

Sterilization of Medical Devices

11th September 2008 Radisson SAS Hotel, Zurich Airport, 8058 Zürich Airport, SWITZERLAND

A 1 day educational event offering industry expertise on critical topics to success in medical devices sterilization and to ensure the safety of product for end-user. Professionals of the Medical Devices and Pharmaceutical sector will be present at the only seminar in Switzerland to describe major sterilization methods including demonstrating the latest requirements and changes.

The seminar offers an opportunity for industry to understand the basics, interpretation, application & being update with recent changes between international and European standards. The seminar will cover issues related to release of products as microbiological contamination before sterilization, manufacturing environment & risk analyses on sterilized products.

The following subjects will be presented:

- Radiation Sterilization: Explanation on the changes, update and overview of current regulation ISO 11137-1,-2,-3:2006 “*Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*”
- EO Sterilization: Principles; Consideration to take during product design; Selection of process challenge devices (PCD's). Changes in ISO 11135-1:2007 and how to apply them: “*Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*”
- Manufacturing process control and Product Bioburden, an overview including requirements of ISO 11737-1:2006 “*Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products*” and its application during manufacturing and sterilization process
- The ISO 14971:2007 “*Medical devices -- Application of risk management to medical devices*” standard for risk management applied to sterile products: How can ISO 14971 help to understand the risks associated to the development and manufacture of sterile medical devices?
- Shelf Life studies of Medical Devices and Medical Device Packages, presentation of ISO 11607-1:2006 “*Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems*” 11607-2:2006 “*Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes*”
- Residue analysis of Ethylene Oxide (EO), Ethylene Glycol (EG) and Ethylene Chlorhydrin (ECH) in Medical Devices and interpretation of the draft version, ISO 10993-7 “*Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals*”
- Swissmedic: Regulatory news in the sphere of medical devices: Revision of the European medical devices directives (93/42/EWG and 90/385/EWG) by directive 2007/47/EU (Integration of software, clinical data, linking to other directives f.ex. machinery, definition of single-use device,...). Revision of the Guidelines on a medical devices vigilance system MEDDEV 2.12-1 rev 5 (Definitions, expressions, timeframe, change in scope)
- Sterilization with X-Rays: The new Technology for radiation sterilization Technology, Regulatory issues, FDA acceptance, advantages, industrial realization in Switzerland

Who should attend:

This seminar is intended for professionals of medical devices or pharmaceutical areas, who are involved in a sterilization process step: QA/ QC managers or regulatory personnel, products managers, product development managers, packaging engineers, marketing personnel. Supplier to the medical devices industry should also be interested like contract packagers and contract sterilizers.

Seminar organizers :

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About the speakers:

Mr. Jean-Louis BOL, President IBA Industrial Activity (Sterilization & Ionization)

At the accelerator laboratory of the University of Louvain-la-Neuve (Belgium) Jean-Louis was an active member of the Management Team and participated in the development of a new type of industrial cyclotron for the production of medical radio-isotopes. IN 1986, that cyclotron was the starting point of Ion Beam Applications (IBA) as a spin-off of the University. Jean-Louis was responsible for the IBA line of products manufacturing and development.

Today IBA is a 2000 employees company and Jean-Louis is responsible for the IBA's industrial activities in the sterilization and ionization applications. He is leading the development of X-ray technology for sterilization based on high power accelerators..

Dr. Dieter R. DANNHORN, CEO & President, MDT Medical Device Testing

He is CEO and president of the internationally active accredited testhouse and CRO "mdt medical device testing GmbH" and of the consulting company "md registration support limited". After his university training as a biologist, he worked for two internationally active pharmaceutical companies before he took over the management position at "mdt" in 1996 and founded the consulting company "mdrs" in 2005. Meanwhile Dr. Dannhorn looks back to 15 years of experience in medical devices, regular testing and compliance with European and non-European medical device regulations (EU, US and Asia)

Mr. Louis EGGER, Microbiologist, J & J Medos S.A. – Codman S.à.R.L - Depuy ACE S.à.R.L.

Currently Sterilization and Microbiology Manager for Johnson and Johnson in Le Locle Switzerland working in the field of Medical Device Industry for over 10 years. In this position he is responsible for validation and monitoring of gamma, ethylene oxide and moist heat sterilization processes, as well as validation and monitoring of clean rooms for various manufacturing units. Besides that, he set-up an on-site microbiology testing laboratory. He is the local representative in sterilization and microbiology working groups of Johnson & Johnson. He has a Master in Biology from the University of Fribourg and a Master in Drink Water supply and Waste Water treatment from the Federal Polytechnical School in Zürich (ETHZ).

Mr. Jonathan LINTOTT, CEO, Andersen Caledonia

Jonathan Lintott has been involved with the sterilization industry for almost 15 years. He started working for Andersen Medical in Hong Kong providing technical support for hospital ethylene oxide sterilizers across Asia. He then moved to the USA as Chief Operating Officer of Andersen Products with responsibilities covering manufacture and sterilization of surgical disposables. In 2000 he co-founded Andersen Caledonia Ltd, a new contract ethylene oxide sterilization and microbial testing facility based near Glasgow in the UK. He is presently managing director of this company.

