

ComplianceOnline Hosts Virtual Seminar on Lead Auditor EN ISO 13485:2016 and EU MDR 2017/745 Regulation

"Lead Auditor EN ISO 13485:2016 and EU MDR 2017/745 - Regulation" Seminar has been added to ComplianceOnline.com's offering.

SAN JOSE, CA, UNITED STATES, June 21, 2021 /EINPresswire.com/ -- ComplianceOnline, the world's leading provider of training for regulated companies is holding a seminar entitled 'Lead Auditor EN ISO 13485:2016 and EU MDR 2017/745 - Regulation.' The seminar will be held on July 12-13, 2021, and will be presented by Prof. Dr. h.c. Frank Stein.



The new medical device regulation EU MDR 745/2017 in the European Union has a lot of new requirements. This new upcoming regulation is also stronger connected to the EN ISO 13485:2016. The understanding of these changes and how to implement last-minute changes until May 2021 is essential to keep your certificates.

The first key for the understanding and the implementation of the changes is the knowledge about the interfaces between the EN ISO 13485:2016 and the EU MDR 2017/745. The second key is to understand which parts of the EU MDR 2017/745 are not covered by the EN ISO 13485:2016. These not covered paragraphs and requirements must be additionally implemented into the quality management system until May 2021. The time is short and immediate action is required.

Learning Objectives:

- Introduction, who must apply the new EU MDR 2017/745 requirements?
- Overview about the changes of the EU MDR 2017/745 regarding quality management

- What are the interfaces between the EN ISO 13485:2016 and the EU MDR 2017?
- Which new requirements of the EU MDR 2017/745 are not covered by the EN ISO 13485:2016?
- Smart and fast ways to implement the changes in your quality management system
- Fast track internal audit to approve the changes

Areas Covered:

- The new scope of the EU MDR 2017/745
- The obligations and roles of the EU MDR 2017/745
- How work the regulation and the EN ISO 13485:2016 together?
- New and updated processes required by the EU MDR 2017/745
- How to implement the required changes until May 2021?

Who Will Benefit:

- CEO's, product manager, quality/regulatory/medical affairs manager, quality representatives of
- Medical device manufacturer
 - Importer
 - Distributors
 - Dealers

For more information or to register for this seminar, [please click here](#).

Virtual Training Through WebEx

Date: July 12-13, 2021 (10:00 AM to 6:00 PM EDT)

About the Speaker:

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.

About ComplianceOnline.com:

ComplianceOnline is a leading provider of regulatory compliance training programs for companies and professionals in regulated industries. ComplianceOnline has successfully trained over 55,000 professionals from 15,000 companies to comply with the requirements of regulatory agencies. ComplianceOnline is headquartered in Palo Alto, California, and can be reached at <http://www.complianceonline.com>. ComplianceOnline is a MetricStream portal. MetricStream (www.metricstream.com) is a market leader in Enterprise-wide Governance, Risk, Compliance

(GRC), and Quality Management Solutions for global corporations.

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