Ajrulla Zuta, Pharmaceut Reg Affairs 2014, 3:3
http://dx.doi.org/10.4172/2167-7689.S1.016

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

EU Medical device regulation

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Medical device manufacturers face global economic challenges in an ever-changing regulatory environment. These changes come in the form of more stringent and complex regulations, higher patient expectations and commercial pressures. The increased complexity of the regulatory environment has provided a great challenge to the medical devices industry since the medical device directives were transposed into the national regulation in the European Economical Area. A solid understanding of the EU directives governing medical devices is paramount. These include: Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC, Medical Devices Directive (MDD) 93/42/EEC and In Vitro Diagnostic Devices Directive (IVDD) 98/79/EC in their latest revision, including the 2007/47/EC amendments to AIMDD and MDD. The presentation covers the regulatory requirements (product classification, labeling, conformity assessment, essential requirements, post-marketing) through the product lifecycle.

Biography

Ajrulla Zuta has completed his Master of Science in Chemistry at the age of 25 year at Gothenburg University, Sweden. He also holds a Regulatory Affairs Certification (EURAC). He is currently the Regulatory Affairs Manager at Breas Medical AB. He has 16 years of experience in the medical device industry. Having worked in different positions/roles for several major medical device companies, he brings extensive experience in product development, regulatory affairs, and quality assurance.

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