Jonathan has been involved with sterilization standards for more than 10 years firstly with AAMI in the USA and then with ABHI in the UK. He has made presentations on the issues of ethylene oxide sterilization and validation to many organizations including the AORN (USA), MDM (USA) and ABHI (UK). He has also spoken at a number of seminars in places such as Berlin, Boston, Dubai, Zurich and Birmingham.

Mr. Pierre-Alain SOMMER, Quality & Regulatory, GESKAL

Pierre-Alain Sommer is a qualified Mechanical Engineer. He obtained a certificate as a Marketing Technician and a certificate in Quality Management.

For more than 20 years, Pierre-Alain Sommer has taken on a variety of responsibilities across Europe within the field of medical technology, including activities in R&D, production, distribution, quality and regulatory affairs.

He has actively collaborated in the development of new products that have involved the implementation of good manufacturing practices, good distribution practices and market vigilance.

He has delivered and received numerous certificates and registration documents related to ISO, CE & FDA requirements in various fields of activity.

In 2002, Pierre-Alain Sommer became freelance and has since then successfully accomplished a large number of missions for medical devices companies due to his personal approach which has led him to the creation of geskal.

Mr. Markus WAGNER, Chemielaborant HFP, UFAG Laboratorien AG

Markus Wagner was Laboratory assistant at CIBA-Geigy, for Residue Analysis until 1987 before getting a degree at Basel Höhere Fachprüfung. From 1987 to 2007, he has occupied multiple positions in Chromatography and since 2007 he his Head Department Gas Chromatography Pharma. He developed, established and optimized the analytical Method of Ethylene Oxide Analysis at UFAG Laboratorien. During the last years he performed the analytics of various sterilization validations successfully.

Dr. Rainer WALZ, Head Analytics, UFAG Laboratorien AG

Rainer Walz studied Chemistry and did a Ph. D. in natural science at the University of Freiburg (Germany). Afterwards he worked as Team Leader QS at Cerestar for a year before joining Fluka as Product Manager Analytical. For more than 6 years he has been responsible for 6000 Certified Reference Materials, Reference Materials and Analytical Reagents. He has actively collaborated in the development in new analytical methods with the IRMM, BAM and Private Analytical Laboratories. Since 2006, he is Head of Analytics Pharma at UFAG Laboratory. In the last the 2 years, he takes responsibility in consulting customers in the field of the Ethyleneoxide residue analysis and published in March 2008 an article about Ethyleneoxide residue analysis in the journal "Chemische Rundschau".

Mr. Markus WEISS, Inspector, Swissmedic, Medical Devices Division

Markus Weiss works since 3 years for Swissmedic and is responsible for market surveillance, especially for reprocessing of medical devices, is carrying out audits in hospitals and handles materiovigilance complaints. He is Technician TS and completed studies in Medical Technology Management (FH) and Auditing (SAQ- Qualicon). He also has long-time experience in technical support and validation for medical devices.

Chairman: Dr. Markus ZOBRIST, SAQ (Swiss Association for Quality)

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Seminar Details:

Seminar Location	Radisson SAS Hotel, Zurich Airport, in walking distance from the gates, or parking # 1, then elevator to floor -1
Language	English
Schedule	From 08:00 Registration 09:00 Opening 12:00 Lunch - networking 13:20 Continuation 18:00 End of seminar
Fees	Fee per person is <u>CHF 350.-</u> Ex.TVA, Includes course materials, refreshments in the morning and afternoon as well as luncheon. Registration fees MUST be paid before admission to the seminar.
Certificate of attendance	A certificate will be given to the participants attending full day seminar.
Cancellation	Cancellation to refund the registration fee will only be accepted in writing before 20 th August 2008. Nevertheless, a registrant can designate a substitute attendee.
Accommodations	For overnight staying, attendees can contact directly the Radisson SAS Hotel Zurich Airport to book a room (see following contacts).
Contacts	For any query regarding the organization of the seminar, the speakers, the program and registration, please contact <u>Mr. Yacine Gérard</u> , +41 (0) 26 676 90 89 or y.b.gerard@medistri.com For any questions regarding the booking of a hotel room, please contact <u>Mrs. Anne Anschlag</u> at SAS Radisson Hotel: +41 (0) 44 800 44 42 or anne.ansschlag@radissonsas.com.

Registration Form Sterilization of Medical Devices

11th September Hotel Radisson SAS, 8058 Zürich Switzerland

The first 100 inscription will be registered.

Full Name _____
Title _____
Company _____
Address _____
Country _____
Tel n° _____ Fax n° _____ E-mail _____

Payment will be executed by e-banking postal transfer

Bank details LEONI Studer AG
Project Nr.370101 (to put in reference)
Account Nr. 1100-1035.810, BIC(Swift) : ZKBK CH ZZ 80A
Zürcher Kantonalbank, CH-8001 Zürich
IBAN CH80 0070 0110 0010 3581 0

Signature:

Date:

I allow the organizers to put my name on the list of participants Yes No

The organizers keep the right to cancel the event (not later than 14 days before the scheduled start) in case there is not enough attendees registered. In this case, all registrants will be notified by phone. The Organizers don't assume financial losses incurred in travel tickets or cancellation of hotel rooms. Any speakers or subject of presentation can be changed without notification.

This registration form is to be sent to Medistri by email (y.b.gerard@medistri.com) or by fax (+41 (0) 26 676 90 85)

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