Swiss MedBRAID

Upcoming Seminar on Sterile Medical Devices

9th September 2015,
Technopark ETH
Technoparkstrasse 1, 8005 Zurich
Switzerland

The Swiss Seminar on Medical Devices

"Key Guidelines for releasing a sterile medical device on the market"

A one day educational and networking event offering industry expertise on critical topics to succeed in medical devices manufacturing and to ensure the safety of product for end-user. Experts in the Medical Devices and Pharmaceutical sectors will be present at the only seminar hold in Switzerland to describe major manufacturing requirements.

The Following subjects will be presented

Chairman

Mr. Sandro Di Labio - B.Braun

Mr. Sandro Di Labio is Head of Quality Management and Qualified Person at B.Braun Medical AG in Sempach since 2009. In his function he supervises quality management and quality control departments at B. Braun's Centre of Excellence for Infection Control, a globally acting manufacturer of antiseptics and disinfectants. His former positions at B. Braun for more than 10 years in different sites as a Head of Regulatory Affairs and Quality Engineering Manager provide him a wide experience in certification of Medical Device Class III drug/device-combination products and for global market authorization submissions for Medical Devices, Pharmaceuticals, Cosmetics and Biocides, as well as expertise in Quality Systems and Validation. Sandro has a degree in Business Administration.

Steam Sterilization

Mr. Michael Maier speaks about physical & technical aspects of moist heat sterilization including the use of steam sterilization by manufacturers of medical devices to be provided sterile. Further he gives an overview of steam sterilization as part of the reprocessing of surgical instruments in central sterilization service departments (CSSD) of hospitals. The lecture concludes with a summary of aspects that need to be taken into account by manufacturers that provide re-processable instruments and implants related to steam sterilization in a CSSD.

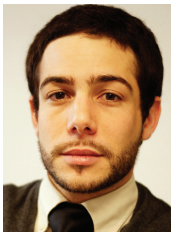
Mr. Michael Maier - Medidee Services SA

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 - Understanding the regulatory requirements

The last revision of the main standard for ETO sterilization, ISO 11135, was released in July 2014 with a transition period of 36 months. This update is a good opportunity to go through the "old" and "new" Regulatory Requirements and give you the tools to assess your sterilization process.
This presentation will give you practical information about Microbiological and Physical Qualifications; validation of ETO/ECH residuals; Frequently Asked Questions by the authorities and the common traps to avoid.

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.

Radiation Sterilization - Gamma

Gamma irradiation using 60Co is the most widely used form of ionizing radiation sterilization. One of the most frequent questions the device engineer asked is how to set the maximum and minimum dose. The maximum does is limited by the packaging material, self-life and materials used for the devices. The minimum does is fully depending on the bioburden level on the devices to be validated. This talk will provide a comprehensive overview about the dose setting, dose audit and their related microbiological tests.

Dr. Ciming Li - Biotronik AG

Dr. Ciming Li is an experienced specialist in the Microbiology and Sterilization fields. He is graduated in Microbiology and biochemistry from the University of Neuchatel and holds a Ph.D. in biochemistry and molecular biology from the University of Lausanne.

He has over 10 years of professional experience in Microbiology Quality Control, Gamma and EO Sterilization as well as Material Biocompatibility. He has been professionally active for the major Medical Device and pharmaceutical Companies in Switzerland. His current position at Biotronik in Bülach has the responsibilities covering the Microbiology Quality Controls and the Sterility Assurance for vascular intervention devices, drug coated combination devices and animal tissue based heart implants.

Practical aspects of sterilization with electron beam

The technology of electron beam sterilization is explained from the viewpoint of a contract sterilizer. For which products e-beam treatment is applicable? What configuration of products can be penetrated? How is a new sterilization project planned?

Advantages and limitations of the technology compared to other radiation sterilization methods. Tips for defining a robust process, examples though output and energy consumption considerations.

Mr. Conrad Günthard - Leoni Studer AG

Mr. Conrad Günthard, born 1962 has a degree as a Pharmacist from the Federal Institute of Technology in Zürich, Switzerland. He worked as a Pharmacist for 3 years after study until rejoining Studer company in1990. He started as Product Manager for the Gamma pallet irradiator project and became Sales Director for electron beam- and Gamma irradiation in 1997. Since the acquisition of Studer AG by LEONI Corp. and integration of the electron beam activities into LEONI Studer AG in 2012 he is the Director of the Buisness Activity Irradiation service. LEONI Studer AG operates a contract irradiation centre in Daeniken, Switzerland with 7 electron accelerators in the range of 1 to 10 MeV for radiation sterilization and crosslinking / modification of technical goods.

Cleaning validation of invasive Medical Device

The lecture of Philippe Etter covers general approaches to cleaning validation of medical devices prior to sterilization. His talk focuses on practical implementation and gives manufacturers inputs how they can address the subject. Philippe includes in his lecture the aspects important for manufacturers of re-processable medical devices that differ from those important for manufacturers of medical devices provided sterile.

