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Webinar on

EU Medical Devices Regulation: The Practice

Date : April 06, 2020

Learning Objectives

- *Principle points*
- *The Scope of the Regulation*
- *General Safety & Performance*
- *EUDAMED*
- *Changes on Notified Bodies*
- *Classification of Devices*
- *Post Marketing Surveillance*
- *Quality Management Systems*
- *Confidentiality*
- *Useful Information*
- *Certification Expiration*
- *CE Marking*

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Areas Covered

- *Human Error as the Root Cause, Trending and tracking*
- *What is Human Error*
- *How is Human Error controlled?*
- *6 step method for error prevention*
- *Human error rates and measurement*
- *Root Cause Determination*
- *Prediction, CAPA effectiveness*

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During this class participants will be introduced to the new requirements in the Medical Device Regulation (MDR), including those related to quality systems, product classification rules, technical documentation, clinical evaluations, Unique Device Identification (UDI), and Postmarket surveillance.

PRESENTED BY:

Yuval Shapiro is the founder of QWV – Quality with Value, QA/RA Services. An expert for products and companies primarily related to medical devices that meet the real needs of their clientele. Substantial experience gained in various multi-discipline technology industries (Military, Telecom & Medical Devices), and give a high-value contribution to quality and reliability projects related to the medical device and telecom industries.

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Date : April 06, 2020

Time : 01 : 00 PM EST

Duration : 90 Minutes

Price: $179

Webinar Description

The EU Medical Device Regulation (MDR 745/2017) represents a considerable change from the directives it is replacing. Device manufacturers who conduct business in the EU must start their transition now in order to meet the deadline. This training is the first peek into this uncharted realm.

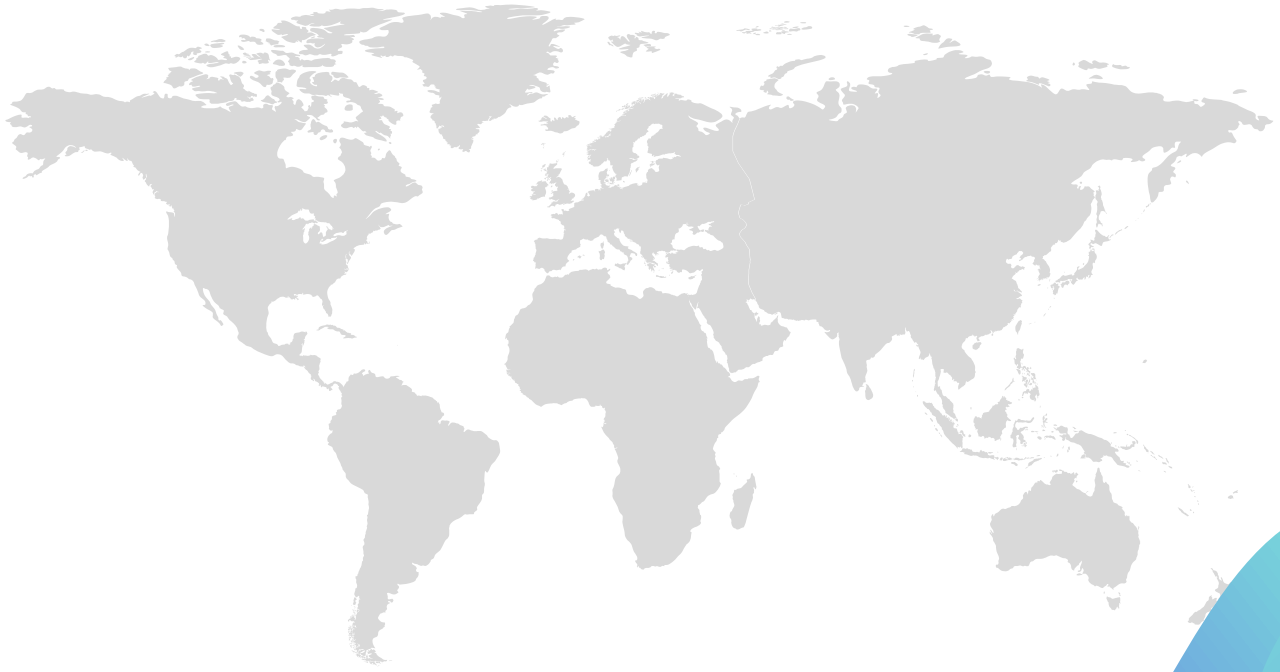
During this class participants will be introduced to the new requirements in the Medical Device Regulation (MDR), including those related to quality systems, product classification rules, technical documentation, clinical evaluations, Unique Device Identification (UDI), and postmarket surveillance.

