Career opportunities in medical device writing: Employee and freelance perspectives

Sarah F. Choudhury[1] and **Gillian Pritchard**[2]

1 CMR Surgical Limited, Cambridge, England, UK

2 Sylexis Limited, Dundee, Scotland, UK

Correspondence to:

Sarah Choudhury, PhD
CMR Surgical Limited
1 Evolution Business Park, Milton Road
Cambridge, CB24, 9NG, England, UK
+ 44 (0)7432634589
sarah.choudhury@cmrsurgical.com

Dr Gillian Pritchard
Sylexis Limited
30/34 Reform Street
Dundee, DD1 1RJ
Scotland, UK
+44 (0) 1382 581545
info@sylexis.co.uk

Abstract

Many regulatory medical writers start their careers in pharma. Whilst many continue in pharma, some also work in medical devices and an increasing number are switching to medical device writing. This article explores how and why writers might move from pharma to medical devices, just write for medical devices, or work in both, and identifies the transferable skills from the perspective of two writers, one who is now employed by a medical device company and another who is freelance. With sound writing skills and broad experience, there is no reason why a writer cannot transition from pharma to medical device writing, work solely in medical devices, or even decide to work simultaneously in both fields.

Introduction

The introduction of MEDDEV 2.7/1 rev. 4 (2016)[1] on clinical evaluation followed by the Medical Devices Regulation (MDR 2017/745)[2] and In Vitro Diagnostic Medical Devices (IVDR 2017/746)[3] has increased the need for and awareness of regulatory medical writing by medical device and diagnostics companies. Consequently, writers with experience gained in the pharmaceutical industry are well-placed to either move to medical device companies or to take on medical device writing projects. In this article two medical writers share their experiences of medical device writing, one as an employee moving to a medical device company and the other as a freelance writer.

How we got to where we are now

The employee route

It was the Summer of 2017 and Sarah was thinking where to go next, having gone from clinical and regulatory to clinical, regulatory and pharmacovigilance, and then back to clinical and regulatory. With a background working in pharmaceutical industries and contract research organisations (CROs), there was experience as both the Sponsor and the Client. Sarah is a clinical writer first and foremost, and even as a line manager, still had a hand in writing to enable her to empathise, advise and mentor the individuals she looked after.

Moving into pharmacovigilance – a completely new area, was a steep learning curve working in a busy leading CRO, which culminated in presenting the EMWA Advanced Workshop on Development Safety Update Reports.

Employed roles have involved working either remotely with the option of working in an office, a combination of both, or being completely office based. However, due to the location, remote working was recently the only option for Sarah. Whilst for many freelancers, remote working is often the only and preferred way of working, Sarah started to miss the human face to face interactions and wanted to get back into science and writing. She was ready for a new challenge and a new working environment and leveraged her association with EMWA since 2006, MEW's journal articles, and her network of colleagues and friends to find out more about medical devices![4–8]

Look beyond the job title; one should also consider clinical scientist/clinical research scientist/clinical specialist roles. If one is interested in specialising in a particular indication the role provides wider scope in providing scientific input into all the steps involved in the preparation of a pre-clinical or clinical study, from planning and set up, interactions with key opinion leaders, surgeons and engineers, involvement in day to day study conduct, data cleaning activities, and production of the study report (amongst other things).[9]

The freelance route

Gillian became a regulatory writer in 2006 when she established Sylexis Limited. Previously she had worked for a pharmaceutical and medical devices consultancy, in clinical development for a global pharmaceutical company, in phase I-II clinical research for a CRO, and in academic clinical medicine. The practical experience of following a protocol, getting ethics approval, and obtaining informed consent, gave useful insight when writing clinical trial-related documents. Working in pharma enhances one's understanding of how medicines are developed, regulated and marketed; useful experience when writing study protocols and reports, clinical summaries and overviews.

Although Gillian's research experience was mostly pharmaceutical, there were opportunities to work with medical devices, e.g., an ambulatory blood pressure monitor and an investigational device for administering insulin. There were also opportunities to learn how medical devices were approved and regulated in the US and Europe and also to conduct phase III clinical trials of a pharmaceutical product delivered by a novel medical device. This pharma experience was then applied to medical device development at a time when ISO 14155 contained only guidance on trial conduct (good clinical practice) and the clinical investigation plan (protocol),[10,11] and when few medical device companies conducted clinical trials. Therefore, when Gillian established Sylexis, she simply continued working on pharmaceutical and medical device projects.

