

The quarterly newsletter of the American Medical Writers Association—Delaware Valley Chapter

UPCOMING MEETING

“Dumbing It Down or Saving Lives? Presenting Reader-Friendly Health Information” — March 23

Find out:

- What consumers have said about confusing health information
- What research has shown about health communication and health outcomes
- What research has shown about health communication and medical liability
- How health care agencies and companies are responding to consumer needs
- What medical writers can do to make consumer information more reader-friendly

About the Presenter

Janet Ohene-Frempong (o-HEN-ee frem-PONG), President of J O Frempong & Associates, is a plain language and cross-cultural communications consultant with more than 25 years of experience in patient/provider communications. Formerly Director of the Health Literacy Project at the Health Promotion Council of Southeastern Pennsylvania, she has conducted workshops and provided consultation on low literacy and plain language communication for a range of health information providers, including: health care systems, government agencies, health insurers, medical publishers, pharmaceutical companies, professional associations, and schools of medicine, nursing and allied health. Ms. Ohene-Frempong is co-founder and principal of the Clear Language Group, a consortium of nationally recognized health literacy experts. She is also a founding member of the Partnership for Clear Health Communication, a coalition of national organizations and health literacy experts working to promote awareness and solutions around the issue of low health literacy and its effect on health outcomes.

Details

- Wednesday, March 23
5:30 p.m. Networking, 6:00 p.m. Dinner, 7:00 p.m. Speaker
- Holiday Inn City Line, 4100 Presidential Blvd., Philadelphia, Pa.
1-215-477-0200 <http://www.ichotelsgroup.com/h/d/hi/1/en/hd/phlci>
- Cost with advance reservation:
Members: \$40, Nonmembers: \$45, Students: \$10
At the door: \$10 more for each category, SPACE PERMITTING

Reservations

- By email: Christina Valente: cmvalente@verizon.net. Please mail your check after emailing your reservation.
- By mail: Lori De Milto, 1018 Hartley Court, Sicklerville, NJ 08081-1109. Reservations and checks (payable to AMWA-DVC) must be mailed in advance to guarantee your reservation. Advance reservations accepted until noon, Wednesday, March 16. No refunds for cancellations received after March 18. NO-SHOWS WILL BE BILLED.

CALENDAR

- **Wednesday, March 23** — “Dumbing It Down or Saving Lives? Presenting Reader-Friendly Health Information,” Janet Ohene-Frempong, MS, Holiday Inn City Line, Philadelphia, Pa.
- **Saturday, April 9** — Princeton Conference, Harrison Conference Center, Plainsboro, N.J.
- **May** — New Jersey Dinner Meeting (Topic, speaker, date, and location to be determined)
- **June** — Pennsylvania Dinner Meeting (Topic, speaker, date, and location to be determined)

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Continuing Medical Education (CME) Standards for Commercial Support

“‘May you live in interesting times . . .’ those of you in CME know what this means.” Karen Overstreet, President of Nexus Communications, began her presentation on “CME Standards for Commercial Support” with a quote that is often attributed to a Chinese curse. Overstreet, who has more than 13 years of experience in the area of medical education, coordinates day-to-day operations, including scientific affairs, program management, editorial services, and educational design at Nexus. She is active in many professional organizations including the Alliance for Continuing Medical Education, where she served for more than 3 years as editor-in-chief of the monthly newsletter *Almanac*. Overstreet discussed the most controversial aspect of the new CME Standards concerns: the mandate to resolve conflicts of interest before designing educational activities.

Evolving Regulation of CME

CME regulations are evolving guidelines that focus on the commercial support of CME products. The regulations aim to limit the controversial aspects of that support and to avoid legal problems.

New Standards for Commercial Support

The new standards are voluntary guidelines that request full disclosure of personal conflicts of interest. These include, disclosing:

- Direct financial relationships—a relationship not primarily held by and mediated through an employer, provider, or other institution
- Expectation of payment directly to the person involved
- Current relationships (those formed within the previous 12 months) as these are of primary concern.

Implications for Writers

Overstreet urged medical writers to learn the rules. She suggested maintaining a network of colleagues for discussing CME issues and only working with CME partners who shared similar views on the guidelines. Overstreet also suggested:

- Using credible reference sources and verifying data
- Adding and documenting peer reviewed content
- Disclosing any relationships that involve direct payment from a commercial supporter.