Also, learn how to plan an efficient transition.

In May 2017 the European Union has released its new regulation concerning Medical Devices. This regulation introduces many challenges to the Medical Devices industry.

Who Should Attend ?

QA/RA engineers
QA/RA managers
Medical Devices Engineers



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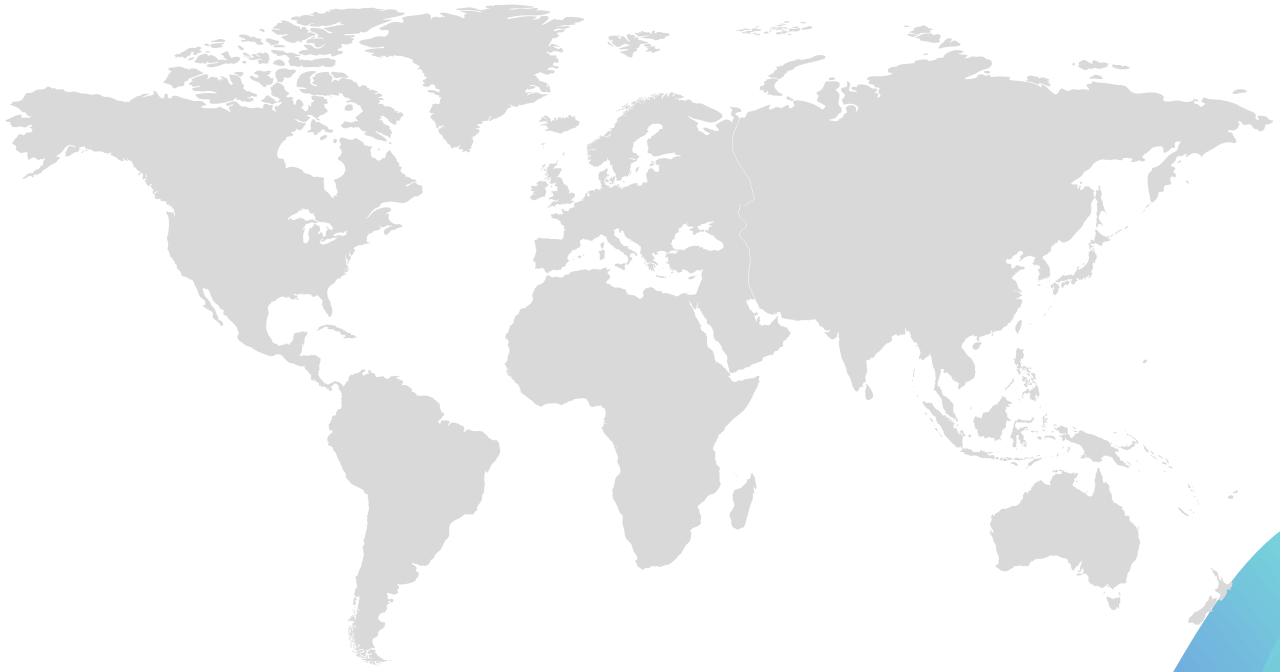
Why Should You Attend ?

One should attend, in order to start understanding what is the new challenge and ways to handle it. How to establish the correct strategy? What is newly adopted as a requirement, and what did not receive a proper answer, yet?
What



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