ComplianceOnline Hosts Virtual Seminar on the Fundamentals of EU MDR and IVDR for Medical Device Companies

"Fundamentals of EU MDR and IVDR – Level 1" Seminar has been added to ComplianceOnline.com's offering.

SAN JOSE, CA, UNITED STATES, June 15, 2021 /EINPresswire.com/ -- ComplianceOnline, the world's leading provider of training for regulated companies is hosting a virtual seminar entitled 'Fundamentals of EU MDR and IVDR' for medical device companies. The seminar will be held on June 24-25, 2021, and will be presented by Kelly Eisenhardt Co-Founder and Managing Director at BlueCircle Advisors LLC.

This 2-day seminar will go into the specifics of the European Union Medical Device Regulation (EU MDR) and the In Vitro Diagnostic Device Regulation (IVDR), provide case studies and share lessons learned so your organization can benefit from the mistakes of others.

The seminar will review the latest changes to the regulations effective and in force for 2020 and will draw out key developments and key dates with particular emphasis on requirements for US firms shipping materials, parts, and products to the European Union.

Learning Objectives:

After completing this seminar, you will gain a better understanding of:
- Reasons for the Medical Device Regulation
- Structure and objectives of the MDR
- Timeline for transition
- Difference between the old requirements (MDD) and the new (MDR)
- Ability to identify the lifecycle of a device and the requirements of the various stages – premarket, design and development, product realization, and post market

- Understand the impact of the regulation changes on “economic operators” (Articles 11, 13, 14)
- How to transition from the old directives to the new regulation
- Identifying high risk devices
- General safety and performance requirements (GSPR Annex 1)
- Review Common Specifications (CS)
- Connection between MDR and ISO 13485:2016
- Technical file requirements and reviews
- UDI and traceability
- Linking to the Quality Management System (QMS)
- Steps of a gap assessment “As Is” and “To Be” for transitioning to new compliance requirements
- Basic understanding of the EUDAMED database for post market surveillance
- Preparing for transition to MDR

Areas Covered:

Topics covered in this seminar include:
- Objectives of the medical device regulation
- Directives replaced with regulation
- Risk based device classification
- Conformity assessment and its relevant changes (Annex IX, Annex X, Annex XI)
- Requirements for technical documentation found in GSPR Annex 1
- UDI and traceability requirements, responsibilities, and impacts (EUDAMED)
- Process for clinical evaluations
- Clinical evidence with supported documentation
- Post market requirements (Annex XIV and Annex 3 Part B)
- Audit management and Notified Bodies requirements for manufacturers, as well as internal audit impact (Article 51, Annex V111)
- Impact on the Quality Management System

Who will Benefit:

This seminar will provide valuable assistance to all personnel in:
- Manufacturers, distributors, and importers of medical device equipment
- Quality and regulatory affairs
- Product engineers focused on medical device products
- Corporate risk management teams
- Suppliers to medical device companies

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: June 24-25, 2021 (8:00 AM to 2:00 PM PDT)

About the Speaker:
Ms. Eisenhardt is Co-Founder and Managing Director at BlueCircle Advisors LLC, a consulting firm providing strategy and programming to address the global challenges of product compliance, business continuity, and supply chain risk management.

Her company's mission is to protect corporate revenues by building product and supply chain compliance programs that meet global requirements, provide the necessary due diligence to maintain and secure new business, and to train the next generation of managers in the compliance field. She is currently working with clients in the electronics, aerospace & defense, plastics, and medical device industries to implement compliance programs for regulations like EU MDD/MDR, RoHS, REACH, Conflict Minerals, supplier code of conduct, and anti-trafficking. With 20 years' experience in IT and Compliance Software Development, her former roles include: Executive Director of Environmental Programs, at Fair Factories Clearinghouse; Environmental Compliance Manager and Design for Environment programs at EMC/Dell Corporation; and Director of Product Management at PTC Corporation for Windchill Product Analytics – an environmental compliance software.

She is also a journalist for industry trade publications such as 3BL, JustMeans, Social Earth, CSRwire, Ethical Performance, and CSR@Risk with a focus on trends in product compliance, supply chain transparency, and corporate social responsibility.
She currently is the host of the BlueCircle Advisors Hour, a radio show on WCRN broadcast along the east coast of the United States and accessible via internet radio stations like Tunein.com. The radio show discusses product compliance topics of interest and includes interviews with leaders in the compliance and technology fields. Podcasts will be available on iTunes, Google Play Store, Stitcher, and more in early September 2019.

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.

For more information on ComplianceOnline or to browse through our training programs, please visit our website.

Priyabrata Sahoo
ComplianceOnline
+ +1-888-717-2436

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