On educating the medical writer

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Abstract

Most medical writers received their education on the job rather than through formal education. These writers may have gaps in knowledge when compared with lists of competencies published by professional organisations in the clinical research and medical writing fields. Formal education from an accredited programme gives a more uniform foundation of knowledge than experience alone or experience combined with short-term training. This article, based on the observations of a regulatory medical writer turned academic programme director, addresses some of the differences between education and training, educational approaches and delivery methods, and potential effects on employment prospects.

Keywords: Medical writing education, Medical writing training, Core competencies, Educational approaches, Educational outcomes

Background

This article is based on my observations as the Director of Biomedical Writing Programs at the University of the Sciences in Philadelphia for the past $4\frac{1}{2}$ years. I began my career as a regulatory medical writer in 1991, at which time I had no education at all in that field. It's not that I lacked education, I had a PhD in Biology, 7 years of post-doctoral experience, and a number of publications to my name. What I had learned by the end of my first week at Wyeth-Ayerst Research was that writing clinical and regulatory documents for the pharmaceutical industry was different from writing basic research results for peer-reviewed scientific journals. Like most medical writers who started their careers in the pharmaceutical and device industries in the 20th Century, I learned 'on the job' supplemented by training that was available through a number of professional organisations. As far as I have been able to determine, no formal education specifically in the field of medical writing was available before 1998 when the University of the Sciences programme began.

Education vs. training

The reader may wonder why I say that education in the field was not available when, clearly, training was available before 1998. Although the two terms, education and training, are frequently used interchangeably, there are, to my mind at least, distinct differences between the two. In the US, academic institutions are usually accredited by regional associations of schools and colleges or by other examining bodies that are recognised by the US Department of Education. Training providers, if they are accredited, are accredited by independent agencies such as the Accreditation Council for Continuing Medical Education or professional organisations. To me, however, the main difference is that education is foundational while training is situational. To clarify further, athletes train for a sport, but if they have come up through the university ranks they will have majored in physical education or a related field. The training builds their muscles and reactions, but the education gives them the understanding of what is happening to their muscles and why certain regimens work better than others.

Other differences between education and training are the extent of exposure to the content, the depth of that exposure, and the detail of assessment of student performance and programmatic effectiveness. Most training lasts from several hours to a day or two at most; assessment is usually straightforward polling of the understanding of content. Agencies that accredit academic programmes prescribe the minimum duration of student–instructor contact that will define a 'credit hour'. A credit hour works out to 15 hours of contact plus additional student preparation and detailed assessment of student performance such as essays and

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research projects over a 15-week semester. Most courses are 2 or 3 credit hours.

Core competencies needed by medical writers

The basic competencies of all professional writers include knowledge of organisation of ideas, grammar, usage, syntax, and the physical and electronic tools of writing. These are not specific to medical writing. Educating medical writers requires teaching the foundations of clinical research including the ethical, scientific, clinical, statistical, and analytical background required for the writer to be an effective reporter of regulatory information and clinical research results. To this end, any formal education programme should provide a curriculum that covers the core competencies of clinical research as described by the Consortium of Academic Programs in Clinical Research (CoAPCR).[1,2] The CoAPCR competency list is summarised in Fig. 1. A model of specific competencies expected of medical writers in general, regulatory, non-regulatory, and management roles has been published by Woolley and Clemow[3] under the auspices of the Drug Information Association Medical Writing Special Interest Area Community. These two competency lists form the basis of the content of an educational programme for medical writers, but do not describe the possible approaches or delivery methods for the content.

Document vs. granular approaches for medical writing programmes

Several approaches are possible in a medical writing programme, but the two that were tried in ours were a document-based approach and a granular approach. A *document approach* means courses that centre on a given document, such as the investigator brochure and its components, or class of documents such as the annual safety report, periodic safety report, and other pharmacovigilance reports. A *granular approach* means courses that examine common components of many documents such as ethics statements and the ethical basis of those statements, adverse event reports and the associated documents such as patient narratives, and efficacy reporting along with the statistical basis of efficacy.

