

AMWA-DVC President's Report for 2007–2008

By Marie-Therese Zenner

It has been an excellent year for the American Medical Writers Association–Delaware Valley Chapter (AMWA-DVC), with positive strides made in many directions.

Membership Demographics

The DVC remains by far the largest and most active of the 21 domestic and international chapters of AMWA. DVC members represent 16% of the global community of medical writers!

Why is this? The Delaware Valley is an excellent place for working in medical communications. Stretching from Delaware to

northern New Jersey, the chapter area continues to be a crucible for both new and established pharmaceutical companies; hospitals; universities; medical communication, publishing, or advertising agencies; nonprofits; medical societies; biotech and other start-ups; and more.

Membership in the AMWA-DVC increased nearly 150% over the last 8 years. DVC maintains one of the highest monthly renewal rates (maximum differential of 5% versus AMWA's average), although DVC membership has declined slightly since 2006.

Every year since 2004, DVC has

recognized individuals who achieved an anniversary of 10 or more years of membership (counting in 5-year intervals). In 2008, we honored 49 members (including a 45-year member) with certificates.

Volunteers

One secret of the DVC's success is the generosity of volunteers. In return, there are many rewards for volunteer work. Involvement increases the potential for peer-recognition. More importantly, dedicated volunteers find invaluable personal and professional satisfaction

See President's Report on page 2.

The Spectrum of Strategic Regulatory Documents

By Charlene A. Tucker

At the AMWA-DVC meeting held on June 26, 2008, in King of Prussia, Pennsylvania, Russell D. Hunter, Manager, Regulatory Affairs for MDS Pharma Services, presented his seminar, "Production of Strategic Regulatory Documents to Support Clinical Trials in a Global Regulatory Environment: The Role of the Regulatory Medical Writer and Document Specialist."

Regulatory medical writers produce high-quality documents for submission to international regulatory agencies including the Food and Drug Administration, Health Canada, and the European Medicines Agency. These documents

include clinical study protocols and reports, Investigator's Brochures, Investigational New Drug (IND) Applications in the United States and clinical trial applications (CTA) in Canada and the European Union (EU), worldwide marketing applications, and briefing and response documents.

After giving the global overview of regulatory documents, Mr Hunter compared clinical trial applications, emphasizing the importance of using document templates and document specialists.

A most useful part of the seminar was his explanation for how the
See Regulatory Documents on page 3.

Inside

AMWA-DVC President's Report for 2007–2008.....	1
The Spectrum of Strategic Regulatory Documents.....	1
Book Review: Breaking the Silence on Cancer and Sexuality	3
New Opportunities to Write About Cancer	4
Volunteer Corner.....	5
In Memoriam	5
Did You Know	5



President's Report . . . from 1

in developing marketable skills in leadership, educational programming, human resources, project management, and technical and financial specialties.

Approximately 64 individuals contributed their time this year, frequently on multiple occasions. In addition, others served as teachers at the Princeton Conference or as authors for this newsletter. We thank all of you! Special recognition to four volunteers was given in the form of presidential awards at the business/dinner meeting in June.

Educational Events

The 12th Annual Princeton Conference was an intensive 1-day event held in Princeton, New Jersey, as part of AMWA's Core Certificate Program. The program offered a choice of four core workshops plus two science-based noncredit workshops; one core workshop, *Writing for Video*, was newly approved for this conference. Conference turnout was good with 68 attendees.

The DVC's own 6th Annual Freelance Workshop was an equally intensive 1-day event held in Blue Bell, Pennsylvania. The program offered four morning presentations and 14 afternoon roundtables on a wide variety of freelance-related topics. Capacity was full, with 74 attendees and 12 registrations received after the cutoff.

Since 2007, the DVC has increased its subsidies of noncurriculum events as a member benefit. Our warm thanks go to the many individuals who organized, assisted, or participated in these successful events!

Delawriter Newsletter

This newsletter saw a great deal of new activity in the past

year. To celebrate the Chapter's 50th anniversary in 2006, special anniversary editions were published in three of the quarterly issues in 2007. In 2008, several content-oriented columns were gradually introduced: "Did You Know" and "Volunteer Corner"; personal stories on the benefits of AMWA membership; and book reviews/science articles.

Web Site

The chapter Web site now serves as the daily liaison for the event calendar, volunteer lists, newsletter postings, and any updates to content. Behind the scenes, work on the code was carried out to facilitate postings. The Web Committee also investigated the practicalities of producing and posting webcasts.

