Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

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

Washington, DC

February 8th & 9th, 2018

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2990.0 (40%)*

~~$7,475.00~~

Register for 10 attendees

Price: **$8,222.00** You Save: $6,728.0 (45%)*

~~$14,950.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

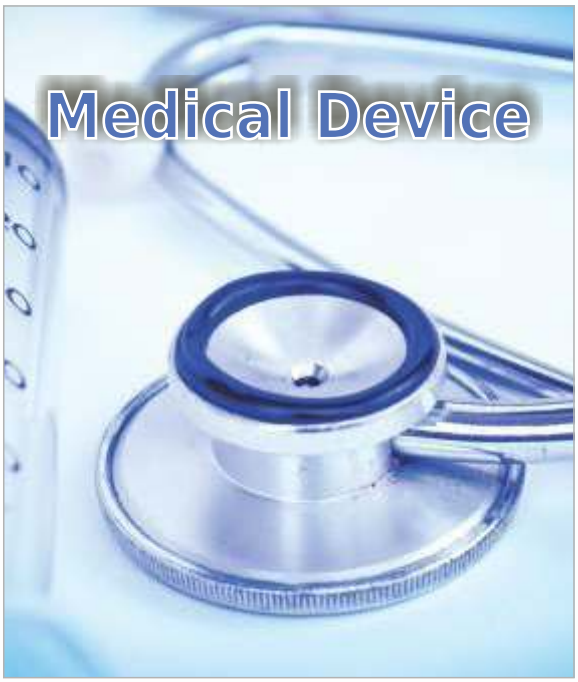
Robert Russell

President, RJR Consulting, Inc.

For the past 9 years, Bob has been President of RJR Consulting, Inc. The company assists the pharmaceutical, medical device and biotech industries in understanding and complying with International Regulations affecting compliance, new product development, manufacturing and quality assurance. RJR has offices in Columbus, OH, Washington, DC, Brussels, Belgium with exclusive affiliates across Asia and Latin America.

Overview:

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.



Agenda:

Day One

Lecture 1: Introduction and Agenda Review

Lecture 2: Medical Device Single Audit Program (MDSAP): Overview, History, Audit Process and Report

Lecture 3: U.S. FDA Overview and Device Regulations

- Device Classification, Licensing Pathways, Human Factors and Usability Studies, Medical Device GMP, Inspection Process, Device Labeling, Combination Products, License Holder Responsibilities
- (NOTE: Each country session will follow a similar format to the information above)

Lecture 4: Canada Medical Device Regulations

Lecture 5: Brazil Medical Device Regulations

Day Two

Lecture 1: Australia Medical Device Regulations

Lecture 2: Japan Medical Device Regulations

Lecture 3: Adverse Event Reporting

Lecture 4: Regulatory Process

Lecture 5: Final Questions and Closure

Why you should attend:

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.

Areas Covered in the Session:

- 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

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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