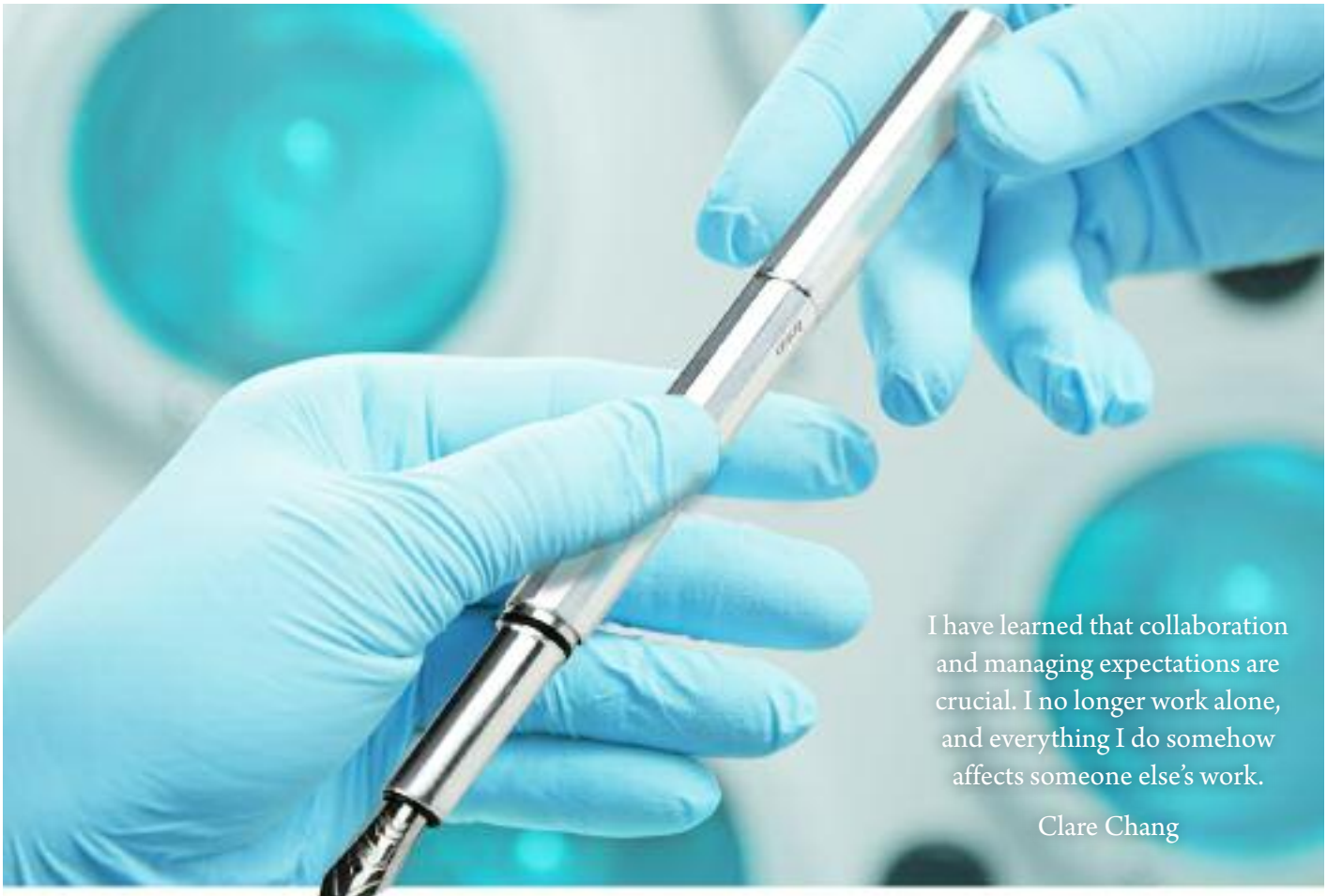

From bench to pen: Life as a new medical writer

Clare Chang[1] and **Zuo Yen Lee**[2]
1 dMed Biopharmaceuticals, Shanghai, China
2 Clinipace, Taipei, Taiwan (Republic of China)

