PART - I

Introduction

Medical writers play a crucial role, not only in the process of drug development but also during the post-launch period. Being a successful medical writer involves understanding the product life cycle of the drug and having a practical approach towards the development of content for all stages of product life cycle. Success also depends on the personal attitude towards work, effective managerial skills, and the ability to train.

Chapter - 1

Medical Writing

Scientific writing began with the documentation of inventions and publication of theories way back from when man began exploring the laws of nature. This has left behind a legacy of the achievements of several scientists and researchers. Traditionally, scientific writing was limited to researchers, scientists or experts, who had to publish their research (academic writings/publications) for the documentation of their work, recognition, and the mutual benefit of fellow-researchers. Medical writing is scientific writing restricted to the profession of medicine. It is an integral part of the drug development process (right from pharmacological and preclinical/nonclinical studies to Phases I–IV studies), wherein a variety of documents are written based on the target audience. Background research papers are written for researchers involved in drug development. Protocol and regulatory writings are mandatory requirements for getting approval and conducting clinical trials. Original research writing is done based on the clinical trials. Subsequently, other documents are written in support of sales and marketing of the drugs developed. Writing for consumers/patient education literature is an extension of the sales and marketing strategies. In this context, medical writing has evolved as profession and medical writers play a key role in producing high-quality documents or articles for use across the drug development process.

1.1 Medical Writing Evolved as a Profession

Over the past decade, alongside the scientific and technological advancements, medical writing has evolved as a full time profession in the healthcare industry. Career opportunities in medical writing have

provided an alternate career path to people specialized in medical and paramedical sciences, especially for those with a pharmacy background. A sudden bloom in this industry has left many of them clueless about the nature of the work, job responsibilities, and the career growth it offers. Despite the uncertainties, medical writing has evolved as profession owing to a number of reasons:

1. Not all researchers and doctors are good communicators, especially in written communication.
2. Writing is a time-consuming process. For many, time is too precious to be engaged in writing alone.
3. Inadequate or lack of communication of research would question the integrity of research done or the researcher himself. Moreover, miscommunication can lead to trial failures and re-trials, which have serious financial setbacks.
4. Journal publication houses are critical about language; poorly written articles would draw a bad reputation.
5. As such the data generated over years of research and experience is so vast that researchers/doctors themselves are unable to process and utilize it.
6. The majority of the publications are in English, which poses a problem to researchers from non-English speaking countries or to those who fail to adapt to the universal language, English.

1.2 Medical Writing Defined

Medical writing is an effective communication tool that helps translate scientific data into meaningful data, which can cater to the needs of target audiences viz., regulatory agencies, doctors, paramedics, pharmaceutical companies, and patients. According to the European Medical Writers Association (EMWA), “medical writing is about communicating clinical and scientific data and information to a range of audiences in a wide variety of different formats.” According to the American Medical Writers Association, “medical communicators write, edit, or develop materials about medicine and health. They do this by gathering, organizing,

interpreting, and presenting information in a manner appropriate for the target audience".

1.3 Medical Writing – Varieties

Medical writers are involved in preparing various documents during the course of the drug development process: clinical research, regulatory affairs, and sales and marketing (Figure 1.1). Pharmaceutical industries employ medical writers for writing regulatory as well as promotional or marketing-related documents. At times, owing to the diversity in writing, all these documents are not prepared in-house; pharmaceutical industries seek professional services from contract research organizations (CRO) and medicomarketing agencies.

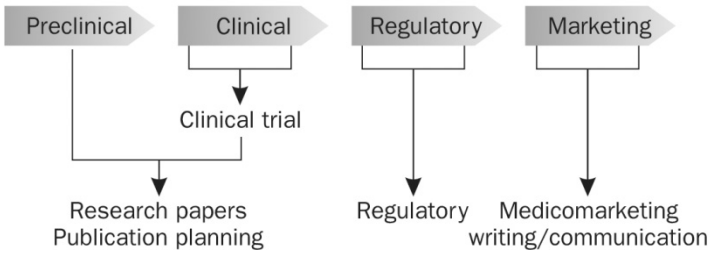

Figure 1.1: Medical writing involved in the corresponding stages of drug development

I would like to discuss only medicomarketing writing relevant to the Indian pharmaceutical industry; nevertheless, it is also worth mentioning that clinicians/academicians as well as pharmaceutical companies approach medical writers to ghost write primary/secondary (review) articles. Medical writers are acknowledged, given co-authorship or sometimes ignored. Medical writing associations are currently making an attempt to legalize ghost writing and give due credit to ghost writers.

