

The Write Stuff



Training a team of medical writers with diverse backgrounds

(Making a silk purse from...many different types of silk)

by **Heather Bishop**

A recent internet search produced the following statement, "No one grows up declaring a wish to be a medical writer...". Although we might feel a little defensive at this sentiment, there is a truth at the heart of it. A truth demonstrated by the large number of medical writers who come to this profession via another.

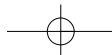
Our medical writing group, established 5 years ago, is no exception to this. Nine of our 10 medical writers began their working life doing something else. Our group includes a former nurse, a pharmacist, a pharmacokineticist, an analytical chemist, a research scientist, a scientific journalist and a project manager. Between us we have 78 years of clinical research experience and 55 years of medical writing experience.

Such a breadth of previous experience is a hugely useful resource and we draw on each other's knowledge on a daily basis. Our diversity of backgrounds means that, as a group, we have experience in many aspects of the clinical research process and there are few medical writing situations that at least one of us hasn't experienced previously.

On the whole, our diversity is a strength. However, the same diversity presents a challenge in terms of ensuring that the team delivers a consistent product, regardless of the individual team members involved. This is particularly important when our final product takes many different forms: a protocol, an informed consent, a case report form, a clinical study report or a clinical overview. The answer to this challenge is training.

Basic training

The backbone of our basic training is a programme of core clinical modules run by Inveresk designed to give new staff an overall awareness of the clinical research process, whatever their previous experience. The hour-long modules relevant for medical writers include study design, adverse event and concomitant medication coding, product safety, Good Clinical Practice and the Clinical Trials Directive. Core courses are augmented by specialist courses, which include statistics and pharmacokinetics. These specialist courses can be adapted to suit the needs of the individual medical writer or a specific project. Additional training is provided through supplementary skills courses such as time management, negotiation skills and assertiveness training, considered by most medical writers to be vital rather than supplemental! A list of mandatory and optional core, specialist and supplementary courses for medical writers has been devised. This list includes target times by which individual courses should be completed, usually within 6 months of joining the company for the majority of the core clinical courses and one year for the specialist courses.



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All medical writers receive training on Inveresk's standard operating procedures (SOPs), style guide and guidelines (e.g. review of statistical analysis plans and a quality control [QC] checklist). SOP training is now conducted using an electronic system of multiple choice tests with automated scoring and recording of results.

The requirement for information technology (IT) training has risen sharply over the last 5 years. The increasing use of electronic publishing systems and ever more sophisticated sponsor-specific templates shows no sign of slowing. Basic IT training currently focuses on standard software and the Inveresk templates. However, external training courses are being used to provide advanced training in areas including desktop publishing software and electronic publishing systems. We expect the quantity and variety of IT training (both in-house and external) to grow over the next few years to ensure the team can continue to meet sponsor requirements.

A more recent innovation at Inveresk has been the introduction of therapeutic area teams (TATs) specialising in oncology, cardiovascular diseases, respiratory diseases, infectious diseases and ophthalmology, with more indications to follow. The primary function of these specialist teams is to provide continuous expertise throughout the clinical research process. The teams also provide staff with ongoing training to maintain cutting-edge expertise. TAT training generally takes the form of lunchtime web-based seminars that are accessible from all Inveresk sites. One or more of the medical writing team is present at every TAT training seminar and feedback is provided to the team.

On-the-job training

During their initial training, junior staff perform QC and review of a wide variety of documents in parallel with a more experienced member of the medical writing team. The resulting comments are then compared and discussed. Only when a member of staff is considered to be competent, are they allowed to perform their own independent QC or reviews. All junior staff are mentored to ensure that advice, assistance and reassurance are available when required.

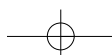
A particularly popular part of our on-the-job training is a day spent on a monitoring visit with a clinical research associate (CRA). This in-the-field experience has proved invaluable for those team members whose previous clinical research experience is data rather than field based.

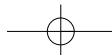
We make good use of our medical writing team's experience by inviting members to present short courses. An especially useful example of this is a presentation on laboratory data given by our former analytical chemist.

Since the earliest days of our group we have held weekly team meetings mainly for scheduling purposes. However, they are also used as a training forum for sharing feedback from the medical writing team, from other departments within Inveresk and from sponsors.

External training

External training is a vital component of our training programme, allowing us to gain access to fresh ideas and new innovations, not only from the trainers but often from other training course participants.





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The EMWA Professional Development Programme (EPDP) forms the core of our external training for new medical writers (and some not so new ones). This decision was made based on the positive feedback on the conferences from those who had attended and we have also had requests from sponsors who were keen to see industry-recognised training and accreditation. EMWA's system of parallel workshops allows training to be tailored to the needs of each medical writer and provides training that is excellent value for money. Specialist external courses are also used to provide additional training on subjects such as statistics and advanced training on various software packages.

Training records and review

Training is currently documented using paper-based training records, supplemented by electronic records of SOP training. The records hold full details of all training, dates and competencies. Training records are reviewed at least annually and new training requirements identified. However, training needs can be identified at any time based on the requirements or interests of the individual medical writer.

Why and where now?

Commitment to a progressive training programme is good for our company, for the individual medical writer and for our customers. In a large team such as ours, training is vital to ensure that the diverse skills that we have are applied consistently.

Future training plans at Inveresk include a move away from paper-based internal training and training records, expansion of our use of the EPDP to all new medical writers and more frequent and specialised IT training to keep ahead of increasingly complex templates and electronic publishing systems. We are also watching the new EMWA advanced level Professional Development Programme with interest.

The diversity of backgrounds within our medical writing group is an asset that we increasingly rely on as studies become more complex and reporting more rigorous. We value this diversity, and plan that our training programmes will support and encourage this, whilst allowing the team to continue to deliver products of a consistent high quality.

Heather Bishop is a medical writer within the European Medical Writing group at Inveresk, a Charles River Company. Inveresk is one of the largest contract research organisations in the world. The European Medical Writing group is managed by Karen Manson.

