The Sydney Chapter of the ISPE Australasian Affiliate

Proudly Presents

Principles and Practices of Manufacturing Sterile Medical Devices

The what, why and how of sterility assurance for terminally sterilized devices

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Overview

What factors are involved in determining the sterility assurance of a medical device? How is sterility assurance controlled and what do we need to do to demonstrate compliance with the stated assurance levels.

Sterile medical devices are regulated through adherence to a number of ISO standards defining how the device should be packaged, how it should be sterilised and how it should be verified as sterile. For terminal sterilisation techniques such as Gamma Irradiation and Ethylene Oxide treatments the process is often outsourced, however it is still important that the manufacturer and supplier of the product has an understanding of what is needed to demonstrate sterility assurance.

ISPE have brought together a group of some of the leading suppliers to the medical device industry in Australia to discuss the requirements and approaches that are used to meet the end goal a Sterile Medical Device.

Where: Marriott Courtyard 7-11 Talavera Road, North Ryde, NSW
When: Friday 8 May
Map: Click here

Cost:
Members $149.00 *incl gst*
Non – Members $199.00 *incl gst*

Register: **Click here**

Presenters:

- Doug Watson (CEO) – Sabre Medical - Packaging Validation
- Barry Cox (Group QA Manager) – Steritech - ETO and Gamma radiation
- Jennifer Wan (General Manager) – ams Laboratories – Microbiological and Residual Chemical Evaluation of Sterile Medical Devices
- Alan Dougherty, (Managing Director) – Chemika.

Who should Attend?

- Regulatory Affairs, Operations and Quality Assurance professionals, managers and technical staff involved in the manufacture of medical devices.
- Research and Development professionals involved in the design and development of medical devices requiring terminal sterilisation.

Take Back to Your Job:

- What are the validation requirements for sterile products?
- How sterilization is achieved using Gamma Irradiation and Ethylene Oxide?
- What testing is required to demonstrate sterility?
- Who is responsible for what stage of the process?

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When:	Friday 8 May 2015 9:00am for a 9:30am start	Where:	Marriott, Courtyard 7-11 Talavera Road, North Ryde, NSW Tel: 02 9491 9500 Map

Agenda:

09.00 – 09.30 Registration and Coffee

09.30 – 09:45 **Welcome and Overview ISPE**

09:45 - 10.45 **Requirements for Packaging of Terminally Sterilised Medical Devices**
Sabre medical

The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation. The design considerations, manufacture and quality assurance of the packaging system for a terminally sterilised products are therefore important to understand.
The speaker will

- Provide a brief overview of design considerations for packaging systems.
- Identify the studies required to demonstrate the suitable of the packaging system over the expected shelf life
- Describe some common equipment requirements for utilising different packaging techniques
- Identify some of the qualification and validation activities required to demonstrate compliance with the requirements of ISO 11607 and ASTM F1980-07.

10.45 - 11.45 **The Principals of Gamma Sterilisation and EtO Treatments**
Steritech

The terminal sterilisation process which medical devices are submitted to require strict controls to ensure the sterility assurance of the finished unit. When identifying the sterilisation process to be used for a product it is important to understand the benefits and drawbacks of each kind and to ensure that appropriate controls are in place to ensure that the product remains safe for the end user.

The speaker will:

- Provide an overview of the facilities and equipment used for terminal sterilisation by Gamma Sterilisation and EtO,
- Identify common reasons for choosing a particular method
- Identify the critical operating parameters associated with each system,
- Describe the validation requirements for ensuring compliance with the applicable ISO standards (ISO 11137 and ISO 11135).

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11.45 – 12.45 **Microbiological and Residual Chemical Evaluation of Sterile Medical Devices**

AMS Laboratories and Chemika

There are several stages of testing required to ensure the sterility assurance of a medical device. Critical to ensuring the sterilisation process can be achieved and validated, is understanding the Bioburden of your product to start with and to ensure that there is no contamination of the product
(microbial or chemical) after the sterilisation process is completed. Our two speakers will

- Discuss the sampling and methods used for Bioburden testing and sterility testing and Ethylene Oxide Residual Analysis.
- Identify the critical equipment and operating conditions for conducting each test
- Describe the validation requirements for each test
- Discuss some of the most common reasons for failures

12.45 – 14:00 **Lunch and Event Closing**

Cost:	**Members $149.00 *incl gst* - Non – Members $199.00 *incl gst***
Bookings:	**Click here to register**
Enquiries:	Mandy Bromilow, **E:**mailto:manager@ispe.org.au **T:** +61 447 279 008
Membership:	Please visit our website to view the benefits of becoming an ISPE member.
About ISPE:	ISPE is a not for profit, non-lobby industry association for healthcare industry professionals with in excess of 20,000 members world-wide. Our core purpose is to prepare these individuals to lead global change and innovation in manufacture or pharmaceuticals and other medicinal products. ISPE's Australasian Affiliate membership is comprised of approximately 400 industry professionals from within its five chapters in New Zealand and Australia.

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