Regulatory Writing: A Different Breed of Writer

By Michelle Dalton

FROM THE 2009 AMWA-DVC FREELANCE WORKHOP

Regulatory writing is "definitely not for everyone," said Linda Felcone, a freelance medical writer, who admitted it "gets horrible after a few years, but it's nice to get back into it and balance it with other types of writing."

Ms. Felcone presented an overview of the regulatory writing world, what it takes to be a regulatory writer, and how regulatory and other medical writing differ during the AMWA-DVC Seventh Annual Freelance Workshop on April 25, 2009, in Blue Bell, Pa. 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 said. "It's extremely high pressure."

That being said, regulatory writers with expertise are "very much in demand. A lot of work has been outsourced to India, not because there aren't good regulatory writers here, but because there are not enough of them for the demand," she said.

However, new federal regulations that make post-marketing safety reporting more stringent and require postings of study results should lead to additional opportunities for regulatory writers.

Breaking In

Although there seems to be an emphasis on degreed writers (i.e., those with Ph.D., PharmD, or M.D. degrees), there are ways for people with bachelor's or master's degrees to break into the field, she said.

"You could niche yourself into writing only serious adverse event narratives," she said. 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." In fact, she said it's "a rare person who possesses both of those skills."

She recommends freelance regulatory writers use two computer monitors—one for the data and one for the template. "In regulatory reports, there are elaborate tables and multiple attachments and sub-attachments. If you're not already one, become an expert in MS Word and Adobe," she said.

Other areas regulatory writers need to know: 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. She recommends fellow AMWA member Tom Lang's *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers* and *Medical Statistics Made Easy* for those completely new to medical and regulatory writing.

"Let's face it," she joked, "we are nerds. We take a microscopic, fine-toothed, beady-eyed review of the information." And that, in a nutshell, is regulatory writing, she said. For people interested in breaking into the field of regulatory writing, she suggested working for a clinical research organization, or applying for entry-level positions in the regulatory department of large pharmaceutical companies, subcontracting for an experienced regulatory writer, taking classes and reading what's available on the topic.

Learn Your Field, or Any Field

"You need to treat learning this field this like a job," she said. Volunteering at organizations such as 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 are normal ranges, and what are the implications if a subject's range is not normal; read the FDA regulations on what makes a good clinical study or protocol; and (if possible) read an entire protocol.

Some of her advice admittedly came from a colleague—Sally Rich, who also advises not to walk 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," Felcone said.

However, in today's economy, especially, "persistence pays off," Ms. Felcone said. "If you really want to do this and persevere, you can."

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