Profile

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The new European medical device regulation and guidance document on clinical evaluation

An Interview with Dr Bassil Akra

The successor of the currently applicable Medical Device Directives (MDD 93/42/EEC and 90/385/EE) combines both directives into one Medical Device Regulation (MDR).

At the time of the interview, the MDR publication date had been scheduled for the second quarter of 2017. (The MDR has now been published and is accessible at http://eur-lex.europa.eu/eli/reg/2017/745/oj). The new MDR adds new requirements to the quality management system of medical device manufacturers, clinical evaluations and post-market surveillance. Moreover, this regulation influences the classification of several devices that are currently on the European market and covers new device categories such as devices for cosmetic purposes and non-viable human tissue. Furthermore, the MEDDEV 2.7/1 Rev 4 guidance document on clinical evaluation of medical devices has been released in June 2016. This revision is more detailed and particularly provides further guidance on the writing and update of clinical evaluation reports. Moreover, this guidance document includes essential details on the type of clinical data that can be used during this process and the responsibilities of the notified bodies.

We are delighted to have the chance of interviewing Dr Bassil Akra, who is a representative of the European Notified Bodies on various clinical task forces and participated in the development of this new guidance document, to gather first-hand information on the matter. He is the Global Director of the Clinical Focus Team at the largest Notified Body, TÜV SÜD Product Service GmbH, and has extensive experience in research, development, quality management and regulatory approval of medical devices, combination devices and Advanced Therapy Medicinal Products (ATMP).

He is a senior expert and internationally renowned speaker on European regulations and a member of the European Clinical Investigation and Evaluation working group. Dr Akra is representing Team NB and NB MED in several European discussions regarding clinical requirements such as MEDDEV and other Guidance Documents on Innovative Devices, as well as a member of the European task force on Safety Update Reporting.

MEW: What was the rationale for the new revision of MEDDEV 2.7/1, while a new MDR is under development?

Dr Bassil Akra (BA): It should be mentioned upfront that the MEDDEV is legally not binding but it reflects the current state-of-the-art method on how to conduct and assess clinical evaluations. Manufacturers are free to either apply the MEDDEV or other comparable methods when showing compliance to the applicable directive(s).

The new MEDDEV was developed as a result of several scandals in Europe and aiming to unify Notified Bodies and Member States, the European Commission decided to put several recommendations and regulations into force. In the Commission Implementing Regulation (EU) No 920/2013, it was required to have a common method and view of designation towards ensuring a uniform interpretation of the requirements. The result of this regulation and the joint assessment was the reduction of the number of Notified Bodies from 83 to less than 60. During these joint assessments, the main finding of the designated Member States and the Joint Research Centre auditor team was related to the clinical evidence and the qualification of the involved resources in the evaluation and assessment of this evidence. Given that the full implementation of the MDR was expected to take several years, the Member States and other stakeholders decided to clarify the requirements drawn by the current medical device directive(s) in an update of the relevant guidance document on clinical evaluation (MEDDEV 2.7/1).

MEW: Which are the expected release date and changes of MEDDEV 2.7/1 Rev 5?

(BA): It is still unclear if a new revision of this document will be prepared and published, as the intention of the European Commission is to draw a clear and detailed regulation avoiding additional guidance documents. Nevertheless, we should say that regulations are never clear for the final user, leading to multiple interpretations. Therefore, guidance documents are always helpful. My opinion is that such a document revision will be necessary when the MDR will be officially published and a new revision referring to this regulation can be drawn.

> The only advice that I can give to the industry and the medical writers is to check all available clinical data for all devices regardless of classification.

MEW: The new MDR mentions several documents which have not been previously required. For which documents do you imagine medical writers could be particularly useful?

(BA): The number of qualified professionals needed for the preparation of these documents is expected to increase dramatically in the next 2 to 3 years. In the beginning, mainly the Clinical Evaluation Report (CER) will require medical writers and professional experts to fulfil the requirements of the new revision of the MEDDEV guidance document. As soon as the MDR is implemented, an increased number of reports will be required, such as the periodic safety update report, the post-market clinical follow-up report and the summary on safety and clinical performance document. All these documents should be combined with an updated CER, as they also include an updated conclusion on the benefit-risk profile of the affected device. Moreover, it should be considered that these reports will be needed annually for devices that are either in

class III or are implantable, requiring further resources on all sides i.e., the manufacturers, the notified bodys and the designate member states.

MEW: With two new regulations, uncertainties are unavoidable. What could medical writers do if they do not know how to apply/interpret the regulations correctly?

(BA): The most important at this point, is communication. TÜV SÜD is performing roadshows worldwide presenting the requirements expected out of these regulations and discussing their implications for the medical device industry. Medical writers that are affected by the regulation changes should continuously get in contact with their Notified Bodies and responsible authorities to understand their expectations and requirements.

MEW: What has been your experience with the new MEDDEV revision so far? Has the rejection rate of CERs increased? Which are the most common mistakes you observe?

(BA): The MEDDEV was published without a transition period leading to many burdens for the medical device industry. To address this issue, as a selected representative of the European Bodies on various clinical task forces and a member of the CIE Task Force, I have tried to agree on implementation timelines with the members of Team NB and NB MED that were communicated to the industry immediately after the implementation of this guidance document. The following steps were recommended:

1. *Manufacturers should prepare an impact assessment and implementation plan within 6 months after the publication of this document.*
2. *Manufacturers should have – latest by the beginning of January 2017 – started to implement the new Revision of the MEDDEV by updating their CERs accordingly. The CERs update schedule should be prioritized based on the establishment and risk levels associated with the device. New device submissions shall be prepared from January 2017 on, following the new MEDDEV Revision expectations.*
3. *Latest by December 31, 2018, all CERs should reflect contents in line with the new MEDDEV Revision.*

Nevertheless, in the case of compliance issues regarding requirements of the applicable directive(s), Notified Bodies will, of course, continue applying case-specific deadlines. Earlier actions may be necessary to resolve compliance issues.

The recommendations from the Notified Bodies were helpful to the industry to prepare themselves for the new regulations. Nevertheless, they did not solve the problem of having enough qualified professionals to update all CERs accordingly. Moreover, new expectations on devices may affect approval plans for new products. For instance, fulfilling the expectations on devices that plan to follow the equivalence approach, using data from similar devices rather than data from the device in question, has become more challenging since it is now indirectly expected to have an access level to the technical documentation which is usually not possible for competitor devices.

MEW: What advice would you give to medical writers?

(BA): The only advice that I can give to the industry and the medical writers is to check all available clinical data for all devices regardless of classification and decide if compliance to the requirements of the current directive(s) and the future MDR can be shown, meaning that the requirements of the new regulations can be fulfilled. In the case of compliance issue, the manufacturer should immediately run a corrective and preventive action (CAPA) and, in the worst-case scenario, rationalize the device. They have to concentrate their efforts on devices for which sufficient clinical data are available, and compliance with current essential requirements and future safety and performance requirements of the MDR can be shown.

MEW: Thank you for taking the time to share this important information with us. Interesting times are ahead, and the opportunities for medical writers will certainly grow!

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