



Medical writing in a contract research organisation

by Karen Donnelly

I often see postings on the EMWA website's dialogue page from people asking how to "break into medical writing". The EMWA careers leaflet is a good starting point; however, I thought that it would be a good idea for some members to provide their own personal insights. To start the ball rolling, I would like to share details of my own career path and current role in a Contract Research Organisation (CRO) so that others may see at least one of the routes that can be taken.

In the beginning...

Having gained a degree in Neuroscience in what now seems a lifetime ago, I worked in research laboratories for six years. During this period, I found that I preferred reporting my results rather than the actual hands-on process of producing them! I decided to embark on a career as a writer and discovered something called "medical writing" which sounded just what I was looking for. Unfortunately, securing a job in medical writing turned out to be more difficult than I expected, with my initial applications for jobs in medical writing being unsuccessful.

Not to be put off, I decided to look at the other options available to me. Obviously, I had my research background and degree with which to impress potential employers, but also needed to get some writing experience under my belt. I noticed that Quintiles were advertising for a report writer who would be responsible for preparing preclinical reports for their Drug Metabolism and Pharmacokinetics (DMPK) group. This post was suited to my knowledge from the laboratory and an excellent starting point for me to move into the pharmaceutical industry.

Preclinical report writing

For my first job in a CRO environment, I spent over three years preparing preclinical reports for bioanalytical studies, including validation studies for HPLC and LC-MS/MS assays and protein binding studies. Preclinical report writing provided a good grounding in the skills that I now use in medical writing.

The preclinical report writing group for Quintiles' DMPK department was a new venture when I joined the company, with only myself and my line manager for the first couple of years. We had the hard job of persuading analysts that they would benefit from handing over the results of their analyses to ourselves, who could provide reporting and quality control of documents. We gradually became busier, recruiting more staff and building a full work schedule.

In making the transition from laboratory work to medical writing, preclinical report writing allowed me to develop and refine my "technical" skills by using word processing and spreadsheet packages on a daily basis. In addition, it introduced me to working with a CRO, including working with different functional groups and customers, working to deadlines and multi-tasking.

Medical writing in a CRO

Preclinical report writing is an excellent place to start when aiming for a career in medical writing, and one of my colleagues also took this path. Although there are limits to the level of interest involved in preclinical reporting (the majority of reports which I worked on focussed on reporting drug concentration data rather than learning about different indications and drug treatments), it does hone skills in the presentation and reporting of data - skills fundamental to medical writing.

The transition into medical writing

In my fourth year of preclinical report writing, the allure of medical writing and working in clinical (rather than preclinical) research was still at the back of my mind, and I decided to contact the manager of medical writing at Quintiles who, as luck would have it, was in the process of recruiting a new medical writer for her group. I have now been a medical writer within a CRO for nearly three years, and find the challenge of clinical report writing interesting and enjoyable.

Medical writing has allowed me to expand upon the skills I developed during my years spent writing preclinical study reports by allowing me to focus on different indications and drug treatments. In medical writing, the presentation and discussion of results is more involved than preclinical report writing. Obviously, results have to be considered in light of the indication or drug treatment being studied, whereas the majority of preclinical reports focus more on the presentation of hard facts (e.g. concentrations of study drug in plasma samples at different time-points) rather than interpretation and discussion of data (e.g. does a laboratory abnormality correspond to a reported adverse event?).

Working with a contract research organisation

There are three main paths for medical writers in the pharmaceutical industry to pursue in their careers: working with a CRO or pharmaceutical sponsor company, or moving on to become a freelance writer. Personally, I only have experience in working with a CRO and enjoy the opportunities that working with such a company provides.

The market for medical writing is growing at a steady rate and CROs in particular are enjoying an increase in demand for medical writing services as our customers' drug development programmes and the pace of these programmes increase, and with company mergers and reorganisation leading to more outsourcing [1, 2]. This in turn has increased the demand for medical writers by CROs, with an accompanying increase in the range of job responsibilities.

