

# Medical Writing As a Career Choice

Medical writing encompasses a wide variety of writing and editing skills and positions. Because medical writing is so diverse, training and career paths are elusive. This article answers frequently asked questions about medical writing and provides sources for education.

Over the past decade or so, I have been asked at least once a week, “How do you get a job as a medical writer?” As the founding department head for the Medical Writing Department at Amgen, I have had the unique opportunity to interview, counsel, and console a number of writers, potential writers, and hopeful writers over many years. Each of these categories is different, and each evokes different questions and perceptions: writers have a job in writing; potential writers are writers who are employed but not in my department; and hopeful writers are intelligent, educated people who think that medical writing is the job, if not the career, for them. Because I have affiliations with the American Medical Writers Association (AMWA) and the Japanese Union of Scientists and Engineers (JUSE) and I also have a long-time enthusiasm for the profession, I am often asked to speak to hopeful writers. This latter group is the target audience for this article, in which I attempt to answer the most commonly asked questions about a career in medical writing.

## *What Is Medical Writing and What Are Medical Writers?*

Medical writing is a term used for many related fields that involve the clear communication of ideas or knowledge about some aspect of biomedical science. Medical writers do not consider themselves to be technical writers. Medical writers write or edit biomedical communications or teach medical writing to others, whereas technical writers write or edit manuals and service documents.

## *What Types of Jobs Exist for Medical Writers?*

Because the term *medical writer* has a broad definition, medical writers work in many different areas, even within the same company. Some medical writers in the pharmaceutical/biotech/device industry (subsequently referred to as “drug sponsors” for simplicity) write the regulatory documents required to obtain product marketing approval. These documents can include investigators’ brochures, protocols, and clinical study reports. Medical writers may write or assist in writing manuscripts based on clinical trial results, or they may write review articles or textbooks.

### TYPES OF JOBS FOR MEDICAL WRITERS

- College and university professors
- Public relations professionals
- Advertising professionals
- Journal editors and publishers
- Print and electronic media writers and editors
- Pharmaceutical/biotech/device company writers, editors, and managers
- Writers or editors for academic investigators

Some writers are not employed by drug sponsors but are instead employed by contract research organizations (CROs), agencies, or medical centers, or they may be freelance writers.

## *What Education Does a Medical Writer Need?*

No one grows up declaring a wish to be a medical writer, because few people are aware of medical writing as a career. Only a few colleges and universities have programs or interest areas in medical writing. Training courses are available from other sources, however, including DIA and AMWA. Most drug spon-

## REGULATORY DOCUMENTS THAT MAY BE WRITTEN ENTIRELY OR IN PART BY MEDICAL WRITERS

Document	Regional Area Applicable
<b>US Only</b>	
Investigational New Drug Application (IND)	US
Biologic License Application (BLA)	US
Biologic License Supplement (BLS)	US
Integrated Summary of Efficacy (ISE)	US
Integrated Summary of Safety (ISS)	US
New Drug Application (NDA)	US
<b>Europe Only</b>	
Clinical Trial Exemption (CTX)	EU (UK)
Clinical Trial Application (CTA)	EU
Marketing Authorisation Application (MAA)	EU
<b>Worldwide</b>	
Common Technical Document	EU, US, Japan
Clinical Study Report	EU, US, Japan, Australia, ROW
Investigator's Brochure	EU, US, Japan, Australia, ROW

EU = European Union; JNDA = Japanese New Drug Application; ROW = rest of world; UK = United Kingdom; US = United States

sors require potential writers to have at least a bachelor's degree in some area of science, often biology, as a prerequisite for applying for a position. Hiring and grade level often are based on possession of an advanced academic degree, previous industry experience, number of publications as either an author or an acknowledged writer, and general related experience.

Because medical writing, particularly the writing of regulatory documents, is a precise and highly regulated process, many drug sponsors only hire writers with experience. Depending on the job available and its grade

level, the experience needed may be a few years as a laboratory bench scientist or in any position involving some writing. Large drug sponsors will rarely hire writers directly from an undergraduate program.

### *What Skills Does a Medical Writer Need?*

Because medical writers work in diverse areas, not all will have or need the same skill set. In general, medical writers, particularly writers in medical writing groups at a drug sponsor company, have a science background. Some medical writers have journalism backgrounds but possess at least rudimentary knowledge of biomedical sciences. Other skills that are useful or necessary, depending upon the job, are a knowledge of statistics and statistical analyses; computer skills, including word processing, graphics programs, and electronic publishing; ability to work in teams; knowledge of current worldwide regulations; knowledge of publishing and promotional issues; and knowledge of the drug development process.