Correspondence to:
Clare Chang
dMed Biopharmaceuticals
298 Xiangke Road, 3/F
301–5, Zhangjiang Hi-Tech Park
Pudong, Shanghai 201210
China
+86 186 168 23601
clare.chang@dmedglobal.com

Abstract
In search of a career that would take advantage of their graduate-level skills, Clare Chang and Zuo Yen Lee found medical writing – a career path few PhD students consider. Within 6 months of graduating, with lots of effort and some luck, they found their first jobs. In this article, Clare talks about her first impressions 2 months into her new career, while Zuo Yen shares her insights from almost 2 years in regulatory medical writing. The two discuss the important similarities and differences with their academic work and how they have adapted to the challenges of their new careers.

Clare's journey has begun!
Clare's dream was to become a research scientist – to make remarkable and ground-breaking discoveries in the lab that would revolutionise medicine. However, as we grow, so do our dreams…so after almost 10 years of pipetting and cell culturing, she realised that it was time for a change from preclinical to clinical research. While exploring her options, she stumbled upon the words "medical writer", which led her on a journey into discovering medical regulatory writing as a career.[1,2]

My first impressions
My experience in becoming a medical writer was rather tumultuous. Not only was I starting a new job, I was starting a new way of life. After almost 10 years in academia, I changed tracks and started as a new medical writer in a contract research organisation (CRO). Less than 3 months


Clare Chang

ago, I was still soloing in the lab and enjoying the beautiful Danish midnight summer sun with the occasional stroll through the forest. Now, as a medical writer, the work is fast-paced, collaborative, and constantly changing, all in the large, fast-moving metropolis of Shanghai, a city that never sleeps.

My on-boarding was tumultuous because I had to tie up all the loose ends of my Danish adventure while completing all the administrative work that comes with changing countries, not to mention starting a new career path in a new country, culture, work environment, and language. Although everything was planned out, there was much that I could not foresee.

Fortunately, my company's Human Resources department helped me obtain my visa, find temporary housing, and receive the boxes containing my life from Denmark. Although I was stressed, they put me at ease by being extremely communicative and supportive. They set me up quickly with the essentials: a working computer, internet, and access to relevant information and resources. In the week leading up to my first day, I received my company email address and all IT-related materials.

Next came the actual job. My on-boarding meeting with my line manager was very comprehensive. She gave me an overview on the medical writing training materials and the company's standard operating procedures (SOPs), and she introduced me to two client-specific tasks. I had imagined that I would spend several weeks reading SOPs and watching how things worked instead of being thrown directly into the frontlines. The first few meetings with clients were quite nerve-wracking because everything was in another language, and I was unsure of the correct business etiquette. Overall, it was a fast-paced, well-planned, and a highly communicative on-boarding process. The company understood my situation and gave me sufficient and manageable work in those first weeks. My manager didn't want me to get bored reading SOPs, so she expected me to jump right in and learn on the job, which was a good approach for me.

Managing projects, time, sponsors, and expectations

During my first month, I was both pleasantly surprised and overwhelmed by the many differences between academia and medical writing in a CRO. I had used many of the skills previously, but applying them to clinical research is a little different. To begin with, as an academic scientist, I was the "subject matter expert" and led projects from start to finish, whereas regulatory writing requires me to find experts from the relevant departments to complete the written documents. Also, while manuscripts in academia are usually written by one person and completed in 6 months to 1 year, regulatory writing projects are collaborative and are completed in just a few months. For example, my first project was a protocol for a phase IV study, where I had to work with the necessary departments to address comments and incorporate changes. Overall, from the time I on-boarded, it took only 2.5 months for the protocol to be reviewed and submitted, even though I was juggling other projects at the same time. I learned that deadlines are much tighter and that reviewing and addressing comments often happen on the fly. Scheduled meetings also are more efficient – there is an agenda with pre-determined discussion points, and meetings end promptly – which is very different from the open-ended discussions and brainstorming sessions that occur in academia.

