Swiss MedBRAID

Upcoming Seminar on Sterile Medical Devices

20th September 2017,
Messe Luzern
Horwerstrasse 87, CH-6005 Luzern
Switzerland

The Swiss Seminar on Medical Devices

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"Validation of Medical Device Sterilization"

A one day educational, visit and networking event offering industry expertise on medical device manufacturing and its release in the market.

The 2017 Medbraid is presented jointly with Swiss Medtech Luzern. You will have the possibility to learn the Medical Device Challenges, visit the exhibition and consult with the experts to discuss your problems, exchange ideas and get answers to your questions.

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The Following subjects will be presented

Mrs. Amy Ehlenfeldt, Medbraid 2017 Chairman, Straub AG

Hands-on International Quality Compliance, Supplier Quality Assurance and Engineering Manager Currently working for Straub AG as Senior Quality and Regulatory Manager. As such she is supporting all R&D, production and R&A quality related needs as well as maintaining the ISO 13485 based quality system meeting FDA requirements and is in charge of the whole internal and supplier audit system.

Her career as Sr. Quality Engineer started by working for Abbott Vascular in 2006, a medical device company producing guidewires, bare metal and drug eluting coronary stents and balloon dilation catheters.

She stayed for 8 years. In this period of time she acquired an extensive experience in the medical device industry as well as leadership and project management skills, by working on projects above staff of various levels of experience, providing guidance, work direction and maintaining schedule. She was also in charge of resolving supplier quality issues as well as start-up activities.

She is a Certified Quality Engineer with the American Society for Quality and a Degreed Chemist from the University of Oklahoma.

Design and development of sterile medical device

The session addresses design & development aspects of medical devices that are

a) to be delivered in sterile conditions

b) to be reprocessed by the health care institutions

The determination of a sterilization method is linked to various design inputs of technical and economical nature. Determining a suitable sterilization method is an iterative process in the feasibility phases of a design and development process. Also, the V&V phase of the development process requires some special thoughts when devices are terminally to be sterilized.

Mr. Michael Maier - Medidee Services SA

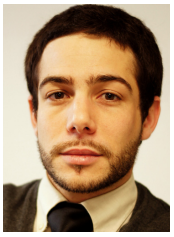
Mr. Michael Maier is co - founder and Senior Partner of Medidee Services SA, a Switzerland based Medical Device Consultancy with a global scope committed to strategic and operational Regulatory Affairs consulting since 2002. Michael performs audits of Medical Device Manufacturers for WHO and Notified Bodies and reviews technical files and design dossiers in the framework of international medical device conformity assessment programs. He started his career in 1996 as a medical engineer in the field of gas dosing devices for ICU ventilators and anaesthesia workplaces and managed design and development teams. Michael earned a MBA from the Business School Lausanne in 2004 and a Medical Engineering diploma of the University of Applied Sciences of Furtwangen in 1996. Michael is a regular speaker and trainer for medical devices, quality management and regulatory affairs related topics on international events and contributes with lectures to training programs of Medidee, Medbraid, Medtech, MEGRA and RAPS.

EtO Sterilization Validation

Even though sterilization with Ethylene Oxide (ETO) is well known and used since decades, the validation of the process always poses new challenges. With the development of new products, new raw materials and the evolution of regulatory framework, the validation strategies must constantly adapt.

This presentation will take as a basis the latest standard for ETO validation, ISO 11135: 2014 and develop on some practical examples taken from real validation projects. An emphasis will be put on the design of the products, the resistance of the natural Bioburden and the ETO/ECH residual testing.

Mr. Yacine Gérard - Medistri SA



Mr. Yacine Gérard is responsible for the management of the Validation and Quality Assurance Department at Medistri SA, a Swiss company specialized in sterilization processes.

Shortly after the release of ISO 11135-1 in 2007, he has been in charge of sterilization validation processes and has handled more than a hundred validation projects covering many different product families such as: implants, catheters, pharmaceuticals syringes, orthopedic devices, sterile kits, ophthalmology devices. All these projects gave Yacine a broad experience with the Regulatory Requirements and Frequently Asked Questions.

Yacine graduated in Management of Technology, with a specialization in Medical Devices and was also trained as internal auditor. Today, he keeps an overview of all activities related to process validation and routine release as he is responsible for the approval of all validation reports and handling of external audits (such as FDA). He is also a consultant and trainer for external companies and acts as a specialist in validation and routine ETO sterilization processes.

Gamma Sterilization Validation

The session addresses the industrial sterilization methods and underlines the criteria for choosing the Gamma sterilization method. This includes:

- Principle of Gamma sterilization
- Relevant standards for validation and routine monitoring of Gamma sterilization
- Validation of Gamma irradiation sterilization (Method 1 and 2, Method VDmax, dose mapping, determination of the maximum allowable dose)
- Transfer of Gamma sterilization processes
- Routine monitoring of sterilization process
- Release of product after Gamma sterilization
- Maintaining sterilization process effectiveness
- Establishing of product families, addition of new or modified devices, establishing product to represent the family
- Sterilization dose audits

Harry Leinwand, M.Sc; CQE - Managing Director

Before starting his GMP and compliance consultancy business back in 2000, Harry Leinwand has served global Medical Device and Pharmaceutical companies as Director of Quality Assurance and Regulatory Affairs.
Among his expert activities for clients in the field of regulatory clearance is the support for compliance of sterilization procedures for Radiation-, EO and Steam sterilization as well as aseptic processing for various products.

Besides his consultancy activity, Harry is training companies on aspects related to sterilization processes and reviews sterilization validation dossiers for European Notified Bodies.

Harry Leinwand is member of the technical committee for sterilization at the Standardization Institute of Israel.

Notified body assessment of sterilization validation file

The session addresses typical pitfalls, failures and expectation from a Notified body perspective on documentation to be submitted for showing compliance with the requirements for sterilization validation. This includes:

- Expectation on Sterilization validation documentation
- Expectation on documentation for Validation of Reprocessing of reusable medical devices
- Expected structure of validation documentation in relation to packaging process and design validation
- Typical Pitfalls and missing information in documentation
- Expectations on reportable changes to the Notified body“

Dr. Johannes König - TÜV SÜD Product Service GmbH

Dr. König is team leader of the scientific team of TÜV SÜD Product Service for review of Design Dossiers / Technical Documentation related to Sterilization and Biocompatibility.

Johannes assesses the documentation of validation of EO-, Radiation- and Moist Heat Sterilization processes and adjacent packaging validation information.

Dr. König also reviews manufacturers' documentation for reprocessing of reprocessable surgical instruments as well as the technical documentation of disinfection products for European market access.

Dr. König has an academic background in Microbiology and a in cellular biology.