

# Medical Devices

## Medical devices – here we come!

The spring EMWA conference held in Barcelona is now behind us – and what a conference it was for medical device writers and those who want to become one! A full symposium day on medical devices with more than 200 registrants and two fully booked medical device workshops showed the interest and need for further training and information on this type of medical writing. Plenty to do for the MD-SIG group who met during the conference to brainstorm on future EMWA offerings such as workshops, webinars, and expert seminar series.

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## “Medical Devices and Technologies – Emerging Opportunities for Medical Communicators”

The 6th EMWA symposium day was for regulatory writers and medical communicators alike, and aimed to provide the perspectives of different stakeholders, including representatives from the European Commission, notified bodies, medical device companies, patient organisations, reimbursement professionals, and lastly medical writers themselves. There was an interesting mix of medical writing experience in the auditorium with approximately a third having less than 2 years of experience, and another third with more than 10 years. This most likely reflects the desire of newcomers to embark on a new field with good job opportunities and the desire of experienced writers to explore new horizons, after perhaps feeling overly comfortable in their area of expertise.

Claudia Frumento kickstarted the day by giving an introduction to the fascinating world of medical devices. Did you know that Ancient Egypt already used medical devices? Aside from medical device classifications and regulations, Claudia also highlighted the pros and cons of writing for medical devices as compared to pharma. Some of the pros for medical device writing were business opportunities, more long-lasting relationships with medical device companies, and the fast pace, with constantly new devices being developed (the time pressure associated with the fast-paced environment was added to the “cons box”).

Gillian Pritchard elucidated on medical writing skills acquired in pharmaceuticals that are transferrable to medical devices. In a nutshell: “Yes, you can” use many transferable skills. If you are considering a transition from pharmaceuticals to medical devices, check out her symposium presentation which is available on the EMWA website. It is also a useful reading material when

preparing yourself for an interview with medical device companies.

Another highlight of the morning was having Paul Piscoi as representative of the European Commission present the medical device regulations. Paul has agreed to have his full presentation available on the EMWA website. If you are working in regulatory medical device writing or considering embarking in this field, this presentation is a must! The sheer volume of all the new guidance documents to come seems daunting at first, but having direct access to first-hand information is extremely valuable.

After the view of the European Commission, Itoro Udofia, head of the notified body, Underwriters Laboratories, gave an insightful talk about what notified bodies are looking for in Clinical Evaluation Reports (CERs). Itoro transformed the complex new regulations in an easily digestible and delightful presentation. “One picture is saying more than 1,000 words” – he explained the increasing scrutiny of the new regulations in relation to the risk of the device with just one simple graph. Importantly, Itoro reminded us of a vital skill a medical writer should have – to know and write for your target audience. And – are you aware of the job opportunities available at notified bodies?

It was impressive to see also the amount of work that goes into the implementation of the new regulations from the side of the European Commission and Notified Bodies, with a lot of effort put in educating people. During the panel session, led by Jane Edwards, Head of Global Communications at the notified body BSI, the audience used the opportunity to ask plenty of questions that led to a lively and interesting discussion.

While the morning session provided a solid

foundation on medical devices and the associated regulations, the afternoon session touched on diverse areas within this field. Following the EMWA symposium tradition of presenting a 360° view, Kyle J. Rose spoke as patient representative of the International Diabetes Federation (IDF). Hearing the patient’s voice is important as we should constantly be reminded that our work ultimately affects patients’ safety. Aside from providing an insight about living with a chronic disease, Kyle talked about one of his areas of expertise, apps, that can be classified as medical devices. In particular, Kyle was involved in authoring the IDF position paper on medical device apps. During the talk as well as during the discussion thereafter, it became obvious what a complex situation the fast-paced environment of apps is, e.g., when is a software update a significant change? What to do if an app is generated by people who might not even know they have developed a class III medical device? Certainly a topic that would need its own symposium.

Ivan Krstic of Elsevier presented on how to use Embase for medical device systematic reviews. The new MEDDEV 2.7.1/Rev 4 guideline on writing CERs does not accept PubMed as sole resource of literature, and rather requests additional databases such as the Cochrane Central Register of Controlled Trials or Embase. The guideline also requires that CER authors are trained on literature searches on PubMed or Embase. If you have attended the symposium – this checkbox is ticked! Certainly, Embase can also be used for all types of systematic literature searches, allowing for broader as well as narrower searches.

On the case example of a bioresorbable scaffold, Myriam Stieler from Biotronik showed



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the full life cycle of a product. She discussed the first considerations to building a prototype, the preclinical tests including bench and animal testing, the first clinical studies, the need for re-design, the CE-mark process, and the possible pitfalls thereafter. The potential impact of the learning curve, both, on how to best implant the device, as well as the competence of the individual operator, need to be considered. Post-market follow-up data are paramount to monitor the safety of a new implantable technology and to ensure that the roll out of a new implantable technology into clinical practice is safe. For instance, some late-emerging issues were observed with a competitor's bioresorbable scaffold which were only detected during post-market follow-up. As these issues were also related to the implant technique, implantation recommendations were published along with a proctoring programmes to assure patient safety. In summary, it is very important to understand that, in contrast to pharmaceuticals, the safety and performance of an implantable device also depends on the implanter.

Patrice Becker presented publication planning at Medtronic, one of the largest medical device companies. He highlighted the challenges and necessities of publishing preclinical studies and the challenges of the fast-changing world of

medical devices. Once the primary study endpoint is reached and data are published, devices are often close to being outdated as the life cycle of a product is so short. Therefore, sound publication planning is paramount. Very useful were his slides related to timelines for individual tasks, e.g., before a conference abstract submission deadline. Myriam and Patrice both closed the loop to the new regulatory requirements for more clinical study data where (at least for the class III devices they are working on) it is in the manufacturer's interest to have sufficient preclinical and clinical evidence because physicians will only consider using products supported by convincing clinical data.

Oleg Borisenko, one of the few experts with an overarching knowledge on medical device reimbursement, was able to provide an introduction to market access in Europe and the associated documents for medical writers in only 30 minutes. Especially helpful were his tips on how to prepare for writing market access related documents – even though getting familiar with this landscape seems to be a giant task! Certainly, everybody interested in reimbursement and market access should take the time to read his presentation thoroughly and follow the recommendations he provided. Despite the complexity and novelty of the topic, there was a

lot of interest from the audience and Oleg proved his expertise by answering all questions succinctly and clearly.

The talks were followed by a panel discussion with active participation from the audience, including questions on US medical device regulations, harmonisation of regulations, as well as the current political situation, i.e., potential implications of Brexit.

We hope that those who attended the symposium had an enjoyable, fruitful and thought-provoking day. We also look forward to reading the symposium report from our “medical device newbies” which will be included in the conference report in the September issue. If made available, the symposium presentations have been uploaded to the appropriate section of the EMWA website.

A huge thank you to the presenters as well as to the audience for asking plenty of questions which helped to make the symposium a success!

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