Whilst being freelance often means working from home and writing alone, this environment can be very appealing – no daily commute, few meetings to attend, no office politics, and the flexibility to fit around family or other commitments – but how does one keep up to date professionally and run a successful business? This is where EMWA has been invaluable. Gillian joined EMWA in 2007 and has learnt much from attending and leading workshops, the Freelance Business Forum, serving on the EMWA Executive Committee, and from friends and the wider EMWA community.

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Learning on the job and adapting existing skills are important. Working on a new type of document with a colleague or as part of a larger team, familiarising oneself with regulations, guidelines and new software programmes, and attending EMWA workshops are all ways of acquiring and honing new skills – whether employed or freelance! This is how Gillian learnt to write clinical overviews and summaries, and then clinical evaluation reports (CERs), and literature reviews. This experience was adapted with each iteration of MEDDEV 2.7/1 and continues with the introduction of the MDR and IVDR.

Employed vs freelance comparison

How does writing about medical devices compare when writing as an employee or freelance writer? Employed isn't necessarily better or worse than freelance status; it's a matter of personal preference, skills and circumstances. Table 1 gives a general comparison from the authors' perspective. Other writers' experiences may differ depending upon the size and nature of the company or the style of freelance work, i.e., several clients and projects or contracted to one client at a time.

What are the transferable skills?

As an employed writer

By a certain stage of career, one will have a sound background in clinical research, analysis and presentation of data, statistics, and writing various types of documents. Sarah found herself back in a laboratory again! Unlike the large global medical device companies, or even many pharmaceutical companies, the responsibility of producing and supporting a wide range of documents and other non-writing activities fell to her.

Therein lie exciting opportunities to transfer project management skills, and her previous clinical/regulatory/pharmacovigilance experience working as part of a multidisciplinary team, to mentor, advise, innovate, deliver, and still benefit from the variety of work. As a professional, don't be deflated by comments or direct feedback – it's part of the job. In smaller companies, there is the advantage of instant feedback and taking time to build and work on relationships.

Why medical devices?

Being in pharmacovigilance and still working in regulatory and clinical gave Sarah the appetite to move into a completely new area. A LinkedIn advertisement led Sarah to her current employer, CMR Surgical Ltd, in Cambridge, UK, developing a new robotic surgery system to improve access in minimal access surgery.[12–14] The idea of

working in a smaller company, working closely with the Directors, all renowned innovators in their field, to drive their vision forward, and to work in more technical environment appealed immensely to Sarah. The company was developing a prototype which gave opportunity for different areas of growth, especially one where a clinical and medical team was growing, and which Sarah would be part of.

The benefits offered by the company were generous and quite novel: generous non-contributory pension, life insurance (8x salary), bonus, childcare vouchers, and on a lighter note, as in Steven Walker's article in *Medical Writing*[4] free fruit!

Sarah now wanted to be part of one product development process. She relished the prospect of working on a prototype which was so close to achieving its regulatory goals – achieving a CE mark, and then a US 510K submission for FDA approval, which considered all the exciting challenges lying ahead from transition of MEDDEV to Medical Device Regulations. She likes the pace, (on most occasions!), being able to develop her own ideas, and freedom to pursue company funded professional development which is balanced with the business needs of a company.

Sarah used the June 2017 *Medical Writing* issue on medical devices to leverage her pharma experience and passion to move into medical devices. The transition point to medical devices was set at the 2018 EMWA Spring Conference in Barcelona where she attended the Medical Devices Symposium and participated in her first medical device related workshops on Literature Reviews and CERs, and presented her pharma workshop on DSURs for the last time.