### *How Do I Get a Job without Having Experience?*

Because the cost of developing a new drug is so high, an estimated US\$800,000,000 per drug, according to the Tufts Center for the Study of Drug Development in 2002, drug sponsors attempt to decrease their time to market as much as possible. Medical writers are often critical members of the team that writes and assembles the marketing applications. Because time is big money, many companies wish to hire only writers who have experience. The process is a veritable catch-22: one cannot be hired as a writer without experience, and one cannot gain experience without being hired.

As stated earlier, no one grows up with medical writing in mind for a career path.

### ACADEMIC INSTITUTIONS THAT TEACH MEDICAL OR TECHNICAL WRITING

Institution	Contact Information	Degree Offered	Comments
DeAnza College, Cupertino, CA	www.deanza.edu	Associate degree; certificate programs	Classes primarily focus on the writing of manuals for technical industry.
San Francisco State University, San Francisco, CA	www.sfsu.edu	Bachelor's degree in technical and professional writing	Students may minor in technical and professional writing, and a certification program is also available.
Texas A & M, College Station, TX	www.tamu.edu	Bachelor's degree in Journalism and Agricultural Journalism; Master's degree in Science and Technology Journalism	Students in the Master's program unofficially specialize in medical writing by including biomedical reporting classes in their studies, by taking biomedically oriented science courses, or by completing an internship in medical writing or a closely related area.
University of California at Berkeley, Berkeley, CA	www.berkeley.edu	Technical writing certificate program	Certificate is offered through the extension program.
University of Southern California, Los Angeles, CA	www.usc.edu	Master's in Regulatory Sciences	Introduction to medical writing as it applies to pharmaceutical, biotech, device, and food supplement industries.
Westminster College, Salt Lake City, UT	www.westminstercollege.edu	Master's of Professional Communications	Students can emphasize medical writing through the selection of appropriate courses.

Almost all medical writers have become writers in some serendipitous manner, perhaps by simply having an advanced degree when an opportunity in a small start-up company appeared.

An excellent way to gain the skills necessary to be hired as a medical writer, particularly a writer who works on regulatory documents, is to obtain a position at a CRO. Many CROs will hire hopeful medical writers with good grades in an undergraduate science program. The starting salary may be lower than that earned by a writer at a drug sponsor, but the CRO will train the hopeful writer in many of the skills needed, including computer skills, writing and editing skills, and knowledge of regulations. Another advantage to working at a CRO is that the CRO writer is often exposed to a wider variety of documents sooner than a writer at a drug sponsor. Given that it takes approximately 10 years to progress a drug candidate through clinical trials, an in-house writer

may work on a new drug application (NDA) or biologic licensing application (BLA) once every 3 to 5 years; a CRO writer may work on parts of several filings for different clients in one year, gaining a broad perspective on international marketing regulations, therapeutic areas, and types of filings.

#### *How Do I Become a Freelance Writer?*

Many people employed in the industry as full-time writers envy the presumed perks of working as a freelance writer: fewer meetings, no direct reports, no supervisor, less politics, and the privilege of working at home in one's pajamas. On the other hand, many freelance writers envy the steady salary and benefits, technical support, camaraderie of office mates, and stock options of writers in the industry.

It is difficult to begin a writing career, particularly as a writer of regulatory docu-

ments, as a freelance writer. Most companies will not hire and train inexperienced hopeful writers, and far fewer, if any, will hire an inexperienced freelance writer to work on regulatory documents. One's time is probably well spent learning the craft at a drug sponsor or CRO and gaining contacts before attempting to embark on a freelance career in writing marketing applications.

Writers of nonregulatory documents (e.g., those who write manuscripts, educational pieces, or promotional materials) may be able to start their careers writing for an academic investigator. In such circumstances, it is often understood that an investigator will

train a writer to write his or her study material exclusively, and that the writer will stay in the position for a number of years.

Medical writing is an exciting and rewarding career. It is personally satisfying to help gain regulatory approval for medicines that help sick people or to have an acknowledgment for writing assistance in a top-tier, peer-reviewed journal. Potential writers need to understand the constraints in obtaining a position at a drug sponsor, but they should also understand that opportunities exist for aspiring medical writers. ■

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