ComplianceOnline Hosts Seminar on MDSAP Implementation & Participating Country Regulatory Processes: U.S, Canada, Brazil

"Medical Device Single Audit Program Implementation & Participating Country Regulatory Processes" Seminar has been added to ComplianceOnline.com's offering.

Medical Device Single Audit Program [MDSAP] Implementation

SAN JOSE, CA, UNITED STATES, May 11, 2021 /EINPresswire.com/ -- ComplianceOnline announced the details of its upcoming one-day that will highlight Medical Device Single Audit Program implementation and the Regulatory Requirements for the participating MDSAP Countries of: U.S., Canada, Brazil, Australia, and Japan.

Global Medical Device Regulations continue to evolve, as devices become more diverse and sophisticated. Understanding the regulations and requirements in your targeted markets will expedite the speed-to-market of innovative products and assist patients needing access to life-saving products and technologies. Government Regulatory Authorities, needing to become more efficient with their time, are looking for ways to better use their internal resources without compromising safety in products, which become marketable. One such example is the Medical Device Single Audit Program [MDSAP], where Authorized Organizations would be allowed to carry out a single GMP audit on medical device manufacturing facilities and have it stand to support registrations across the current participating member countries: U.S. Canada, Brazil, Australia and Japan. Health Canada has now made the MDSAP process mandatory for all licensed products in Canada.

This 6-hour seminar is focused on understanding the Medical Device Single Audit Program, the scope of the program, how to apply, the Authorized Organizations, the rating system developed, and what you can expect when signing onto the program. The webinar will discuss how such audits are organized, what to expect during an MDSAP audit, how does it differs from a typical certified body audit, and document movement and timeline expectations in receiving the

facility's certificate.

Learning Objectives:

- The Medical Device Single Audit Program (MDSAP)
- Device Classification
- Licensing Pathways
- Medical Device GMP
- Inspections
- Device Labeling
- License Holder Responsibilities
- Timelines and Fees
- Country Specific Cultural Considerations and Challenges
- Adverse Event Reporting

Who Will Benefit:

This seminar will provide invaluable assistance to all personnel in the Medical Device industry, who have a stake in expanding their business into a MDSAP participating country and for those interested in more information about MDSAP and how it may apply to them.

This seminar will be particularly useful for those involved in research and development, document creation for regulatory submission, data handling and for those conducting/monitoring/coordinating clinical investigation, performing risk management and post-market vigilance/surveillance. This seminar is a must for those who are looking to apply for a medical device registration and product license in a MDSAP country.

Those employees working in the following roles will significantly benefit by attending:

- Regulatory Affairs
- Quality assurance, quality control, and quality systems
- Product development personnel
- Contract research organizations
- Business management
- Site managers
- Senior and executive management
- Contractors and subcontractors
- Distributors
- Consultants

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: May 26, 2021 (11:00 AM to 5:00 PM EDT)

About the Speaker:
Bob is a Global Regulatory and CMC expert with 28 years of prior industry experience in international regulatory management and compliance, global business development and global supply chain management. Mr. Russell formerly held senior leadership positions, in these functional areas, at Dow Pharmaceuticals and Cordis-Dow Medical Devices. His experience and knowledge span Healthcare Authority's requirements and regulatory processes across Life Science products.
For the past 18 years, Bob has been President & CEO of RJR Consulting, Inc. The company assists the pharmaceutical, medical device and biotech industries in understanding Regulations affecting compliance and in conducting product registrations with their clients in more than 95 countries.
He holds a BS / MS in Chemistry.

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
email us here
Visit us on social media:
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