SAN FRANCISCO
EVENTS LIST

Medical Device Single Audit Program [MDSAP] Implementation & Participating Country Regulatory Processes: U.S., Canada, Brazil, Australia and Japan

Date : Jun 21, 2018 - 08:30 AM

Event URL : http://www.sfbayeventslist.com/events/medical-device-single-audit-program-mdsap-implementation-participating-country-1521210854

Organizer : NYMT

Venue :

Location : TBASan Francisco, CAUnited States,
San Francisco, CA, US, ZIP: 0001

Medical Device Single Audit Program [MDSAP] Implementation & Participating Country Regulatory Processes: 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 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.

This two-day 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 seminar will discuss how such audits are organized, what to expect during a MDSAP audit, how does this differ from a typical certified body audit, along with document movement and timeline expectations in receiving the

facility's certificate.

The key Regulatory Requirements for Medical Devices will also be covered for the participating MDSAP Countries of: U.S., Canada, Brazil, Australia and Japan.

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 two-day 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

AGENDA

DAY 01(8:30 AM - 4:30 PM)

- Registration Process: 8:30 AM – 9:00 AM
- Session Start Time: 9:00 AM
- Introduction and Agenda Review
- Lecture 1: Medical Device Single Audit Program (MDSAP): Overview, History, Audit Process and Report
    - Program Overview
    - MDSAP Audit Process
    - MDSAP Audit Cycle
    - Country additions to MDSAP Participation
    - MDSAP Audit Procedures & Forms
- Lecture 2: U.S. FDA Overview and Device Regulations
    - Device Classification
    - Clinical Trials / IDE
    - Licensing Pathways: 510k, De Novo, PMA
    - Human Factors and Usability Studies
    - Medical Device GMP
    - Inspection Process
    - Device Labeling
    - Combination Products
    - License Holder Responsibilities
- Lecture 3: Canada Medical Device Regulations
    - Regulatory Authorities & Structure
    - Device Classification
    - Import / Export
    - Marketing Clearance
    - License Application Types
    - License Amendments
    - Establishment License
    - Quality System Requirements
    - Clinical Trials
    - AE Reporting
    - Inspections
    - Packaging & Labeling
    - Traceability
    - Fees

DAY 02(8:30 AM - 4:30 PM)

- Lecture 4: Brazil Medical Device Regulations
    - Country Overview & facts
    - Healthcare Authority & Structure
    - Country Establishment & Licenses
    - Requirements for Devices
    - Clinical Trials
    - Device Classification
    - Device Registration
    - Packaging & labeling Requirements
    - Medical Device Testing
    - Variations / Amendments / Renewals
    - Timelines
    - Fees
    - Post Marketing Vigilance
    - Patents & Trademarks
    - Import / Export
    - Advertising
- Lecture 5: Australia Medical Device Regulations
    - Government Structure / Healthcare Authority
    - Medical Device Regulations
    - Country Establishment
    - GMP / Conformity Assessment
    - Essential Principles
    - Clinical Trials
    - Packaging & labeling
    - Vigilance Reporting
    - Import / Export
    - Fees
    - Timelines
- Lecture 6: Japan Medical Device Regulations
    - Regulatory Agencies & Structure
    - Agency Consultations
    - Pharmaceutical & Medical Device Law
    - Clinical Trials
    - Business Entities / Country Establishment
    - Licensing Options
    - MAH Overview / Personnel
    - Types of medical Device Licenses
    - ICH / Japan
    - Facility Audits
    - Device Classifications
    - Device Registration
    - Device Labeling
    - Timeline / Fees
    - Cultural Considerations

- Lecture 7: MDSAP Adverse Event Reporting / Common Themes
- Lecture 8: Regulatory Process / Working with Global Agencies
- Final Questions and Closure

SPEAKER

Robert J. Russell
President of RJR Consulting, Inc

Robert J. Russell, (Bob) is the President of RJR Consulting, Inc., a Global Regulatory Consulting company, specializing in understanding regulatory issues for the pharmaceutical, medical device and combination products industry. Bob has more than 30 years of experience working with FDA, EMA, Healthcare Authorities and Agencies across Latin America, Middle East and Asia / Pacific supporting clients projects in these regions. Licensing, registrations, GMP, DMFs and borderline products are core competencies of the Course Director.

Prior to entering the consulting field, Mr. Russell was the Global Director of Regulatory Affairs for two Fortune 100 manufacturers of Drugs and Medical Devices. RJR's offices are located in every major region with in-country experts on staff handling local regulatory needs. Bob has a BS and MS in Chemistry.

Please contact the event manager Marilyn (marilyn.b.turner(at)nyeventslist.com) below for:
- Multiple participant discounts
- Price quotations or visa invitation letters
- Payment by alternate channels (PayPal, check, Western Union, wire transfers etc)
- Event sponsorship

NO REFUNDS ALLOWED ON REGISTRATIONS
Prices may go up any time. Service fees included in pricing.

This event is brought to you by:
Metricstream, Inc. - NewYorkEventsList
http://www.NyEventsList.com
http://www.BostonEventsList.com
http://www.SFBayEventsList.com

VIO180305CRE JOA180316CEV

Event Categories :

www.sfbayeventslist.com