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European Medical Device Regulation / key changes overview

Date : Aug 07, 2018 - 09:00 AM - Aug 08, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/european-medical-device-regulation-key-changes-overview-aug-2018

Organizer : GlobalCompliancePanel

Venue : WILL BE ANNOUNCED SOON

Location : 1 Main St,
Los Angeles, CA, United States, ZIP: 00000

Europe's new Medical Devices Regulation 2017/745 (MDR) takes effect in May-2020. That seems like plenty of time, but smart companies should start planning their CE transition strategy right away. With manufacturers all over the world transitioning to the MDR and ISO 13485:2016 in the next few years, Notified Body staff shortages and work backlogs are likely to cause delays.

This two-day seminar will provide you insights that allow you to identify the best transition strategy for your company based on your product range, certification cycle, markets you serve, and your Notified Body.

The new Regulations contain a series of extremely important improvements to modernise the current system. Among them are:

- Stricter control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- The reinforcement of the criteria for designation and processes for oversight of Notified Bodies
- The inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations
- The introduction of a new risk classification system for in vitro diagnostic medical devices in line with international guidance
- Improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification
- The introduction of an "implant card" containing information about implanted medical

devices for a patient
- The reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations
- The strengthening of post-market surveillance requirements for manufacturers
- Improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance

What does the medical device industry see as the biggest challenges in implementing the new regulations? Apart from the reclassification of IVDs, the disclosure of technical documentation in the OEM-PLM or supplier relation, clinical trials and the Unique Device Identification (UDI) system do represent challenges.

The number of Notified Bodies in Europe fell from 80 to 60 between 2013 and 2016. It is expected that there will only be 40 Notified Bodies in Europe in 2018. And many of the existing ones might only be able to offer a reduced scope of services. Moreover, there is a shortage of people with the necessary qualifications. Quality management and clinical trials specialists are urgently needed.

The medical device industry, and especially small and medium-sized enterprises, will have to hire additional staff for dealing with regulatory affairs issues. The companies also expect huge additional costs for certification, and reductions in the R&D area. Negative effects are also expected in terms of the number of products launched, i.e. fewer products will be placed on the market. The industry also expects delays in the certification of new products.

Becoming compliant with the new regulation requires resources, time and most likely investments (e.g. in clinical investigations, UDI). The question is if small enterprises can and will invest in their current product portfolio. Now these small companies are often innovative and bring new ideas to the market. However, will they continue if the cost-benefit ratio changes? A possible scenario is that venture capital will help, while on the other hand, chances are high that part of the start-ups will be acquired by other manufacturers.

But there are, at the same time, opportunities.

As a manufacturer, you may profit from the new regulation as well if you secure the certification under the MDR in a timely manner. You will be able to secure your market position as you have now. It is very likely that your competitors will not have the certifications finished on time, and the consequences are that, for the time being, competitors will not have market access to sell. This leads to a competitive advantage for those companies who started and finished compliance with MDR in a timely manner. It is also likely that competitors will reduce their portfolio or parts of it due to the high costs of collecting clinical data, in order to keep the current claims and intended use of the marketed devices.

In every company the situation and compliance level are different. The needs of companies also differ. Still, in most cases, it is advisable to start with a GAP-assessment covering technical documentation and QMS. The results will lead to a master impact matrix, which in turn gives the input for a strategic plan which outlines the realisation phase and defines the projects that need

to start in the implementation phase.

This seminar will give you the knowledge to start this process.

Why you should attend:

Medical device and diagnostics manufacturers are likely to face huge challenges to implement the new requirements imposed by the new European Medical Device Regulation. This does not so much refer to global players (or multinational corporations) and/or those with more than 250 employees. These companies will not be impacted as dramatically as they have the financial and human resources to cope with the upcoming changes in the certification process. Small and medium-sized companies will, however, not find it so easy to implement the new requirements.

