

Medical Writing and Scientific Writing: A Valuable Career

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Abstract: New discoveries, ideas and thoughts emerging in clinical and research field need to be effectively communicated to different health professionals, patients and regulatory departments. All the scientific data should be written in appropriate manner in the field of medical research. A medical writer compiles all the data and then writes it down in a scientific well- structured manner to make them comprehensible to audience. The medical writer's themselves may not be original researcher or scientist but they works with physician/scientist to generate the data in an appropriate manner. It includes writing of regulatory, safety and publishing documents related to educational materials in health and health care products. Scientific writing is the way of publishing manuscript of research, carried out to make it communicable between researchers, scientist and medical professionals. Manuscript writing/construction is the final frontier to make the research publish appropriately without being incomplete. It should be done in stepwise manner. Both require good communication and writing skills to develop an effective communicable data in required format. Medical and scientific writing demand has grown considerably in last few years. Medical field graduates having science and research understanding can look at medical/scientific writing as valuable career option. Purpose of this paper is to increase knowledge about medical & scientific writing job profile and provide a blueprint to develop the skills and aptitude for writing scientific data and manuscript.

Keywords: AMWA, EMWA, AIMWA, CRO's and KPO's.

MEDICAL WRITER

In the last five years, medical writing is 4th most outsource service which increased from an estimated \$345 million in 2003 to \$694 million in 2008 according to Center Watch analysis[1]. Many research studies are developing in medical field, more new drugs are being discovered and medical devices invented in pharmaceutical companies in which various scientific documents need to be formulate for submission to regulatory authorities and also for publishing scientific articles in journals. In this, medical information is generated in appropriate manner for medical professionals as well as for general public or scientific targeted audience. These can be accessed through internet which is a powerful medium for connectivity to new research and scientific studies. While a medical qualification is not critical, deep seated understanding of how to interpret and present clinical data is important. Medical writing, in a broad sense, is not new to India. Ancient Atharva Veda, Sushruta Samhita, and Charaka Samhita from India are well known medical treatises but medical writing as a service industry began in India around 2005[2].

Mainly pharmaceutical/healthcare regulatory companies, Contract Research Organizations (CROs) &

Knowledge Process Outsourcing companies (KPOs), Health Service Providers, Media and Medical Journals, medical institutions, healthcare websites require medical writer. That's why requirement and growth of medical writing professionals is growing tremendously. So, learning medical writing can be the beginning of a full-fledged profession.

Documents for different purposes involve different writing style and skills. So they contribute towards preparation of different types of documents like:

- Writing common technical documents,
- Clinical study reports ,
- Clinical and nonclinical overviews and summaries,
- Research documents,
- Clinical study protocols,
- Investigational brochures (IB),
- Product labels,
- Training and promotional materials, publications, and web content.

Rapid growth in the medical writing business has also made increase in the number of institutes offering medical writing courses. Life sciences and pharmaceutical sciences postgraduates and PhDs have

started moving from the research and development sector to medical writing. A number of medical professionals are seeking medical writing as the preferred choice for their careers. Growing number of aspiring medical writers are trying to become certified medical writing professionals.

TYPES OF MEDICAL WRITING

There are two types of documents which are made by medical writer, one is regulated document which should be formatted according to guidelines and other one is non-regulated type. Each of the types of medical writing is meant for a special set of audience, e.g. doctors, patients & general public, medical representatives (MR) or regulatory agencies. Hence, the level of technical data information is formed in required manner according to the targeted audience[3].

Medical education

For Physicians – textbooks, conference materials, e-learning modules and patient education material.

Marketing health care products

Promotional materials for doctors and MR, product monographs, brochures, hand-outs. Internet content for physicians and patients (consumers)

Article publication

Journal articles / manuscripts (research articles, case reports, review articles), abstracts, posters & presentations

Research document

Clinical trial protocols, research documents, Investigator's Brochure, Research proposals

Journalism

Newspaper and magazine content

Regulatory submission documents – Common Technical Document (CTD) modules such as nonclinical and clinical overviews & summaries, expert reports, safety & efficacy summaries; Periodic Safety Update Reports (PSURs), Periodic Adverse Drug Experience Reports (PADER), Annual safety reports (ASR).

Knowledge required for medical writing

- Domain knowledge which includes: Medical & therapeutic area knowledge, drug development process, pharmacology, drug safety, technical guidelines knowledge
- General Knowledge and writing skills which includes: Language & grammar, literature / reference searching, interpretation and presentation of research data, ethical and legal issue knowledge[3].

