SECTION EDITORS



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Out on Our Own

Editorial

Greetings, readers.

Networking is a key tool for running a successful freelance business. As business owners, freelancers not only have to interact with clients, but also seek to develop professional networks with other colleagues. The chief advantage in the latter is that it offers an opportunity for exchanging tips, sharing experiences, increasing client portfolio, as well as collaborating. The biannual EMWA conferences, especially the Freelance Business Forum, are indeed fantastic platforms to do this. However, such face-to-face networking is an activity that has to be considered in light of investment – of time, of money, of effort – and the question is how to engage in effective networking without making a huge investment. In this issue of OOOO, Peter Llewellyn, the Managing Director of NetworkPharma Ltd and a networking leader in medical communication circles, offers a possible solution. Towards the end of 2017, Peter started organising weekly web-based meetings for MedComms Workbook subscribers to log in and participate in group discussions. In his article, Peter discusses his idea and presents testimonials from freelancers who have participated in these online networking events.

The medical device industry is growing in leaps and bounds. Indeed, the symposium at the recent EMWA conference in Barcelona dealt with medical devices. In addition, two of the workshops held at the conference offered attendees an insight into the various regulatory guidelines and laws regarding evaluation and approval of medical devices in the European Economic Area. These developments offer another vast area for medical writers, including freelancers, to be of service. Gauri Jawdekar-Abraham, a freelancer based in Germany, shares with us her story on how she serendipitously got in the field of writing for medical devices, her becoming a freelancer, and what opportunities and challenges she foresees in her journey as a medical device writer.

I hope you will enjoy these articles.

I would also like to inform you that this will be my final editorial for OOOO. Since November 2015, I have had the pleasure and privilege of helping our contributors publish their articles...nay, their experiences, their thoughts, their ideas ... their stories, in OOOO. These were the stories, shared by those who went down the freelance path much before me, that I found useful when I started my freelance business in Germany. I am sure many others as well have found the OOOO as a useful guide. As an editor, I read these stories first-hand, and they always served to tell me that while we freelancers come from all sorts of diverse backgrounds, we are all alike in that we are adventurers. I am glad I had the opportunity to serve the OOOO and it is time now for me to pass the torch on to Laura Kehoe, a fellow Freelance Business Group subcommittee member. Laura is an experienced editor, having been with the journal Hepatology for a number of years before starting her freelance business. I am sure Laura will bring more to OOOO, starting with the September issue, and I wish her the very best.

Many thanks to our brilliant editorial staff for all their help with publishing OOOO and above all, thank you for submitting your articles which make OOOO such a wonderful read.

Satyen Shenoy

Opening up the room

"If you put interesting people together in a room then interesting things happen." I've been running MedComms Networking community activities (www.MedCommsNetworking.com) for more than 11 years and this has always been my mantra. We have proven it many times now, and the same will be true of organisations like EMWA. But what defines the "room" these days?

I would argue that real-life, in-person meetings always offer the most opportunities for those interesting things to happen, but they also present many challenges especially, dare I say it, for freelancers. You're busy. The cost of attending events can be prohibitive. Even if the events (like the MedComms Networking events) are free to attend there is still the cost of travel, and the opportunity cost – you could be working more billable hours instead. Or you might be working from your boat in the Caribbean, where there aren't too many relevant meetings taking place for



medical writers. But in practice, wherever you are based, the odds are that the meeting you really want to attend is never just around the corner at a time when you have nothing else to do! What about the kids? The puppy? The pottery classes? Didn't you become a freelancer to gain more control over these varied aspects of life?

Well, yes. Though I would also argue that as a freelancer you need to recognise you are now running a small business. You are not just a writer

now. You're the IT department, the accounts department, the sales and marketing department, the training department, and much more besides. A business requires investment of time and money to succeed. That must surely include time spent learning from others, meeting prospective clients and collaborators, and – importantly in my opinion – allowing yourselves the opportunity to think outside your box. How else do you develop yourself and your business?

For a couple of years now, I have been running the MedComms Workbook subscription service for freelancers who work in and around medcomms (www.MedCommsWorkbook. com). Whilst that includes sending out work opportunities, I don't find that the most interesting aspect. What interests me most is how we can facilitate education, networking, support, and collaboration amongst those subscribers so their businesses thrive.

I run regular events in the UK where freelancers can meet and chat face-to-face, and I have tried very hard to encourage individuals to organise their own informal local gatherings, but we're constantly facing those challenges we have already identified. So, can I use technology to add another dimension and open more opportunities?

I was sceptical. My experience to date had not been inspiring. I knew the technology was out there, but too often it didn't really work or it required much more money or resource than I had to do it properly. But at the end of last year I started playing with Zoom meetings (www.zoom.us) and my opinion changed. If we aren't at a tipping point yet then we are very close, and the potential benefits are significant.

