Getting Your Foot in the Door

Editorial

GYFD congratulates the EMWA Internship Forum team for another great event in Barcelona.

Also in this edition, first time attendee Clare Chang shares with us some insights she gained in her quest for getting that first medical writing job. I am sure we will hear more from Clare in our forthcoming issues.

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Barcelona Internship Forum recap

A little less than half a decade ago I completed my EMWA foundation certificate and began my search for a position as a professional medical writer. Although I was pleased with the workshops and the level of instruction provided by EMWA, I was still without relevant professional experience and felt discouraged by how many open positions required such experience.

At the 2015 Autumn conference in Den Haag, I met Danae Rokanas, another prospective medical writer. Our conversation soon turned to the topic of how one breaks into the medical writing industry without having had a job in it. We thought about how we could use EMWA's resources to develop some kind of a scheme where aspiring medical writers seeking experience could be matched with companies willing to provide such experience. The EMWA Internship Forum was born, and 6 short months later, we had our first event at the 2016 spring conference in Munich.

Beatrix Doerr kindly served as the chair of the Internship Forum for our first two events. After last year's Internship Forum in Birmingham, she passed the baton to me. Even though the Internship Forum was partly my idea to begin with, I have to admit I found it daunting to actually have to lead and organise it!

As the Internship Forum is a relatively young endeavour, the Internship Forum team and I have tried to make adjustments and improvements for each subsequent event. Some of these changes have been logistical, such as the space and time allotted for the event. The ultimate goal is to make the Internship Forum as beneficial as possible for the applicants and the companies that participate.

For the most recent Internship Forum held this past May in Barcelona, we tried to address two possible barriers to participation for prospective medical writers, namely language and location. Many people entering medical writing will be required to demonstrate professional, (near) native-level English skills even though English is their second language. For some prospective medical writers, travelling to the Internship Forum or moving to another city for an internship (or both) may not be possible.

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Sara Rubio was a recent addition to this year's Internship Forum team and was indispensable in shaping our approach to this year's event. Sara gave an opening presentation on her experiences and perspectives as a non-native English speaker working professionally as a medical writer. Being a Barcelona native, Sara also worked behind the scenes in soliciting participation from local medical writing companies, thus giving local applicants the opportunity to find an internship that did not require relocation.

We also had talks from Phil Leventhal on gaining experience for a first medical writing job, and from Stephen Walker on his experiences in offering internships through the Internship Forum. Jackie Johnson was on site to offer CV and career coaching. And of course, we had companies (both Barcelona-based and from elsewhere in Europe) offering internships.

Looking back on the first three Internship Forums, I am of course pleased at what we have accomplished in this short period of time. I am also relieved that my own initiative did not crash and burn when left under my guidance (a big thanks to the Internship Forum team, Sara, Aimée, and Nathan, for their help!) I am looking forward to organising the next event and making it even more beneficial for all participants.

Bis zum nächsten Mal, in Wien! (Until next time, in Vienna!)

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Regulatory medical writing for academic scientists

I'm a classic born and bred research scientist. I'm like one of those lifelong students who has just ridden the education train all the way to the last stop and earned a glowing Ph.D. It's a known fact that there is a gap we need to cross when we move into the clinical research side of things. However, like many before (and after) me, I thought that taking on projects in applied sciences and translational science would help me bridge that distance. Little did I know that when I started scratching the surface of clinical research to get to regulatory medical writing, that I would be entering a whole new world (Table 1).

What is regulatory writing and why do I need to know about clinical research?

Regulatory medical writing is the development of clinical documents that follow the life-cycle of a product that will enter clinical trials all the way to market authorisation and into post-marketing studies. These are also documents that are sent to the health authorities for assessment. Based on this definition, I think it's pretty self-explanatory why knowledge of clinical research is fundamental to regulatory writing.

Shifting my academic research goggles

Scientific training in academia has a very specific mode of thinking when it comes to experimental design and analyses. When one is working with in vitro and animal models, the stakes are not as high; we're moulded to really emphasise innovation and cutting-edge technologies.