Public Relations Initiatives

The DVC is seeking to further awareness of the chapter as a major partner in the local life sciences industry. In March 2007, the DVC registered on the newly formed database www.look4science.com. Later in 2007, the DVC engaged in discussions for a joint exhibit with the College of Physicians of Philadelphia and became the first group to be received in-house at the Robert Wood Johnson Foundation. In related efforts, the Promotions Committee, working with AMWA, was formed in fall 2007 to provide a volunteer speaker's bureau for presenting the field of medical writing, for instance, to university audiences. In March 2008, the DVC strengthened relations with Drexel University's College of Medicine via Web site links highlighting a speaker from the National Center of Excellence in Women's Health.

Financial Report

The Finance Committee also was very active throughout fiscal year 2007–2008. According to the Treasurer's report to AMWA, at the close of the fiscal year on June 30, 2008, funds totaled \$19,740.61 in the chapter's checking account and \$29,783.49 in the chapter's money market account (total of \$49,524.10 versus \$59,268.47 at the same time in 2007). These are the funds associated with all activities (inflows and outflows) of the last fiscal year. Receipts and expenditures were within budget, as of June 30, 2008, and closed within budget for the fiscal year. Since revenues were below \$50,000, an internal rather than external audit is required and will be conducted by the chapter's Finance Committee.

After the chapter applied for and received federal nonprofit 501(c)6 status in 2006–2007, the Finance Committee oversaw the initial nonprofit tax filings to the IRS and Commonwealth of Pennsylvania in 2007–2008. Both the IRS and the Commonwealth accepted the chapter's tax filings as a nonprofit organization under existing federal and state laws. The subsequent application for sales tax-exempt status in Pennsylvania, however, was unsuccessful because we did not meet the strict, multi-point requirements of a charitable organization.

Marie-Therese Zenner, PhD, is Immediate Past President of AMWA-DVC for the 2008–2009 fiscal year and is Principal of Zenner BioMed, Grant/Proposal Writing, in Haverford, PA.

Calling All Writers

Want to write for the *Delawriter*?
Send ideas and stories to:
Delawriter@amwa-dvc.org

Book Review: *Breaking the Silence on Cancer and Sexuality*

Reviewed by Don Harting

B*reaking the Silence on Cancer and Sexuality: A Handbook for Healthcare Providers* (Pittsburgh, PA: Oncology Nursing Society; 2007) by Anne Katz, RN, PhD, is terrific. It came to my attention as a member of the judging panel for one of the new book awards given during the AMWA annual conference. I gave this book the highest score among books I've reviewed so far.

The author has credibility. In addition to having her registered nurse certification and doctoral degree, Anne Katz works as a

sexuality counselor for an agency responsible for improving cancer care in the province of Manitoba, Canada.

This book is well-organized and complete. First, Dr Katz reviews previous research literature on human sexuality. She then provides a primer in human sexual functioning. The most useful part of the book, however, is the series of chapters examining in detail how various tumor types impact sexuality. These chapters also discuss how current treatments—along with their side effects—may affect sexuality.

Interspersed throughout the text are questionnaires that nurses can use to help them assess patients' sexual health and improve communication with patients about sex. Case studies add variety along with readability.

Nurses will find this book to be a valuable resource on this essential yet seldom-discussed aspect of oncology care. As a working editor in the oncology field, I particularly liked the layout, which appeals to the eye and does not intimidate the reader. The

See Book Review on page 4.

Regulatory Documents . . . from 1

sections of a traditional IND map to the newer electronic Common Technical Document (eCTD) format (Table 1).

After examining eCTDs, Mr Hunter discussed the requirements for CTAs. Some of these requirements are similar to those in an IND. For submission to Health Canada, CTAs include CTD Module 1 (administrative/clinical information), Module 2 (summaries), and various chemistry, manufacturing, and control appendices. For EU member

states, major components of CTAs include the Investigator's Brochure, investigational medicinal product dossier, and clinical study protocol. Both IND applications and CTAs also include a cover letter, clinical study protocol, and quality summary. The differences among the three types of applications are more varied. For instance, unlike INDs, CTAs for EU member states require a protocol synopsis in the local language and a copy of a manufacture importation license, while CTAs for Health

Canada require information on clinical trial sites and a list of refusals by Canada's Research Ethics Board and similar foreign boards.

At MDS Pharma Services and many pharmaceutical companies, document specialists prepare and maintain document templates. These templates are important for high-quality, strategic documents. They contribute to uniformity of published output, consistency of tabular summaries, and efficiency of medical writing resources, allowing medical writers to focus on content.

In this age of eCTDs, this timely presentation offered valuable information for regulatory medical writers charged with preparing clinical trial applications in a global environment.

Charlene A. Tucker, BS, MS, has worked nearly 30 years in the pharmaceutical industry and is Senior Director & Group Leader, Regulatory Medical Writing for Cephalon, Inc, headquartered in Frazer, PA.

