

Medical Communication

SECTION EDITOR



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Editorial

Dear all,

In this first issue of 2019, I present an article from Julia Forjanic Klapproth and myself on one of the latest “hot topics” – medical writing apprenticeships.

This topic is something that I know many experienced medical writers feel very strongly about, and it is a topic very close to Julia’s and my hearts’. The ability to mentor and pass on knowledge and support to newer medical writers is one of the greatest things about EMWA and one of the things I personally value the most. However, most people need far more than mentoring and the excellent EMWA workshops to truly grow and develop the extensive skill set needed by a medical writer. Julia and I have spent many years training new (and experienced) medical writers, and we describe our thoughts and concept in this issue’s article. As we explain, the model of apprenticeships is not new to many industries, and we have found that it works brilliantly for medical writing. Surely it should be far more widespread?

This issue’s article is a heartfelt plea to the Industry to take the training of medical writers even more seriously than they do now. It can sometimes be difficult to build a business case for investment in training, and if you are pushing on a firmly closed door, I hope that this article will encourage and help you to open it... even if just a little.

Bestest,
Lisa

How to build a medical writer – new training for a new breed

Training medical writers has never been an easy task – there is a specific and demanding set of skills needed to tease out the crucial messages from data, manage stressed and pressured teams effectively, and keep up with the constant changes in the regulations and updates to templates. It is rare that an individual has all of these skills and most must be acquired and honed. There are many different suggestions and methods to train writers – all with varying degrees of success and aimed at slightly different outcomes. This article suggests a holistic approach of medical writing apprenticeships that the authors have been using for many years, based on the principle that medical writing is a craft not a defined check list, and the best way to learn any craft is from a skilled and experienced “master craftsman”.

Everyone involved in preparing regulatory documentation in the pharmaceutical industry is always on a desperate look out for excellent medical writers with years of experience writing the documents they need. But those mythical beasts are few and far between. The reason for this is that there is very little training provided across the industry to actually produce medical writers – let alone excellent ones.

In fact, although the discipline of medical writing is no longer new, the path to becoming a medical writer is often shrouded in mystery. The training that is available to anyone new to the profession varies considerably and very much depends on the institution hiring the new medical writer. Most medical writers learn the job by the “sink or swim” method: they are hired based on signs of potential and a basic skill set, given a set of journal Instructions to authors or the ICH regulations and some data, and told to “carry on”. Or, they decide to become freelance medical writers – because they have a science degree and they know how Word works, so they just follow the regulations and try to figure it out. It is not surprising that so many documents are so poorly written with this as the status quo of becoming a medical writer.

Some companies offer some form of internal

on the job training, which can be anything from being given the SOPs and internal company writing guidelines and told to ask if they have any questions, right through to specialised sequences of training carried out by both internal and external trainers. However it is done, and to whatever extent, two things are true: there are costs associated with training a new writer in terms of time and budget, and without training, both the writer’s skill set and the end product suffer dramatically.

In fact, good medical writing is more than just a skill set, it is a *craft*, which means that it takes time to learn and hone. Medical writers must take material from various sources, of various quality, and mould that information into a succinct story. On its own, the ability to communicate ideas clearly is a craft unto itself. But in addition, medical writers must have the ability to work with many different contributors and accurately capture what all of those people envision is the right story to tell – often teasing out the key messages from tangential ideas to help keep the story focussed and meaningful. The combination of crafting thought into the written form and guiding teams through mountains of data and sometimes heated and politically charged discussions is a dual skill set that must be developed and refined to cultivate medical writers who are masters of their craft.

Most companies who recognise the importance of training their medical writers work with a mentoring concept, in which less experienced writers have a designated, more experienced writer they can turn to for help, support and guidance. Medical writers are well aware of mentoring – the Australasia Medical Writers Association has a formalised mentoring programme for medical writers¹ and some universities offer mentoring opportunities to students for medical writing.² Mentoring is traditionally defined as “a process in which a more skilled or more experienced person, serving as a role model, teaches, sponsors, encourages, counsels and befriends a less skilled or less experienced person for the purpose of



promoting the latter's professional and/or personal development".³ Combined with other methods of teaching (e.g., workshops, conference attendance, training courses), the rewards of this form of teaching can be immense to both the company and the employee, and higher staff retention rates and job satisfaction scores are seen.⁴ The concept is also embraced in the pharmaceutical industry, and 'mentoring ability' is often a requirement for more senior level writers.

