Webinar on

New ISO14971: 2019 Risk Management Standard for Medical Devices – Implementation

Learning Objectives

- *Risk-based approach*
- *Risk Management fundamentals*
- *Risk Analysis*
- *FMEA*
- *ISO14971: 2019 Medical Devices — Application of Risk Management to Medical Devices*
- *ISO/TR24971: 2020 - Medical devices — Guidance on the Application of ISO 14971*

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Mr. Shapiro shall present the basic principles and practices of Risk Management and Risk Analysis. The risk-based approach has become a key element of quality management and as a fundamental process in the design and development of medical devices products.

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. Substantial experience gained in various multi-discipline technology companies and give a high-value contribution to quality and reliability projects related to the medical device and telecom industries. More than 25 years of experience in QA; including MD&D RA & QA;QMS (21CFR - Part820, ISO13485, TL9000, CMDCAS, ISO9001). EH&S Systems; QA/RA representative in R&D Projects; Risk Analysis as per ISO14791& ISO31000; EMC & Safety Certifications.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

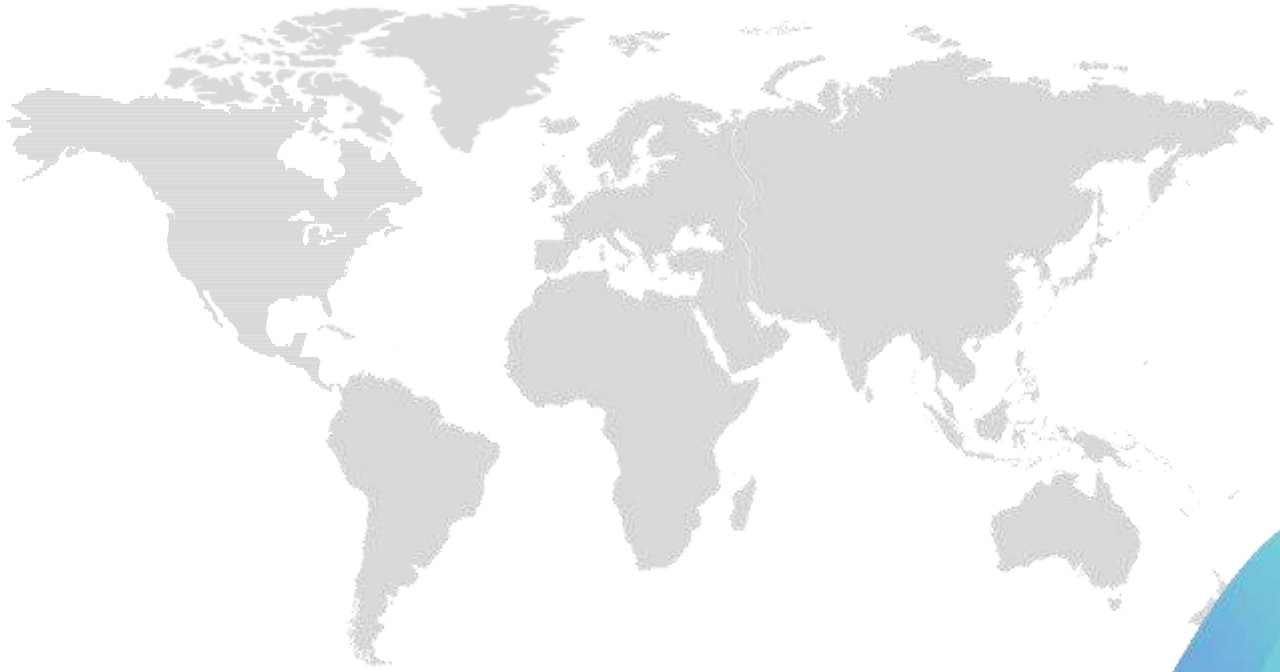
Webinar Description

Mr. Shapiro shall present the basic principles and practices of Risk Management and Risk Analysis. The risk-based approach has become a key element of quality management and as a fundamental process in the design and development of medical devices products. This process has been streamlined within ISO14971 standard and has become the best practice to show the application of risk-based approach implementation in the design and development stages of the medical device. The presentation shall include how to implement best practice tools to manage risk analysis and risk management. In addition, the webinar shall present the changes in the new revision of the standard.