Table 1. Differences between academic and clinical research

Area	Academia	Clinical Research
Specimen	• Non-human subjects (cells, tissues, pre-clinical models)	• Humans
Writing	• Individual authorship is important – publish or perish • Do not need to consider regulatory requirements but need to adhere to good publication practices and journal guidelines • Writing and publishing results is an academic requirement to graduate and move up the ladder	• Individual authorship is not important (team effort – usually in the form of an institution or company) • Ethical, legal, and regulatory requirements are important • Writing up results is an ethical and legal requirement
Datasets	• Small (few samples) to large (big data e.g. sequencing datasets) • Open access or accessible if you subscribe to the journal	• Large to very large (can get up to hundreds and thousands of patients) • Clinical trial data transparency
Data analysis	• Less validation requirements	• Qualified statistician does the statistical analysis on the results using validated software
Documents	• Short to long • Page limit restrictions • Examples: dissertations, publications, abstracts, posters, slides	• Long • Less strict with page limits • Examples: clinical study report, investigator brochures, common technical documents, risk management plans. Patient informed consent forms are the exception and are usually short and have a page limit
Audience	• Scientists within similar fields such as supervisors, other academics, and peers	• Varied audience including health authorities, ethics committees, clients, patients, and healthcare professionals
Focus	• Innovation • New breakthroughs • Impact factors • Generating publications • Soliciting research funds	• Safety of patients • Quality of the products • Efficacy of the products • Bringing products to market • Ensuring ongoing safety (pharmacovigilance)
Timelines	• More laid back; long timeline (e.g. 3-6 years for a Ph.D)	• Fast-paced work environment (time is money!)
Communication	• Other scientists • Supervisors • Physicians	• Clients • Health authorities • Key opinion leaders • Biostatisticians • Medical affairs department • Regulators • Healthcare professionals • Clinical researchers

The sexier the molecular tools, the better. All in all, a good proof of concept study is all you need. This means that we're more focused on innovation and discovery and tend not to think about risks, safety, quality, and efficacy. As a consequence, when a hypothesis is formed, the way the experiment we design tend to omit safety. Imagine my personal paradigm shift when I started learning about clinical development, especially when it came to the design and interpretation of results of clinical trials. The quality, safety, and efficacy of treatment products are central to clinical research. Although it's rather straightforward, I was not used to implementing systems (or even thinking about such systems) when I designed an experiment.

So where did I start?

As I was going through my Facebook feeds one day, someone from the Cheeky Scientist Association posted an article entitled, "Get A Clinical Research Job – The Beaver Method." The author of this wonderful piece addresses the frustrations many job hunters go through with finding a clinical research job (highly recommended reading). Essentially, the first thing is to "broaden your understanding about clinical research". Luckily there are many free resources online. The University of California, San Diego on Coursera offers a fantastic programme on drug development that takes you through a thorough understanding of what you have to think about during the different clinical trial phases. Johns Hopkins University on Coursera has a course on the design and interpretation of clinical trials. Not only do they get you into the clinical research mindset, but also get you familiar with the clinical jargon. Following this, I recommend reading the ICH guidelines on Good Clinical Practice (E6), General Considerations of for Clinical Trials (E8) and Structure and Content of Clinical Study Reports (E3). Finally, the US FDA hosts education events for small businesses (Small Business and Industry Assistance Education Events). Most of these are free and you can attend them in person or online. The recorded webinars are also posted on http://sbiaevents.com/past-sbia-events/. I recently attended one and also received an attendance certificate. Honestly, there are so many events and free resources out there – put on your thinking cap, be resourceful!

But I have no experience! How do I overcome the Catch 22 situation?

There is only one word: Networking. I don't want to believe it either because I'm also a rather introverted person. As academics, we pride ourselves in our technical skills, our academic excellence, and being able to shoulder it all. On top of that, maybe one of the reasons why academia is attractive is because of the solitude and being able to work on our own projects. Over time, we're surrounded by more and more academics and it becomes hard to envisage that the world actually values other skills. Networking isn't about going out and meeting a bunch of people, begging for a job, or trying to impress a future boss. Networking is taking an interest in the people you're engaging with. Listen to their stories. What do they need and how can you help? Network to help you expand your professional network and to talk to industry professionals and hear about their lives. Large companies might be a dream, but you won't know what it's really like on the inside unless you know an insider! When you start networking and reaching out, people will start taking notice of you. You need to let people know who you are and why they should care.

Tools of the trade?

You can find professionals on LinkedIn and through LinkedIn groups. One way of networking online is by writing a simple email to compliment someone's blog or writing. In-person networking such as career fairs and local networking events gives you that personal touch. It also helps to be targeted by joining professional associations (such as EMWA). Finally, networking takes time. Rome wasn't built in a day. You need to stay committed. Remember to follow up. It took about 3 to 6 months before most of my contacts warmed up to me. Some may never and that's fine, too. It's important to find the right chemistries for you. Networking is a marathon for your entire career. It has taken me a little over a year since my first (out of 200+) applications to find the right position. I have just been offered an Associate Manager, Medical Writing position for a small CRO in Shanghai. There is a saying from China that roughly translates to "Sometimes you don't hold on because you see hope, rather, it is because you held on that hope appeared".

References

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