CAROLINA CONNECTIONS

Carolinas Chapter—American Medical Writers Association

Spring 2005

President's message

Mentoring: the greatest legacy

By Jenny Walker

Last fall, the AMWA Carolinas chapter held a joint gathering with the Society for Technical Communication to celebrate longtime joint member Lottie Applewhite's 80th birthday. As I sat listening to the impromptu tributes being given to Lottie, the thing that struck me the most was the number of people who said what a mentor Lottie had been to them. Several people spoke of how much they had learned from her and, most importantly, how willing and eager she had been to teach them. I thought that was the greatest legacy one could leave—that you made a difference in someone's life and helped them along the way. You will never be forgotten by that person. I also hear a continuing refrain at almost all of the AMWA events I attend—that of people trying to get into the field who ask, "How do I become a medical writer (editor, etc.)? How do I break into the field?" The most common answer I hear is "luck."

It is too bad that we have to depend on a lucky break to be able to do something we have a talent for and could do well, if only given a chance. I think it is incumbent on all professionals who have "made it" to reach out to others and help them along. We should be mentoring people new to the profession who are so desperately looking for their lucky break.

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Gopen to address AMWA Carolinas Chapter on Thursday, May 5

Renowned Duke writing professor, George Gopen, PhD, will be the featured speaker at the next AMWA meeting.

Gopen's topic will be "Writing from the reader's perspective." Gopen is a professor in the University Writing Program and the English department at Duke University. He is a dynamic, exciting speaker.

Please plan to attend the meeting, May 5 at 7 p.m. at the Friday Center in Chapel Hill. For directions to the meeting, please visit the chapter's Web site, www.amwacarolinas.org. Click on the link to the next meeting under "What's new?" then click the link to the Friday Center.

In This Issue

Editor's note

By Tara Hun-Dorris

It has been a busy few months for the AMWA Carolinas Chapter. Numerous members attended the annual conference in St. Louis last fall. We've also had high turnout at our two most recent chapter meetings: a celebration of Lottie Appewhite's 80th birthday held in conjunction with the local chapter of the Society for Technical Communication and a panel discussion about medical writing hiring practices of key Triangle companies.

For a list of upcoming AMWA Carolinas luncheons and meetings, visit the Web site www.amwacarolinas.org.

In addition, new AMWA president Jenny Walker has continued the tradition of monthly AMWA networking luncheons held the last Friday of the month in Durham. Check AMWA's Web site for information about the location of upcoming lunches, which are held at various restaurants in the Durham and RTP areas. These lunches are a great opportunity to chat with other medical writing professionals in an informal setting.

The Carolinas chapter is always looking for new ideas and activities. If you have suggestions for an upcoming activity or event that might be of interest to chapter members, please contact one of the officers listed in the blue box on page 3 of this newsletter.

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We live in a society that expects—demands—instant gratification. Most employers are looking to hire only people with experience. And we are all too familiar with the mantra, "How am I to get experience when no one will hire me so that I *can* get some experience?!" Potential employers too often shrug off this question, willing to let that be someone else's problem. Many times people in this profession who have little or no experience are hired only when an employer is "desperate" and cannot find anyone with the experience being sought.

In my first career, I had the true privilege of working for a woman who ardently believed that it was our professional responsibility to help people trying to get started in that career. Sometimes when we were filling a position, we would hire someone with experience. But regularly interspersed with these occasions were those when she would tell the department that we were going to hire an entry-level person. Her decision to do so was not based one bit on monetary concerns—she did not do it because it was less costly or because we did not have the money to hire someone with experience. She did it because she felt it was the right thing to do. We also regularly hosted interns, and anyone who has ever worked with an intern knows that it requires far more from the company or institution than it will ever "get back" from the intern.

But you will never be forgotten by that person you were willing to be a little inconvenienced for and take a chance on. And who knows, you may end up with someone who becomes a true asset to your company or institution and to the profession. What better accomplishment can you achieve? What better legacy can you leave? We should all try to be more like Lottie Applewhite and my former boss. Let's face it—it is very difficult to leave a mark on this world that we live in today. But we can definitely make a difference in the lives of individuals. It's the right thing to do—for them, for ourselves, and for the profession.

The electronic common technical document

Where did it come from and what is next?

By Peggy Boe, RN

Pharmaceutical industry and regulatory experts from around the world assembled in 1990 to form The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH). The primary goal of the ICH was to establish common international guidelines for the submission of pharmaceutical dossiers. To date, the common technical document (CTD) guidelines represent the best attempt at achieving the ICH's goals.

The CTD is neither perfect nor universally accepted as common. The ICH never claimed that the CTD would be a one-size-fits-all global dossier. The regional national requirements remain uncommon, and the

To "e" or not to "e"? That is the question

CTD for the most part consolidates those requirements in one module of the CTD. What is common about the CTD is the modular presentation of the remaining summaries, reports, and data required by all.

