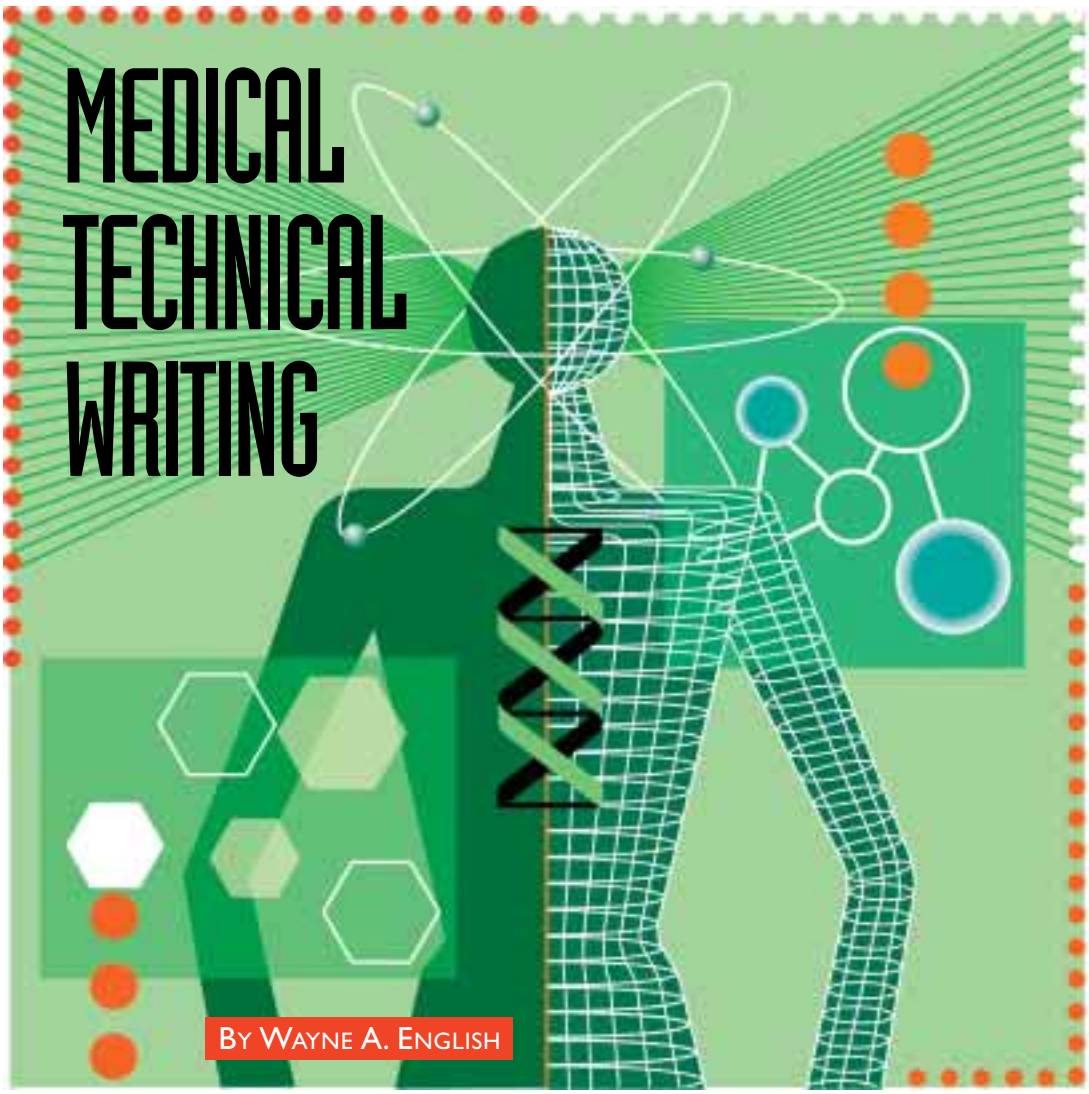
MEDICAL TECHNICAL WRITING



By Wayne A. English

In a multibillion-dollar-per-year industry, medical technical writers are well situated between companies that manufacture drugs and medical equipment and the federal government, which regulates the manufacture of drugs and medical equipment. The government requires that these companies produce specific types of documents, which must be of a very high standard. This situation creates lucrative opportunities for technical writers.

This article will discuss two Food and Drug Administration (FDA) documents: the Premarket Approval (PMA) and the Premarket Notification (PMN), also called the 510(k). While medical technical writers might be asked to write user and technical manuals or sales and marketing material, these documents are outside the scope of this article.

Categories of Medical Technical Writers

Medical technical writers fall into four broad categories.

- **Technical writer.** Salary range: $32,000–$75,000 yearly. This position does not require a four-year degree. Responsibilities include writing instructions and manuals.
- **Quality assurance analyst.** Salary range: $37,000–$84,000 yearly. This position requires a four-year degree. Responsibilities include writing technical procedures, work instructions, and internal QA documents. These documents cover the manufacturing process of the medical device in question. The devices are manufactured under the close eye of a QA specialist.
- **Regulatory writer.** Salary range: $42,000–$90,000 yearly. This position requires a four-year degree. The primary responsibility is writing documents for submission to the FDA, including PMAs and PMNs (described below).
- **Consultant.** Salary range: $75–$100 per hour. This position depends entirely on the writer's background, education, and experience and the client's needs. Consultants normally have extensive education, skills, and experience and are responsible for the most advanced and demanding tasks, such as writing the PMN and PMA.