Table 1. Selected Contents of IND and eCTD

IND Item Number and Name	eCTD Module Number and Name
3 Introduction	2.5 Clinical Overview
4 General Investigational Plan	1.13.9 General Investigational Plan
5 Investigator's Brochure	1.14.4.1 Investigator's Brochure
6 Protocol	5.3 Specific Study
7 CMC	2.3 Quality Overall Summary
8 Pharmacology and Toxicology	2.4 Nonclinical Overview and 2.6 Nonclinical Written and Tabulated Summaries
9 Previous Human Experience	2.5 Clinical Overview and 2.7 Clinical Summary

Book Review . . . from 3

author's tone is also appealing—it is authoritative and a bit academic, but still accessible. References to research studies and outside resources are plentiful, and the author identifies manufacturers when specific products are mentioned.

One Disappointment

The indexing, titles, chapter headings, and illustrations are all excellent. I did experience one disappointment, however. The chapter on prostate cancer mentions external beam radiation therapy, brachytherapy, and cryosurgery, but there is no reference to more advanced surgical techniques. Computer-assisted radiation, also known by the trade name Cyberknife, is now available at many large hospitals and academic medical centers.

At \$70 per copy, this book is unlikely to become a best seller, even if it is about sex, but I highly recommend it to anyone with an interest in this field.

Don Harting, MA, edits material in the oncology field for AOI Communications, LP, in Exton, PA.

New Opportunities to Write About Cancer

By Don Harting

Oncology is currently a hot therapeutic area for medical writers and editors. IMS Health, a pharmaceutical market research firm, predicts global sales of cancer drugs will grow at a compounded annual rate of 12% to 15%, reaching \$75 billion to \$80 billion by 2012.

IMS predicts that the growth rate for oncology products will be nearly double the forecasted rate for the global pharmaceutical market. Two factors contributing to the growth are aging baby boomers in the United States and the increasing number of cancer patients receiving chemotherapy in Europe and Japan.

New Agents and Advances

Some of the most promising new agents are active against blood cancers, especially chronic leukemia and multiple myeloma. Advances have also been made in breast and kidney cancer, as researchers devise ingenious ways to kill tumor cells and spare healthy ones.

Much of the related communication work available requires writers with regulatory experience to prepare Investigational New Drug Applications for the Food and Drug Administration. There is also plenty of available work in developing marketing materials and teaching doctors and nurses how to use the new drugs.

Artistic Skills in Demand

Writers with artistic skills are also in demand. Major drug companies are donating large sums of money to support the psychosocial needs of cancer patients. Eli Lilly is sponsoring a traveling exhibit of paintings by cancer patients, while GlaxoSmithKline is sponsoring a Cannes-like documentary film contest. Writers in Hollywood and New York drafted scripts for a September prime-time TV special aimed at raising money for cancer research. This unusual event combined the anchors of three major networks—ABC, NBC, and CBS—in a show reminiscent of the Academy Awards. The money raised by all this star power will strengthen an important oncology resource in the Delaware Valley: the American Association for Cancer Research, headquartered in Philadelphia, Pennsylvania.

Look for information on additional oncology resources in the Delaware Valley and beyond on the cancer resources section of our chapter Web site.

Don Harting, MA, edits material in the oncology field for AOI Communications, LP, in Exton, PA.

AMWA-DVC ANNOUNCES NEW JERSEY FALL MEETING

Desk-side Yoga

Presented by Robyn Shumer, MPH, CYT

Monday, November 17, 2008

5:30 PM–8:00 PM

Princeton, NJ

Details are available at the DVC's Web site
www.amwa-dvc.org.

Volunteer Corner: New Pennsylvania Advisory Committee Helps DVC Offer Great Programs

By Lori De Milto

This summer AMWA-DVC established a virtual Pennsylvania Advisory Committee to help find and select the educational programs for our meetings in Pennsylvania. The committee helps us develop ideas for topics and speakers. One member might suggest a great topic, while another might refine the topic or know a possible speaker. Committee members rank the ideas, resulting in a list of meeting suggestions that may interest our members.

An Interesting, Easy Way to Volunteer with AMWA-DVC

Having more people on the committee will make it even more

effective, since each member brings a different network and perspective. It's very easy to participate in this committee. The chair (currently me) e-mails a list for feedback and ranking, and then synthesizes the responses, circulating revised lists for comment as needed.

In addition to new members, we're also looking for someone to chair the committee, as I'll soon be devoting my attention to the next Freelance Workshop (in April 2009). I'd be glad to help the new chair learn the (easy) ropes.