Europe and Japan now require sponsors to submit dossiers in the CTD format; it is not yet required in the United States, but it is highly recommended. By the end of 2004, the Centers for Drug/Biologics Evaluation and Research (CDER and CBER) reported having received over 200 CTD submissions. Yet there remains one additional component of the CTD that sponsors should consider: to "e" or not to "e"? That is the question.

For the electronic CTD (eCTD), the "e" does not simply mean submitting the CTD electronically. The "e" also encompasses the use of extensible markup language (XML), which allows reviewers to browse and search within one eCTD and across global eCTDs. Although this technology remains difficult for a large contingent in the industry, CDER reported having received approximately 40 sample eCTDs as of May 2004.

It is the XML technology that distinguishes the eCTD from a CTD, ie, the eCTD contains an XML backbone that serves as a replacement for the portable document format (PDF) table of contents that would be included in an ordinary electronic CTD submission. The actual process of creating an XML backbone is a job for the functional groups responsible for final submission publishing. There are also several software programs on the market to assist with providing the XML backbone for the eCTD. Therefore, submitting an

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Meet the 2005 Executive Committee

It has already been a busy year for the 2005 executive committee. They have planned the spring conference and a chapter meeting and are busy planning upcoming events. Below please find information about the chapter officers. For contact information, please see the blue box on page 3.

President, Jenny Walker: Jenny is a clinical research professional and medical librarian. She is employed as a clinical research communications specialist III with the communications department at the Duke Clinical Research Institute (DCRI). She works as a medical writer, primarily preparing study-specific material for research sites involved in clinical trials administered by DCRI. She has 20 years experience as a health sciences librarian at the University of Massachusetts in Amherst and as director of a medical library at Durham Regional Hospital. Jenny has a master's degree in library science, with a concentration in academic medical librarianship from the State University of New York at Albany, a bachelor's degree in journalism from UNC-Chapel Hill, and an associate's degree in clinical trials research from Durham Technical Community College. Jenny has also completed AMWA's multidisciplinary core curriculum certificate in biomedical communications.

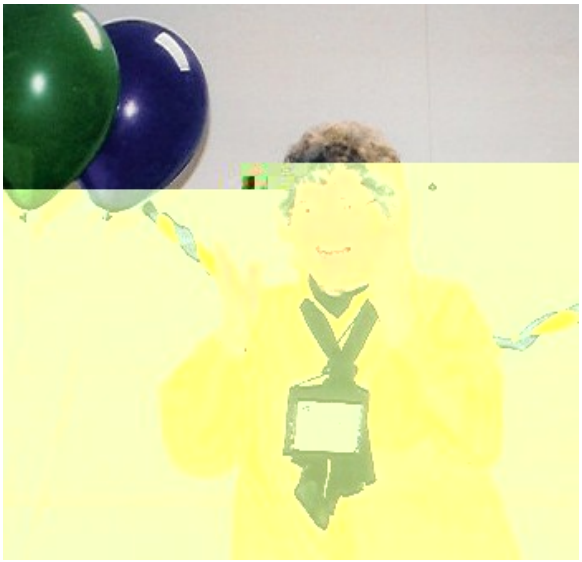
President Elect, Jennifer King: Jennifer is the president and principal writer at August Editorial, which handles a variety of biomedical publications, including protocols, peer-reviewed manuscripts, review articles, book chapters, posters, abstracts, and annual reports. Prior to starting her own business, Jennifer was a senior editor at DCRI and a senior writer at MicroMass Communications. She holds a BS in biology from Wake Forest University and a PhD in cell biology from Duke University. Jennifer has also written articles for national magazines, such as *American Legacy* and US Airway's *Attaché,* and is working on her first novel.

Secretary, Carol Bader: Carol is assistant director of medical writing at Rho, Inc. Prior to that, she was the manager of medical writing at i3 Research. Carol also spent several years in medical publishing, where she edited publications in a variety of areas, including allied health, internal medicine, and orthopedics. Carol has an MS in zoology from the University of Maryland in College Park and a BS in biology from UNC-Chapel Hill. Carol has earned AMWA's core curriculum pharmaceutical certification.

Treasurer, Sam Uhl: Sam is a senior medical editor at NewsRx, a publisher of weekly online health information to research, business, and consumer groups. Articles are grouped into publications by special interest so that subscribers can quickly scan newsworthy, relevant data. Sam has experience writing, training, and managing staff and projects in the health care medical billing, insurance, and pharmaceutical industries. He has also co-owned a successful technical writing and public communications firm with Michael Uhl in Buffalo, NY, prior to moving to North Carolina. Sam has a BA in public communications from SUNY at Buffalo and is enrolled in the AMWA writing/editing certificate program.

Newsletter editor, Tara Hun Dorris: Tara is president of THD Editorial, Inc., which provides medical and environmental writing services. Medical writing services primarily include continuing medical education and regulatory writing. Prior to becoming a freelance writer, Tara was a senior medical writer at i3 Research. Tara has also worked as a staff writer/associate editor at a water quality federation and as communications director for two North Carolina-based non-profit organizations. Tara has a BS in journalism from West Virginia University in Morgantown and a master's degree in mass communications from the University of South Carolina in Columbia. Tara has also completed AMWA's core curriculum pharmaceutical certification.