Necessary Skills

An analytical mind and a strong technical education are your greatest assets in seeking one of these positions. In this business, the ability to write well is not enough. Good candidates are those with at least a bachelor of science degree in nursing, biology, physics, chemistry, physiology, or engineering. These backgrounds will show the client that you have strong skills in physical science or biology. And those skills are imperative for writing high-quality medical documents.

In addition, clients will want to see writing samples. Samples that show you have what it takes include the following:

- Manuals for technical or electronic products
- Procedures and instructions
- QA documents created from your own original research. These documents should be referenced to medical standards and regulatory requirements.
- Demonstrated knowledge of the sections of the Code of Federal Regulations (CFR) that govern the medical industry. See ***www.fda.gov*** and the description that follows.
- Demonstrated ability to interpret corporate policies and procedures to fulfill the intent of the CFR.

Be sure your samples convey your ability to handle complex scientific concepts. The client will want to see that you can think critically and write highly technical

material cogently. You can see why the physical sciences and medicine are such important backgrounds for these jobs and why medical technical writers command high salaries.

Federal Regulations

The FDA directly affects much of what you will be doing as a medical technical writer; therefore, you will need to know the content of Title 21 Food and Drugs Part 800 of the CFR, because it directly pertains to your work. Further, your work will need to satisfy the CFR. You can access the relevant portions of the CFR at ***www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200321*** or obtain a print copy at ***www.access.gpo.gov/su_docs/chklst/chklst.html#21***. Study the CFR carefully. This knowledge is mandatory for working on a PMA or PMN.

You should also be aware of the following government and medical industry links:

- The U.S. Government Printing Office: ***www.access.gpo.gov/index.html***.
- The FDA Center for Devices and Radiological Health: ***www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814***. This link is directly applicable to medical devices.

The Premarket Approval

A PMA is an application to request clearance to market, or continue marketing, a Class III medical device. Some examples of what the FDA would consider Class III devices are: implanted defibrillators, synthetic ligaments, and implanted drug delivery systems. PMAs are the most stringent device-marketing applications required by the FDA. In theory, the FDA has 180 days to review the PMA and make a determination on it. In reality, the review time is usually longer. Before a PMA is approved or denied, an FDA advisory committee reviews it at a public meeting and provides the FDA with its recommendation.

Approval of a PMA is contingent on an FDA determination that the PMA contains evidence and reasonable assurance that the device is safe and effective for its intended use.

Because so much is riding on the PMA, a great deal will be riding on you. The consequences of the PMA are far-reaching for the company—and the patient. After all, these products will be used by the public, perhaps even by you. Think of knowing that you participated in the approval of a device that you, your friends, or your loved ones may someday be intimately acquainted with (or literally connected to). A great deal of money, time, effort, and potential ride on getting a PMA submitted and approved. If it is approved, the company goes to market with the device; if not, they don't.

The regulation governing the Premarket Approval is Title 21, CFR Part 814. Additional information can be found at ***www.fda.gov/cdrh/pmapage.html*** and ***www.fda.gov/cdrh/devadvice/pma***.

The Premarket Notification or 510(k)

The PMN or 510(k) takes its name from Section 510(k) of the Food, Drug and Cosmetic Act, ***www.fda.gov/cdrh/510k.html***. Confusion sometimes arises from the fact that there are two names for the same document. You can download information on the 510(k) in Zip format at ***www.fda.gov/cdrh/510khome.html#download***. Each downloadable Zip file contains information about the releasable 510(k)s for various periods.

The Food, Drug and Cosmetics Act requires device manufacturers to notify the FDA at least 90 days in advance of their intent to market a medical device. Unlike the PMA, a 510(k) requires demonstration of substantial equivalence, which means that the new device is as safe and effective as a legally marketed preexisting device. Further, the FDA determination is based on these criteria:

> A device is substantially equivalent if, in comparison to a predicate device, it has the same intended use as the predicate device and (i) has the same technological characteristics as the predicate device or (ii) has different technological characteristics that do not raise new questions about safety and effectiveness and the sponsor demonstrates that the device is as safe and effective as the legally marketed device.

Many new devices are considered to be substantially equivalent. This does not mean that they have to be identical to predicate devices. It does mean that their safety and effectiveness is not in question with respect to the device's intended use. So then, substantial equivalence is based on the design, energy used or delivered, materials, performance, labeling, biocompatibility, standards and other characteristics. More information on Substantial equivalence can be found on the FDA's Web site. Search for: Premarket Notification Review Program 6/30/86 (K86-3) blue book memorandum.

Under certain circumstances there are simplified paths for obtaining Premarket Notification approvals. They are the Special 510(k): Device Modification and the Abbreviated 510(k) options. The requirements for using either of these options is described in FDA guidance documents available on their Web site.

Finding Work

A search with AltaVista or Google for medical devices will reveal a plethora of leads. Also see the American Medical Writers Association Web page at ***www.amwa.org*** and check with your local technical service agencies, as they will likely be trying to place technical writers in the very companies you are looking for. Also, don't forget the Yellow Pages.

Medical technical writing is a lucrative career for the scientifically astute writer. Take some time to acquaint yourself with 800 CFR, update your résumé, and put together writing samples, and you could be on your way to a new career—one that pays very well indeed.

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