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EUROPE – New regulations – What impact will the proposed new regulations in Europe have for medical device manufacturer?

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Abstract

Europe developed their Medical Device regulation much later than US did it. The implemented the Medical Device Directive (93/42/EEC), and this has been having some update since it was introduced in 1995. Last update was the Directive 2007/47/EC. These Directives are implemented by the EU member states into national law, with the possibility to add minor modification, like requiring local language on labeling. In Europe Medical Device manufactures are controlled according applicable standard, like ISO 13485:2003 and their quality system are audited and certified by Notified Bodies.

During the last few years, mistrust to whether the system ensures safe and efficient products have been raised by member states, the public and by the European Commission. A great example is the so called “Breast implant scandal”, where a company used non-medical grade silicon, simply to save money. For these reasons, and due to that the medical device industry has developed over the last several years, the European Commission developed in September 2012 a new European Law for Medical device regulations. The session will focus on what impact this so called ReCast will have for the Medical device manufacturers selling in Europe. It will explain how the process is to implement these regulations and the estimated timeline. It will explain the different proposal in details, including Technical terms like UDI, EUDAMED, eIFU and the scrutiny process. It will present what the European Commission suggest should enhance control of manufacturer and Notified Bodies.

Biography

Toni Jorgensen has studied Chemistry and IT at Danish Technical University and University Of Witwatersrand in South Africa. After his MSc and PhD work he did a Pharma MBA and is a certified Lead Auditor. His Regulatory, Clinical and Quality/Compliance experienced started at Medtronic, and after this he has been in different leading position within the Medical Device & Pharmaceutical industry, in company such as Johnson & Johnson and Coloplast. The last more than 6 years he is working in Switzerland for Straumann, where he is the Global Vice President for Corporate Regulatory Affairs and Compliance. He has been participating in Medical device harmonization groups like AHWP (Asian Harmonization Working Party) and GHTF (now IMDRF) for more than 10 years.