Challenges within medical writing

Kari Skinningsrud, freelance medical writer in Limwric as, Norway and PR Officer of The European Medical Writers Association (EMWA) 2005-2009 discusses key issues in medical writing.

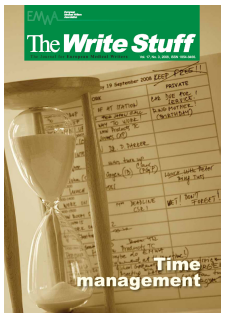
The Executive Committee of EMWA would like to open up the "black box" of medical writing to a broader community and to clarify the role medical writers have in various settings— a role which is often misunderstood. So, who are medical writers, what do they do and what are the key issues and challenges in medical writing?

Some medical writers have a language background, but most have at least one scientific degree and many have worked as researchers— the common denominator is that we enjoy writing. I think one explanation for medical writers being especially nice people (EMWA conferences are very friendly and this is the PR Officer speaking) is that taking the decision to write for others also implies being willing to give others the credit for one's own work, although we do want to be acknowledged.

Some writers specialise within a medical field or become expert writers of one type of document, but most of us work across medical specialties and with several document types. The majority of medical writers work for the pharmaceutical industry (as employees, in CROs or as freelancers) and report the safety and efficacy of drugs in various predefined document formats with regulatory authorities as the target group or in publications intended for medical journals. Others work with health communication through preparation of educational documents or press releases, by summarising key content from conferences or by market support in various ways.

The dubious practice of ghost-writing concerns employing medical writers to draft manuscripts for publication in medical journals, without mentioning or acknowledging them. EMWA is opposed to ghost-writing, and has been proactive to prevent it by producing guidelines on the role of medical writers in developing peer-reviewed publications (1). That being said, we do believe that medical writers have a legitimate role in preparing manuscripts for publication; it should just be transparent how things are done and who has done what. Medical experts always have to take responsibility for the content of a medical publication, but to remain experts in their field they may not have the time necessary to draft and finalise all manuscripts relating to drug development, and still have time left to treat their patients, do their own independent research and keep on top of their field. They may not even be very good writers or communication experts, as different skills are needed to be a good doctor.

Numerous guidelines are available on how to write clinical study reports, investigator's brochures, patient information leaflets, clinical trial overviews and other documents relating to clinical trials, and all medical journals have their own instructions for authors. These instructions have much in common, but differ enough to require thorough reading. Europeans, Americans and Japanese have a set of common guidelines (International Conference on Harmonisation [ICH] guidelines [2]) related to drug development, but the national authorities do not always interpret them in the same way. New guidelines emerge, old ones are revised, and a medical writer has to keep up to date.
Knowledge of guidelines is a "must" for a medical writer. Medical writers must also be able to quickly reach a level of understanding that is deep enough to allow them to have meaningful discussions with the other experts and authors involved in the production of the final document. Drug development is a business where coming first to market means practically everything. When patents expire, sales revenues on the product for innovative pharmaceutical companies are often drastically reduced. The third issue of The Write Stuff (EMWA's journal) in 2008 was about time management. Medical writers tend to become squeezed between late incoming data and the wish by management for "stretch goals" (also known as shorter deadlines!). The squeeze gets steadily tighter as news about competitors drawing closer to the finish line tick in.



Despite this deadline pressure, medical writers are expected to formulate concise, clear and accurate texts that balance the findings within a study, put it all into a larger context, and of course, to never make spelling miscakes such as this one. To be able to do this, it is necessary to get a solid grasp on the hard facts and see them in relation to each other, which necessarily takes some time, and is rather a challenge when revised versions of data sets keep appearing until the day before that "drop dead deadline". Needless to say, detailed, well-controlled processes are essential to do everything as efficiently as possible. The medical writer must also appreciate the entire process, see their own contribution in the right context, and know when there are good reasons to argue their case, and when there are not. The ability to communicate with experts within other disciplines and from other cultures is thus a vital skill. Added to all this, different types of medical writing requires different skills. For example when writing educational material and health communication to non-experts, the writer must be more aware of the needs of a broader audience so the writing, though still rigorous, needs to be more alive, appealing and less detailed than the typical regulatory text.

The pharmaceutical industry is one of the most globalised industries in the world; some have said that "globalisation" often means "we all do it the American way". Indeed, most pharmaceutical companies are managed from the USA, and the FDA is perhaps the most difficult regulatory body when it comes to drug approval, so there is some truth in this statement. Effective cross-cultural communication is a crucial but underestimated skill for medical writers and many other professional groups. Lack of skills in this area has even been identified as the cause of failed mergers, but this has rarely been given sufficient consideration when mergers are planned. In today's world, pharmaceutical companies seem to be merging all the time; departments in different countries and organisations are thrown together often with insufficient preparation on how to combine working procedures and work environments. Mergers across time zones open up for working around the clock, and outsourcing to countries where labour is cheaper (frequently to English-speaking India) is increasing. Managers should realise that some of the money saved in this way needs to be used to facilitate the more complicated work conditions in a business that is already extremely complex.

Medical research has to be well presented for new knowledge to be widely understood, disseminated and implemented. Good medical writing is an uncommon skill, and those who have it need to maintain and sharpen it. EMWA offers training in many areas that will improve medical writers' skills, from drug development to language and writing, medical communication, medical science and a wide range of professional techniques such as statistical thinking for medical writers, data presentation and cross-cultural communication. EMWA's professional development programme (EPDP) offers foundation and advanced certificates in medical writing—the requirements for them and all the training offered are detailed in the EPDP brochure available on EMWA's website (www.emwa.org).

1. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin* 2005;21: 317-321.
2. www.ich.org

Friendly medical writers during an EMWA conference in Malta 2005