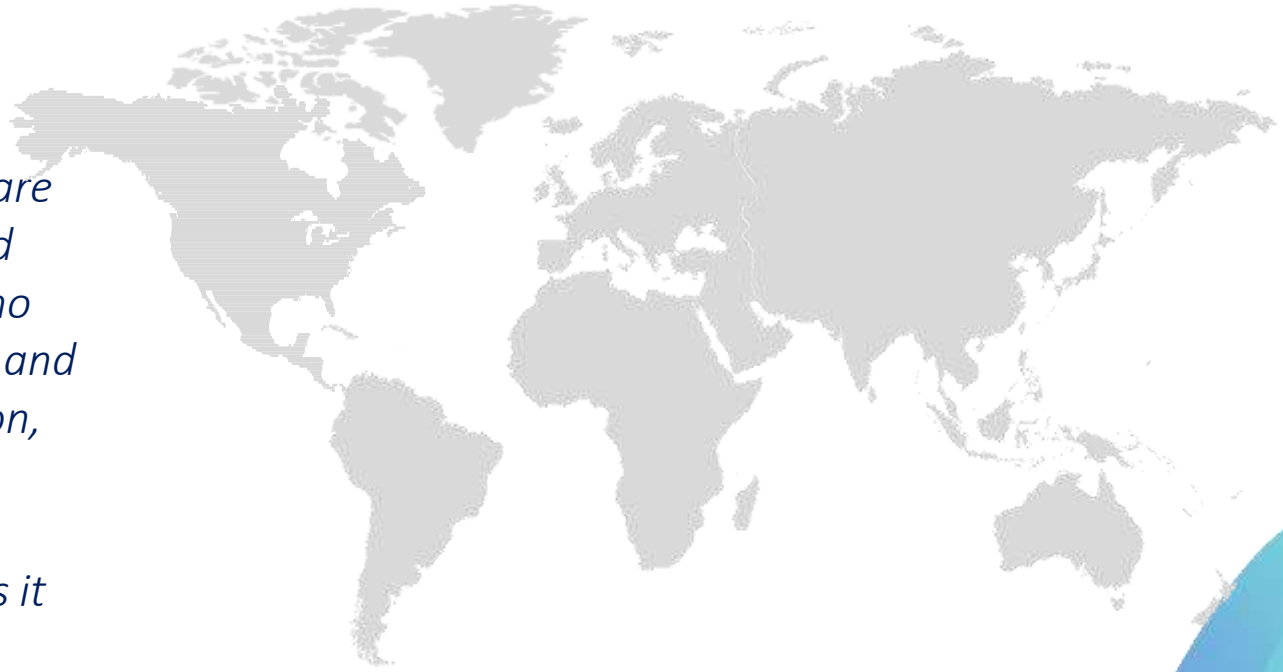
Risk approach has become a mandatory practice during the Product Realization of Medical Devices. This practice should be applied as per ISO14971: 2019, the brand-new revision of the well-known and practice standard.

Who Should Attend ?

Quality Assurance Managers, Quality Assurance Engineers, R&D Managers, R&D Engineers, Production Managers, and Production Engineers



Why Should You Attend ?



This webinar is intended for engineers and managers in the medical devices industry who are required in the line of their job to be acquainted with the Risk Management process or those who are familiar with the risk management process and would like to refresh their knowledge. In addition, this presentation presents the new ISO14971: 2019Medical Devices — Application of Risk Management to Medical Devices and compares it to the previous revision of the standard (2007/2012). Also – the presentation presents the new ISO/TR24971: 2020 - Medical devices — Guidance on the Application of ISO 14971.

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