I have learned that collaboration and managing expectations are crucial. I no longer work alone, and everything I do somehow affects someone else's work. For example, if I write a patient informed consent form for a study, I need to communicate with people in clinical operations to make sure that what I am writing actually happens at the study site. When resolving an issue or addressing a comment, in some cases, we need to inform the sponsor so that we are on the same page and know what to expect and when. Furthermore, sometimes unexpected things happen and timelines and tasks can change, so I have had to learn to keep the people who need to know what is happening informed while not overloading them with emails and information.

Dealing with language differences

Even though I can speak and understand Mandarin Chinese, I have never been properly educated in the language because I did not attend a Chinese school – I learned Chinese from talking with my parents, family, and friends, watching Chinese TV, and reading the occasional book or article in Chinese. Now I am thrown into medical and regulatory jargon and concepts in both English and Chinese… as if the English learning curve were not steep enough! So, naturally, I was a bit nervous about working in Chinese. Despite not being completely confident with my Chinese, my line manager has not shied away from sending me projects that require Chinese proficiency, so I have had to learn quickly. Just recently, I had to align an English protocol of over 100 pages with its Chinese counterpart – all within a week. The first day, it took me 8 hours to align 5 pages, but by the end of the week I was getting though 20 to 30 pages a day. My colleagues also know that Chinese is not my strength and have been a great help, and, of course, I have helped them whenever they have needed assistance in English.

Building rapport with colleagues

During an interview, I was asked, "Do you think you can build rapport quickly and be persuasive? How do you do it?" The first thing that came to mind was people that exude confidence are the centre of any party. More recently, I have learned that building rapport requires building credibility, which in turn requires being confident enough to speak your mind, ask questions, and help people whenever possible. In addition, in China, sharing your non-work life, often through social media, is important for building rapport with colleagues. This has been an adjustment for me because I am used to keeping my personal and work lives separate, but on the positive side, sharing our personal lives helps us overcome the hierarchical structure that often comes from working in a company.

Further down the medical writing road: Zuo Yen's journey

After 6 years in academic research in Switzerland, biologist Zuo Yen decided to switch to medical writing and was reassured of her choice after attending EMWA's first Internship Forum in Munich.[3] The EMWA conference and the Internship Forum have provided Zuo Yen access to the medical writing industry and many experienced medical writers. Six months after the EMWA conference, she finally started her journey as a medical writer upon a referral to a company in Taiwan.[4] After almost 2 years, she has gained good understanding of a medical writer's life and the new challenges it presents to academic scientists.

Zuo Yen Lee

My experience adapting to the challenges of medical writing

Clare's experience of starting her new job remind me of my early days as a new medical writer. Like her, I needed to apply and adapt skills from my academic training, especially time and project management. Even after 2 years, I find myself constantly re-adapting these skills for every new project; each project has different timelines, expectations, and unforeseen glitches. I have learned that a good medical writer should be able to react promptly to whatever situation arises.

Perhaps one of the biggest of these challenges is meeting somewhat unrealistic timelines proposed by the sponsor. I need to first gauge my capacity and capability and then determine whether the sponsor's expectations are too ambitious and try to understand the reason behind the urgency. Finally, I have to work together with the team to come up with the best solution and determine whether additional communication and negotiation with the client or delegate are needed or whether the task can be delegated to a colleague. At times, it can be a challenge to find a balance between meeting the sponsor's expectations and delivering sufficient quality.

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>
> Zuo Yen Lee

I have also found that, as a medical writer, I need to remain flexible and open-minded and to constantly expand my knowledge across different therapeutic areas. In academia, I was trained to master a single subject in depth. Now, I need to prepare for a wide breadth of subjects. For example, I might be working on a new drug for lung cancer in the morning, another drug for hepatitis in the afternoon, and conducting a meeting towards the end of the day with a sponsor who has a new flu vaccine. Upon receiving a new project, I may need to read up on a topic that I do not know or catch up with new developments in a therapeutic area that I worked on a year ago. I often have to do this quickly and as I go, which can be a challenge.