Compared to the MDD, MDR 2017/745 introduces a life-cycle approach to ongoing CE Marking compliance. Conformity assessment procedures are more complex, and equivalence will be more rigorously interpreted.

Clinical data and Clinical Evaluation Report (CER) will face heavy scrutiny and require recurring updates. Manufacturers must also fulfill increased post-market surveillance requirements, perform more Post-Market Clinical Follow-up (PMCF) studies, and deliver Period Safety Update Reports (Class IIa devices and above).

Transitioning to the MDR might seem overwhelming and many companies don't know where to start. The first step is to assess your current level of compliance. A thorough Gap Analysis will generate a task list for updating your procedures and documentation. A smart next step is to examine your current clinical data and Clinical Evaluation Report to make sure you comply with MEDDEV 2.7/1 rev 4. Notified Bodies are already requiring a higher level of overall quality for clinical evidence, and complying with clinical data requirements will be a major hurdle for many companies. As a next step, a portfolio assessment should be carried out to determine for which products investments in MDR compliance are justified. Finally, the implementation strategy needs to be defined and executed.

This two-day seminar will provide key guidance and interpretation of the changes to the regulation and will be of value to all those who are involved in placing a medical device on the market, and anyone who requires an essential overview of the new medical device regulation and its impact on the industry and working practices.

The seminar will also present an approach for SME enterprises to manage the challenge of getting into MDR-compliance with reasonable efforts.

Areas Covered in the Session:

- Scope of the MDR and a definition of a medical device
- Classifying medical devices under the European MDR

- Conformity assessment procedures and the role of Notified Bodies
- Safety and performance requirements
- Navigating standards under 2017/745/EU
- Clinical evaluations and "new rules" on adequacy of clinical data
- Clinical investigations and Clinical Research Organizations
- Economic Operators - their roles and responsibilities
- UDI in Europe and how it compares with US FDA UDI requirements
- Post-Market Surveillance (PMS) and Post-Market Clinical Follow-up (PMCF)
- Vigilance requirements for Europe
- The role of the Personal Responsible for Regulatory Compliance (PRRC)
- Planning your transition to the MDR

Who will benefit:

This seminar will benefit professionals at various levels in the following areas:

- Regulatory Affairs
- Clinical studies
- Vigilance
- PMS
- Quality systems

Day 1 Schedule

Lecture 1:

- Introduction
- Fundamentals of the new EU MDR

Lecture 2:

- Pre-Market
    - Classification
    - Conformity assessment route
    - Labelling

Lecture 3:

- Pre-Market
    - UDI
    - Clinical
    - Supply-Chain upstream
    - Supply-Chain downstream

Lecture 4:

- Workshop

Day 2 Schedule

Lecture 1:

- Post-Market
- Vigilance
- Post Market Surveillance
- Post Market Clinical Surveillance

Lecture 2:

- Own Brand Labelling

Lecture 3:

- 8 steps towards MDR compliance

Lecture 4:

- Workshop

Stefan Menzl

Principal Consultant, Qserve

Stefan Menzl has more than 20 years of experience as senior leader in the healthcare industry.

In his current role as Principal Consultant for the Qservegroup, he provides strategic and hands-on support in the Regulatory, Quality and Clinical areas to the medical device industry.

He most recently served as Global Vice President Quality & Regulatory Affairs for Paul Hartmann AG. Before joining Paul Hartmann, he was responsible as functional leader for the Quality, Regulatory, and Clinical areas in companies like Abbott, Advanced Medical Optics, Edwards Lifesciences and Baxter.

Besides his expertise in the Regulatory, Clinical and Quality areas, he also gained experience as General Manger, leader of remote global teams and functional manager of mergers and acquisitions, spin-offs and integration of acquired companies.

Stefan holds a Ph.D. in Biotechnology.

He has published numerous articles related to Quality and Regulatory matters, as well as a training book on CE marking in Europe. He acts as subject matter expert and author for RAPS Education Development. Additionally, he has been lecturing on 'Regulatory Affairs EU & USA' at the University of Pforzheim.

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