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Advancing Industry Leaders

COMPLIANCE NEWSLETTER 10/2018

ARE YOU READY FOR ARTICLE 88 OF THE MDR?

Medical device manufacturers should use the time leading up to the MDR

How well prepared is your company to meet the requirements of European regulation 2017/745 for medical devices – known as the "Medical Device Regulation" or "MDR" for short? The MDR will result in a more detailed definition of known requirements or even the introduction of new requirements for the medical device industry. And while the transitional period for the MDR – currently scheduled to end on May 25, 2020 – is seemingly large, the issue should still be given the highest priority.

Trending to become mandatory

With the new regulation, trending will become mandatory by law. Which means: manufacturers will have to report "any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side effects that could have a significant impact on the benefit-risk analysis...and which have led or may lead to risks to the health or safety of patients, users or other persons..." (MDR 2017/745, Article 88).

Statistics – a mommoth task

For most manufacturers, this will be extremely difficult to realize within the next two years. Especially since each manufacturer has to choose the proper statistical model as the basis for their market observations. Furthermore, they will also have to investigate which model they had been using for their benefit-risk analyses to date – meaning they will have to closely examine the extent to which their clinical evaluations are based on consistent and verifiable statistics.

FDA NEWS

A recent warning letter to a Japanese API manufacturer shows that data integrity is still in focus of the FDA inspectors worldwide. In this case, the inspectors observed inadequate control over the firms HPLC systems. The reliability of the firm's data was questioned in general, due to the observed deviances from cGMP.

ICH NEWS

ICH issued three new topics that will be subject to ICH harmonization. Among these is a planned Guide ICH Q13 regarding Continuous Manufacturing a way of production that will radically change the manufacturing of pharmaceuticals. This reflects also the need to harmonize regulations regarding Process Analytical Technology (PAT) and batch-independent production processes.

That in and of itself can prove to be a mammoth task, since clinical evaluations were generally created based on scientific literature, which in turn, was usually checked for quality. Meaning what was examined was the validity of the literature and the author's qualifications, the verifiability of the patient population and equivalence of the medical device. Statistical questions played a much smaller role and were frequently based on in-house data from complaint management.

Identify and eliminate compliance risks

Add to that the fact that many manufacturers established a practice of relativizing reported complaints by considering them in relation to units sold – although there was rarely a proactive attempt to estimate the number of unreported complaints. Furthermore, many companies did not effectively collect information on "expected undesirable side effects", such as on the effects of product application, e.g., skin burns where electrodes were placed on a patient during defibrillation.

Exactly these and other details of information collection and data verification should be on a company's compliance agenda within the context of the MDR. Article 88-compliant will be manufacturers who

- Have a multidisciplinary team actively address these tasks
- Define a statistical model
- Have proactive complaint management
- Set up interfaces to risk management, product development and sales with their customer or user contacts
- Combine all of these aspects with the post market surveillance plan that will be required under Article 84 of the MDR in mind.

Is your company perfectly prepared to tackle these and other challenges of the MDR? We would be happy to assist you with further technical information and with the implementation arising from the new statutory requirements of the regulation.

Author Martin Rümke is a Lead Business Consultant Medical Device at msg industry advisors ag. He specializes in consulting in the fields of medical devices, compliance and quality management. Please feel free to contact Martin Rümke by e-mail at martin.ruemke@msg-advisors.com or by phone at +49 171 86 56 285.

FDA GUIDES 2019

The U.S. FDA has issued a list of medical device guidance documents that are intended to be published in 2019. Among these are the final versions of guidelines regarding the UDI compliance dates for Class I devices, Clinical and Patient Decision Support Software and draft guidelines on premarket submissions that relate to cybersecurity of medical devices and software contained in medical devices.

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