal of Breck & Company, a medical communications organization based in St. Davids, PA.

Regulatory . . . from 5

oneworldhealth.org (San Francisco) may also help newcomers gain a better understanding of the regulatory world.

While waiting for your first break into this type of writing, improve your knowledge base, she advised. "And you have to be flexible," she said. If a particular disease state is unfamiliar, she suggested reading a children's book on the topic, then "graduating" to reading a college-level textbook on the topic.

"But you may not need that level of understanding or expertise in the subject matter," she said. As an example, she suggested people learn what each lab value in a standard panel means, what the normal ranges are, and what the implications are if a subject's value is not normal. Ms Felcone also suggested reading the FDA regulations on what makes a good clinical study or protocol, and if possible, reading an entire protocol.

Some of her advice came from a colleague, who suggested not walking away from a low-paying job if it includes on-the-job training. "It is somewhat difficult to transition from medical writing to regulatory documents," Ms Felcone said.

Michelle Dalton, an award-winning journalist and director of Dalton & Associates, specializes in the development of manuscripts, abstracts, posters, monographs, and medical conference coverage in a variety of specialties.

Why Do We Need GPP2?

By Julie Munden

At the AMWA-DVC chapter business meeting on June 30, 2009, in King of Prussia, Pennsylvania, Jim Gurr, PhD, Director of Publications and External Communications at Wyeth Research in Collegeville, Pennsylvania, presented a talk about good publication practices. In his presentation, Dr Gurr spoke about the newly revised "Good Publication Practice for Communicating Company-Sponsored Medical Research (GPP2)" as a member of the Standards and Best Practices Committee of the International Society for Medical Publication Professionals (ISMPP).

A Changing Environment

Dr Gurr outlined why the GPP2 is necessary. Industry publication practices are still making headlines. As a result, changes have occurred in how clinical trial results are reported, such as: (1) Declaration of Helsinki (2008) emphasizing accuracy and completeness in ethical obligations of those reporting research results, (2) greater accessibility of clinical trial information including results, and (3) professional organizations developing codes of practice (eg, ISMPP, AMWA).

The GPP2 was built on the GPP1 and involved a period of 10 months of global review presented to 288 invitees worldwide in academia, journal publishing, medical communication agencies, pharmaceutical companies, and professional organizations. The GPP2 is designed to provide recommendations related to publication practices for individuals and organizations involved in communication of medical research sponsored by pharmaceutical, medical device, and biotechnology companies. The goal of the GPP2 recommendations is to help individuals and organizations maintain ethical publication practices and comply with current legal and regulatory practices.

Demonstrating Core Qualities

Dr Gurr called for individuals and organizations following good publication practices to demonstrate 5 core qualities in their articles and presentations:

Integrity—through accurate, objective, balanced writing; honest attribution of authorship; the absence of duplicate publications; and allowing full access to data

Completeness—through clear description of research hypotheses, reporting unbiased results, discussing limitations of study design, and publishing results regardless of the outcome

Transparency—through making clear the source of funding, disclosing conflicts of interest, and acknowledging all contributors and research sponsors

Accountability—through authors and presenters taking responsibility for their work

Responsibility—through publishing results in a timely manner, respecting intellectual property, and respecting the responsibilities of contributing individuals and organizations for good publication practice.

Implementing these qualities when publishing articles and presentations is the aim and ultimate goal of the GPP2.

Julie Munden has been a freelance medical editor and writer for over 6 years. Her company, Blue Ink Communications, provides editorial and writing services to various medical communications and interactive agencies.

Publication Planning: A How-to, but First a Should We

By Kate Casano

On May 16, 2009, Cynthia Kryder, MS, launched her "3-hour tour" of publication planning at this year's Princeton Conference. The presentation was subtitled "From Should We to How Do We," and included an opportunity for participants to prepare a strategic publication plan for a fictional new drug—Writemor, indicated for relief of moderate to severe writer's block.

Recent developments in drug development and communication—such as fewer pivotal clinical trials per new drug, shorter lead times for reporting results at conferences and in journals, an increased variety of target audiences, and a highly competitive marketplace—make it more important than ever to introduce a new drug using a carefully developed publication plan, Ms Kryder said. It does not help the case for publication planning that much of its language is marketing-speak, with its "key messages" and "KOLs" and "target audiences," reinforcing the inaccurate notion that publication planning is driven by a pharmaceutical company's marketing department. That being said, however,

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Pub Planning . . . from 6

the ultimate goal of publication planning is to increase sales.

Publication planning begins a few years before the launch of a new drug. Medical writers typically are involved in planning via medical communications agencies hired by pharmaceutical companies. Pharma supplies the core team of professionals who provide guidance for a literature search and gap analysis, which is a detailed presentation of the literature in the therapeutic area of interest during a specified date range. The gap analysis typically includes general articles about the indication and articles about the target agent and its competitors. It also summarizes the share of the "publication voice" occupied by each competitor, the journals and conferences relevant to the therapeutic area, and the target audience for each, the type of articles that have been published (such as reviews, guidelines, preclinical studies, or controlled trials) and, most importantly, the gaps and opportunities available for publications about the new drug.

As an example, Ms. Kryder showed a gap analysis for a new drug and a single competitor, covering 10 years and several hundred publications. The analysis, which she said represented 5 months of work, consisted of a series of tables that summarized the literature by article type, target audience, indication, message, year of publication, and journal, with cross-tabulations among these categories. A gap analysis would also include summaries of each article and an overall narrative summary. Following the gap analysis, a SWOT analysis (strengths, weaknesses, opportunities, threats) may be carried out, but this does not ordinarily involve a medical writer. The steps mentioned thus far comprise only the first assessment step of a publication strategy. Following the assessment, there are 3 additional steps: planning, execution, and evaluation.

After this introduction and a review of what it takes to develop a publication plan, Ms Kryder turned the workshop participants loose to develop a strategy for the fictional Writemor. Planning was based on a gap analysis graciously provided by the instructor. "Publications" included not only journal articles, but also meeting posters and abstracts as well as CME events and materials. Participants discussed the various key messages, identified target audiences, and developed a plan to build awareness of the drug pre-launch and to maintain momentum for a year post-launch, a 3-year period altogether. By the end of the "3-hour tour," participants discovered that publication planning is complicated and can require the ability to fit a great number of projects into a limited time span.

Kate Casano is a past president of AMWA-DVC and a freelance medical writer in Philadelphia and central New Jersey.

Seeking Web-savvy Volunteers

Do you have experience designing or maintaining Web sites?
Join the Web Site Committee and help redesign and/or maintain the DVC Web site.
For more information, please contact Lisa at webchair@amwa-dvc.org.

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**News and notes from the
American Medical Writers Association–
Delaware Valley Chapter (www.amwa-dvc.org)**

Calling for Fresh Ideas

AMWA-DVC is able to provide high-quality programs, such as the Freelance Workshop and the Princeton Conference, because of the many volunteers who give their time and expertise to benefit all of our members.

We welcome more volunteers to maintain our level of programs and educational offerings and to bring new perspectives to program planning.

Don't be shy! Volunteer and help us expand our base of thinkers and doers so we continue to be the chapter that the others envy.

Contact Linda Felcone to find out how you can help at:

volunteer@amwa-dvc.org

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