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Proposal for new legislation in Europe

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In September 2012 the European Commission presented its proposal for a new regulatory framework for medical devices, active implantable devices and *in vitro* diagnostics. The background to the new proposal is multifaceted. The main reason is that the commission believes that the current framework is simply getting too old. It has not, they say, kept pace with the rapid technological developments in the field over the last twenty years. Additionally rules are interpreted different in the different member states which create trade barriers between countries which were the opposite meaning with CE-marking. Moreover, it can make the safety of the patients depends on where in Europe you are situated. Major changes are that the directives instead will be national legislations, which do not give room for different interpretations when the rules are introduced. Further changes are wider product scope, further responsibilities and rights for authorities and Notified Bodies such as unannounced factory inspections (same as with the FDA) and sample testing, introduction of a qualified person (5 years QA/RA experience) within the company, enhanced traceability, tougher rules for clinical trials and the clinical data etc. The proposal is expected to be adopted in 2014 and would then gradually take effect between 2015 and 2019. This presentation will cover the major changes in the proposal and the impact it will have on the product and the overall process.

Biography

Micael Johansson has a long career with product development and RA/QA issues. He finished his master degree in 2002 followed by six years at Intertek SEMKO (test house/notified body). He then changed to a product developing company, Maquet Critical Care and was heavily involved in development and standard issues for ventilators and anesthesia machines. A new turning in the career led to consulting, first as manager for an in house developing department as well as responsible for regulatory specialists. Now he works as senior consultant at Symbioteq, a regulatory and quality expert company. At Symbioteq he is part of the management board. Micael has the latest years been member of several standard committees, both national and international. Micael Johansson has for several years given open courses at the Swedish Standard Institute in areas such as legislation, risk management and standards.

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