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Complaints handling and post marketing surveillance

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Abstract

Compliance to the European Medical Devices Directive (MDD 93/42/EEC), In Vitro Diagnostic Medical Devices Directive (IVDD 98/79/EC), FDA Quality System Regulation (21 CFR Part 820), and ISO 13485:2003 requires Medical device manufacturers to develop, implement and maintain processes for medical device complaint handling and post market surveillance in accordance with these requirements.

Over the last several years, users and regulatory agencies are becoming less tolerant of medical device failure. Most regulatory agencies are placing greater emphasis on handling of customer complaints, post market surveillance as a way to improve risk management and protect public health. Integration of post market surveillance systems is becoming more and more important due to this increased emphasis and scrutiny by regulators around the globe. My presentation "*Medical Device Complaint Handling and Post Market Surveillance – Importance and Integration with Quality Management System*" will give medical device manufacturers an opportunity to learn about current Complaint Handling and Post Market Surveillance requirements and how to integrate these requirements in the quality management system. At the conclusion of the presentation participants will understand aspects such as the legal basis for these requirements, categories of post market systems, integration with risk management and vigilance processes of QMS, implementation of closed loop PDCA cycle with PMS requirements, parties/stakeholders involved in PMS and so on.

Biography

Harshit Thakkar is a Project Manager for DEKRA Certification B.V. in Chalfont, PA, USA. DEKRA Certification B.V is a leading European notified body for MDD, IVDD and AIMDD Directives and is also a leading certification agency for ISO 13485 (including CMDCAS) and ISO 9001 quality management system certifications. Mr. Thakkar is a lead auditor for CE audits and ISO 13485/ISO 9001 audits (including CMDCAS) and also performs Technical File and Design Dossier reviews for clients seeking CE marking for non-active and active medical devices. Mr. Thakkar has seven years experience of working in the medical device industry in the field of engineering, quality and regulatory affairs. Mr. Thakkar holds a Masters Degree in Biomedical Engineering from University of Southern California, Los Angeles, USA and Bachelors in Biomedical Engineering from D. J. Sanghvi College of Engineering, Mumbai, India.