Opportunities for development

Working with talented individuals and across many regions are just two things that Sarah likes about her new job. She plays a pivotal part in data collection and authoring the study plan/protocol. In this role, she has completed a surgical theatre access training course, trained in Good Laboratory Practice, refreshed training in Good Clinical Practice, and gained new skills writing for validation studies to show proof of concept in pre-clinical models and usability studies looking at the perspective of the user as well as the device.[13]

In addition, the company is looking at innovative approaches to surgical studies under the IDEAL collaboration, (Idea, Development, Exploration, Assessment, Long-term monitoring) framework for evaluating surgical innovation and robust data capture through a registry not only

Table 1. Medical device writing – employed vs freelance comparison

Work characteristics	Employed	Freelance
Product vs project	Involved in all aspects of a product development and throughout product life cycle, e.g., work with engineers in laboratory, post market surveillance. Opportunities to get back into the laboratory and do pre-clinical work.	Only involved with writing documents for a project e.g., CER.
Variety of work	Limited to the company's products and therapeutic areas.	Variety of products and therapeutic areas.
Employer and clients	Work for one company at a time.	May work for several companies/clients at the same time.
Remuneration	Regular salary and benefits, e.g., pension, health care, life insurance, discretionary bonuses, paid annual leave and sickness benefits that may offset a lower salary than in a pharma company, especially if moving to a small company.	May not have regular income or benefits. No paid annual leave.
Job location flexibility	Depends on employer and company culture.	Usually more flexibility of when, where and how to work.
Career development and training	Opportunities may, or may not be, supported by employer. May have access to in-house training. Opportunities to attend other conferences. Some employers will support EMWA membership and training.	Must pay for and organise one's own training and career development. EMWA is particularly useful.
Pharmaceutical projects	Move away from pharmaceuticals.	May continue working on both pharmaceutical and medical device projects.
Business activities	Will be involved in corporate activities, especially if working for a large company.	Must manage own freelance business as well as working on projects.
Transferable skills	Writing, IT, therapeutic area knowledge, scientific and regulatory expertise.	Writing, IT, therapeutic area knowledge, scientific and regulatory expertise.

promotes transparency but establishes comprehensive, long-term surgical data collection which can be used to improve patient safety.[12] Registry and real-world evidence/real-world data is a topical subject for medical writers, mandated by the FDA.

Writing for pharmaceuticals vs medical devices

Like pharmaceuticals, the medical device industry has its own regulatory systems which are just as demanding and scrutinising. The need for quality, peer reviewed, validated documents is pertinent to both industries following recent scandals.[15-17] Medical devices, however, have shorter product life cycles, going from development to market in three to seven years. Technological improvements are typically available within two years of a previous iteration, and whereas improvements in medicines might take 10-20 years. Many medical device documents follow similar structures to those required for pharma.[4] With this in mind, after three years in medical devices there's a good chance of seeing the device either get to market or stay on the market.

Writing for devices includes an assessment of device performance outcomes which are dependent on the experience of the operator and team, and setting, such as evaluating learning curves, quality variations, and alleviating equipoise problems. These are some of the interesting challenges to be considered for document writing for devices.

Sarah has produced slides for Investigator Meetings and might have the opportunity to attend one. In future, there will be opportunity to write Post Market Surveillance and Post Market Clinical Follow-up document which draw on safety narrative writing skills and DSURs.

As a freelance writer

The transferable skills for writing about medical devices as a freelancer are mostly the same as those for an employee writer, namely good writing and computer (IT) skills, sound regulatory document expertise, scientific/ medical knowledge, and the ability to adapt existing skills and knowledge to new situations.

Whereas an employed writer might be limited to a particular therapeutic area or type of medical device, a freelance writer might work across a range of therapy areas and types of device. This means being comfortable switching between different subjects; today an expert in spinal fixation devices, the next day discovering the nuances in different coating materials for drug-eluting coronary stents, and the following week writing about a glaucoma treatment. With each new project one has to 'get up to speed' and learn about the medical device and the disease being treated. This can be a useful exercise – particularly with the rigorous requirements of MEDDEV 2.7/1 and the MDR to present current knowledge and demonstrate that a device is state of the art.

Just as there is variety in therapeutic areas, there is also variety in the needs of clients.