Moving Forward

Beginning in May 2005, compliance with these guidelines is required. Overstreet noted that “providers have considerable discretion in determining the mechanisms they will use to identify and resolve conflicts of interest.” She encouraged interaction and discussion with partners in CME. She urged all those involved to, “Take a look at everything before jumping the gun and making policies more stringent than they need to be.”

Overstreet provided the following Web sites for those interested in learning more about the regulations:

- www.acme-assn.org
- www.naamecc.org

A Word of Thanks

The November 16 AMWA-DVC meeting took place in Radnor, Pa. and was well attended. Much thanks to AMWA-DVC member Karen Overstreet who suggested the meeting topic and offered to present it. We also thank Program Chair, Andrea Laborde for dealing with many late registrations, and working with the Radnor Hotel to secure a room large enough for us all.

Third Annual Freelance Workshop and First Getting Started in Medical Writing Workshop

On Saturday, January 15, AMWA-DVC presented the *Third Annual Freelance Workshop and First Getting Started in Medical Writing Workshop*—a full-day program on topics of interest to both new and established medical writers. This year, we had 68 attendees at the freelance workshop and 74 attendees at the getting started workshop. Most

attendees stayed for both workshops. The morning session featured a panel of experts that presented key issues for freelancers. Afternoon presenters addressed subjects most relevant to those just getting started in medical writing. A networking lunch provided the opportunity to meet fellow medical writers and panelists from both sessions.

Special thanks to our Freelance Workshop Co-Chairs Dorit Shapiro and Christina Valente and Getting Started Workshop Chair Lori De Milto. Special kudos to Dorit Shapiro, who handled the registrations and logistics for both workshops.

This issue of the *Delawriter* features recaps of some of the presentations from both sessions.

Marketing Yourself as a Freelance

From the Freelance Workshop

By Deborah Early, PhD

Marketing is vital for freelances. Barbara Rinehart, MS, a freelance medical writer with more than 14 years experience in pharmaceutical and marketing writing, presented the opening session at the AMWA-DVC *Third Annual Freelance Workshop*. During her 14-year membership in AMWA, Rinehart has presented roundtables and workshop topics on both the local and national level.

After establishing that workshop attendees were a mixed group (most were current freelances, and about one-third wanted to become a freelance), Rinehart outlined 10 key steps in freelance marketing.

Ten Steps to Freelance Marketing

1. Know yourself. The objective of knowing yourself better is being able to better define your market (step 2) and develop your product (step 3). Useful tools that may help a medical writer achieve this objective include:

- Taking personality tests
- Evaluating goals, objectives, and motives
- Listing strengths, weaknesses, fears, and personal preferences
- Being introspective and writing down your observations.

Rinehart gave examples of personal preferences such as some individuals may not like to travel, and a member of the group suggested experience through trial and error will help freelances gain a better understanding of their personal preferences.

2. Research your niche market. In addition to knowing yourself it is important to know your market. You should thoroughly research the market to give yourself an objective evaluation of who

might buy your services. Rinehart mentioned examples of clients such as institutions and health care companies. She suggested starting a database of these.

3. List your skills. Before approaching such organizations it is helpful to list your skills—identifying areas such as services and subject areas that you cover. Listing your skills will help you identify gaps in your skill base that you can fill by undertaking training, writing for lay organizations, and volunteer work.

4. Create winning sales materials. Freelance writers have some basic needs, including business cards and a resume with a list of services. After the initial set up, freelances may develop a brochure, letterhead, logo, and create their own Web site.

5. Reach out and disseminate sales materials to your niche market. This step is as important as creating the materials. Use any and all methods available to you such as cold calling, current contacts, and direct mail.

6. Follow-up, follow-up, follow-up. Rinehart reminded participants that clients need to see a writer's name 7 times to remember them and that discerning follow-up is necessary (e.g., try not to follow-up with a client on a Monday morning or Friday afternoon).

7. Refine your process on the basis of past success. Analyze which sales materials and dissemination methods worked and which did not.

