

Sterilisation for Medical Devices

4th - 5th December 2007, Kempinski Hotel Bristol, Berlin, Germany

Pre-Conference Workshop: Monday 3rd December 2007

Selecting the best sterilisation method for your product can be very challenging and requires careful consideration. This interactive workshop will demonstrate the strengths and weaknesses of each sterilisation method, highlighting which sterilisation method is most appropriate for each type of medical device.

Day 1: Tuesday 4th December 2007 - Standards for Sterilisation and Process Validation

08:30 Registration and coffee

09:00 Opening remarks from the Chair

09:10 Introduction to regulations for sterilisation and expectations of the Notified Body

- Discover the process by which the standards have been changed
- Understand the reason for the updates to the standards
- Describing the Notified Bodies role in sterilisation
- What are the Notified Bodies expectations and how does this affect you?
- Learn the common problems faced by manufacturer with validation and discover how you can avoid these

09:50 ISO 11137:2006 Parts 1-3 - Standard for Gamma Radiation Sterilisation

- What are the main changes to the standard and how will this impact the sterilisation process
- How is the updated standard related to the previous and existing standards?
- Why are there now 3 parts to the standard and what does each part mean?
- Discover how the sterilisation dose is established and the importance of this
- Understand the scope of the standard and what is not covered by the standard

10:30 Networking refreshment break

11:00 ISO 17665-1:2006 - Moist Heat Sterilisation

- Understand the scope of the standard and its implications for you
- Discover what the standard means for the steam sterilisation process
- What are the differences to the previous standard and what impact does this have
- The validation process described in the standard

11:40 ISO 11135: 2007 - Standard for Ethylene Oxide Sterilisation

- How has the standard evolved over the past 5 years and what are the implications for the manufacturer
- Establishing the requirements and guidance for validation and routine control of ethylene oxide sterilization processes for medical devices
- Limitation of ethylene oxide sterilisation for spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt Jacob disease
- Comprehend the validation process for ethylene oxide sterilisation

12:20 Question and Answer session

12:40 ISO 10993-7 Ethylene oxide sterilization residuals

- What are the latest updates to the standard?
- Uncover the implications these latest updates will have on manufacturers and sterilisers
- Discover allowable limits for residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) in individual EO-sterilised medical devices
- Determine the procedures for the measurement of EO and ECH

13:20 Networking lunch

14:30 ISO 11138:2006 Parts 1-5 - Sterilization of health care products; Biological Indicators (BI)

- Identify the scope of the standard and understand what each part represents
- How do the updates to the standards impact the sterilisation process
- Understand how BI's can be used with different sterilisation methods
- What are the limitations of the standards and how can this be overcome

Dr Brian Kirk, *Senior Technical Services Specialist, 3M*

15:10 ISO 11607:2006 Parts 1 and 2 - Packaging for terminally sterilized medical devices

- What have the changes been and what are the implications of these updates
- Learn the requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use
- Limitations of the standard with regards to the sterile barrier system and aseptic packaging

15:50 Networking refreshments

16:20 Department of health memorandums (HTM)

- How are HTM 2010, 2030 and 2031 being harmonised?
- Understand the implications of the harmonised memorandum for patient safety
- What is the scope of the new HTM 101 memorandum?
- Discover what the three parts of the memorandum represent

17:00 Process Validation – Common Issues

- Uncovering the common pitfalls with process validation
- The difference between different sterilisation methods for process validation
- Best industry practises for completing process validation
- How have the updated standards effected the validation process

17:40 Discussion Panel

18:00 Closing remarks from the Chair and end of day one

Day 2:- **Wednesday 5th December 2007 -Methods for Sterilisation and Regulatory Impact**

08:30 Coffee

09:00 Opening remarks from the Chair

09:10 Case Study: Gamma Radiation as a method and impact of updated regulations

- Hear our experiences of using Gamma Radiation as a sterilisation method
- Understand impact of the updates standards have had
- The relationship with the sterilisation contractor
- What challenges are faced with the validation process

09:50 Case Study: E-Beam and X-Ray sterilisation as a method and impact of updated regulations

- How E-Beam and X-Ray are being used for sterilisation
- The implications the updates standards have had on the processes
- The process validation involved for E-Beam and X-Ray sterilisation
- Discover the challenges faced using E-Beam and X-ray for sterilisation

10:30 Networking refreshment break

11:00 Case Study: Steam as a sterilisation method and impact of updated regulations

- Our experience of using steam as a sterilisation method
- Understand the changes caused by the updates standards
- Hear common issues encountered with steam sterilisation
- The validation process involved with steam sterilisation

11:40 Case Study: Using Ethylene Oxide for sterilisation and understanding the impact of the new regulations

- Common issues with ethylene oxide as a sterilisation method
- The limitations of ethylene oxide as a sterilisation method
- What is the best method for process validation when using ethylene oxide
- The driving need for quick release times

12:20 Question and Answer session

12:40 Parametric Release – Improving release time

- How have the recent standards updates effected the use of parametric release
- Understand why parametric release is preferable to using biological indicators
- Learn how parametric release can decrease the quarantine time for your devices
- How comparable is parametric release to radiation sterilisation

Jan Douglas, *Sterilisation Manager*, **William Cook**

13:20 Networking lunch

Emerging Methods of Sterilisation

14:30 Cold Sterilisation methods

- Situations where cold sterilisation is most appropriate
- Limitations of liquid sterilisation
- How can liquid chemical sterilisation be monitored
- Standards involved in cold sterilisation and the process validation method

15:10 Gas plasma sterilisation

- The advantages of gas plasma as a sterilisation method
- Understand the limitations of gas plasma
- Discover how the turnaround time for gas plasma sterilisation is significantly less than other sterilisation methods
- What are the current regulations and standards governing gas plasma

15:50 Networking refreshments

16:20 Advances in Biological indicators

- Hear the latest developments that are being made with biological indicators
- What implications have the updated regulations had?
- Why are biological indicators the most reliable method for ensuring sterilisation
- Comparing biological indicators with parametric release; pros and cons

Klaus Hahnen, *European Technical Service Specialist, 3M*

17:00 Device design consideration for sterilisation

- What considerations should be made when designed a medical device required sterilisation?
- Understand how the recent updated regulations have impacted medical devices
- Choosing a sterilisation that is suitable for your product
- Best industry methods for product design

17:40 The role of packaging in sterilisation

- Hear what considerations are needed when considering the packaging to be used in sterilisation
- What are the limitations of materials for each sterilisation method?
- Understand the impact of the updated standards
- Ensuring compliance and validation for sterilisation packaging

18:00 Closing remarks from the Chair

Post-Conference Workshop: Thursday 6th December 2007

Completing process validation for sterilisation can be a very taxing experience for any manufacturer. This workshop will enable you to learn the best techniques for completing process validation and discover the subtle difference that exist between each sterilisation method