ComplianceOnline
The Largest GRC Advisory Network

ComplianceOnline In-person Seminar

2-day In-person Seminar:

Medical Device Sterilization: Corrective & Preventive Action

June 14 & 15, 2012, 9 AM to 4 PM PDT, Irvine, CA

Venue:

Hotel:
Hyatt Regency Irvine
17900 Jamboree Road
Irvine, California,92614
USA

Speaker:

Lisa Foster
Principal, Adiuvo QS & SA Consulting

Ms. Foster began her medical device career at Sterigenics International in 1989. Throughout her tenure, Ms. Foster has held various quality assurance positions at both the facility and Corporate levels where she served as Sterigenics Vice President of Quality Assurance from 1997 – 2004 and as Vice President SteriPro Labs & Consulting from 2004-2011. Most recently she has started her own firm, Adiuvo QS & SA Consulting and has a joint relationship with Blue Skies LLC.

Ream More...

Speaker:

Karen Welch
Senior Partner, Center for Risk-based Strategies (CRS)

Ms. Welch is a Senior Partner with Center for Risk-based Strategies (CRS), a company focused on improving the bottom line of regulated companies. She has over 20 years of experience in the Medical Device, Pharmaceutical and Diagnostics industry with a primary focus in Quality Improvement and Quality Systems. She held positions of increasing responsibility, both technical and managerial, at Abbott Laboratories, Sybron International, AbTox, and Aksys, Ltd. Throughout each of these positions she actively practiced Continuous Improvement and Six Sigma techniques to help design quality into the product as opposed to 'checking it in' at the end. Ms. Welch was in charge of Quality Assurance and Quality systems relating to all aspects of the manufacture and release of FDA regulated products.

Ream More...

Course Description :

Sterilization is a critical aspect of device approval and release. Though this is indeed fact, manufacturers sterilize product as a matter of course, without expert sterilization assurance personnel to guide them through potential problems in sterilization. As the world and meaning of CAPA continue to evolve in the medical device industry, further misunderstanding arises when faced with determine root cause and corrective (or preventive) action for any variation in this critical process in device manufacture.

The course will begin with an overview of EO sterilization, explaining which aspects of the process often cause confusion. This will be followed by process validation and what paperwork is required to provide 'documented evidence' ; and finally what are typical deficiencies encountered in the EO process. Next a detailed explanation of Radiation Sterilization will be given. Specific to Radiation Sterilization is the required sterilization dose, which will be covered in depth – how to determine sterilization dose and how to maintain the validated dose. Process validation will be covered as well as the typical deficiencies encountered in Radiation Sterilization and Validation. Critical and non-critical deficiencies will be covered and when this should trigger a CAPA. Finally contract sterilization will be reviewed with the specifics of how to deal with CAPA when you are not directly responsible for sterilization.

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2600 E. Bayshore Road Palo Alto, CA 94303 | Ph: +1-888-717-2436 Fax: 650-963-2556

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AGENDA

CONFERENCE DAY ONE:

- Introduction to Industrial Sterilization
  - EO sterilization and Validation
    - Documentation & Maintaining Validation
    - Typical Deficiencies: Critical and Non-critical
  - Radiation Sterilization & Validation
    - Determining and Maintaining Accurate Dose
    - Process Validation & Documentation
    - Typical Deficiencies: Critical and Non-critical
  - Contract Sterilization

CONFERENCE DAY TWO:

- Introduction to Corrective & Preventive Action - CAPA(½ Day)
  - Applicable Regulation & Standards
  - Why CAPA
  - When does a deficiency require CAPA?
  - Root Cause Determination
  - Actions to Prevent Recurrence
  - CAPA Tools & Methodology
- Workshop (½ Day)
  - Utilizing CAPA tools to solve sterilization deficiencies
  - Utilizing CAPA tools to solve typical quality deficiencies
  - Instructors will lead attendees through several 'real case' exercises related to CAPA and sterilization & quality deficiencies; attendees will present findings to the rest of the group.

Who will benefit:

This course will be beneficial to the following personnel in Medical Device Manufacturing and Sterilization facilities:

- QA Personnel
- CAPA Team Members
- SA Personnel
- Quality Engineers
- Operations Managers
- Anyone with direct hands on experience with sterilization & troubleshooting

Send Your Team for Maximum Benefit

Get your team up to speed!

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Register below by clicking on Register now and then change your quantity in the shopping cart. For each additional attendee you will get 20% discount in additional attendee fee.

The discount will be calculated automatically.

Call +1-888-717-2436 with any questions

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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 ***Medical Device Sterilization: Corrective & Preventive Action*** on

Price: $899

☐ Thursday, June 14 and Friday, June 15, 2012, 9 AM to 4 PM PDT, Irvine, CA

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 .....

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