

How to Build a Medical Writer: Medical Writing Apprenticeships—New Training for a New Breed

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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. One reason for this is that there is very little training provided across the industry that is actually tailored to 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 still often shrouded in mystery. The training available to those new to the profession varies considerably and very much depends on the institution hiring the new medical writer. Many 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 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (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 if this is the status quo of becoming a medical writer.

Some companies (in particular pharmaceutical companies) offer some form of internal, on-the-job training, which can vary from providing the trainee with the SOPs and internal company writing guidelines and letting them ask questions, right through to specialized 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 quality of their end product will suffer.

In fact, good medical writing is more than just a particular skill set, it is a *craft*, which means that it takes time to learn and hone. For example, medical writers must take materials from various sources, of various quality, and mold all relevant information into a succinct and coherent story. On its own, the ability to communicate any idea (whether scientific or not) clearly is a craft unto itself. However, on top of this, 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 focused 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. The newly updated “medical writing competency model” outlines beautifully the core skills, knowledge, and abilities required of a medical writer, but does not address the mechanisms to acquire them.^{1,2}

Most companies that recognize the importance of training their medical writers use a mentorship approach, in which less experienced writers have a designated, more experienced writer as a mentor to provide help, support, and guidance. 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 (eg, 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 Medical writers are well aware of mentoring—the Australasia Medical Writers Association has a formalized mentoring program for medical writers,⁵ and some universities offer mentoring opportunities to students for medical writing.⁶ 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 formalized meetings at regular intervals, with the mentor and mentee going about their daily lives with little interaction in the interim.⁷ 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.”⁸ 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 not only to explain what should be done but also to show the pupil how to do it. This is a true apprenticeship. It incorporates the traditional methods of workshops and training courses, as well as 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, 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,^{6,9,10} but true apprenticeships involve a level of on-the-job training and learning that goes far beyond traditional mentoring and are rare.

In the case of medical writing, it isn't necessary for the “master” to be a single person. A medical writing apprenticeship hinges on working closely with master 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. Working closely with several experienced writers on different projects has the added advantage of sharing a broader knowledge and experience base with the apprentice.

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. As the apprentice demonstrates their ability to handle specific pieces of the document, they are given more complex sections to produce, and the process of review and revision continues until the apprentice is fully competent.

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 through 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 learns how to make the many decisions a medical writer is confronted with.

In addition to the day-to-day guidance provided by the “master” medical writer, a true apprenticeship also involves regular course work over the duration of the apprenticeship program to deepen the apprentice's theoretical knowledge and academic understanding of the area in which they are specializing. It is possible to meet this need in the context of medical writing by means of onsite and online training courses available from organizations such as the European Medical Writers Association,¹¹ the American Medical Writers Association,¹² and the Australasian Medical Writers Association,¹³ 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.¹⁴ 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.

With increasing legislation, decreasing timelines, and the new technological/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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Writing the Basic-Science Hypothesis: A Practical Guide for Medical Writers

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Why can't anyone write a hypothesis? During my relatively short tenure as a medical writer and editor, I've asked myself this question one too many times. My own background is in the basic sciences, in which research is guided by a hypothesis—a scientific statement that guides experiments and is supported or rejected by the experimental outcomes.¹⁻³ The hypothesis is a key concept in the scientific method,¹⁻³ visualized here as a continuous process (Figure).

Despite the prominent place of the hypothesis in basic-science research, it is my experience that PhD-level investigators often struggle to write one (although their research is inherently hypothesis driven). Several things could explain this—deficits in mentoring and graduate-level education in research methods, as well as lax publishing standards, for starters. Although medical writers and editors can't fix these issues at the root, we can help investigators communicate their hypotheses clearly and concisely.

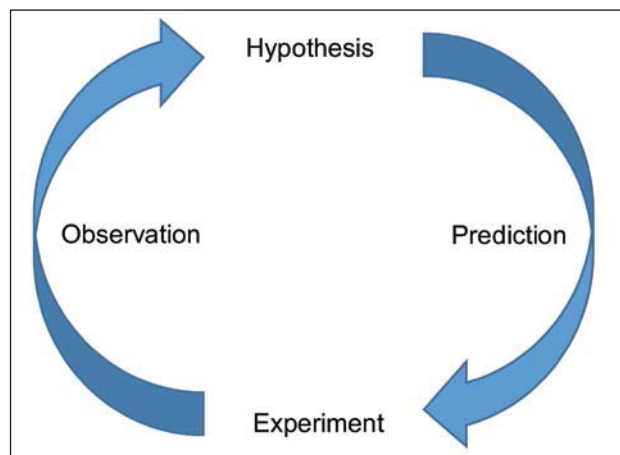


Figure. The scientific method is a continuous process. A hypothesis informs predictions, which inform experiments. Experiments produce observations, which are used to modify the hypothesis.