If you're interested in joining or chairing the Pennsylvania Advisory

Committee, please contact me at: loriwriter@comcast.net or 856-232-6821.

Pennsylvania Advisory Committee Members

Many thanks to the committee members: Brian Bass, Lisa P. Breck, Linda Felcone, MA, Eileen Girten, MS, Darlene Grzegorski, MS, Robert P. Hand, MSc, Cynthia L. Kryder, MS, Janet Manfre, Ana Maria Rodriguez-Rojas, MS, and Barb Woldin, BS.

Lori De Milto, MJ, is a marketing medical writer based in Sicklerville, NJ.

Did You Know...

Google's shortcuts and features include:

- **Currency converter.** Enter the amount and units you want to convert (eg, *754 dollars in euros*)
- **Calculator.** Enter your equation (eg, *72.5 * 1.9*) or units to convert (eg, *6 feet 2 inches in centimeters*)
- **Phonebook.** Enter a name and state (eg, *Tom Jones, NJ*) and Google displays the name, address, and phone number, if available
- **Package tracking.** Enter your tracking number (USPS, FedEx, UPS) and Google provides a link to the tracking page for your package
- **Weather.** Enter the city and state after "weather:" (eg, *weather: Red Bank, NJ*), and Google displays current weather information and the 4-day forecast

See Did You Know on page 6.

In Memoriam

Doris Fletcher, a Life Member and Fellow of AMWA, passed away peacefully on August 21, 2008. She was active in the Metropolitan New York and Delaware Valley chapters for many years.

Dorit Shapiro, an active AMWA-DVC member and volunteer (former co-chair of the Freelance Workshop and Web site), passed away October 12, 2008. More information is available on the AMWA-DVC Web site.

Delawriter

Published quarterly by the American Medical Writers Association—Delaware Valley Chapter (www.amwa-dvc.org)

Executive Editor: Barbara Rinehart, MS

Co-editors: Alan M. Struthers, PhD, and Eileen Girten, MS, Delawriter@amwa-dvc.org

Production: Jennifer Maybin, MA, ELS

Editorial Consultants: Elisha Darville, Elizabeth A. Manning, PhD, Monica Nicosia, PhD

Changes of address/information:

E-mail: ronnie@amwa.org

Mail: American Medical Writers Association
40 West Gude Drive, Suite 101
Rockville, MD 20850-1192

Phone: 301-294-5303



AMWA-DVC
c/o Alan Struthers
164 Main Street
Manasquan, NJ 08736-3559

PRESORTED
First Class Mail
U.S. Postage
PAID
Bellmawr, NJ
Permit No. 1485

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

6

Did You Know . . . from 5

- **Travel conditions.** Enter the name of the airport (eg, Newark airport or EWR airport) and Google provides a link to www.fly.faa.gov where you can view weather-related information
- **Flight tracking.** Enter the flight number (eg, CO11 or Continental 11) and Google displays the departure time and estimated arrival time

Thanks to Darlene Grzegorski, MS, for contributing this information.

Not Getting Our E-mails?

Add these e-mail addresses to your e-mail safe list to make sure you receive our announcements:
amwa-dvc-members@dudley.casano.com
amwa-dvc-announce@dudley.casano.com

2008–2009 Executive Committee and Key Volunteers

President
Barbara Rinehart, MS
President@amwa-dvc.org

President-Elect
Lisa P. Breck
PresidentElect@amwa-dvc.org

Immediate Past President
Marie-Therese Zenner, PhD
PastPresident@amwa-dvc.org

Secretary
Cynthia L. Kryder, MS
Secretary@amwa-dvc.org

Treasurer
Michael G. Pappas, MS, PhD
Treasurer@amwa-dvc.org

Publicity Chair
Shirley Bonnem
Publicity@amwa-dvc.org

Membership Chair
Elizabeth A. Manning, PhD
Membership@amwa-dvc.org

Web Site Chair
Lisa Vawter, PhD
Webchair@amwa-dvc.org

Program Chair (Acting)
Janet Manfre
Programs@amwa-dvc.org

New Jersey Program Chair
Kira Belkin, PhD
NJPrograms@amwa-dvc.org

Newsletter Chair
Alan M. Struthers, PhD
Delawriter@amwa-dvc.org

Education and Princeton
Conference Chair
Brian Bass
Princeton@amwa-dvc.org

Freelance Workshop Co-Chairs
Lori De Milto, MJ
Jennifer Maybin, MA
Freelance@amwa-dvc.org

Volunteer Coordinator
Jennifer Maybin, MA
Volunteer@amwa-dvc.org

Delegates
**Barbara Rinehart, MS, and
Lisa P. Breck**
President@amwa-dvc.org and
PresidentElect@amwa-dvc.org