



The Future of Medical and Technical Writing

by Stephen de Looze

In many ways, medical writing is its own worst enemy. The reason is that the better the writing, the more invisible it becomes. In contrast to literary writing, where the writing itself is in the foreground and to be enjoyed for its own sake, the aim of medical writing is to transmit complex information and key messages to the reader as unobtrusively as possible. This may be appreciated by some readers, but because most people cannot write well, the invisibility of good technical writing is precisely that—mostly just not seen. For instance, a well-designed table usually looks "obvious", even simple, and may seem as if it took but a few minutes to draft. What the average reader will not perceive are the days of struggle, of grappling with the key message and secondary messages of the table, and experimenting with different designs to produce the best result. The same of course applies to figures, to text, and indeed to overall structure of complex documentation. The quality of the writing will only be obvious to most readers when it is bad—when readers have to rack their brains over some text, a table, or a labyrinth of interrelated documents all of which impede comprehension. Admittedly, many non-writing colleagues do agree that we writers perform a useful function, but this is somewhere between a "glorified secretary" and (at my company) a "walking German-English dictionary". I mention this, not to downplay the essential roles of secretaries and translators, but to stress the unique skill set of writers.

The notion that new technologies will somehow make medical writers redundant arises out of this misconception. It is a notion that has, in different manifestations, been proposed to me over many years. "As far as I am concerned, good science, even if badly written, is all that we need". "A submission is really only about P-values". "With suitable software, a study report can be generated entirely automatically from the data". These are real-life statements that I have noted from senior managers in our company—as it happens, a clinician, a statistician, and a clinical pharmacologist.

Writing Text

I suspect that all professional medical writers have their private collection of awful, or unintentionally hilarious, or plain indecipherable text that they were given to review or edit. Obviously, writers must bring all their language skills to bear on such monsters, and medical prose is of course especially prone to convoluted language. Working on a multi-disciplinary team, the writer usually has to convince the clinician that it is no slur on his or her professionalism for the text to be written simply and clearly for a non-specialist readership.

Writing submission documents, particularly clinical study protocols and reports, can be greatly facilitated by standardization of text modules. Thanks to ICH and other international changes, the scope of such standardization has been much extended. This applies particularly to text that embodies company policy or international GCP requirements, where seemingly innocuous changes to wording can undermine company

standard operating procedures and international regulations. However, clinical trials come in all shapes and sizes, and so standard modules must be devised in different versions to suit different scenarios. These modules can be built into "libraries", and programs such as Word can be embellished with simple macros and on-screen dialogue boxes to facilitate selection of the appropriate text module. Despite such tools, many clinical trials will not fit into the straitjacket of a pre-defined standard, and the writer must review and adapt the standards as appropriate, either for an individual report, a series of reports or a given development. Standard text modules notwithstanding, most of the really important text in a clinical study report will only be written *de novo* as the results of the trial become available and are interpreted, once again drawing on writing skills.

Designing Tables and Figures

"Medical writing" often conjures up "narrative text", but a great deal of medical writers' time is spent on designing tables. Anyone who has worked with tables will know of the many potential pitfalls. Which information is best placed in the table title? How are the columns and rows to be arranged? Which information in the column and row titles? Or footnotes? Which data must be selected, and how should the table be linked to other tables or appended listings? On multi-disciplinary teams, it is often the bio-statistician who needs convincing by the writer that it is not necessary to mention in the table everything that is in the database, that the table is more than an amorphous "container" for any item of data coming off the line printer.

Again, standardization by means of templates coupled with standard statistical programming will facilitate table generation, an activity that is often rate-limiting during the final stages of dossier production. As with standard text, table shells will need frequent adaptation to specific projects, and sometimes, as results become available, alternative designs may emerge as being more appropriate to demonstrate the "message" from the data. The skills and experience of the writer on the team will be crucial to these steps. The application of writing skills to the production of figures is entirely analogous to the generation of tables. With suitable software, libraries of "figure shells", in which wording and figure design are pre-specified, can be created and "populated" with data sets using pre-defined programming.

Building Submission Dossiers

When building submission dossiers, medical writers and their colleagues on project teams are challenged to produce, usually in a timeframe that is frighteningly short in comparison with the overall development time, coherent documentation of hundreds of thousands of pages that will allow regulators access to the mass of data while keeping a comprehensive perspective and a focus on the essential message. This activity has two elements: writing layer upon layer of summary-level documents and assembling the entire package in a logical way, complete with "navigation aids", in other words a clear hierarchical structure, cross-references, indexes and hyperlinks.

