ComplianceOnline
The Largest GRC Advisory Network

ComplianceOnline In-person Seminar

2-day In-person Seminar:

CAPA Systems for Medical Device Manufacturers

Thursday, December 06 and Friday, December 07, 2012, 9 AM to 5 PM EDT, Boston, MA

Location:

Grand Hyatt San Francisco
345 Stockton Street,
San Francisco, CA 94108
Phone: (415) 848-6091

Course "CAPA Systems for Medical Device Manufacturers" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

Course Description:

Implementing an effective system for corrective action and preventive action can be a major challenge. FDA illustrates the point in its published information on Warning Letters. FDA cited the CAPA subsystem in 81 of 89, 91%, of Warning Letters issued in 2010, the most recently available data. The CAPA subsystem includes nonconforming material, corrective and preventive action, and complaints (820.90, 820.100, 820.198). The trend continues in recent warning letters.

This interactive two-day course provides the tools you need to develop and implement an effective medical device CAPA system. In addition to FDA QSR, the course covers the corresponding requirements in ISO 13485 as well as the linkage to risk management in ISO 14971. Corrective action requirements extend beyond the basic QMS to include field actions, so the course includes adverse event reporting, Corrections & Removals, Field Safety Corrective Actions, and Field Safety Notices.

CAPA does not stand alone; it is most effective when it is an integral part of the Quality Management System and influences all of the other subsystems. The overarching objective of the course helps the participants develop the tools and methods. The course utilizes a broad variety of available material including FDA guidance documents, Global Harmonization Task Force (GHTF) guidance documents, ISO guidance documents, and European Union medical device guidance documents (MEDDEV).

Speaker:

Dan O'Leary

President at 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.

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Course Outline:

Day One – The Regulatory Framework

- Understanding corrections, corrective action, and preventive action
- Principles of FDA's Quality System Regulation (QSR)
- Principles of ISO 13485:2003
- Contrasting QSR and ISO 13485
- Requirements for the CAPA subsystems
- Using the GHTF guidance document
- Complaints and corrective action
- FDA MDRs and EU Vigilance
- FDA Corrections and Removals
- EU Field Safety Corrective Action and Field Safety Notices
- Understanding MEDDEV 2.12-1 Rev 7

Day Two – Tools for an Effective System

- What CAPA does
- Using the FDA guidance documents
- Metrics for a CAPA system
- Metrics for the impact of CAPA on other subsystems
- Investigation and problem solving methods as CA
- Improvement methods as PA
- Quality tools for CAPA
- Interactive exercises using quality tools
- Concepts of data analysis
- Sources of quality data
- Statistical tools for CAPA
- Interactive exercises using statistical tools

Course Objectives:

- Develop the tools and methods to create an integrated CAPA system.
- Explain the difference between correction, corrective action, and preventive action and understand why they are different.
- Gain knowledge of the medical device CAPA regulatory requirements including FDA QSR and ISO 13485.
- Evaluate common problem solving and improvement methodologies, explain the quality tools, and apply them to the CAPA system.
- Understand "appropriate statistical methodology" to analyze data and identify existing and potential causes of quality problems.
- Identify the linkages between complaints, corrective action, and risk management.
- Understand the regulatory requirements for corrective actions in the field for both the US and the EU.

Who will Benefit:

While the course is specific for medical device companies, any company can benefit from an effective CAPA system. It is ideal for:

- Quality Managers
- Quality Engineers
- Regulatory professionals
- Operations Managers
- Manufacturing Engineers
- Risk Managers
- Complaint system team members
- CAPA team members

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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 +1-888-717-2436.
- Call +1-888-717-2436 or Fax your PO: 650-963-2556.
- Pay your check to (payee name) "MetricStream Inc" our parent company and Mail the 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

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ +1-888-717-2436 or email us @ editor@complianceonline.com

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event.
On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($200) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, 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 ***CAPA Systems for Medical Device Manufacturers*** on

☐ Thursday, December 06 and Friday, December 07, 2012, 9 AM to 5 PM EDT, Boston, MA
I understand the fee includes the workshop, all course materials and lunch.

Register for 3 and 4th person gets a free pass.

Attendee 1 : Name ..... Title ..... Email .....

Attendee 2 : Name ..... Title ..... Email .....

Attendee 3 : Name ..... Title ..... Email .....

Attendee 4 : 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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