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2-day In-person Seminar:

Radiation Sterilization of Medical Products - Beyond the Basics

By: **Gerry O Dell**, President, Gerry O'Dell Consulting

Location: Broomfield, CO | February 1-2, 2018

SPEAKERS

Gerry O Dell, President, Gerry O'Dell Consulting

Gerry O'Dell, is owner and President of Gerry O'Dell Consulting, a consulting firm based in the United States with medical device and pharmaceutical clients around the world. Prior to starting Gerry O'Dell Consulting, she worked for Johnson & Johnson Medical, Inc. as the Manager of Laboratory & Sterilization Services which managed the sterilization program for J&J Medical in addition to providing laboratory testing services to several J&J companies. Before becoming a part of Johnson & Johnson Medical, Gerry was Manager of Sterilization Services at Critikon, Inc where she started as a Lab Technician. She holds both a Bachelor and Master of Science degree in Microbiology from the University of South Florida and has over twenty-nine years of experience in the medical device industry.

LEARNING OBJECTIVES

Upon completing this course on radiation sterilization of medical devices participants will:

- Understand how to select product polymer materials for optimal product performance after radiation sterilization processing.
- Know how to complete an optimal validation test design – inclusive of dose, dosimetry, sample size, accelerated ageing, ASTM standards, & thermal analysis.
- Understand the effect of product design and assembly on bioburden, product safety and the success in executing the validation journey.
- Understand all the foundations of a successful radiation sterilization program – materials, bioburden, validation, maintenance of validation.
- Understand the impacts of all regulatory guidances on the radiation sterilization process.
- Perform risk assessments effectively.
- Understand where companies miss the mark in triggering, investigating and executing bioburden action levels and quarterly sterilization audits.

COURSE DESCRIPTION

This two day highly interactive course will cover all aspects of radiation sterilization validation, materials selection and processing implementation. This workshop has been designed to help attendees learn the ins and outs of all the radiation modalities, materials selection, and validation of the sterilization process per ISO 11137.

Additionally, 483 case studies will explore how to avoid the operational and legal issues that arise from nonconformance with regulators (FDA) and auditors.

Learn from two of the foremost validation, materials, and operations leaders in the marketplace. The course instructors have decades of experience in microbiology, validation, operations on traditional as well as tissue/biologic and combination products. Save time and money by attending this course dedicated to increasing your knowledge in radiation sterilization.

WHO SHOULD ATTEND

This course is designed for medical device, biologic products, and pharmaceutical professionals who desire to get a complete understanding of the validation and use of radiation sterilization for their products. Following personnel will benefit from the course:

- Senior quality managers
- Sterilization managers
- Quality professionals
- Regulatory and Compliance professionals
- Production supervisors
- Manufacturing engineers
- Production engineers
- R&D engineers
- Process owners
- Quality engineers
- Quality auditors
- Medical affairs
- Legal professionals

AGENDA

Day One (8:30 AM – 4:30 PM)

Registration Process: 8:30 AM – 9:00 AM
Session Start Time: 9:00 AM

A. Review of the radiation sterilization – modalities, history, strengths and limitations, terms, processing parameters.
- History/Terms
- Gamma, E-beam, X-ray – Is there a best choice?
- Irradiator Designs and Processing Variables
- Dose Rate and Distribution
- Costs - Contractors, In-house Systems

B. Process Validation – Part I
- History – Kilmer and Beyond
- VD Max
- Method 1
- Method 2
- Dose Audits

C. Materials Selection - Radiation Effects
- Polymer Chemistry
- AAMI - TIR # 17
  - Guidance Offered
- Desirable/Undesirable Changes
  - Brittleness
  - Color Change
  - Odor
  - Hardness/Softness
  - Films, Adhesives
  - Crosslinking/Toughness
- Stress – Out of Our Parts, Out of Our Lives
- Supplier Databases and Websites

D. Process Validation – Part II
- Bioburden Sampling
- Sterility Testing
- Family Grouping
- Dose Audits

E. Product and Process Design – It all starts in R&D
- Critical Decision Points
- The Shotgun vs a Targeted Approach
- Molding/Extrusion
- 3D Printing

F. Bioburden Control and Epidemiology
- Environmental Control
- Control Levels
- Bioburden Excursions
  - Typical Causes and How to Fix Them
  - People and Processes

G. Laboratory Issues
- Choose a Good Partner and Save Time
- Bioburden Counts – What does it Mean
  - Recovery Efficency
  - IDs – Where did that come from?
- Sterility Failures
  - Typical Causes and How to Address Them
- Planning Timeline

H. Basic Biocompatibility

Day Two (9:00 AM – 4:30 PM)

I. Packaging – Design & Materials
- Regulatory Requirements
- Design Latitude – Pouches, Trays, Materials
- Materials to be Avoided
- Breathability Requirements

J. ISO/AAMI/FDA Standards
- ISO 11137-1
- ISO 11137-2
- ISO 11137-3
- TIR #
- FDA Guidance

K. Unique Materials
- Polypropylene and Polyethylene
- PC, Polyester

L. Product Validation
- Dose Limits
- Attributes – Design Limits
- Accelerated Aging

M. Unique Aspects of Different Product Types
- Biologics and Tissue Sterilization Validation and Processing
- Pharmaceuticals
- Combination Products Sterilization

N. Product Validation Summary/Planning… Planning…Planning

O. Learning from 483's - Case Study Exercise from current FDA Warning Letters

P. The SAL Debate
- 10-6, 10-3, 10-4
- North America, Europe, ……

Registration Form

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.
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Seminar Topic: Radiation Sterilization of Medical Products - Beyond the Basics

Date & Location: .....

Attendee Details:

	Name	Title	Email
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Attendee 2			
Attendee 3			
Attendee 4			

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