Once again, there is a vital need for medical writing skills and experience, and an ability to envisage the entire, finished package very early in its development. This vision will guide the focus on certain studies and analyses, in turn influencing the design of tables and need for certain document modules. Only with this vision can development of the documentation begin far in advance of database closure, and only

this approach will allow a real reduction in overall development time. There is a well-known Chinese saying about the journey of a thousand miles beginning with a single step. You are in big trouble, at least as far as deadlines are concerned! It is often the insight and experience provided by the writer that prevents those first steps from heading down the wrong road. Pharmaceutical developments frequently do not conform to a standard model, and in addition, much of the guidance is vague or incomplete, or, if applied to the letter, will not result in a reviewer-friendly dossier. Many decisions must be taken as to how to apply regulatory guidance to the dossier in hand. The medical writer will sometimes need to convince the regulatory expert on the project team (who often seem overly in awe of "the guidelines") that a certain amount of creative adjustment is needed to accommodate the information available in a coherent manner.

None of these medical writing activities, which relate to dossier *concepts*, will be greatly affected by new technologies, though dossier publishing tools will tremendously benefit the work of the medical writer in technical dossier assembly. For instance, if cross-referencing can be automatically carried over and updated from individual document level to dossier level pagination series, a second round of validation of these links (which some tools may also convert to hyperlinks in electronic dossiers) becomes unnecessary. The new technologies help sharpen the distinction between the more intellectual and more technical elements of creating documents and dossiers. Medical writers in some environments may be involved in both aspects, but the increasing complexity of the technology may lead to sub-specialization.

Customising dossiers for different pharmaceutical regions (notably the USA, the EU and Japan) consumes medical writing resources during the most critical phase of dossier preparation, with the additional challenge of ensuring cross-dossier consistency. New document management technologies may, to a limited extent, permit simultaneous construction of regional submissions by mapping common elements to pre-defined locations in different dossiers. However, many submission-level documents are not common across dossiers. The biggest step forward will be a successful outcome of the ICH M4 topic, the "Common Technical Document". If such a step is achieved, it will be medical writers once again who will be challenged with interpreting and applying the guidance to real-life situations. We must not forget that even within Europe, where a "common technical document" has been in force for many years, the various national regulatory authorities only converged slowly; even today, companies experience startlingly different assessments of their marketing authorisation applications by the different European regulatory authorities.

Developing Standards

Standards are in continuous development and always require interpretation. Experience is proverbially the best teacher, and this is nowhere more important than for developing standards, whether for internal company guidance and templates, or for international regulations. Experienced medical writers can and should take the lead or make major contributions when it comes to developing standards for technical documents. During their daily work, writers must apply internal and external guidelines to real-life documents. On project teams, they must integrate cross-functional contributions. Consequently, they are sensitive to the limits of standardization, they gain experience as major users of standards and templates, and hence can refine standards based on practical experience. As I have stressed earlier, standardization must not be a straitjacket. However, the process of deviating from standards must itself be defined

and regulated, and once again, experienced medical writers provide crucial insights towards achieving this.

The new technologies, if they are to be used effectively, will require their own levels of standardization. An important maxim is "requirements drive technology and not vice versa", and medical writers can make vital contributions towards defining requirements that make the application of the new technologies a success.

Looking into the Future

Far from compromising the role of the medical writer, information technology has opened the door wide to an explosion of healthcare information and an awareness of the need for professional medical writers. I was particularly pleased to hear a comment last year from a prominent and ubiquitous European regulator, who told me that in his opinion, medical writing will be a major growth industry in the years ahead. Regulators are, of course, directly on the receiving end of dossier writing, and so perhaps it is not surprising that recognition of the role of medical and technical writing in assuring quality of regulatory documentation should come from that quarter. I hope that senior managers in the pharmaceutical industry will also come to realize that poor writing will mean longer review times and more objections (even if only because of misunderstandings), and may cast a shadow on the validity of the entire data package. All of this leads to delays in review and approval of submissions—delays which are generally entirely avoidable by good writing, which is a small investment relative to the overall costs of drug development, but one that will pay off handsomely when it comes to getting new drugs to the market more quickly.

It is a truism that any tool is only as useful as the craftsman that uses it. With regard to medical writing, we must keep in mind that electronic publishing systems and other software, standard operating procedures and even regulatory guidance, are tools and as such, essentially a means to an end. That end is the flow of healthcare information, whether to regulatory agencies, physicians or the general public. Medical and technical writers are crucially important to the correct application of these tools and optimising the flow of healthcare information.

To quote Bob Bonk, from his excellent recent book *Medical Writing in Drug Development* (New York: The Haworth Press, 1998), medical writers "capture, meld, disentangle, juxtapose, and reassemble biomedical information into logical packages for varied audiences." These activities require not an electronic but a human brain. Medical and technical writers in the pharmaceutical industry must understand the pharmaceutical research and development process, must understand biomedical information, must understand regulatory guidance and its limitations. They must also bring to bear on this knowledge the insight and rhetorical skills needed to understand the audience, hold the reader's attention, present the key message, guide the reader's interpretation, and gain the reader's confidence. They have a bright and challenging future.

Dr Stephen de Looze
Hoechst Marion Roussel
Bldg. H-840
D-65926 Frankfurt am Main, Germany
stephen.delooze@hmrag.com
Tel: (49) 69 305 7225 Fax: (49) 69 305 80070

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