Medical writers in drug development and marketing

by Keith Dawes and Katherine Kauper

To be a successful medical writer there are a number of 'prerequisites', often contained in job descriptions: a life science academic education, flawless English language skills, the ability to express medical data accurately, customer focus, a commitment to quality, an ability to be flexible and highly organised, team skills, a familiarity with industry standards, and the ability to work to tight deadlines. These are all valuable skills, but let us go further and explore where medical writers can contribute and hopefully provide some useful advice along the way.…..Read on!

Functions of medical writers

Most medical writers are employed by pharmaceutical companies, contract research organisations (CROs) or communications agencies. There are also freelance medical writers, and medical journalists (or regular contributors to scientific journals) who can be broadly classified as medical writers. The tasks of individual medical writers will vary, as those who work for CROs and the pharmaceutical industry are often employed in the preparation of regulatory documents, whereas communications agencies often prepare promotional/marketing related items. However irrespective of their working environment the role of professional medical writers in preparing and contributing to a finished document is often pivotal.

A well-organised medical writing department, as for a large pharmaceutical company, will have numerous functions. Predominantly these will involve input into scientific documentation, which can be at all levels of drug development (see Box). Consultancy is also a key role for medical writers, clients and colleagues often ask for advice on issues ranging from document templates or regulatory requirements, information for a protocol, style or branding for a product, quality control and marketing messages for a product or presentation. Medical writers also contribute to discussions on development programmes, trial designs, data analysis, product launch and marketing activities and should be proactive in ensuring clarity in wording, document quality, marketing messages and construction of scientific arguments. Effective interaction with team members, external consultants, clients and investigators is also a necessary role of medical writers.

Typically medical writers will be responsible for handling multiple activities within a given project, with back up support from designated team members. If this is not daunting enough, medical writers often work in multiple indications with different drug classes. Experienced medical writers with a broad knowledge of numerous therapeutic areas, drug development, marketing and sales can be seen as an encyclopaedic figure, a 'jack of all trades' and a master of communication.

Product lifecycle: examples where medical writers can contribute during a product lifecycle. For the successful development, launch and maintenance of a product, planned deliverables are interdependent.

1. Identification of target molecules
2. Scrutiny of drug candidates: product development plans
3. Clinical studies (Phase I - Phase IV): regulatory documents, investigator brochures, protocols, newsletters, analysis plans, safety reports, study reports
4. Submission/launch: submission dossier, launch manuals
   The product: branding guidelines, product monographs, Q&A documents, strategic publication planning/manuscripts
   The company: product resource documents, staff workshops, internal newsletters, competitor assessments, launch meetings
   The market place: product sales materials, slide kits, advisory boards, websites/multimedia, opinion leader development, external newsletters
   Congresses/events: expert's meetings, regional/global meetings, abstract books
   Public relations (PR)/press releases: media monitoring, PR manual, PR communiqués, core press materials, publicity campaigns, press releases
5. Life-cycle management/new indications: maintaining product awareness (both through marketing activities and customer education)
6. Patent expiry: strategic market assessments

Team skills for medical writers

Medical writers interact with a variety of people, each with a particular investment in a project, and good team skills are a key prerequisite for employees. Medical writers who are not natural team members (who avoid the telephone in favour of e-mail) or are ineffectual in face-to-face meetings will find their working lives more difficult. Managers will also be required to spend extra time focusing their efforts to complete projects successfully. Hence team skills need to be developed and maintained. This can be done through appropriate training, assigning projects correctly and by nurturing staff to participate more openly. Professional training programmes also instil confidence in new medical writers.

Dealing with different perspectives or stakeholders in a project can also be difficult for a medical writer (see Box). The potential for conflict needs to be minimised. Notably marketing and clinical perspectives clash or marketing and

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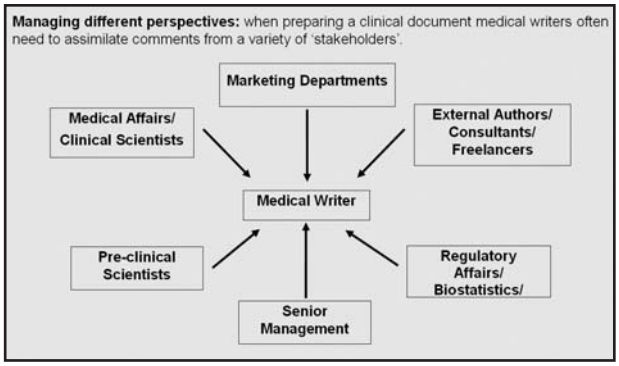
sales may have different ideas (or country affiliates). It is often necessary for the medical writer to facilitate pragmatic discussion between groups to prevent project delays, or to ensure the consistent delivery of product messages. If there is a key deadline to be kept it may be necessary to force issues into the open to get a resolution. Clashes between marketing and external authors are also common. Again open communication along with maintenance of scientific rigor is the best way to resolve these conflicts.