I now run a weekly video-based meeting I refer to as a "virtual coffee morning", for subscribers to the MedComms Workbook service. The rest of this article will read like an advert for Zoom so I should make it clear I am simply a customer. I have no stake in their service and I'm sure there are other similar services – I just haven't found anything that works quite so well, so easily, and so inexpensively. What interests me mostly, though, are the principles it demonstrates for working smarter, more than the specific platform itself. And how such easily accessible technology is now offering real advantages for groups of remote workers. Well, like freelance writers wanting to network.

So, I asked some of the subscribers to the MedComms Workbook service what they think

and they articulated the benefits so much better than I could.

Working in your "own bubble" can limit your horizons and close your eyes to developments in medcomms that have not yet touched you. It is sometimes easier to shy away from networking opportunities that may challenge your view on things. You just can't appreciate the benefits of sharing experiences, knowledge, and ideas in a safe environment until you give it a go. Don't be put off by corporate speak or hyperbole about networking. At its core is the common sense of getting together to chat about how working could be better; technology transforms this to broaden the reach to a diverse range of people you would never have the opportunity to meet otherwise. Susanna Ryan, Medical Writer, UK

I think Zoom works beautifully. It's a lot less effort to follow what is happening than a teleconference. For me, these drop-in virtual coffee mornings provide reassurance and advice about handling business problems and ideas on making the most of opportunities available for editors.

Petra Roberts, Medical Editor, UK

I've found the Zoom meetings really useful in expanding and strengthening my network. I'm not able to join in every week, but I have found it useful when I do find the time to join the meetings, and I've always come away with some useful information and new contacts. It really helps to know that there is a community and we can help each other with tricky situations or celebrate achievements.

Jen Lewis, Medical Writer, UK

I've been able to hear perspectives/experiences from other freelancers (with diverse career backgrounds), which I've found really valuable. It's always reassuring to hear how other freelancers have managed similar situations to those that I've encountered. It's easy to become isolated when working as a freelancer, so this is a great way to bring the freelance medical writing/communications community closer together, and to learn from each other." **Howard Donohue, Medical Writer, UK** The Zoom coffee mornings are a great chance for me to chat with and share experiences with my fellow freelancers. I have found the Zoom platform very easy to set up and use, and I look forward to our regular meetings. **Mina Varsani, Medical Writer, UK**

I've found the Zoom MedComms meetings to be a proactive practical way of discussing some of the practical everyday financial and business challenges of freelancing. It's good to see and hear first-hand opinions from real people live on screen, rather than just reading these online. You realise you're not the only one facing these challenges. I've picked up some valuable tips, names and solutions for my current and future freelance business. Plus, it's a great way to meet peers and potential clients without leaving your office.

Corinne Swainger, Medical Writer, UK

What I appreciate about the Zoom meetings for freelancers is to see the international perspective of similar challenges and different solutions in different counties for freelancers. Another benefit is that it is simply fun to meet different colleagues in different countries once a week. Freelancing can be lonely sometimes.

Kris Overby, Medical Writer/ Editor, Sweden

I think that Zoom is a fabulous initiative, particularly for inter-country contact. As a freelancer, it's sometimes hard to justify using potential working hours to network, but I think this is a personal objective some of us should probably work on.

Amy Whereat-Terdjman, Medical Writer, France

Zoom meetings with several other MedComms Workbook subscribers have been packed with practical advice, and a refreshing reminder that I am not alone in my diverse freelancing concerns. Although Zoom meetings do not replace face-toface networking, this is certainly the next-best approach in my opinion. Galadriel Bonnel,

Medical Writer, France

As a freelance medical writer who is working from a yacht while travelling, I am delighted to have the opportunity to take part in the Zoom meetings. Due to living and working this way, I have zero opportunity to network face-to-face with other freelancers, so I am finding the discussion about general and specific issues related to the freelance business environment really helpful. Plus, it is good to put faces to names and learn a little bit more about what is going on in the lives of other freelancers. I am definitely feeling more connected to my fellow freelancers – and aware of important issues relating to freelancing – since attending the meetings. Sarah Smith, Medical Writer/

Editor, currently on a boat in Martinique

So yes, even a freelancer based out in the Caribbean can now join in and catch up on the gossip and learn from her peers and gain from the professional support that comes from having a supportive network. Using Zoom we not only have informal conversations, but also can share screens to collaborate on projects, present training talks, involve guest speakers and much more. As for the technology – if I can do it now, anyone can. Give it a go yourself with your own network. There really is no need to feel isolated.