Mr. Philippe Etter - Medidee Services SA

Philippe Etter 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. Philippe Etter holds 20+ years of practice in the development and market transfer of medical devices. His experience is built on design, industrialization and CE marking of critical products such as active medical devices, implants and active implants. Philippe is specialized in accompanying projects from A to Z including clinical strategy, investor relationship and leadership coaching. Philippe holds a Master of Science of the EPFL and a European degree III in sterilization of medical devices. Philippe is regularly giving in-house trainings for global medical device corporations on compliance related subjects.

Characteristics of medical device to be provided sterile

Wikitoria Herbet explains how an OR nurse prepares the instrument table and how sterile hand-over for instrument and implants is performed. Based on the explanation of the workflow she concludes what needs to be taken into account from manufacturers of instruments and implants in order to provide their products in a useful manner for the OR nurse to best ensure safe and efficient preparation of an intervention

Mrs. Wikitoria Rebecca Herbert

Wikitoria is a registered nurse from New Zealaand. She completed her Bachelor of nursing in 2008 and moved to Perth (west Australia) where she was employed by Royal Perth Hospital (RPH). Then she moved to Switzerland where she worked in several Swiss German hospital such as the Inespital (Bern). During her training and work in the operations theatre Wikitoria has gained insight in a variety of interventions and the related surgical instruments and medical products.

Packaging design for different types of sterilization

There are still too many mistakes done during the design of a packaging that should be used for a sterile product. Based on that status, Daniel Ziebarth will give you an abstract of the existing packaging technologies and material including the pros and cons of each regarding the sterilization process used. The presentation will also introduce some new packaging material and concept that can be interesting according to the product configuration.

Mr. Daniel Ziebarth - Südpack Verpackung GmbH

Daniel Ziebarth is working for Südpack Verpackungen for more than 5 years . He made his studies in several german packaging companies and graduated from the High school of Münich as Process engineering for paper and packaging. He is also member of association of German Packaging Engineers. As development engineer, Daniel is involved in the definition of future packaging and improvement of actual ones in close collaboration with laboratory, R&D department from Südpack Medica Department, customer demands and suppliers. This strategic position led him take part of several Seminar where he can present the result of the packaging testing and help the medical device company choosing the good packaging for their application.

Packaging Validation

Leading the talk on packaging validation will be Anecto Lead Programme Manager and ISO 11607 expert Noel Gibbons who has a vast amount of expertise in this area and has spoken about it on numerous occasions at some of the biggest medical conferences and seminars in the world.

The talk will provide an overview of the challenges facing manufacturers of medical device packaging and will also be highly informative to all those operating in the medical device sector who will have regularly encountered the ISO 11607 standard which outlines the requirements for choosing and validating packaging used as medical device packaging. While the ISO 11607 standard is not mandatory, it is stringently adhered to by industry leaders and compliance to it is seen as a necessity for all manufacturers. This makes attendance at Noel's talk something to be strongly considered by all operating in the sector.

During the talk Noel will give a broad overview of packaging validation and the ISO 11607 standard. He will highlight the questions that manufacturers may not have considered in the development of a package and the importance of the various packaging considerations from the earliest days of the medical device product lifecycle.

Mr. Noel Gibbons - Anecto Ltd.

Noel Gibbons is the Lead Program Manager at Anecto. He has significant experience in a wide variety of areas including package testing., package integrity testing, quality and international test standards. He has presented seminars internationally on medical devices & pharmaceutical testing including the requirements of ISO 11607 and other test standards. He has also provided training on the requirements of ISO 11607 to companies throughout Europe and is a member of a number of ASTM and NSAI packaging committees.

EU Regulation for reprocessing SUD, what manufacturers need to know

Reprocessing of single use devices is a hot topic. Legislation differs in EU member states. Dr. Suzanne Halliday from BSI explains how the proposed "Regulation of the European Parliament and of the Council on medical devices" addresses this topic and outlines the key facts manufacturers of Single Use Devices need to be aware of under the current regulatory framework and what the main changes would be in case the proposed regulation will be accepted.

Dr. Suzanne Halliday - Medical Devices BSI

Dr. Suzanne Halliday is currently the Head of the Medical Devices Notified Body at BSI. She has been working for BSI for 11 years as a Technical Specialist, QMS Assessor, Team Leader and Head of Operations and Training. These roles have required her to learn the regulatory requirements of the European Union, Australia, Brazil, Canada, Japan, USA, Taiwan and other countries to facilitate manufacturers bringing medical devices to market. Prior to joining BSI she has more than ten years of experience in research and development including clinical trials of adult joint reconstruction and paediatric orthopaedic devices. Her experience comes from seven hospitals and three universities in five different countries.