Medical Devices

SECTION EDITOR

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Editorial

Medical devices should certainly be included on any list of trends in medical writing. That impression was only reinforced by the strong interest in device writing evident at this year's EMWA spring conference. The three medical device workshops on offer were fully booked and the expert seminar series was well-received. On a personal note, I was thrilled to see the growing opportunities for medical device writing at EMWA. Starting out as a medical writer in 2004 the job fascinated me, but I had my doubts about whether it was a good fit for someone with an engineering and orthopaedic research background. Writing for pharma was clearly the training focus at my first EMWA conference back then, but in 2019, I am happy to say I have found my perfect medical writing niche!

In my first contribution as section editor for Medical Devices, I would like to update you on the lively discussions that took place during the expert seminar series in Vienna. I also want to thank Beatrix Doerr for her many quality contributions as the previous section editor. I hope to continue her work with the same commitment to raising awareness about the exciting world of medical device writing.

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Expert Seminar Series: Updates from the medical device industry

The first expert seminar series on medical devices was offered following on the resounding success of the Medical Device Symposium held at the 2018 EMWA Conference in Barcelona. The session included three presentations from industry experts and concluded with a panel discussion.

Drug-device combination products: regulations and documentation

Mr Viky Verna (Vice-president, confinis ag, Switzerland, and formerly employed at the US Food and Drug Administration) kicked off the session with a presentation of the intricacies of regulations for drug-device combination products. The definition of combination products differs by regions but can be generally defined as a product consisting of two or more regulated products. Think of transdermal patches for drug delivery, inhalers, or pre-filled injection pens. In the United States these products follow a single regulatory pathway with specific requirements determined by the product's *primary mode of action* (PMOA). The PMOA is the most important therapeutic action of the product. In contrast combination products do not have their own separate regulatory pathway in Europe. Such products are regulated as either a device or medicinal product (drug) according to the *principle intended action* (similar to the PMOA) resulting in two main regulatory pathways:

- Medicinal products with a medical device component
- Medical devices incorporating an ancillary medicinal product.

In both cases, the combination products will need to comply with the European medical device regulation (MDR) or the in-vitro diagnostic regulation. This adds new requirements, including involvement of a notified body, for products that previously would have primarily followed the pharmaceutical approval route. The result is increased regulatory burden for both medicinal products and medical devices.

Innovation in combination products is occurring at a rapid pace. The evolving regulatory framework and expected industry growth present a unique opportunity for medical writers with an understanding of both the pharma and medical devices worlds. Watch this space as more regulations and guidance are expected to come.

Medical device approval in Europe, US and Japan: Similarities and differences

The second session of the morning featured Ms Myriam Stieler (Director Medical Affairs, BIOTRONIK AG, Switzerland) comparing the medical device approval processes in Europe, US, and Japan. The responsible parties providing approval in the three regions are the FDA (specifically the Center for Devices and Radiological Health) in the United States, the notified bodies in Europe, and registered certified bodies or the Pharmaceuticals and Medical Devices Agency in Japan. There are also some slight differences in the risk-based classification of medical devices between the three regions. With the EU MDR implementation, approvals in Europe are expected to become more difficult. In contrast, the US and Japan are making efforts to harmonise their approaches that could potentially speed up the approval process in these regions. It was interesting to learn that for Japanese submissions there are no guidance documents available, and the process depends heavily on the individual reviewer assigned. It is essential to have local staff to support Japanese submissions. Ms Stieler also recommended to have consultations in parallel with the US and Japan whenever possible rather than expecting Japan to accept the position of US regulators. Overall the presentation provided useful insights for medical device writers supporting global submissions in these three regions.

Clinical evaluation, PMS/PMCF – Requirements for plans and reports requirements with impact on medical writing

Ms Susanne Gerbl-Rieger (Director Clinical Audit, TÜV SÜD, Germany) presented the perspective of a notified body in her talk on clinical evaluation and post-market surveillance activities of interest for medical writers. She began with an important disclaimer – expect many changes still to come. Many guidelines and common specifications are still being written, so this is a constantly evolving space. She strongly

recommended to read the MDR – all of it – and to keep monitoring for new developments as different aspects of the regulation are implemented. In particular, the common specifications for clinical investigations, clinical evaluation, and post-market clinical follow-up, when finalized, will provide more information and important guidance for medical writers. She stressed that quality counts, and there are many aspects for compliant medical writing. It will be essential for medical writers to be involved in the overall process of the clinical evaluation, and experienced medical writers can make an important contribution in the creation of key documents including the clinical evaluation plan (which includes a clinical development plan), clinical evaluation report, the summary of safety and clinical performance, and the post-market clinical follow-up plans and reports. Ms Gerbl-Rieger also emphasised that manufacturers are not the only ones forced to adapt to the new regulations. Annex 7 of the MDR describes the specific responsibilities and requirements for the notified bodies under MDR, and the impact on notified bodies is significant. The increased resources needed to comply with MDR have resulted in an expansion of the resources at TÜV SÜD. They have almost doubled the size of their team to support the duties required under MDR.

Panel discussion

Beatrix Doerr and Art Gertel joined the speakers for the final expert panel discussion moderated by Racquel Billiones. A wide range of topics were raised including the EUDAMED (the European Databank on Medical Devices), transparency issues for medical devices, and the use of registries to support post-market clinical follow-up requirements. EUDAMED will eventually serve as a repository for results of medical device studies, but it will take time until a large number of results are there. From an industry perspective, a consequence of MDR implementation could be a risk that small and innovative companies will not be able to afford to bring new products to the market. Overall the audience was very engaged, and the discussion continued well beyond the allotted time…only ending when we were finally asked to leave the room so that it would be ready for the next sessions.