MDR Compliance

In 2017, the new European Medical Device Regulation (MDR) and the Regulation on In-Vitro Diagnostic Medical Devices (IVDR) came into force. These replace the existing directions on medical products.

EXCO supports a client by ensuring compliance with the requirements of the new EU MDR/IVDR. This includes indivdual consultation with recommendations for action and the specific implementation of entire work packages.

Implementation

EXCO was commissioned by the client's Regulatory Affairs and Quality Assurance department to assess the existing development process for regulatory and legal compliance with the EU IVDR.

The following tasks were defined:

- Performance of a GAP analysis, evaluation and adaptation of the Regulatory / Quality Guidelines to relevant regulatory and legal requirements
- Ensuring the regulatory compliance of processes and products, taking into account the quality requirements of ISO 13485 and the new EU IVDR
- Cross-departmental implementation of processes and coordination
- Advice and support for process managers in creating, managing and maintaining the processes

Measures

By clustering the MDR requirements into sub projects a conclusive gap analysis was performed. A catalogue of measures required was established and actions taken in close cooperation with the Notified Body. The medical devices were approved according to the new MDR classification rules.

With tailor-made service packages, EXCO supports our customers in fulfilling all new requirements result from the MDR.

Cristian Stelzl-Slavu, Senior Quality Process Consultant

Customer benefit

- Efficient support of client's core compliance team
- Short-term availability of MDR specialists
- Remote and on-site deployment of the MDR specialists
- One contact for all sub-projects

Client

Manufacturer of pre-analytical systems, Switzerland/Germany

Your expert contact - Projects Switzerland

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