However, mentoring usually takes the form of formalised meetings at regular intervals, with the mentor and mentee going about their daily lives with little interaction in the interim.⁵ To truly learn the craft of medical writing, merely providing a mentor to guide and offer advice on occasion is rarely enough. As for any skilled craft, what is needed is a true apprenticeship. The Lombardo and Eichinger 70/20/10 Learning and Development model states that approximately "70% of knowledge or development

comes from on-the-job experiences, tasks, and problem solving, 20% from feedback and from working around good or bad examples of the need, and about 10% from courses and reading".⁶ Medical writing is no different and should be learned on the job and under the tutelage of a master craftsperson – someone who already has the knowledge and skills to not only explain what should be done, but to *show* the pupil how to do it. This incorporates the traditional methods of workshops and training courses, but with added, intensive, ongoing on-site training given on a one-to-one basis.

Apprenticeships require investment from all involved – from the company that must give the time to its employees to work together, and from the supervisor and apprentice, who must both invest time and energy in a learning experience that can last months or even years. Whilst this approach is well known and finely honed in other industries,⁷ the idea of apprenticeships for medical writing is almost unheard of. Many

articles have been written extolling the virtues of being able to learn under the guidance of a more experienced writer,^{2,8,9} but true apprenticeships involve a level of on the job training and learning that goes far beyond traditional mentoring and are rare.

A medical writing apprenticeship hinges on working closely with medical writers who are very experienced and skilled in the area that the apprentice is trying to learn, and it moves far beyond traditional mentoring. Ideally an apprenticeship will last as long as it takes for a trainee writer to grow into their craft, culminating in their demonstrable ability to produce and manage complete documents on their own to everyone's satisfaction. This is a process that can take anywhere from 3 to 5 years, and varies with each writer. Everything the apprentice writes is reviewed and revised by an experienced writer, who then explains the rationale for the changes made. Working closely with several experienced writers on different projects has the added

advantage of sharing a broader knowledge and experience base with the apprentice. Shadowing the experienced writers as they work with authoring teams helps the apprentice learn what types of issues are worth fighting for and which ones can be accepted as is. They learn and understand what decisions they can make on their own and which ones they need to get team input on; what information they should spend time researching and what they should go back to their experts for. It is the balance of 'getting on with it' to pull the document together from what is available and knowing when to go back to a team to get further advice or trigger important team discussions that makes a good medical writer an added value to their teams. It is the knowledge transfer from the experienced writers to the apprentice on a day-to-day basis at all levels of the job that the apprentice learn how to make the many decisions a medical writer is confronted with.

In addition to the day-to-day guidance provided by the supervisor, a true apprenticeship also involves regular course work over the duration of the apprenticeship programme to deepen the apprentice's theoretical knowledge and academic understanding of the area in which they are specialising. It is possible to meet this need in the context of medical writing by means of on site and online training courses available from organisations such as the European Medical Writers Association,¹⁰ the American Medical Writers Association,¹¹ and the Australasian Medical Writers Association,¹² all of which offer certificates in many areas of medical writing. Other courses of varying length and cost are also available – including master's degree courses.¹³ Unfortunately, these training options are used by many companies as the sole method of teaching their writers, without the essential day-to-day training that new writers need to then learn how to apply the theoretical tools they have learned. If the industry wants and expects to have medical writers who excel at their craft, then these two parts must go hand in hand.

It should also be noted that training is not just for new or inexperienced medical writers – writers of all levels and experiences can and should benefit from ongoing training. The field of medical writing is ever evolving and ever changing and so ongoing continuing professional development is crucial for anyone working as a medical writer, and the issues surrounding the best way to achieve this training applies to writers of every level.

With increasing legislation, decreasing timelines, and the new technological and artificial intelligence-based advances in medical writing,

the demands on medical writers, and the requirements of their skill set are increasing exponentially. We truly are demanding a new breed of medical writers who must not only be expert writers, but robust enough to adapt on an ongoing basis to new regulations, an increasingly stressed pharmaceutical industry, and to having more and more responsibility placed on their time and skills. It is an exciting and thrilling time to be a medical writer – increasing demands bring with them increasing opportunities, but training for this “new world” cannot be done with training courses and mentorships alone.

Good medical writers are born...but excellent medical writers are created through apprenticeships.

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