The complete spectrum of writing right from drug development up to marketing is discussed briefly through Figure 1.2.

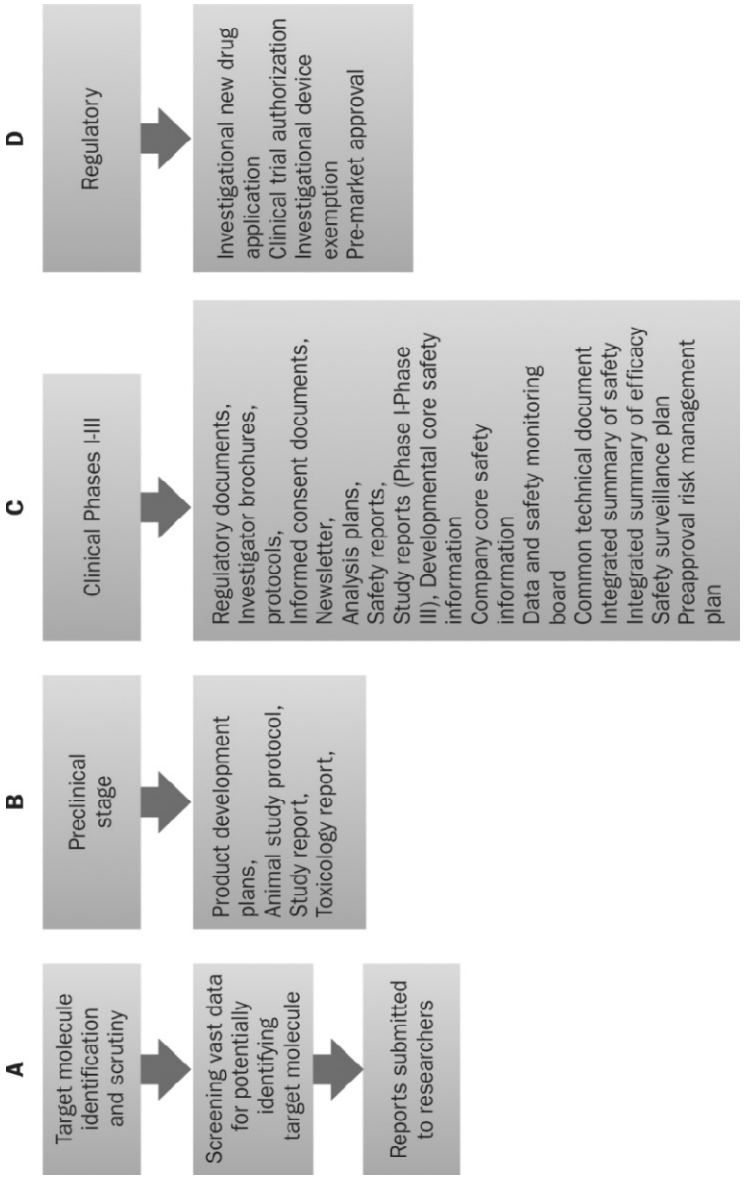

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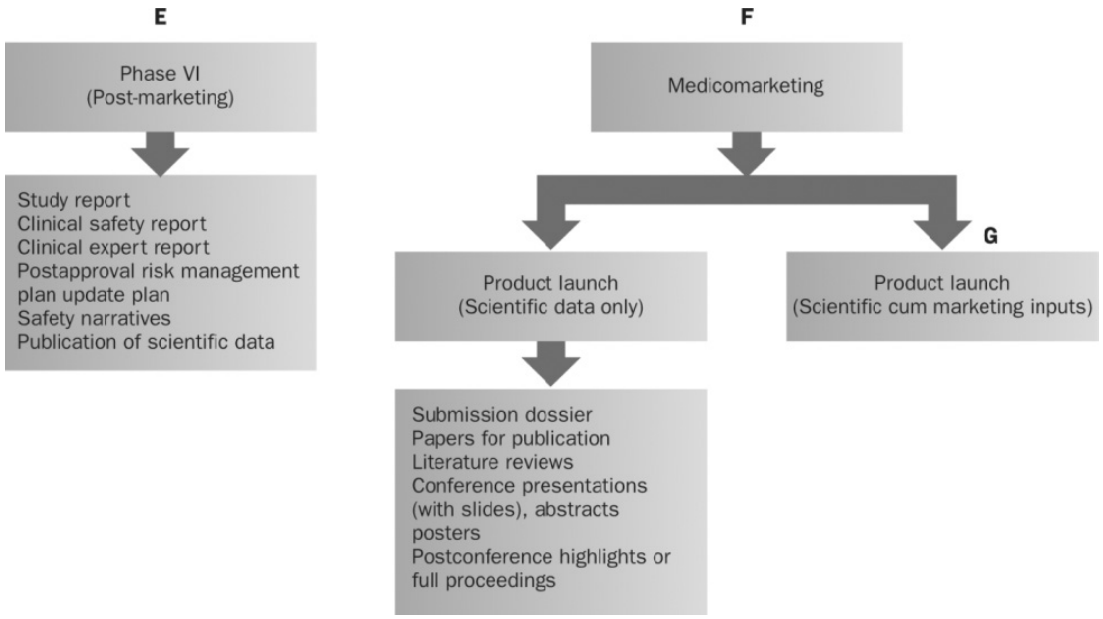