- Large companies and CROs may simply need resource – they have document templates and standard operating procedures and will supply the literature search outputs, but they don't have enough writers in-house to write up literature reviews and CERs. This can be a great way to learn how to write such documents.
- Small companies, however, may not have either in-house writers or the expertise to conduct literature reviews or prepare CERs to the current MEDDEV 2.7/1 or MDR standards – they want an experienced writer who can help and advise them, conduct the literature searches and write the documents using their own templates and software e.g., EndNote for reference management. For these clients, prior medical device writing experience is essential.
- There is always more than one way of writing a document, and freelance writers see lots of variations. This is an opportunity to see what works well, what doesn't, and to adapt and develop document templates and writing styles. For example, provided the guideline or regulation is being followed, it may be a matter of company style or determined by the volume of literature whether the literature review is a separate document or a section of the CER, or whether the data extraction table is an appendix to the literature review or in the body of the report.

> By a certain stage of career, one will have a sound background in clinical research, analysis and presentation of data, statistics, and writing various types of documents.

> The development of technologies and an evolving regulatory environment mean that manufacturers will need knowledgeable writers.

So, whilst the transferable skills might be similar between writing about medical devices as an employee and freelance writer, the range of projects and level of expertise required may be different.

Next steps ...

Judge a man (woman) by his questions rather than by his answers: Before moving into medical devices – think about the type of role and department one is applying to; understand the job description, career development and promotion opportunities. What is the medical device's classification and is it marketed? This gives an idea of the development, strategic and regulatory plan for the device. Ask about the experiences and qualifications of the project teams. Often medical device companies can be small start-up companies – so websites such as Glassdoor can't help. One may delight in perhaps being the only, or the most experienced medical writer. Will one be mentored or be mentoring? Don't be put off. Use networks, e.g., EMWA, and faith in medical writing skills to confidently take on the challenge.

If part of a newly formed and growing clinical and medical team, ask about participating in laboratory-based studies, in addition to writing responsibilities. Would one be happy interacting with external consultants, surgeons, and clinical teams? Would one be comfortable working with cadavers, animal pre-clinical models, and brushing up on physics? Does the role involve preparing data in the format required for regulatory approval or scientific publications? Does the role require negotiating with and managing vendors and contractors? Does one have to travel and work offsite?

The development of technologies and an evolving regulatory environment mean that manufacturers will need knowledgeable writers. Could medical device writing be a career option worth considering?

Conclusions

In this article two medical writers, one employed and the other freelance, have explained how they came to write about medical devices, shared their experiences and highlighted the transferable skills between writing about pharmaceuticals and medical devices.

In conclusion,

- Writing about medical devices isn't so different from pharmaceuticals;
- Medical device writing opportunities exist for employed and freelance writers;
- The transferable skills are the same whether employed or freelance and are determined by previous career route and experience;
- With the freelancer route – opportunities to still work with pharmaceutical products;
- EMWA can help with writing for both medical devices and pharmaceuticals;
- Don't worry, we're all learning together! Employers will understand this.

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Disclaimers

The opinions expressed in this article are those of the authors and not necessarily shared by their employer, clients or EMWA.

Conflicts of interest

Sarah declares no conflicts of interest. Gillian writes about medical devices for several clients.

