

*Webinar on*

# **EU MDR-Introduction in to The European Medical Device Regulation**

# 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*



This course will give an introduction to the European Medical Device Regulation.

**PRESENTED BY:**

*Prof. Dr. Dr. h.c. Frank Stein, a medical engineer, medical engineering experience since 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 EMEA, APAC, LATAM.*

On-Demand Webinar

Duration : 90 Minutes

Price: \$200

# Webinar Description

The EU MDR 745/2017 is a complete game change 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. The introduction will give an overview about the structure, term definitions, the requirements for the quality management system and the technical documentation, how a smart implementation of these requirements in the quality management system and the technical documentation is possible and finally how to prepare the audits according to EU MDR.



# Who Should Attend ?

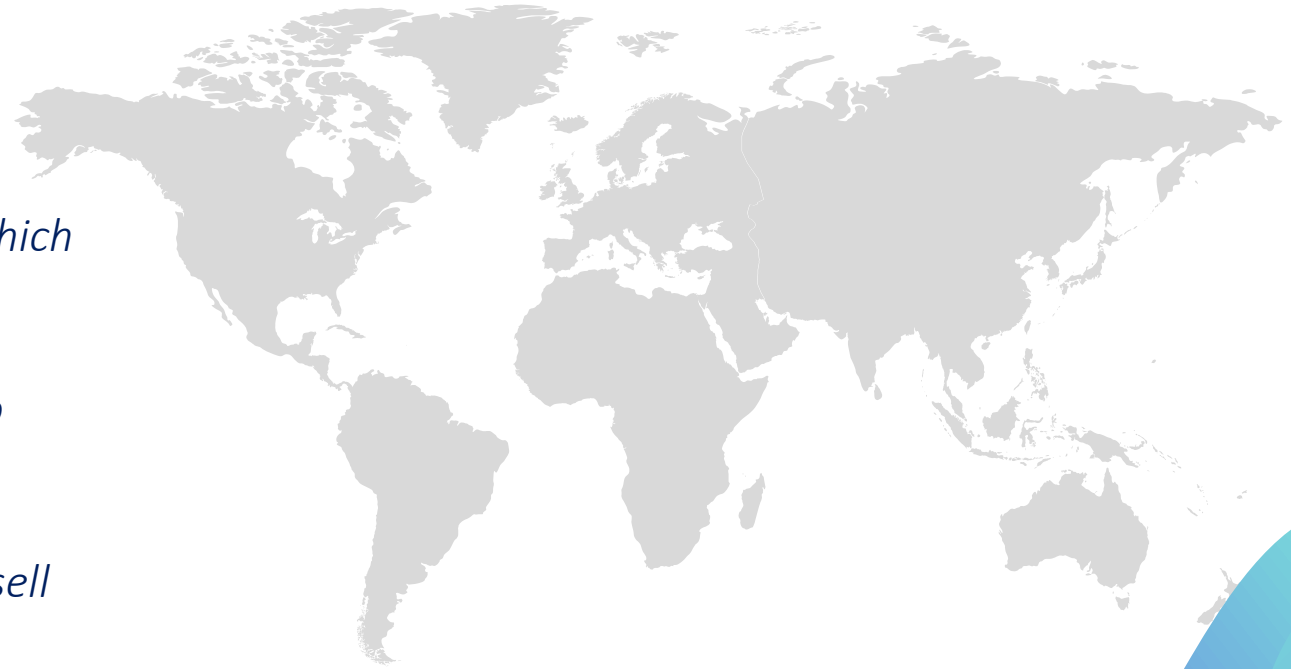
*CEO's of companies, which sell to Europe*

*Regulatory Affairs Managers of Companies, which sell Europe*

*Quality Managers of Companies, which sell to Europe*

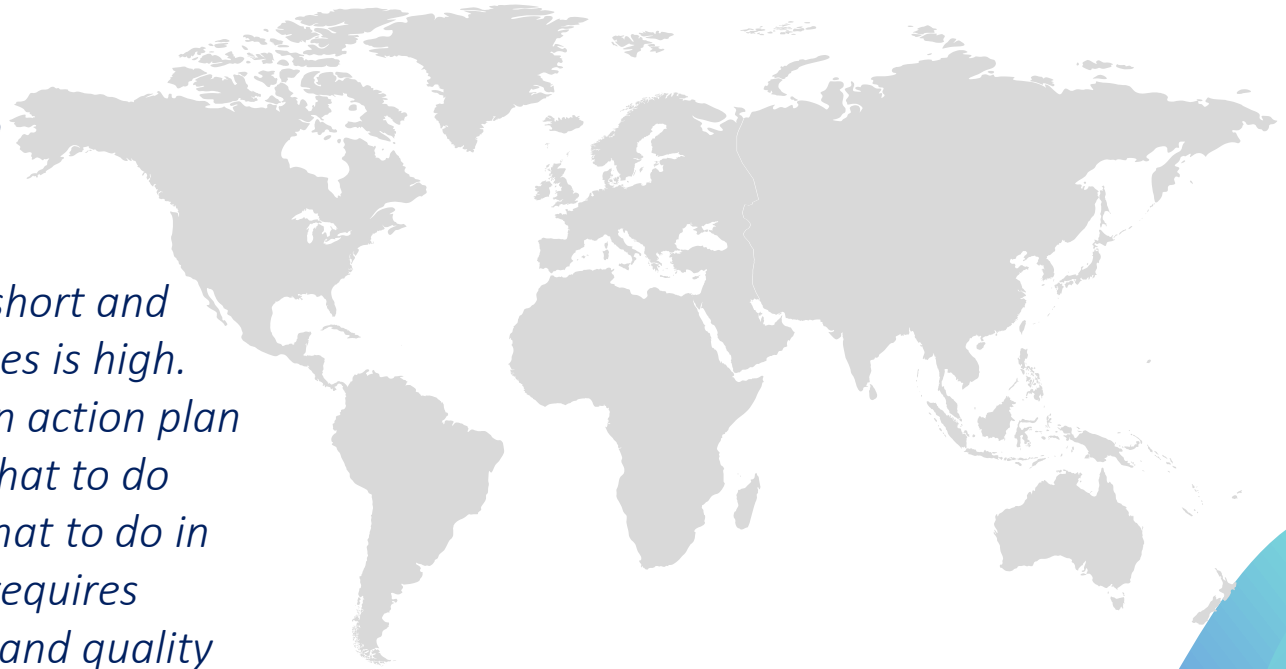
*Quality Representatives of Companies, which sell Europe*

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



# 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 change 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 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.*



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