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Finding my way in the world of freelancing - in vitro medical devices

My foray into freelancing

As clichéd as it might sound, I am a true believer in grabbing opportunities. I also firmly believe in creating opportunities for myself. When I embarked upon my trans-Atlantic journey from Los Angeles to Germany 7 years ago, little did I foresee myself considering a career in medical writing, let alone in the *in vitro* diagnostic (IVD) medical device sector. However, when a series of events presented me with the opportunity to write for IVD medical devices, I grabbed it. It has been a satisfying change. There was a big learning curve. The IVD sector, which is classified under medical devices, is an industry in itself. I got to see first-hand the need for qualified writers to communicate product-related material in a precise and articulate way. The power of communication is also reflected in software designs, which needs to be easy to understand and yet have an aesthetically pleasing appearance.

After a change in circumstances, I transitioned into freelancing, already armed with a client. This gave me an opportunity to work across a range of IVD devices instead of writing for just one product line. I was able to work with multiple clients ranging from mid-sized to big companies. So far there are no regrets from a change in career. I enjoy the flexible working hours, especially while caring for a young family.

Opportunities

IVDs have become crucial for providing information that is necessary for making clinical decisions and managing diseases. The German IVD market is dominated by small and mediumsized companies. Frequently they lack dedicated



teams or departments to write medical communication or regulatory documents. In such instances, the work needs to be outsourced, thus providing opportunities for freelancers. 2018 is an especially exciting time for medical writers. On the one hand, they are being recognised as professionals,¹ and on the other hand, there is a need for generating a range of technical documents, especially due to a significant change in the EU regulations for IVD medical devices.

The new IVD Regulation, (EU) 2017/746 (IVDR),² which was published in May 2017, provides a 5-year transition period for manufacturers of IVD devices to implement the necessary changes. This is challenging because it requires a complete change in the mindset of how

things were done before the IVDR came into place. For example, under the old 98/79/EC In Vitro Diagnostic Medical Device Directive (IVDD),³ manufacturers were responsible for ensuring that their products, with the exception of some devices, comply with the essential requirements of the directive before affixing the CE marking. However, under the new IVD regulations, manufacturers will be unable to do so. Instead they will require a notified body to certify their products for them. Overall, the number of regulatory documents to be completed will increase.

Another example of an opportunity for medical writers is the impact that the new regulations will have on the overlap between the IVD and pharmaceutical industries. IVD medical devices known as companion diagnostics (CDx) are used for personalised medicine (also known as precision medicine) to ensure the right therapy for the right group of patients at the right time.⁴ With the new risk-based classification, CDx will fall under class C, the second-highest category. CDx is defined as: [an] IVD device which is essential for the safe and effective use of a corresponding medicinal product to:

- Identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
- Identify, before and/or during treatment, patients likely to be at a risk of serious adverse reactions as a result of treatment with the corresponding medicinal product⁵

Often medicinal products and CDx are developed independently following different schedules and regulatory requirements. They are paired with each other only towards the end of the development phase. This approach leaves a gap in the process of obtaining evidence and validations. More cooperation between the pharmaceutical and IVD industries will be required to co-develop the medicinal product and CDx. Synergistic business models will be seen in the future to enable simultaneous review and approval of both the drug and CDx.⁶ Consequently, medical writers will be required to prepare and coordinate regulatory documents for both.

Challenges as a freelancer and the way forward

After talking with other freelance writers, I realised that my journey to freelancing has been a bit unconventional because it started relatively

quickly in my infant medical writing career. The norm is to first work for companies or clinical research organisations, gather significant writing experience, and then branch out on your own. So, I find myself in a bit of a chicken-and-egg conundrum: How do I find more clients and how do I get more experience? Neither one seems possible without the other.

Instead of heading towards a downward spiral in trying to solve this conundrum, I created my own action plan – invest in experience and keep networking. Organisations such as EMWA have given me the perfect platform to implement that plan. The diverse workshops offered in the EPDP training programme have helped me to expand my medical writing skills. Interacting with members of EMWA and the Freelance Business Group has been an incredible way to learn from their experiences.

This definitely helped and will help me to move forward, albeit with a bit of uncertainty in getting further clients on board. Irrespective of how one starts out on their own, everyone is faced with a unique set of opportunities and challenges. The best way to take chances and overcoming challenges is by not giving up.

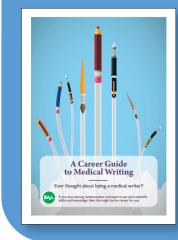
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EMWA's Medical Writing Career Guide

Included in the guide:

- What is medical writing
- The different types of medical writing
- The skills and qualifications needed to be a medical writer
- Where medical writers work and what they do
- How to get started
- How much to expect to get paid
- Career prospects for medical writers

Download at: https://www.emwa.org/resources/useful-reading/ a-career-guide-to-medical-writing/