Figure 1.2: Complete spectrum of writing.



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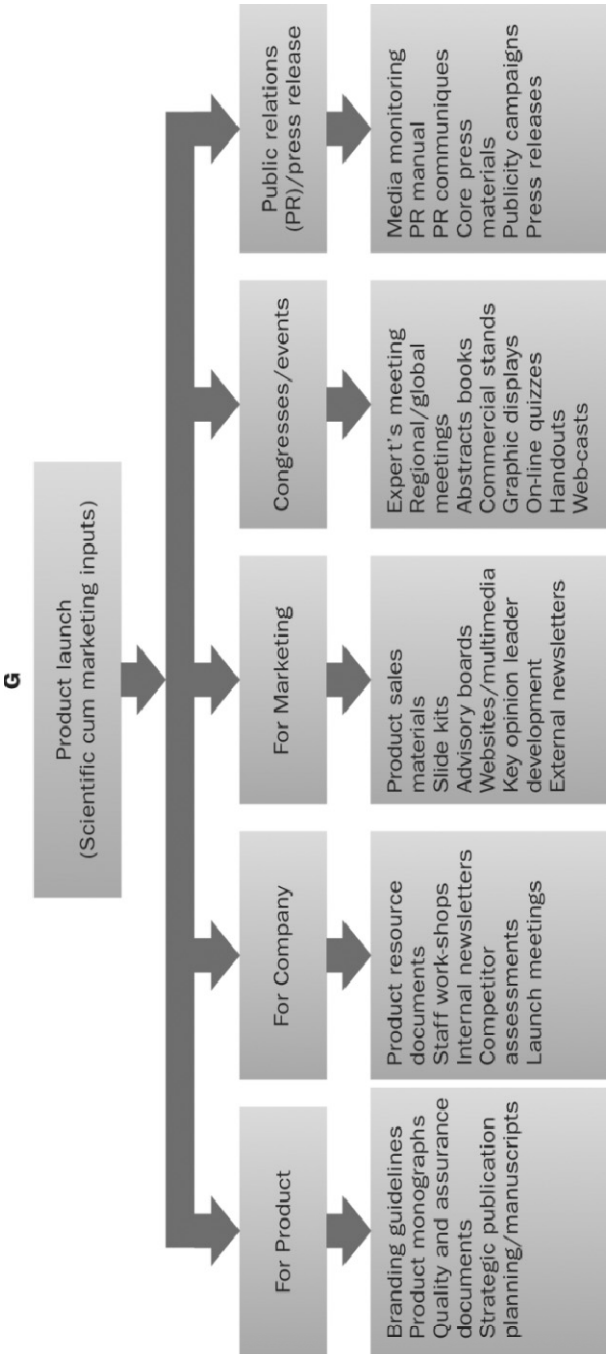

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