Ultimately, we have found that a blend of document and granular approaches is most successful for the core of the programme. Granules of theory are incorporated into overview courses such as drug development for medical writers, continuing medical education, promotion of medical products, and therapeutics. The central documents that incorporate these (e.g. New Drug Applications, the Common Technical Document, and scientific and clinical journal article writing within publication planning) are taught as applications of the document granules. The details of different

1. Scientific Concepts and Principles of Research Design			
Medical terminology	Descriptive statistics	Research design principles	Design validation
2. Medical Product Development			
Drug/device development cycle	Global regulatory agencies and their roles	Regulatory website familiarity	Conflicting global regulatory policies
3. Ethical Considerations and the Responsible Conduct of Clinical Research			
Evolution of ethical conduct of human research	Current ethical standards applied to human research	Controversies regarding the application of current standards	Revision of ethical standards in parallel with new research areas and results
4. Clinical Study Operation and Regulatory Compliance			
Varying roles of different clinical research personnel	Informed consent documentation	Regulatory and clinical documentation required for clinical research	Case study familiarity
5. Study and Site Management			
Selection of study sites and training of site personnel	Site initiation, monitoring, audit, and closeout. ICH GCP practices	Patient recruitment practices and health record documentation	Investigator relations and investigator meetings
6. Data Management and Informatics			
Clinical trial data collection and data flow	Review, tracking, and resolution of data errors	Data quality control and assurance planning	Database lock and frozen file techniques
7. Communication of Scientific Data			
Plans for communication between sponsor, CRO, and sites	Data presentation methods including tables, graphs, listings	IMRAD publication writing, posters, and other scientific presentations	Literature searching and literature review
8. Professionalism, Teamwork and Leadership			
Professional issues in intellectual property, ethics, plagiarism, and conflicts of interest	Meeting coordination and facilitation	Cultural competency and understanding of cultural diversity	Leadership, team processes, critical thinking, and human resource issues

Figure 1: Eight competency domains and selected competencies from the CoAPCR Domains and Competencies of the Consortium of Academic Programs in Clinical Research. The competencies displayed were selected by the author and is not comprehensive, the complete list of competencies can be found at: https://docs.google.com/file/d/0BzEWyRPWlbdBLWtmM09kUm5uRUk/edit?pli=1.

regulatory roles or marketing writing roles are fleshed out in an on-going stream of elective courses that are available on a scheduled or one-time basis.

Online vs. onsite?

Delivery of content can be online, onsite, or a combination of both. We have found that 100% online delivery of courses works best because it allows the widest possible geographic reach. Most of our students are in North America, including Canada and the United States, but we have had overseas students as well. Our online delivery includes both asynchronous classes (students do not have to be online simultaneously) and synchronous (generally webinars but also some mobile social media delivery). Because there is no requirement to be online at a specific time, asynchronous delivery is probably the most convenient form for students; synchronous delivery is useful because it is more efficient when the content is complex and requires significant question-and-answer interaction between instructor and students.

Conclusion

In the present pharmaceutical/device industry environment, medical writers who have had an education in medical writing will offer potential employers a candidate with broader understanding of the field and more flexibility in performing the tasks required than candidates with some experience but limited background. This translates to candidates who are more likely to benefit from experience and training in an on-going position when hired.

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Author information

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One-day Symposium on Writing for Health Economics and Market Access at the EMWA Conference in Manchester

EMWA is pleased to invite you to a one-day symposium on Writing for Health Economics and Market Access on Thursday 9 May 2013.

Medical writers are increasingly involved in this area, whether through writing reimbursement submissions, helping companies communicate the economic value of their products, or reporting data from economic and quality of life endpoints. Writing is also a key part of the job for many health economic and market access professionals who do not think of themselves primarily as writers.

This timely event includes an overview of economic communication needs, the do's and don'ts of writing for health technology assessment (HTA) submissions, a run-through of the newly published CHEERS guidelines on reporting pharmacoeconomic evaluations, and a session on proving value in elderly populations, who account for such a large proportion of the market for drugs and devices. In addition, a representative from NICE will talk about its decision-making process and the principles of HTA.

We hope to see you there! The symposium is open to members and non-members and offers excellent value for money, so please do spread the word among your colleagues. Register via the EMWA website, under 'Conferences'.

The EMWA Conference is being held at the Manchester Central Convention Complex, Manchester, England, from 7–11 May 2013. This year, the conference opens at 18:00 with a networking event entitled *Better communication means better patient outcomes: vision or illusion?* which promises to make an exciting start to the usual top-quality programme offered.