

Regulatory Matters

Editorial

More often than not, freelancing means juggling between running a business and writing. Training may not be at the top of the list for freelancers despite its importance in keeping oneself abreast of the changing

regulations, new policies and guidelines, and for maintaining professional performance. In this issue, Kathryn White gives us a few tips on keeping up with training as a freelancer.

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Training: Lessons in self-leadership

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Training courses – such an integral part of our working life as an employee. E-learning modules, standard operating procedures (SOP) updates and, if you're lucky, external workshops where you can escape the office for a day or two and enjoy a free coffee and possibly lunch. Every year, you probably review your training achievements with your manager to appraise your performance and identify any gaps in your experience.

Then, the twinkly promises of freelance life and freedom seduce you. Suddenly, your daily routine is finding clients and then holding on to them, completing projects on time while making sure invoices are issued, chasing payments to protect your cash flow, and ensuring you have more projects lined up. Training and continued professional development fade into the background.

Keeping up as a freelancer

As freelance medical writers, we are business owners. We have many hats to wear and several roles to juggle to keep our enterprise afloat. Yet, we owe it to our clients to keep abreast of the latest regulations, relevant guidelines, and recommendations. Where required, we need to

be aware of recent developments in our chosen therapeutic area(s). After all, we want to offer the best service for our clients, do we not? This also means we should improve our writing skills and knowledge, thereby ensuring we foster longevity in our business and client relationships.

Training becomes solely our responsibility when we are self-employed, so here are a few suggestions for maintaining professional development.

Make time for training

First and foremost, get into the habit of setting time aside for training, just as you would for other business management tasks. Allocate time, perhaps once a month, to review the areas relevant to your business.



Keep a training record

Set up a spreadsheet or equivalent to record the training you complete. Review it periodically or at least once a year so you can see where there are any gaps. Include the date the training took place, the name of the training company or trainer and their accreditations, and the topics covered. I also include whether the training took place online or face-to-face.

I have never been asked by my clients for this documentation, but some freelance colleagues have, so it pays to have this information readily available. One such colleague was made aware of the Italian Decree relating to Clinical Research Organisations. The decree defines the minimum requirement for personnel – including contractors – who perform clinical study activities involving data collection from at least one Italian site. The decree requires “a minimum of 30 hours of applicable training every calendar year”.

It is a good business practice to ensure our training is recent, relevant, and recorded. Furthermore, this record acts as a great prompt for updating your curriculum vitae and summary of experience.

Informal and formal training

List the topics you need to be accustomed to, which will help you to create your training record. Include reading relevant guidelines and recommendations, such as the International Council for Harmonisation (ICH) guidelines, pharmacovigilance regulations, and legislation relating to medical devices, as well as reading clients' SOPs, and regularly checking for updates. All these activities are classed as training, so

document them. Sign up for content alerts from industry-related groups such as the Committee On Publication Ethics (COPE), Transcelerate Biopharma Inc, and therapy-related websites and journals – then information is automatically sent to you.

Become familiar with trusted sources of training and coaches. These include, of course, EMWA workshops and webinars, which offer formal training for which you receive a certificate of completion. Consider completing the EMWA Professional Development Programme and earn foundation and advanced level certificates to add to your training portfolio. Peter Llewellyn of NetworkPharma runs the MedCommsNetworking.com community activity which includes excellent free webinars for everyone and face-to-face meetings around the UK. He invites speakers from a wide variety of companies relevant to medical communications. Online resources enable us to access training globally. For example, the American Medical Writers Association (AMWA) offers webinars and tutorials which can be purchased and downloaded without needing an AMWA membership.

