ComplianceOnline
The Largest GRC Advisory Network

ComplianceOnline In-person Seminar

Understanding and Implementing the Medical Device Directive

January 26 - 27, 2012, San Diego, CA

RAPS approved. Earn 12 RAC points

Location:

Omni Hotels & resort,
675 L Street San Diego,
California 92101.
Phone: (619) 231-6664

"Understanding and Implementing the Medical Device Directive" This course is certified by RAPS. Attendees are eligible for 12 RAC points on completion of the Seminar.

Most medical devices marketed in the European Union must follow the Medical Device Directive (MDD); IVD device and active implantable devices have other directives. The MDD can be complicated, especially for US companies, because the MDD's approach is different than the regulatory approach in the US. For example, under the MDD your company makes "submissions" to a private company that you hire, not to a government agency.

This interactive two-day course will help you comprehensively understand details of the MDD and implement its requirements. Attendees will learn how to classify devices, select the appropriate conformity assessment path, prepare the required documentation, and maintain it. During the course, participants will have exercises that apply the principles and help solidify learning.

The instructor addresses the details of the MDD and includes other significant issues such as the Quality Management System (ISO 13485), Risk Management (ISO 14971), Clinical Evaluation (MDD Annex X), and the role of harmonized standards.

Speaker:

Daniel O Leary
President, Ombu Enterprises, LLC

Dan O'Leary has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs. He has a Masters Degree in Mathematics, focusing on logic and number theory. His professional experience relates to quality, regulatory, reliability, and operations management.

Dan is a regular speaker at international conferences including ASQ, ISM, and RAMS. Dan teaches courses in reliability methods, medical device regulations and practices, statistical methods, management systems (ISO 9001, FDA QSR, & ISO 13485), and project management. Dan is an ASQ Certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; he holds an APICS certification in Resource Management.

What past attendees say about this course:

"With the simple approach take by Dan, anyone can learn how to complete a successful MDD implementation."

- ***Quality Specialist, Rochester Medica***

"Dan OLeary displayed complete and total Mastery of the subject in this presentation, and in his answers to the questions asked from him."

- ***Quality Manager, Parker Hannifin Corp***

"I enjoyed Dan's course very much. The Instructor and materials were excellent and the information he taught will be very helpful to my Company."

- ***Compliance Coordinator, Diagnostica Stago, Inc.***

Course Objectives:

- *Understand the role of product directives in the EU.*
- *Learn the medical device classification system and how to apply it.*
- *Comprehend the conformity assessment paths and how they apply to particular devices.*
- *Understand the Essential Requirements and how to document compliance.*
- *Learn the role of ISO 13485 as the fundamental Quality Management System.*
- *Understand the requirements for*
- *Risk Management and the use of ISO 14971*
- *Integrate the Clinical Requirements in the MDD into the essential requirements and risk management processes.*

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AGENDA

CONFERENCE DAY ONE:
Thursday, Jan 26, 2012

Medical Device Directives

- Development, aims, and implementation of medical device directives in the EU
- The application and differences of the directives that cover medical devices
  - The Medical Device Directive (MDD)
  - The Active Implanted Medical Device Directive (AIMDD)
  - The In Vitro Diagnostic Medical Device Directive (IVDD)
- Relationship to other product directives
  - Machinery Directive
  - Personal Protective Equipment Directive

Compare & Contrast EU & FDA Procedures and Requirements

- Device classes
- Marketing "approval"
- Quality Management Systems
- Role of the Notified Body

Understanding the MDD

- Medical device classification in the EU (by directive)
- Software as a medical device
- Technical File and Design Dossier
  - Constructing and maintaining the documentation
  - Auditing and sampling by the Notified Body
- Annex I – Essential Requirements
- Using harmonized standards to satisfy the Essential Requirements
- Conformity assessment paths in the directives
  - Compliance Options by Device Class
  - Annex II – Full Quality Assurance System
- Information Provided by the Manufacturer (Labeling & IFU)
  - MDD Annex I, Essential Requirements, Section 13
  - EN 980:2008 Symbols for use in the labeling of medical devices
  - EN 1041:2008 Information supplied by the manufacturer of medical devices

CONFERENCE DAY TWO:
Friday, Jan 27, 2012

Definitions and Concepts (Workshop)

- EN ISO 13485:2003/AC:2009 Medical devices – Quality management systems – Requirements for regulatory purposes

Risk Management Systems

- EN ISO 14971:2009 Medical devices – Application of risk management to medical devices

Clinical Evaluation

- Clinical Evaluation (MDD Annex X & MEDDEV 2.7-1)

Post Market Surveillance

- Medical Device Vigilance System (MEDDEV 2.12-1)

Safety and Surveillance

- Creating a unified approach during the development and production phases
- Creating a unified approach for activities after delivery

Who will benefit:

This course benefits anyone involved in quality or regulatory compliance for medical devices marketed in the European Union and is ideal for quality, regulatory, and clinical professionals working in the health care, clinical trial, biopharmaceutical, and medical device sectors.

- Regulatory Managers
- Quality Managers and Directors
- Marketing Managers
- Clinical Managers
- Export Compliance Managers

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Click here for more info

www.complianceonline.com
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Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1- 650-620-3937.
- Call +1 - 650-620-3937 or Fax your PO: 650-963-2556.
- Mail your check to: ComplianceOnline (MetricStream, Inc), 2600 E. Bayshore Road, Palo Alto, CA 94303.
- Please fill this form with attendee details and payment details and fax it to 650-963-2556

Terms & Conditions

Payment is required by the date of the conference. We accept American Express, Visa and MasterCard. Make checks payable to MetricStream Inc.
(our parent company)
Or, register by phone: +1 (650) 620-3937

Cancellations and Substitutions

Written cancellations received at least 15 calendar days prior to the start date of the event will receive a refund - less a $150 administration fee. No cancellations will be accepted - nor refunds issued - within 15 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future ComplianceOnline event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that ComplianceOnline cancels the event, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Registration Form

☑ **YES!**

I want to attend ***Understanding and Implementing the Medical Device Directive*** on

☐ Thursday, Jan 26 & Friday, Jan 27, 2012, 9 AM to 5 PM PST, San Diego, CA

Price: **$1999** per registration

I understand the fee per attendee includes the workshop, all course materials, and lunch for 2 days.

Register for 4 and the 5th person goes FREE !!!

Attendee 1 : Name ..... Title ..... Email .....
Attendee 2 : Name ..... Title ..... Email .....
Attendee 3 : Name ..... Title ..... Email .....
Attendee 4 : Name ..... Title ..... Email .....
Attendee 5 : Name ..... Title ..... Email .....

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(Payment is required by the date of the conference.)

Please fill this form with attendee details and payment details and fax it to 650-963-2556

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