A good medical writer is responsible for helping sponsors comply with the latest regulatory requirements. So, another challenge is that I have to remain up to date on the ever-changing regulatory landscape. For example, in light of the recent global trend in making clinical data available publicly, new policies have been introduced to strengthen the protection of personal data. In Europe, the EMA has implemented the Policy 0070[5] and the General Data Protection Regulation,[6] which strongly affect how we write our clinical reports for European sponsors. Just recently, I realised that the guideline on influenza vaccines released in 2016[7] replaced five other guidelines that I had been following religiously! I also need to be knowledgeable of regulatory requirements in Asia. For example, although clinical regulatory documents in China have largely followed the ICH guidelines since 2017, the National Medicinal Products Administration has retained some of their unique local requirements for submission, such as certain components in the appendices of a clinical study report.[8]

The bright side

Because each project is different and because I have to remain up to date with new knowledge and regulations, there's never a dull moment. Unexpected situations happen often, and I need to react quickly, but I always get the support I need from my colleagues. To produce a sound report, I have to collaborate with biostatisticians, medical experts, other more experienced writers, and the sponsor. I also often need the assistance of clinical research associates and, of course, the project manager, who helps liaise with the sponsor and negotiates reasonable timelines on my behalf. Not only do I work with internal departments, including data management, clinical operations, and business development, I also work with external collaborators, such as physicians, scientists, innovators, and sometimes even regulators. Working across these many functions and disciplines – and working in the "real" world–makes life as a medical writer in a CRO exciting, and even though I sit alone in front of a computer typing away on a document on my own, I do not feel lonely.

Conclusion

Few PhD students consider a career of medical writing. The term may sound too unfamiliar or even dry to people in the academic world. Some even consider it "leaving science". But switching to medical writing does not mean leaving science – it is a way to explore a new dimension of science. We medical writers are doing what we love …. and loving what we do! Admittedly, making the transition to industry can be intimidating to academic scientists. Finding where your interests and competencies lie will make the transition easier.

Disclaimers

The opinions expressed in this article are the authors' own.

Conflicts of interest

The authors declare no conflicts of interest.

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Author information

Clare Chang is a scientist at heart. Her thirst for knowledge has taken her on a journey from Africa to Asia and finally Europe where she graduated in 2018 with a PhD degree in Nanoscience from Aarhus University in Denmark. She started her position as Associate Manager in Medical Writing at dMed Biopharmaceuticals in August 2018.

Zuo Yen Lee graduated in 2016 with a PhD degree in biology from ETH Zurich. She has more than 8 years of combined experience in scientific research and the diagnostics industry. Since January 2017, she has been a Medical and Regulatory Writer at Clinipace Taiwan.

Getting Your Foot in the Door

How Jennifer Clemens did it

My career as an editor began in the mid 1990s for an environmental company. This opportunity was my first true "Getting My Foot in The Door" moment because I was persistent. I knew I wanted to apply my dual degree in English and Business Communications as an editor or a writer, but I had taken a job straight out of college purely to pay the bills and that was not in my field. After I had an interview for the editor position, I surreptitiously left my desk at lunchtime every Friday and used a payphone outside my office to call the person responsible for hiring. This was back in the days before cell phones, so I needed to resort to clandestine methods. I know that tactic of calling is not used as often today, and in fact, we often read "no calls, please" on job ads. However, my contact there had told me to "feel free to stay in touch", so I did! After a few weeks, I was hired, learned the Chicago Manual of Style, and created my first in-house style guide. I felt I had finally found my professional calling.

In the year 2000, I transitioned to scientific and medical editing for a medical communications (medcomm) agency where I learned American Medical Association style inside and out as their sole editor for numerous clients' manuscripts, posters, continuing medical education materials, and slide sets. It was then that I heard about BELS (Board of Editor in the Life Sciences) and earned my certification by studying for several months and then taking their international exam. My career since then has taken me in other exciting directions, such as Team Lead Editor for an online publisher and then to pharmaceutical companies, another medcomm agency where I specialised in digital content, and CROs where I learned about regulatory submissions. Now I'm happily placed at Merck and parlaying my experience as a subject matter expert into patient narratives and training new hires. None of this would have been possible had I not persisted with that awkward payphone call every Friday early in my career.

I surreptitiously left my desk at lunchtime every Friday and used a payphone outside my office to call the person responsible for hiring.

Jennifer Clemens, ELS
Medical Writing
Clinical Technical Editor
Global Clinical Trial Operations, Merck
jennifer.clemens@merck.com