Scientific and Regulatory Writers

OVERVIEW

Scientific and regulatory writers are a subset of medical writers, who work in the pharmaceutical, biotechnology, or research industries, responsible for presenting research findings and data in a clear, concise manner. They are often logical, data-driven individuals, with a desire to present research, write protocols, or draft regulatory documents in an orderly fashion. They are responsible for communicating results from clinical trials to the FDA, drafting prescription leaflets for new drugs, or writing up manuscripts to submit to medical journals, among other roles.

As the pharmaceutical and biotechnology industries grow, there continues to be an increasing demand for scientific and regulatory writers. They collaborate with scientists and clinical researchers to accurately convey scientific findings, and craft regulatory documents for submission to governmental and industry regulatory bodies. Although both terms, regulatory and scientific, may be used concurrently to describe a writing role, there are some differences in responsibilities. Regulatory writing is a field narrower in scope, usually drafting documents for approval of a drug or product by a regulatory body, such as the FDA, while scientific writing may be a term that can be applied more broadly to individuals who write scientific, highly technical, or research documents for various purposes.

	Regulatory Writers	Scientific Writers
Types of Documents Written	-drug package inserts -clinical study reports -protocols -INDs or new drug applications -safety and efficacy summaries -adverse drug experience reports	-IRB proposals -informed consent documents -abstracts and journal manuscripts -other research documents or items for publication or presentation
Intended audience	Regulatory bodies or ethics committees (FDA, scientists)	Physicians, scientists, general public
Employer Type	Pharmaceutical company, Medical Device Company	Research company or medical communications agency

JOB RESPONSIBILITIES

Job responsibilities may vary slightly depending on particular position, but are overall relatively similar between scientific and regulatory writers. The writing is technical in nature, often with very specific protocols delineating outline and content inclusion. Regulatory writers are those considered to draft clinical documentation for research and approval of new drugs by the FDA

(in the US), and are therefore subject to strict guidelines for submission and approval. Scientific writing is a more inclusive term that can refer to those working on technical, research, or protocol type documentation in a variety of scientific or clinical areas, but generally not as tightly regulated as regulatory writing. Scientific or regulatory medical writers should be comfortable with data and analyzing research findings because often projects may include compiling reports from raw data.

Job responsibilities may include:

- Reading statistical reports and compiling data into succinct summaries and reports.
- Preparing research proposals, informed consent documents, abstracts, or journal manuscripts.
- Writing reports on adverse drug incidents, or the safety and efficacy of a drug.
- Writing summaries of different phases of clinical trials for submission to the FDA.
- Drafting INDs or NDAs (for investigation or approval of new drugs) according to common technical document (CTD) protocol for submission to the FDA.
- Drafting prescription information to be included in drug package inserts.
- Collaborate with other professionals including statisticians, clinical researchers, and editors to review protocols, clinical guidelines, manuscripts, or other documents.
- Competently perform medical literature searches to supplement documents.
- Writing or updating of investigators brochures providing all known information about a drug being studied.
- Review of statistical tables and figures for errors, or formulation of appendices

WORK ENVIRONMENT & SCHEDULE

Scientific and regulatory writers can choose to work as a freelancer, taking on writing assignments as they please; work as a consultant to pharmaceutical companies at a medical communications agency; or work as an employee of a pharmaceutical, research, or biotech company. Generally, those working as freelancers have the most schedule flexibility, but also potentially less stable work flow and pay.

Working in scientific or regulatory writing may be stressful at times due to large amounts of data to review, regulatory document guidelines to follow, and writing deadlines to meet for drug submissions. On occasion, long hours may be required to complete a writing assignment or project. As with many writers, hours are often flexible and at the control of the writer, which requires excellent time management skills. Writers need to be comfortable with criticism and revision of their work as necessary for proper submission.

There is often a wide variability in the tasks and domain areas required of scientific and regulatory writers. Physicians hoping for more continuity may be able to specialize by working for a particular clinical research organization focused in a particular field, such as neurology or immunology. They may also find that working in the pharmaceutical industry writing regulatory documents allows them to perfect their craft because although the subject matter for the drug submission may change, the format of the documents is very standardized.

REQUIRED SKILLS AND TRAINING

No specific degree is required to work as a scientific or regulatory writer, although most have at least a bachelor degree in a science or writing-related field. A degree in an area of life sciences such as medicine, pharmacy, microbiology, nutrition, or biochemistry is generally preferred. Many writers have a professional or advanced degree such as RN, MD, or PhD. Scientific or regulatory writers must also be familiar with the protocols guiding the industry in which they work, such as the Common Technical Document (CTD) guiding the outline of documents submitted to the FDA in the pharmaceutical industry. Often employers provide all appropriate resources and updates regarding education of these protocols.

Required skills include:

- Ability to express information clearly and succinctly.
- Clear understanding of medical content and terminology.
- Understanding of research design, statistics, and ability to interpret data.
- Understanding of basic chemistry, pharmacokinetics, and pharmacodynamics.
- Understanding of protocols or governing bodies overseeing industry (such as ICH, CTD, and FDA for pharmaceuticals)
- Comfortable performing medical literature searches and reviews.
- Clearly communicate and collaborate with interdisciplinary teams including scientists, clinical researchers, and editors.

IS THIS THE JOB FOR ME?

Scientific and regulatory writing may appeal to physicians or healthcare providers with an interest in research and clearly conveying technical medical language. Regulatory writers may feel a sense of satisfaction in knowing the work they contribute assists in getting a drug or product to market, influencing the lives of the general public. Depending on the specific position, there is the potential to compose a wide variety of documents for different therapeutic areas, so the variety could provide a stimulating and educational work environment. This is not an area for creative writing, and instructions are very well delineated. Therefore, if you despise ambiguity and like having specific instructions and protocols to follow, this career may be well suited to you.

Physicians who have worked in academic research, written clinical guidelines, or worked in quality improvement (QI) at their institutions may enjoy working in scientific and regulatory writing conveying safety, regulatory, and clinical summary information. Although scientific and regulatory writers often write across a variety of therapeutic domains, subspecialty trained physicians may have the potential to use their extensive knowledge and training to consult or work for a research or pharmaceutical company with a focus in their subspecialty.

As much as writers in these positions are afforded time alone for the actual writing process, there is a lot of collaboration with individuals in other fields. This may not be the field for someone who prefers to solely work alone. A large part of this job is synthesizing reports and

summaries from raw data, therefore those who fear statistics or piles of data may not find this job enjoyable.

Resources:

Hughes, M. Careers in Medical Writing: Regulatory Writing-What's That Then? (2001). Retrieved from http://www.sciencemag.org/careers/2001/05/careers-medical-writing-regulatory-writing-whats-then

Katz, N.R. Your Career as a Biopharmaceutical Regulatory Writer. (2012). [pdf] Retrieved from http://www.raps.org/WorkArea/DownloadAsset.aspx?id=4358

New Medical Writer Toolkit (2017). [American Medical Writers Association resource]. Retrieved from http://www.amwa.org/page/toolkit_Details#Understand_Role

Sharma, S. How to Become a Competent Medical Writer? (2010). Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3149406/