Contract research organisations provide many different writing opportunities across the clinical development phases, from clinical research reports to protocols, manuscripts, patient information sheets and informed consent forms. Writers can be involved in preparing the protocol, the accompanying informed consent form and the subsequent clinical study report for a project and so be involved in the clinical study from the startup activities onwards. Involving medical writers in the drug development process from an initial stage has advantages and can have a positive effect on drug development, one of which being that we are trained to recognise the audience and the way in which a particular project document will be used [3]. In addition, CROs have a wide spectrum of customers who all have different requirements in terms of templates, language, presentation, etc. Such a variety of customers also brings a variety of indications to work on, whether it be hypertension, Parkinson's disease, diabetes or oncology. Medical writers within a CRO can therefore be exposed to a wider variety of documents (and indications) in a shorter timeframe than writers within a pharmaceutical sponsor company [4, 5].

As part of a medical writing group within a CRO, I am provided with a range of resources to assist me in my role. The medical writing group itself provides the full support of a dedicated team, with my colleagues having different levels of experience and knowledge to share. The team structure ensures that there is always someone on hand to provide an independent quality control review of documents, so ensuring the quality and accuracy of our deliverables. In addition, a team is useful if writer's block occurs, and having an independent reviewer ensures that nothing is missed. We also have other colleagues who provide assistance and information. For example, we work very closely with the biostatistics group, who provide us with the study results and are on hand to address any data issues which we may spot during the preparation of our reports. The biostatistician is available to review the clinical study report from a statistical perspective, while we provide medical writing input during our review of statistical analysis plans and associated shells for tables and listings. (A commentary on "life as a statistician in the world of medical writers" appears in an earlier edition of *The Write Stuff* [6]). We also benefit from the advice of medics specialising in particular indications, who are able to review documents and provide assistance in the interpretation of data. Data management, regulatory affairs, quality assurance and project management departments all provide a supporting role. An additional resource is Information Services, which can obtain any required publications. These immediate resources may also be available in pharmaceutical sponsor companies; however, freelance writers may not have such ready access.

Where next?

Working with a global CRO provides many career opportunities. The medical writing career path is sustained by the development of detailed job descriptions and a detailed set of job competencies, which include both technical and non-writing-specific skills (e.g. therapeutic and statistical knowledge), allowing progression from entry level to senior level medical writer [4]. Upon reaching the top of the medical writing ladder, the CRO environment provides alternative opportunities, the most natural progression being project management: in following a job competency framework, medical writers within CROs can develop the necessary skills in project management and financial awareness which will enable transition beyond the medical writing role. Global CROs also provide opportunities to expand medical writing skills by working with, or indeed in, other countries, e.g. within Quintiles, working with our US colleagues expands our knowledge of US medical writing processes and associated regulations.

Of course, other than a CRO, the pharmaceutical sponsor company or freelance routes can be pursued; perhaps someone else would like to take up those stories...

Karen Donnelly

Quintiles Limited, Scotland.

karen.donnelly@quintiles.com

Web: www.quintiles.com

References:

1. Korieth K. Medical writing market appreciation. *The CenterWatch Monthly* 2004;11(7):113.
2. Hooper CL, Zucker JA. Successful outsourcing in medical communication. *American Medical Writers Association Journal* 2005;20(2):75-6.
3. Dyke Ford J, Bernhardt SA, Cuppan G. From medical writer to communication specialist: expanding roles and contributions in pharmaceutical organizations. *American Medical Writers Association Journal* 2004;19(2):411.
4. Gordon K. Medical writing as a career choice – a CRO perspective. *DIA Forum* 2004;40(1):18-9.
5. Foote M. Medical writing as a career choice. *DIA Forum* (2003);39(2):1821.
6. Gordon K. A two-sided test of normality (life as a statistician in the world of medical writers). *The Write Stuff* 2004;13(1):17-9.