GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Webinar on

Is Your Quality Management System Up to Date for the New European Medical Device Regulation Starting in May 2020?

Learning Objectives

- *New quality management processes according to EU MDR additional to the required EN ISO 13485:2016 quality management standard for medical device companies in Europe*
- *New requirements in the product documentation*
- *New requirements in Post Market Surveillance*
- *New Requirements in Clinical Evaluation*
- *New Requirements in Post Market Clinical Follow up*
- *New Requirements in company staffing e.g. “Responsible Person” for MDR*
- *EUDAMED-Database*

GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

This course will give an introduction to the European Medical Device Regulation with the requirements for your quality management system.

PRESENTED BY:

Prof. Dr. h.c. Frank Stein, medical engineer, medical engineering experience for 25 years, clinical and research experience in cardiac surgery and cardiology, industrial experience in ophthalmology, neurology, traumatology and dental implants, active implants, active devices, international project and regulatory consulting experience in Europe, North-America, Asia, Australia, Arabic Countries, Latin-America.

GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

The EU MDR 745/2017 is a complete game-changer to the old law of the MDD 93/42/EEC since 1993 with a couple of updates. The time is very short and the number of requirements and required changes is high. The training will show, how to conduct a gap analysis, an action plan and how to be on track until May 2020. Learn, what to do into the quality management department and what to do in the regulatory affairs department. The EU MDR requires changes in both areas. Technical documentation and quality management are strong connected e.g. in the processes post-market surveillance, post-market clinical follow-up, clinical evaluation, risk management, technical documentation, complaint management, vigilance management and the new required role of the “responsible person” similar to the pharma law.

This course will give an introduction to the European Medical Device Regulation with the requirements for your quality management system. The introduction will give an overview about the structure, term definitions, the requirements for the quality management system and an outlook to the technical documentation with needs for the quality management system., how a smart implementation of these requirements in the quality management system is possible and finally how to prepare the audits according to EU MDR.

Who Should Attend ?

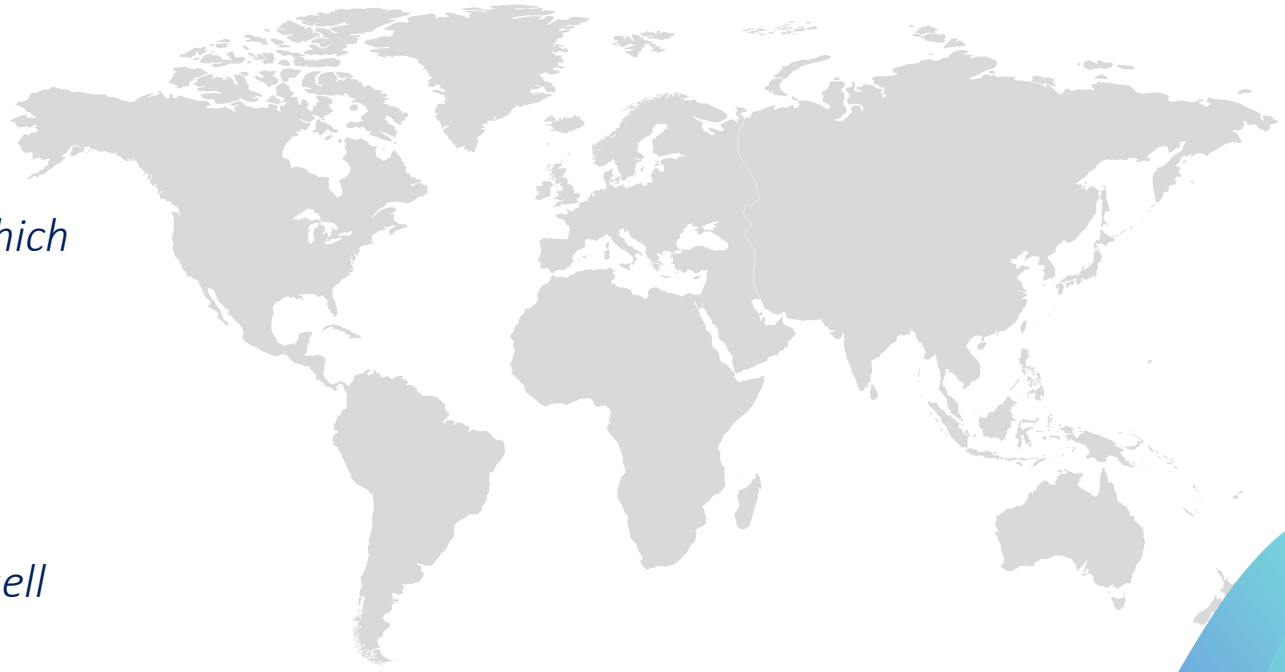
CEO's of companies, which sell to Europe

