ComplianceOnline Launches Virtual Seminar on In-vitro Diagnostics (IVD) Regulations

"In-vitro Diagnostics (IVD) Regulations in U.S./Europe/Canada" Seminar has been added to ComplianceOnline.com's offering.

SAN JOSE, CA, USA, March 4, 2021 /EINPresswire.com/ -- ComplianceOnline, the world's largest GRC advisory network, has officially launched registration for the Seminar 'Navigating through Maze of In-vitro Diagnostics (IVD) Regulations: A systematic approach from Regulatory Strategy to Regulatory Approvals in U.S./Europe/Canada' with Haja Sittana El Mubarak, Senior IVD consultant, Biologics consulting Inc. The Seminar will be held on March 11-12, 2021 (11:00 AM to 06:00 PM EST).

In-vitro Diagnostics (IVD) products provide critical information on patient's health condition, based on which the healthcare provider develops and administers treatment plan. Although IVDs are medical devices, they are regulated under a separate set of regulations in U.S., Europe, and Canada.
This 2-day interactive course on in-vitro diagnostics is structured to understand the different set of IVD regulations, how to navigate through this maze of IVD regulations, and to win regulatory approvals. This In-vitro Diagnostics (IVD) course will make the attendees understand the IVD regulations and develop regulatory strategies that secure regulatory approvals.

Learning Objectives:
After completion of this two-day interactive course on IVD, the attendees will be able to:
- Understand why IVD is regulated differently.
- An overview of IVD Regulations – U.S. FDA., Europe (MDD), Canada.
- Develop Regulatory Strategies and determine Regulatory Pathways.
- Inclusion and exclusion of data and information for different submission.
- Format and Content of premarket submissions.

- Product Label and Labeling for IVDs.
- Working and interacting with the reviewers and regulators.
- Tips and Suggestions to secure rapid regulatory approvals.

Who will benefit?
This interactive course is specifically developed for individuals, who are responsible for the design, development, manufacturing, marketing, and distribution of IVD products. This course is highly recommended for personnel involved in any of the following functions:
- Department Managers (middle management)
- Research & Development (R&D)
- Product Design & Development
- Validation Engineering
- Regulatory Affairs
- Quality Assurance
- Quality Control
- Manufacturing/Production

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For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: March 3-4, 2021 (10:00 AM to 5:00 PM EST)

About the Speaker:

Dr. El Mubarak is a Senior IVD consultant at Biologics consulting Inc. She has over 12 years of FDA experience spent primarily in the Center of Devices and Radiological Health (CDRH). Haja served for five years as the agency subject matter expert in Serological and Molecular Diagnostics of Viral Infections, representing the agency in providing consults, outreach and training to national and international stakeholders. Dr. El Mubarak has extensive experience in pre- and post-market regulation of in vitro diagnostic devices (IVDs) and is an expert in working with a variety of submission types including; 510(k)s, PMAs, IDEs, de novos, pre- submissions,

513 (g)s, and post-market submission.

Dr. El Mubarak has extensive knowledge of FDA regulations and policies, solving complex regulatory policy issues and communicating regulatory policies to internal and external stakeholders. She has an established record in developing regulatory guidance, Agency reports, internal policies, GHTF documents and CLSI documents.

Dr. El Mubarak has over 20 years of technical experience, in diagnostic virology, molecular biology, serology and IVD device development in clinical laboratory, academic research and regulation. She is an talented communicator, experienced in problem solving, stakeholder engagement and negotiation. She has taken multiple leadership roles in the agency in the areas of strategic planning, change management, training, outreach and championing diversity in workplace.

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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