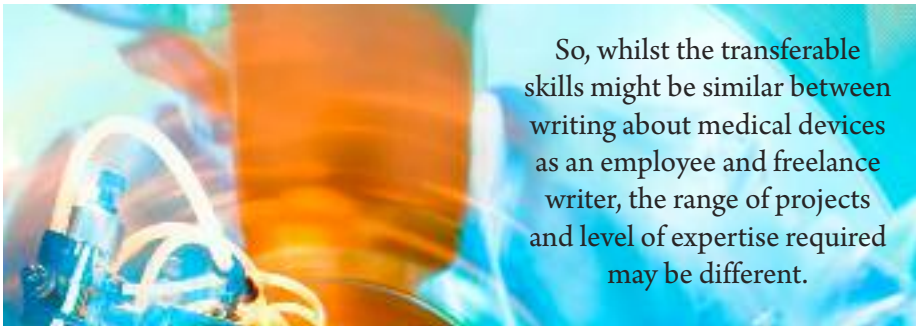
References

1. European Commission. MEDDEV 2.7/1 revision 4. Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC. 2016.
2. European Commission. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Official Journal of the European Union. 2017;L117:1–175.
3. European Commission. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. Official Journal of the European Union. 2017;L117:176–332.
4. Walker S, Opie J, Whitman S, et al. Writing for pharmaceutical or medical device companies: a survey of entry requirements, career paths, quality of life, and personal observations. Med Writ. 2016;25:21–9.
5. Opie J. Life as a medical writer for a medical device company. The Write Stuff. 2011;20:88–9.
6. De Faoite D. Medical devices: an exciting industry at a crossroads. Med Writ. 2017;26:1–2.
7. Doerr B, Whitman S, Walker S. Writing for medical devices compared to pharmaceuticals: an introduction. Med Writ. 2017;26:8–13.
8. Billiones R. Medical devices in the disclosure era and the role of medical writers. Med Writ. 2017;26:32–4.
9. Association of the British Pharmaceutical Industry. ABPI Careers. 2016 [cited 2018 Dec 7]. Available from: http://careers.abpi.org.uk/Pages/default. aspx.
10. Standardization IOf. ISO 14155–1:2003 Clinical investigation of medical devices for human subjects. Part 1: General requirements. 2003.
11. Standardization IOf. ISO 14155–2:2003 Clinical investigation of medical devices for human subjects. Part 2: Clinical investigation plans. 2003.
12. Marcus HJ, Hughes-Hallett A, Payne CJ, et al. Trends in the diffusion of robotic surgery: A retrospective observational study. Int J Med Robot. 2017;13.
13. Rassweiler JJ, Autorino R, Klein J, et al. Future of robotic surgery in urology. BJU Int. 2017;120:822–41.
14. Albright BB, Witte T, Tofte AN, et al. Robotic versus laparoscopic hysterectomy for benign disease: a systematic review and meta-analysis of randomized trials. J Minim Invasive Gynecol. 2016;23:18–27.
15. Feldwisch-Dentrup H. New clues why a French drug trial went horribly wrong. American Association for the Advancement of Science. 2017 [cited 2018 Dec 7]. Available from: https://www.sciencemag.org/news/2017/06/new-clues-why-french-drug-trial-went-horribly-wrong.
16. Vince G. DN9226 UK drug trial disaster the official report. New Scientist Ltd., 2006 [cited 2018 Dec 7]. Available from: https://www.newscientist.com/article/dn9226-uk-drug-trial-disaster-the-official-report/.
17. Devices FIfDaM. Silicone gel breast implants, from Poly Implant Prothèse Company. 2017 [cited 2018 Dec 7]. Available from: http://www.bfarm.de/SharedDocs/Risikoinformationen/Medizinprodukte/EN/silicone_breast_implants_PIP_info.html.

Author information

Sarah Choudhury, PhD, is a Clinical Scientist at CMR Surgical Ltd since 2018. Worked in contract research organisations (CROs) and pharmaceutical companies as a permanent employee. She served on EMWA's Committee during 2011 to 2014, presented a Development Safety Update Reports (DSURs) Workshop, before moving from pharmacovigilance and regulatory writing, into medical devices.

Gillian Pritchard, MSc, MRCP, MFPM, MBA, is the director of Sylexis Limited, a consultancy providing regulatory writing services for pharmaceutical and medical device companies since 2006.



So, whilst the transferable skills might be similar between writing about medical devices as an employee and freelance writer, the range of projects and level of expertise required may be different.

How Ansgar Dressler did it

Getting Your Foot in the Door

Career transition: From statistics to medical writing

At the time I finished my studies and got my degree in statistics in 1997, I had never heard of medical writing, as is probably true for any student, even in the medical field. After my studies, I joined what was then Hoechst Marion Roussel (and later became Aventis, Sanofi-Aventis, and finally Sanofi) as a biostatistician. In the broad interdisciplinary field of clinical development, I closely collaborated with the data management, programming, and medical departments, and also with medical writing. Not only did I learn about the existence of medical writing and its role, but also did my first steps into the field of medical writing when I drafted the statistical analysis plan or the statistical methods section of a clinical study protocol. Although being used to and enjoying the core work of a statistician, i.e., applying appropriate statistical methods to analyse and summarise data, I also liked the aforementioned writing side of my work.

In the early years of my career as a statistician in the pharmaceutical industry, I was fortunate to get to know Julia Forjanic-Klapproth, Barry Drees, and Douglas Fiebig who all belonged to the medical writing department at that time, and who would found their own company, Trilogy Writing and Consulting GmbH, in 2002. Shortly before, in 2001, the entire development department of Sanofi-Aventis had been spun off and became the full-service clinical research organisation, Covidence (later renamed Accovion and then acquired by Clinipace), which gave me the opportunity to experience the whole spectrum of clinical development from the perspective of a service providing company.