Requirement of Solid writing skills and clear understanding

- possess good project management and coordination skills as they need to work with different stakeholders
- avoiding the duplication of efforts especially when working with global teams
- ensure that the documents written by them comply with regulatory or other guidelines in terms of content, format, and structure[4].

Important Medical writing associations:

- AMWA(American Medical Writers Association): founded 1940
- EMWA(European Medical Writers Association): founded 1989
- AIMWA(All India Medical Writer's Association): founded 2007

Medical Writing is NOT Just About Writing

It is a type of diverse project portfolio each day: on any day you can do anything from abstracts to marketing brochures, regulatory submissions to conference material. All of these projects are inter-related, and all activities effectively communicate the science behind company or study. Medical writing is an extremely interdisciplinary field which allows you to work or collaborate with clinicians, regulators, R&D, marketing, clinical education, biostatistics, data management, legal departments, public relations teams. It is a field of infinite learning [5].

Cause of increased demand for Outsourced Services

Increase in outsourcing medical writing in last few years is due to growing amount of documentation required by regulatory authorities during the drug development. Another factor is facing economic pressure from expiring patents which have drastically cut jobs. This makes increase in outsourcing medical writing best option to reduce their costs and still find better ways to get the work done.

Rising of medical writing profession in India: Current status

Medical writing has expanded significantly in India starting from around 15 years ago. Pharmaceutical companies globally preferred India for clinical research outsourcing due to its lower cost and infrastructure equivalent to international standards and availability of a huge talent pool of skilled clinical research professionals and owing to English being the business language of the country. There are different types of organizations employing medical writers in India—both service providers and pharmaceutical sponsors. Some sites suggested that 60–65% of medical writer employed with IT/BPOs, KPOs, or communication companies; around 25–35% in CROs and 5–10% may be working in Pharma companies. However, Indian pharmaceutical company are also in the way towards

outsourced medical writing for product development and preparation of regulatory document for global submission. It has been estimated that India handles 5–7% more regulatory writing than the USA in volume. The global market for medical writing was estimated to be around \$1.3 billion in 2013. That's why there is wide scope for the growth of this business in India and also as a career.

AIMWA basically works towards bolstering the medical writing services in India to meet the international standards. It gives a room for acknowledgement of medical writing professionals. On a secondary level, it also helps in building professional circle as it gives space for scientific discussions and interactions on national as well as international level. Such massive networking helps the interested individuals to get expert advice directly. AIMWA also manages for training and certification in this field to encourage aspiring writers. AIMWA provides a great learning platform for medical writing freshmen as well as professionals[4].

Challenges faced by medical writing in India

Most medical writers received their education on the job rather than through formal education. Formal education from an accredited programme gives a more uniform foundation of knowledge than experience alone or experience combined with short-term training. That causes facing of different problems in medical writing profession by Indian writer[4].

- Lack of professionalism and technical writing skills: There is an inability to present scientific data and arguments in a logical flow, resulting in documents becoming just “data dumps.” We need to make conscious efforts to develop better language and data presentation skills in our writers.
Solution: Medical writing training program
- Lack of global experience: India is new in this field; it requires some more years to overcome this problem. The experience will, of course, come with more years of writing documents in different domains or fields.
Solution: Be part of internal and external training programmes, national and international conferences, and even providing opportunities to work on-site at global locations in every domain.
- Quality issue: There is a perception of “quality” issues when documents are authored in India.
Solution: Improve the writing skills, we need better tools to monitor and improve the quality of our writing.
- Lack of training programme system: there is no standardized training system or governing body in medical writing and institutes in India which can govern the quality of training and give some standards to it.

Solution: Globally collaborated certified training system by industry which may provide internship to potential writing aspirants in reputed companies.

Training program and their resources for medical writer

Training in this discipline usually involves,

- In-house training, this may involve training in drug development process, drug safety and medical statistics, different kinds of regulatory documents & their requirements and style guides.
- Two or three days training by MNCs (Multinational companies) under experienced experts, working in global medical writing.
- Training under senior and experienced person
- Self -study from globally formulated data obtained from different source like internet and regulatory documents.

