



Medical writing: A fine profession in a "fine" city

by Lim Soo Hwee

When I answered an advertisement in the local newspaper for the position of medical writer with a pharmaceutical company a few years ago, I had little clue about its job function. Suffice it to say that I thought I met the criteria described (minimum of a bachelor's degree in the life sciences, a rudimentary knowledge of statistics, and a research background) and wrote in. A few rounds of interviews, an anxious wait, and a telephone call later, and I was sitting in Novo Nordisk's office located in the busy business district of Singapore. The company has a clinical team comprising clinical research associate, data manager, statistician and medical writers in its headquarters in Copenhagen as well as in offices in Singapore, Japan and the US. The climate for conducting trial activities in Asia is increasingly favourable because of Asia's rising awareness of and interest in clinical trials, its potential patient pool, and the lower cost of medical care. Accordingly the company's Asia-Pacific regional office deemed fit to expand the clinical team and I became the second medical writer employed to report the trials conducted.

Recruiting medical writers in Asia is not easy. As a profession, medical writing is relatively unknown outside Europe and the United States; hence experienced writers are difficult to come by. The right candidate should be self-motivated and have sufficient scientific knowledge. Competency in the English, language is essential. Not only have candidates to be competent in, and comfortable with writing and thinking in English but they must also write simply in English. Someone once said he nearly dozed off while reading a trial report. Was the content too dry or the writing too technical, or perhaps it was both? Though no Jules Verne, for want of boring the reader to tears, I always strive to write simply and clearly, and attempt to vary the style of expression, to the extent permissible.

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Is my typical day as a medical writer working in a pharmaceutical company any different from the day of such a writer in Europe or the US? I cannot exactly say. When I first started, there were a couple of days of orientation and training on Standard Operating Procedures (SOPs) – a writer's "bible"

of sorts. Reading the SOPs wasn't exactly a breeze, rather it was quite mind-boggling. Certain processes such as reviewing raw data listings, trial validation plans, statistical analysis plans, and statistical outputs (tables, figures, selected listings) were daunting, not least to say tiring on the eyes. In the early days, putting my signature on the approval page while still ruminating on the analysis plan caused trepidation. By-and-by, things fell into place.

My clock starts ticking once I am assigned a piece of work. I am responsible not only for preparing the report but also for the compilation of the appendix documents, as outlined in the ICH guidelines. Sometimes, I review and provide input to trial design and the protocol as well. There is the trial validation plan (a series of electronic checks on the data) prepared by the data manager, which requires attention, followed by the statistician's analysis plan for the trial. Prior to the data being "ready" for review, I will have to plough through hundreds of pages of raw data listings checking for inconsistencies

The Write Stuff

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that may have escaped the electronic checks applied. When the data are "ready", I participate in the database release meeting and discuss actions required on deviations of importance and relevance to the interpretation of the results. Then, there are the results meetings where the statistician communicates the essence of the trial results to the team. In between all these reviews and meetings, I am busy compiling the documents (as an appendix for regulatory purposes) that are needed for preparing the report. After all this, the real action begins when I have to first digest the tables, figures and listings, ruminate and then put the results into simple English.

Time is of the essence in medical writing as key performance indicators (in weeks) are a measure of a writer's efficiency. Hence, deadlines are an ever present menace. However, a writer often abides by Murphy's Law. That said, accuracy of the report should never be compromised by doing a rush job. Because producing a report involves many processes and personnel, the ability to multi-task and good time management skills are desirable qualities of a writer. Good human relation skills are essential, especially when pushing deadlines.

Other than the preparation of the integrated clinical trial report, I am also actively involved in the coordination, planning and preparation of abstracts, posters and slide presentations for local or international conferences, according to the requests from both internal and external "clients". Then, there is the communication of results in the form of manuscripts. The occasional ad hoc request for translation (from English to Chinese) or vetting of translation text may also come in. It is usually urgent and despite the challenges of time and the language constraints of the medical text, it is highly satisfying when the work is completed on time to the client's satisfaction. Being "experienced" now also means a more varied workload such as coaching new writers. There is also the periodic review, assessment and revision of instructions, the study reports that land in my mail box with an impossible review schedule to meet, or the documentation and archiving, piled high and on the dangerous verge of a paper avalanche at the slightest tremor of the table top. Learning to deal successfully with different personalities is what I consider the most tedious part of the job. However, I derive great pleasure in being able to meet unexpected challenges in the job and the personal growth that accompanies them.

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Although the department does not have a fully functional medical information unit, medical writers such as myself will occasionally assist in the dissemination of medical literature (internal distribution only) or processing the requests for literature from both external and internal customers. Together with an assistant, I am also responsible for maintaining a small library of acquired published manuscripts that has ballooned to nearly 6000 over the years (excluding books and journal subscriptions).

Singapore is a multi-racial nation where people of different faiths coexist peacefully. She is vibrant and continuously re-inventing herself in order to stay ahead of competition. In the years of nation-building, we have learnt to laugh a bit at ourselves. And why is Singapore a "fine city" you ask? If you happen to visit this tiny, sunny island near the equator, you may notice signs that prohibit smoking, littering, food/drinks on the local transport, etc., where a breach will find you a few hundred to a few thousand dollars poorer. Welcome to the "fine city"!

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