8. Keep your current clients happy. Workshop participants agreed that it is easier to keep a client than obtain a new one. The group suggested a number of ways to keep current clients happy including: delivering a good product on time,

being available, keeping the client informed, and offering an additional service that is new or beneficial to the client.

9. Generate new clients. Rinehart suggested that freelances consistently and constantly prospect.

10. Deliver an excellent person and product every time. Rinehart reminded writers that their good reputation will spread through word of mouth and bring more opportunities.

Dr. Early is a regulatory medical writer and is currently Membership Chair and Secretary for AMWA-DVC.

Annual Princeton Conference: April 9

AMWA-DVC's annual Princeton Conference will be held on Saturday, April 9 at the Harrison Conference Center in Plainsboro, N.J. The following four core curriculum workshops will be offered:

- English Usage and Abusage (G)—Edie Schwager
- Electronic Regulatory Submissions (PH)—Art Gertel
- Organizing the Biomedical Paper (EW/FL)—Howard Smith
- Investigational New Drug Applications (PH)—Larry Liberti

In addition, two noncredit workshops will be offered: one on the preparation of Informed Consent Documents (ICDs), and one on the use of XML for data submissions.

A broadcast email with a link to the registration flyer will be sent to all AMWA members.

What Employers Look for in Medical Writers

From the Getting Started Workshop

By Darlene Grzegorski

Speaking to an audience of new and established medical writers, James Gurr, PhD, and Victoria Seidenberger of Global Clinical Communications at Wyeth Research in Collegeville, Pa. shared their insights into the role of the medical writer at a large pharmaceutical company. Gurr is associate director of clinical publications—a group of 8 that writes and manages publications and publication plans for projects in phases 1-3. Seidenberger is director of the training, quality and compliance section, which provides training, auditing, and editorial services to Global Clinical Communications. Gurr and Seidenberger described the organization of the group, providing actual numbers to help paint a picture of how publications and regulatory documents are managed at their company.

The publications group at Wyeth consists of 2 clinical writers, a technical writer, a publications specialist, and an administrator. Gurr pointed out that medical writers do more than prepare manuscripts, abstracts, and posters from trial data. They develop strategies for publication plans, chair publication subcommittees, and coordinate agency and freelance support. They also coordinate the review and sign-off on clinical research and development publications, which Gurr called “quite an arduous task.”

The regulatory group consists of 32 clinical writers as well as 3 technical writers, 3 technical editors, 2 clinical editors, and 2 clinical document quality specialists who ensure that clinical documents adhere to the technical requirements of documentation in the era of electronic communication. This group is responsible for clinical study reports

(CSRs), investigators’ brochures (IBs), annual and quarterly reports, summary documents, and labeling. Seidenberger explained that the trend towards greater regulation in the pharmaceutical industry is also creating a push for standard operating procedures (SOPs).

Expectations of a Medical Writer

Some of the expectations of a regulatory writer in this setting are:

- Familiarity with guidelines, regulations, and SOPs
- Competency in relevant software applications
- Document planning and preparation skills
- Attendance at meetings
- Service on committees.

In light of the greater emphasis being placed on electronic formats to eliminate document corruption, Seidenberger commented: “It’s a lot more difficult than when I started years ago with a manual typewriter and the help of a pad and pencil.”

Workload and the Freelance’s Role

Gurr illustrated the typical annual workload of the publications group at Wyeth, which currently has 60 compounds on the market and in the pipeline. These figures summarize their 2004 projects (numbers performed internally and externally, respectively): 61 manuscripts (19 + 42), 350 abstracts (40 + 310), 275 posters (83 + 192), and 31 presentations (22 + 9).

The data clearly showed the extensive involvement of agencies and freelance writers. In his opinion, Gurr pointed out that, “Agencies are more expensive and deliver less quality product than freelancers,” typically charging twice as much as freelance writers, especially for abstracts and posters. He added that because of this, Wyeth’s policy is to use freelance writers as often as possible. Emphasizing this belief, he commented that you get a “better quality product when you have a good relationship with a writer.”

