

Strategic medical writing for device submissions

Julia Forjanic Klapproth of **Trilogy Writing & Consulting** explains why it is time to start using strategic medical writing in the world of device submissions.

Until recently, the documents needed for device evaluations were not well defined and were generally written by one person (often a medical writer), essentially on their own. Now, with the increased regulatory requirements brought on by the EU medical device regulations from 2017, more people are getting involved in preparing the clinical evaluation reports (CERs) and the writing game is changing.

Input is needed from a team of CER contributors and reviewers, including a clinical specialist who understands the environment the device is to be applied in; a regulatory expert who has knowledge of the regulatory background for the class of device and who can inform the medical writer about the assessor's expectations based on prior discussions with the CER regulatory assessor; the safety surveillance group to provide details of post-marketing surveillance; and someone who can provide depth of knowledge on the technical development and characteristics of the product.

Many of these newly formed teams do not have experience in preparing regulatory documents and are unsure of how to make

these documents do what they need to.

More than ever, the medical writer is there as an advisor to provide knowledge gleaned from writing many regulatory documents in the arena of drug development and understanding the needs of regulatory guidelines. With larger teams, the role of the medical writer becomes more strategic, as they serve to ensure all functions on a CER team (medical affairs, clinical, safety surveillance and research and development) provide necessary input while helping mediate cross-functional differences of opinion on what messages there are to tell.

Writing scientific documents as a collaborative process, instead of as a single author, does not come naturally to many contributors. Experienced medical writers often serve as a kind of glue for the different functions on the CER team. They pull team members together by focusing them on telling a cohesive narrative – this is achieved by effective interpersonal skills. Strong argumentation and leadership skills are needed to challenge and guide a team to find the best way of presenting complex data sets, and telling the story consistently and clearly.

Furthermore, although scientists understand the principles and ideas behind the science of what they are working on, many are not skilled at communicating those ideas in the written form. For device documentation, the science behind the product is an important part of the story to be told. There is a lot of non-medical data to be described in addition to the clinical data. The scope of scientific knowledge that medical writers bring to these documents is very relevant in order to effectively tell the whole story of the device. Experienced medical writers have the skills to interpret scientific data and present it in a way that meets the regulatory goals, ensuring that agency reviewers will clearly understand the messages to be told.

Well-honed tricks for new sectors

In the world of drug development, this role of strategic medical writing to assist dossier writing teams in pulling ideas together has been applied for decades. Now that the world of devices has become more regulated, this role of the medical writer has become important to efficiently produce CERs that aid the clinical evaluation of devices. Medical writers experienced in writing submission dossiers for drug applications are well versed in applying the evidence-based principles required by the new EU medical device regulations.

By tapping into this experience, device manufacturers have access to a well-developed skill set that will make producing and updating CERs less of a burden, and ensure these documents are truly fit for purpose. ●

References available on request.

A Clinical Evaluation Report team
WITHOUT a Strategic Medical Writer on it



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The strategic medical writer is a 'glue' to hold the CER team together.

For further information

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