Chapter events draw large crowds



By Tara Hun-Dorris

Recent chapter meetings have ranged from networking/career discussions to informal birthday parties.

This winter, AMWA members heard from a variety of people who hire medical writers throughout the Triangle. Panelists included Tim Garver, Lineberry Research Associates (representing a contract research organization); Deb Marion, Duke Clinical Research Institute (DCRI; representing a medical journal); Elena Cleary, Schwarz Biosciences (representing a sponsor); John Daniel, DCRI (representing academia); and Carol Williamson, Sandler & Recht (representing an advertising company). They provided detailed advice about what they do and do not look for in new hires.

The fall meeting, held in conjunction with the Triangle chapter of the Society for Technical Communication (STC), was more of a celebration than a formal event. AMWA and STC members gathered to celebrate the 80th birthday of one of the icons of medical/technical editing. Lottie Applewhite, who has served as a mentor and an inspiration to numerous writers and editors, was honored with speeches and cake. Lottie was generous enough to provide wine, making the event quite a celebration (see pictures). Lottie reminisced about getting her start in medical communications and then talked about her career through the years. Approximately 30 STC and AMWA members attended the event.

AMWA is hosting a spring meeting on May 5 (see page 1 for details). Watch the Web site and e-mail for details about upcoming chapter meetings. Meetings are held on weekday evenings, locations vary, everyone is welcome to attend, and the chapter always provides a delicious range of appetizers for snacking.

Did you know…

AMWA is currently encouraging members to actively recruit new members through their "Each One Reach One" campaign. If you refer a new member, you are entered into a drawing for one of three prizes:

- Complimentary registration to the 2006 annual meeting to be held in Albuquerque, NM
- $200
- A copy of AMWA's self-study workshop, *Basic Grammar and Usage for Biomedical Communicators*

For each member you recruit, you get one entry in the drawing, which will take place on September 1, 2005. The form to fill out for referring new members is available on the AMWA Web site, www.amwa.org.

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eCTD (versus an electronic CTD with a PDF Table of Contents or a paper CTD) should not affect medical writers, who will still create all documents in Microsoft Word or WordPerfect and render them to PDF, which remains the standard format for supplying electronic documents.

There is, however, still a steep learning curve for most professionals who contribute to an eCTD submission. Rest assured that agency reviewers are experiencing a similar learning curve as they receive more dossiers in this format. The curve is especially steep for those who are proactively pursuing the ultimate of eCTD benefits – submitting a US Investigational New Drug (IND) application in eCTD format.

In the US, many sponsors assumed that additional guidance for submitting an eIND in eCTD format was forthcoming. CBER did issue an eIND guidance in 2002 that basically followed the model of the original electronic-submission guidance for the US New Drug Application (NDA) (http://www.fda.gov/cber/gdlns/eind.htm); however, CDER chose instead to wait for finalization of the eCTD guidelines. In August, 2003, CDER and CBER issued a combined draft guidance that incorporates the eIND into the logical life-cycle sequence present in the eCTD (http://www.fda.gov/cder/regulatory/ersr/ectd.htm). CDER is now highly recommending that sponsors take advantage of that format to expedite submissions.

Sponsors must consider various factors when deciding whether to submit an IND in eCTD format. The original NDA electronic submissions mainly affected the regulatory affairs, medical writing, and statistical groups responsible for the final submission. Now, internal process changes needed to prepare an eCTD also affect other upstream groups, including writers of data management, clinical trial, nonclinical, and chemistry, manufacturing, and controls documents. Writers in these functional groups need to have some working knowledge of the eCTD guidelines because creating a successful eCTD submission means planning for the eCTD from the moment a sponsor identifies a candidate new chemical entity.

So, what is next? At the very least, savvy sponsors should be preparing documents in the CTD format. Submission writers should know in advance whether the plan is to include paper or electronic documents and plan accordingly, eg, they should use a professional template designed to create documents that are not only consistent and guidance-compliant, but that also meet granularity specifications for the CTD structure. Writers who work with proactive sponsors that are eager to reap the life-cycle benefits of the eCTD beginning with the IND will need further training. Having the willingness and ability to embrace change, technology, and continuous education is paramount in today's, and tomorrow's, pharmaceutical environment.

For more information on this subject, CDER encourages sending questions to ctd@cder.fda.gov.

Peggy Boe, RN, is the director of medical writing at Image Solutions, Inc. (ISI), a leader is providing global regula tory submission software and services, medical writing, and innovative eCTD document template solutions. Peggy is one of AMWA's CTD workshop leaders and is a frequent presenter at Drug Information Association conferences. Peggy's background includes registered nursing and eight years in the pharmaceutical industry.