It's very likely that as a freelance writer, you will work across many different therapeutic areas. Therefore, it is imperative that you familiarise yourself with each area you work in. Some clients will only award the work to writers with experience in a therapeutic area. Others will understand that we can read around the topic and gain sufficient understanding to enable us to produce good quality documents. Regulators provide helpful guidance on conducting clinical investigations in various diseases and conditions. For example, the EMA and US FDA have guidelines for conducting clinical studies in patients with respiratory diseases, diabetes, and oncology, to name a few. So, it is worthwhile reviewing the documents on their websites.

Training from clients

Some clients offer their contract medical writers training on in-house SOPs, relevant regulatory guidelines including Good Clinical Practice (GCP) updates, or on business-related information such as data integrity or business ethics, or on the use of in-house or external IT systems such as Datavision or Endnote. Remember to record this training. Clients may offer training in a particular therapeutic area though this is generally informal. They may provide basic background information with the primary purpose of putting their product into context. Information about a particular disease or condition and current therapeutic options can

usually be obtained from clinical documents such as the investigator brochure, protocol, and clinical study report, which may be provided – or requested – when you begin a project.

In the past, I have been asked by a client to produce regulatory documents I hadn't written before. I accepted the work but was transparent about my lack of experience. At the time, I was reviewing some contracts and increasing my fees because it had been a while since I'd done so. For this particular client, I kept my rate unchanged. I felt they were giving me a fantastic opportunity to learn on the job and provided an investment in my future. My strategy paid off and that same company remains a customer and pays me the same fee as others. So, be aware of less obvious training prospects.

Networking

Learn from your peers. Experienced writers have a wealth of knowledge so be brave and ask them questions. I've found medical writers to be a friendly bunch and happy to help. It goes without saying that EMWA conferences and workshops are excellent for picking up valuable tips from fellow writers as well as building up a network of fabulous colleagues!

Don't forget to brush up on your writing skills

We are writers and communicators, so we want to continually improve our skills in this area. There are a wealth of online resources, books, and tutored courses which cover various aspects of writing. However, I believe the best way of refining our writing ability is by writing and reading widely. Where possible, ask a colleague to review your pieces of work occasionally or ask an experienced writer to become a mentor. Each time I have done this, I have learned something new.

One of the most exciting aspects of freelancing is the breadth of topics we may cover compared to when we are employed. Furthermore, many of us write regulatory documents as well as create medical communications content. We cannot be experts in every area we work in unless we specialise. Yes, we can read around a subject, and we have the background training to comprehend scientific/medical information, but we often collaborate with more than one client at any one time. Therefore, we lack the expertise that in-house physicians and regulatory/clinical team members have for a product or project. I think it is important that our clients are aware of this, particularly if they have not worked with medical writers before. Otherwise, clients may think we can work in isolation with very little



background information. The EMWA guidelines which describe the role of medical writers in developing journal articles¹ provide an excellent reference to send to such clients. I feel it's important that they understand our responsibilities and what we bring to the project.

It's not just about medical writing

Before I made the leap into self-employment, I consulted with a wise former colleague of mine who had already set up her own business. She advised me not to go freelance unless I was willing to devote time to learning business management skills. Small businesses often fold within the first five years of setup because of burnout.² It's critical that as a freelancer, you understand the different roles you play as the director/owner of your own business and that you set time aside to learn management skills, including self-leadership. You are no longer an employee – the success of your enterprise is now down to you. Often, our fears are about not finding sufficient clients – but what if you start acquiring too many? This can and does happen. So, you need to put processes and systems in place to avoid you, the solopreneur of your own destiny, from becoming the bottleneck of your own business. If you can afford to do so, I would

highly recommend investing time and money in having business coaching – someone to hold your hand, certainly in the early days of your business, to boost your confidence. For longevity, client relationships must be nurtured, and word-of-mouth is your best business card.^{3,4}

And, finally...

As freelance medical writers, we must be self-motivated to keep abreast of our training – and be willing to invest time and money into our development. We owe it to our clients to brush up on our skills and knowledge so we can continue to create quality output.

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The opinions expressed in this article are the author's own and not necessarily shared by EMWA.

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