Managing different perspectives: when preparing a clinical document medical writers often need to assimilate comments from a variety of 'stakeholders'.

Effective use of a medical writing department also requires planning as the ability to identify potential bottlenecks and plan contingencies is a key skill in any team effort. Assigning a study report to be drafted and controlled by a medical writer at the start of a project can alleviate other members of an unwelcome burden, and can prevent team members from becoming 'too close' with the potential for delays and team conflict. The medical writer in conjunction with the project leader will be responsible for fielding all input into a document and for chairing appropriate meetings to resolve any issues. If there are a wide variety of opinions, closed, one-on-one meetings should be avoided as issues need to be discussed openly with all team members.

Managing medical writers

Medical writing can be stressful and employees can also feel isolated and unappreciated. Commonly these feelings are increased in small medical writing departments or if line management is inadequate. Hence effective management processes should be in place.

Clear job descriptions need to be written so that employees know what is expected of them (including a list of core skills). Training programmes should be established to allow medical writers to obtain their core skills and to gain new skills, and there should be regular appraisals and professional mentoring. A clear career structure should be established, which must be transparent and based on achieving set goals (outlined in appraisals). Clear line management needs to be established and administrative support should be available. Managers may need to act as internal advocates to enhance the profile of a medical writing department, and medical writers should be considered as experienced professionals who can contribute at all levels of a project. Work variety, new challenges and fair work distribution will also help team building and motivation. Ultimately the aim for an employer should be to train, maintain, develop and retain medical writers.

Practical skills for medical writers

A medical writer's list of skills could also include knowledge of scientific publishing and the requirements of the publishing industry (and also a basic statistical training). Medical writers also need some practical skills to be effective including computing, proofreading and editing skills. For new medical writers the importance of acquiring good proofreading and editing skills cannot be overlooked.

For non-medical writers proofreading is often thought of as a brief review to find and highlight errors, but professional proofreading has a different meaning and is separate to editing. For professionals proofreading is comparison either between two versions of the same document (e.g. a word copy and a typeset copy) or within the document to find inconsistencies and errors. Editing is correcting and improving a document (e.g. correcting grammar, improving sentence construction) for readability, to adhere to a specified editorial style, and to prepare the document for the next step in the process. Often this clear distinction between editing and proofreading becomes blurred for medical writers. However, as document quality should be a primary focus of any medical writing department efforts need to be made to encourage a 'proofreading/editorial reflex' in all new medical writers. Additionally consistency and quality can be ensured through established operating procedures, the use of style sheets/checklists and by ensuring clear review processes for draft documents.

In summary medical writers play a vital role during drug development and post product launch. Moreover experienced medical writers have a number of skills that increase their value to a company, knowledge of different indications and drugs, an understanding of all stages of drug development, launch and marketing, the ability to help pragmatic decision making, and a thorough understanding of quality. Their success is dependent on personality, team skills, effective management, appropriate training and use of practical skills. Companies should be proactive in training, mentoring and retaining these valuable employees.

The authors acknowledge their professional colleagues who over the years have provided the basis for this article through discussion and practical advice.

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Recommended reading for medical writers:

The Chicago Manual of Style: The Essential Guide for Writers, Editors, and Publishers (15th Ed). University of Chicago Press, 2003. ISBN 0226104044.
The Science Editors' Handbook. Maisonneuve H, Enckell PH, Polderman AKS, Thapa R, Vekony M (Eds). Published by EASE, the European Association of Science Editors, 2003. ISBN 0-905988-13-2.
Wager E, Field EA, Grossman L. Good Publication Practice for Pharmaceutical Companies. Current Medical Research and Opinion 2003; 19: 149-154.
Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. From the International Committee of Medical Journal Editors (http://www.icmje.org).
The CONSORT statement. Comprising a checklist and flow diagram to help improve the quality of reports of randomised controlled trials. (http://www.consort-statement.org).