Regulatory Affairs Managers of Companies, which sell Europe

Quality Managers of Companies, which sell to Europe

Quality Representatives of Companies, which sell Europe

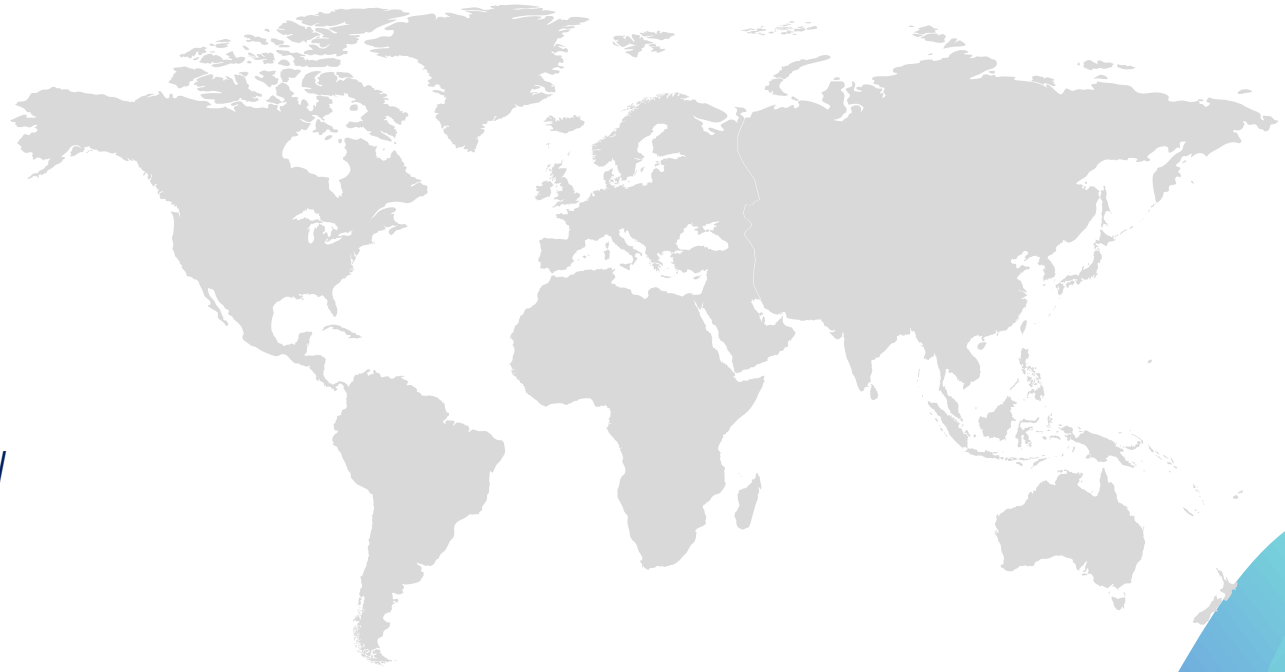
Other managers, which need to deal with regulatory or quality guidelines



GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Why Should Attend ?

You should attend to learn more about the EU MDR, because you must have the new regulation implemented in your company until May 2020. The EU MDR is a complete game-changer to the old law of the MDD since 1993. The time is very short and the number of requirements and required changes is high. Learn how to plan and conduct a gap analysis, an action plan and how to be on track until May 2020. Learn, what to do into the quality management department and what to do in the regulatory affairs department. The EU MDR requires changes in both areas. Technical documentation and quality management are strongly connected e.g. in the processes post-market surveillance, post-market clinical follow-up, clinical evaluation, risk management, technical documentation, complaint management, vigilance management and the new required role of the "responsible person" similar to the pharma law.



GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

To register please visit:

www.grceducators.com
support@grceducators.com
740 870 0321