When, for private reasons, I planned to leave the Frankfurt area and move to near Munich, and thus wanted to change my job, Julia, who I closely worked with basically in all projects during our first years in the pharmaceutical industry, offered me to join Trilogy as a medical writer. Of course, such a change in disciplines is a major step, especially since I liked the work as a statistician. But from my past experience I also knew that I would like the work as a medical writer, and given the other benefits, e.g., being an integral part of a small growing company and the possibility of working from home, I accepted the offer. Thus, after more than eight years in the pharmaceutical industry as a biostatistician I joined Trilogy in 2006 as a medical writer, and I have never regretted that step.

But what exactly changed? Aside from the obvious, that I moved from mostly dealing with numbers to mostly dealing with words, I find the work as a medical writer more diverse with regard to the different indications you work on and the different people and functions you work with. As a statistician I almost entirely worked in one indication (diabetes), and in fact became the statistics lead for diabetes within the company. I mainly interacted with the programming department. As a medical writer, however, I have worked in many different indications and not only interacted with many different departments, but also coordinated teams to get documents finalised on time. Even after more than 12 years as a medical writer, there are still new challenges and learning opportunities with every new project, e.g., a new indication, a new document type, or new team constellations with new responsibilities. I believe I would not have had such diversity of experience as a statistician, at least not in the position I had and not to this extent. And, of course, in my work as a medical writer I stay in touch with statistics, and my background in statistics often comes in handy when interpreting statistical outputs.

So, looking back at my career in the pharmaceutical industry, I have been happy with my decision to side step from biostatistics into medical writing, which I love to continue doing in the future.

Ansgar Dressler
Medical Writing Manager at Trilogy Writing & Consulting GmbH

Getting Your Foot in the Door

How Christine Møller did it

It was a unique combination of circumstances that led me to work in the editorial office of a medical journal, which was the reason I joined EMWA.

After meeting my husband-to-be, I arrived in Denmark intending to teach English, but was held back by my lack of recognised qualifications and by my inability to speak Danish. Needs must, however. So, instead of pursuing a full-time teaching career, I embarked on a succession of temporary positions.

I eventually gave up any hope of teaching and took a job at the British Council Library. When the library closed, the future looked bleak. As luck would have it, *Acta Pathologica et Microbiologica Scandinavica (APMIS)* was advertising for an editorial assistant. As one door closes another door opens.

I got the job at *APMIS* because I had worked for the British Council – even if I had only been stamping library books, showing people round the language section, and handing out pamphlets on life in the UK. Character references were written on official notepaper. All that evidently did the trick.

The tasks at *APMIS* initially included correspondence and registration of manuscripts. Later I also found myself doing language revision, editing texts, and making contact with the editorial board, authors, and reviewers.

The next step was when I attended a meeting in Tunbridge Wells organised by the *European Association of Science Editors*. On my return, I gave the Editor-in-Chief a glowing report of the communication workshop held by John Kirkman. A quick phone call resulted in John holding courses for us throughout Scandinavia. The goal was to encourage promising young researchers to submit their articles to *APMIS*. The groundwork had been laid for a career in medical writing.

Finally, one day everything came together: native English language, a British degree and teaching qualifications, employment as a liberal studies lecturer in the UK, teaching in Denmark, experience at the British Council Library, an understanding of what it takes to get a manuscript published, and inside knowledge of the workings of an editorial office. A former member of *APMIS*'s editorial board was instrumental in setting up the first medical writing courses at the Faculty of Health and Medical Sciences, Copenhagen University. This adventure was followed by many other courses, presentations, seminars, and workshops here and at other hospitals and research institutes, both in Denmark and abroad. Along the way, my firm Medical Manuscripts was established.

The rest, as they say, is history.

It was a unique combination of circumstances that led me to work in the editorial office of a medical journal, which was the reason I joined EMWA.

Christine Møller, BA, Dip Ed
Christine is Assistant Editor of *APMIS Journal of Pathology, Microbiology and Immunology*. She is also director of Medical Manuscripts and teaches courses in medical writing for PhD students and others interested in improving their language and communication skills.