SCIENTIFIC WRITER

The Internet destroyed the ecology of traditional science journalism, drying up ad revenues and pushing “old school” mass media toward extinction. But the new technology opened a wider landscape for digital science writers online. Before the 1960s, science news was largely technical writing for “trade” or specialized journals. In 1970s, big newspapers and the television networks were assigning a few journalist reporters to a permanent science “beat” that covered everything from asteroids to zygotes. In the 1980s and 1990s, “serious” newspapers and the television networks added science and health correspondents. Degree holding scientists and physicians were on camera and on staff to provide perspective on the news[6]. And so we come to the current age of digital science writing in which research work is communicated between researchers from different sites using scientific writing skills.

Science writers research, write and edit scientific news, articles and features. They write for business, trade and professional publications, specialist scientific and technical journals, and the general media. Writers need to be able to understand complex scientific information, theories and practices. They also need to be able to write in a clear, concise and accurate language that can be understood by the general public.

Publishing manuscripts is the only way by which scientists communicate with each other. Research that remains unpublished in one form or the other is essentially incomplete or undone. Publishing has become vitally important even for clinicians for a variety of reasons, including career advancement and for international collaborations between scientific fields.

However, after overcoming these barriers in conducting a research study, one is faced with another daunting challenge, that is, to write a research work for publication. Writing a manuscript is like giving shape to your ideas.

PATH TO SCIENTIFIC WRITING

- Read the major science news outlets.
- Notice what the writers are doing in their articles, how they bring you in, the metaphors they choose, and how the story is organized.
- Online classes to hone your skill in writing.
- Write every day, for yourself or on a blog to become good writer.

The new kind of science writing is creating opportunities for scientists who can use their bench training to interpret research and their writing skills to make the lab world accessible. There are many types of manuscripts such as case reports/series, review articles, letters to editor and photo essays. This article provides a blueprint of building up the manuscript in step wise manner[7].

Thing to be considered prior to writing

- Review the literature
- Know study data well
- Settled Authorship
- Selection of journal

TITLE AND ABSTRACT

The title and abstract gives reviewers the first impression of the scientific content. The abstract may be the only section available freely; it provides the readers an opportunity to comprehend the rationale, methods and results of your study without reading the full text.

INTRODUCTION

The introduction is where we tell the readers why we did the study. It must be relevant to the study and narrow down from a general overview of the subject to the specific question the study addresses.

METHODS

The purpose of writing the methods section is to enable another scientist to reproduce the study again and compare the results.

RESULTS

As a general rule, the results must satisfy all the questions (that is, outcome measures) raised in the preceding sections.

DISCUSSION

The purpose of the discussion is to give a perspective to your findings.

CONCLUSION

This should be the last statement of the discussion where one summarizes the key element of one's study in light of the existing literature: What is new and why it is relevant to know.

Qualification or basic requirement for science writer

- Science degree (graduates or post graduates).
- Very good writing skills which can be achieved by doing writing from graduation or after that.
- Science graduates may do post- graduation in science journalism in which they can build up their writing career.

You need to show

- Impressive written and oral communication skills;
- Science background with good knowledge of research studies
- ability to think and format the document according to audience
- good team management skills
- determination, flexibility and motivation;
- Good keyword and typing skills in computer programs.

Responsibilities of writer

Activities depend upon the nature of the role and who they are writing for[8]

- Producing articles for publication in print and online according to guidelines
- Attending academic and press conferences.
- visiting research studies
- Reading and research study media and literature, e.g. scientific papers, company reports, newspapers, magazines and journals, press releases and internet resources
- To plan the content of a document for publication.
- Conducting scientific searches.
- Edit the work according to feedback.

Career prospects for science writer

- Begin your career by working in local media or publications with a small audience. After building up your skill, writers can aim to work for larger organisations.
- Increase your knowledge by writing science books. After several years, you can try to move to more senior editorial positions.
- Career advancement at all stages depends on ability, performance and initiative. Writers who want to advance should seek out every opportunity to get a good article in front of an editor and preferably published by a respected organisation.

CONCLUSION

The pharmaceutical industry is observing an upward move for regulatory and manuscript writing in India. In the present pharmaceutical/device industry,

medical writers who have had an education in medical writing will offer potential employers a candidate with broader understanding of the field. In the past few years, Indian writers have evolved to become key members of the clinical study teams in the drug development process and research work carried out by scientists. The Indian writing market has been steadily growing, and the current circumstances clearly indicate that this trend will continue because industry experts believe the demand for medical and scientific writing will continue to grow. The more you do it to increase your skills, the better you get at it in future from these two fields. We hope that this article helps viewers to develop the skill and aptitude to choose medical and scientific writing valuable carrier for their future.

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