Seidenberger presented the 2004

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Delawriter

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productivity of the regulatory group (numbers performed internally and externally, respectively), explaining that the nature of regulatory documents requires them to be handled differently: 83 CSRs (63 + 20), 33 IBs (33 + 0), 69 annual and quarterly reports (62 + 7), 152 summaries (152 + 0), and 94 other documents (94 + 0). Some regulatory documents can't be contracted out because they require a great deal of clinical expertise and often need to be completed in a very short time frame that most freelance writers couldn't accommodate.

Desirable Qualities of Medical Writers

In discussing desirable qualities in a medical writer, Seidenberger and Gurr agreed that enthusiasm was at the top of the list, saying they look for a person who will “go the extra mile.” Seidenberger also stressed the importance of being able to attend meetings: “Face time is so important. It makes your life easier.” Other qualities included:

- Ability to gather, synthesize and critically analyze large amounts of data
- Ability to express ideas succinctly
- Scientific/medical background (but not necessarily a PhD)
- Expertise in 1 or 2 therapeutic areas, plus a willingness to learn
- Willingness to commit to a series of related manuscripts or documents.

Last, but not least, Seidenberger and Gurr listed another important quality: a sense of humor. Pointing out that a medical writer is representing an organization, they said having a “thick skin” and not taking criticism personally is essential. Chasing details and reconciling discrepancies, and being able to communicate with many people from different disciplines were also noted. Gurr described the plight

of the medical writer as: “You're the last one to get the information, but you're still expected to work miracles!”

How to Get into Medical Writing

Unruffled by the seemingly demanding environment and high-level expectations, the audience wanted to know how to get into these types of medical writing positions. Seidenberger suggested several approaches, including working through a temp agency to get an idea of what's involved. For writers submitting an unsolicited resume, she said it was important to show a strong interest in writing, for example, by being a member of AMWA or taking

writing courses at a university. She advised against trying to portray yourself as an expert in too many disease states. Gurr offered another practical suggestion: do a little research on the company you are applying to and direct your efforts at their pipeline.

From the employer's perspective, Seigenberger concluded, “We need to have people who are serious about medical writing as a career.”

Darlene Grzegorski is a senior project manager/medical writer at Educational Resource Systems, Inc. in Red Bank, N.J.

From Bench Scientist to Medical Writer

From the Getting Started Workshop

By Darlene Grzegorski

How to transition into medical writing is always the core question for those who are new to the field, and most find the catch-22 of needing experience to get a job and needing a job to get experience frustrating. Dr. Lynne Lederman, an academic and industrial research scientist turned freelance writer, led an afternoon session that, despite the title, revealed many inventive tips for aspiring medical writers from all backgrounds.

One of the challenges that aspiring and even established medical writers encounter is not having any writing samples, or not having access to samples that they can distribute (for example, because their writing centers on propriety information). One suggestion Dr. Lederman made was to take a newspaper article reporting on a medical or scientific issue and ask yourself, “Did the press get it right?”—then write your own summary. Another was to take a hot topic in the news these days—Lederman suggested the

over-the-counter sale of statins—and write an article. Members of the audience drew on their own personal experiences: workshop leader Robert Hand a veteran freelance writer with extensive regulatory experience, related how he wrote for a physician's newsletter in order to have something tangible to showcase his talents.

Another area of uncertainty for new medical writers is trying to figure out what you're good at. “Start small,” says Dr. Lederman. “If you have a scientific degree,” she added, “that already gives you an area of expertise to start with.” She also suggested taking advantage of talking to fellow AMWA members. On the subject of doing a project for free, she said, “Having a sample with your name on it is a ‘payback’.”

The significance of other aspects of medical writing was also raised as another area where new writers could develop marketable skills. “Part of being a medical writer involves skills

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in formatting, project management, and technical aspects of electronic documents,” said Dr. Lederman.

As to a formula for getting started, Dr. Lederman pointed out, “A lot of it is serendipity.” Though it’s frustrating for aspiring writers to hear this theme throughout the field of medical writing, it should be encouraging to know that so many people have become successful by going down such diverse paths.

The question-and-answer session revolved around practical suggestions from the panel and audience on good places to get started, including names of companies and the types of job descriptions to look for. Workshop Chair Lori De Milto offered: “Don’t be afraid to look into something that isn’t your goal,” pointing out how entry-level positions in copywriting and copyediting could open the door to greater possibilities.

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