Swiss MedBRAID

Medical Devices - Seminar 2010

6th September 2010

Radisson Blu Hotel, 8058 Zürich Airport

Switzerland

Development, Manufacturing, Release

A one day educational and networking event offering to industry expertise on critical topics to success in medical devices manufacturing and to ensure the safety of product for end-user. Experts in the Medical Devices and Pharmaceutical sector will be present at the only seminar hold in Switzerland to describe major manufacturing requirements including the latest changes.
The seminar offers an opportunity for industry to understand the basics, interpretation, application & being update with recent changes on the standards. The seminar will cover issues related to manufacturing of products, microbiological contamination of product, clinical trial & sterilization.

THE FOLLOWING SUBJECTS WILL BE PRESENTED:

- **Clinical evaluations and clinical trials for medical devices - Dr. Gert Bos**
  Clinical evaluation is an essential part of the validation of medical devices. The presentation will focus on the essentials of the routes to compliance: literature review or clinical trial. It will highlight the changes to the clinical requirements within the Medical Device Directive, as last amended by 2007/47/EC.
  - Clinical validation: the routes to compliance
  - Amendment to the existing directive
  - Impact on clinical data and clinical trials
  - Understanding the clinical evaluation reports and reviews
  - Post-marketing surveillance and risk analysis

- **EN ISO 11607(2006) : Packaging for terminally sterilized medical devices - Mr. Michael FANGON**
  Part 1: Requirements for materials, Sterile Barrier Systems and Packaging Systems.
  Part 2: Validation requirements for forming, sealing and assembly process.
  This standard applies to healthcare facilities, medical device manufacturers and globally, everywhere the medical devices are sterilized. Part1 describes the general requirements and Part 2 specifies the validation requirements for the packaging closure process.
  The presentation will identify the requirements for the medical device manufacturer, in order to be in line with ISO 11607 parts 1 & 2., and the different implications for the end users (ex : healthcare facilities)
  - Sterile Barrier System
  - Protective packaging
  - Packaging systems
  - Sealing validation

- **Microbiological Monitoring of Medical Devices and Clean Rooms – Importance and Approaches based on ISO 11737-1 and ISO 14698 -1/ -2 respectively – Dr. Christian GIANINAZZI**
  Microbiological contamination of a product is a key factor for the validation of a sterilization process. The present talk will address reasons, parameters and procedures for microbiological monitoring. Potential sources for contamination will be discussed, including clean rooms and personnel involved in manufacture of products to be sterilized. Additionally, emerging risks from not performing microbiological screening will be presented.

- **Water used in Medical Devices Manufacturing – European and US pharmacopeias – Dr. Karen HEATON**
  Water is regularly used in the manufacturing process of medical devices especially for cleaning purposes. However water can be a major source of biological and pyrogen contamination.
  The following areas will be covered:
  - General introduction to different types of water and the standards they must comply to
  - Introduction to microbial contamination of water and the type of organisms that are found
  - Biofilms, what they are and their importance
  - How to test water, sampling methods and laboratory test procedures

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- **Method for prediction of ethylene oxide lethality and cycle development - Mr. Gary MITCHEL**
  Historically there has been much misinformation regarding the effective range of temperature and gas concentration on ethylene oxide lethality. In the past ethylene oxide concentrations have been calculated based on pressure differential and has been considered to be the same in the load and in the chamber; the presentation will show that gas concentration is also a function of the gas being charged (EtO or diluent gas), load and sterilizer volume.
  A method will be presented for calculation of gas concentration within the product and sterilizer chamber and data will be presented on how cycles can be modified to optimize gas concentration in the product and minimize effects of load volume on product gas concentration.

- **Directive 2007/47 EC - Successful implementation of the key revisions to the medical device directives – Mr. Pierre-Alain SOMMER**
  Directives 90/385/EC relating to active implantable medical devices and 93/42/EC concerning medical devices have been amended in September 2007. 21st of March 2010 was the deadline and Medical Device Manufacturers should have implemented new requirements of Medical Devices Directive (2007/47/EC). This presentation will focus on the necessary steps to comply with the Medical Devices Directives and will discuss the revised requirements based on a case study.
  Areas covered:
  - CE Marking Conformity Assessment
  - Key changes
  - Steps to comply
  - Documentation

Who should attend:

This seminar is intended for professionals of medical devices or pharmaceutical areas, who are involved in product release, process release, 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 subcontract manufacturers.

- **US-FDA 510(k) submissions- Requirements and their practical implementation - Mrs. Sandra SONIEC**
  The purpose of a 510(k) submission is to obtain FDA clearance to market a medical device in the United States. The 510(k) process applies to all devices that are not subject to PMA and not exempt from 510(k) requirements, these are in the majority of cases class II devices. A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. This presentation provides and overviews of 510(k) requirements supported with practical examples.
  Areas covered:
  - 510(k) requirements, the meaning of substantial equivalence and predicate devices
  - 510(k) submissions types: Traditional, Special and Abbreviated
  - Third party reviews
  - Practical implementation

- **Software Development Lifecycle (IEC 62304) - Mr. Beat STEFFEN**

The use of computing technologies in medical electrical equipment introduced a level of complexity which is exceeded only by the biological systems of the patients, for which the medical electrical equipment is intended to diagnose and / or treat. This is also reflected in the updated Medical Device Directive 93/42/EEC where software now is explicitly considered an active medical device, whether integral with the device or as a standalone product.

IEC 62304 "Medical device software - Software lifecycle processes" is recognized by FDA and SFDA (China) and was harmonized in the European Union on 28th November 2008. A claim of compliance with IEC 62304 now provides a presumption of conformity with the MDD and AIMD for software.

ABOUT THE SPEAKERS:

Dr. Gert BOS – *Head of Regulatory and Clinical Affairs, BSI Notified Body, UK*

Gert W. Bos has 17 years of experience in lifesciences (devices and pharma), in university, industry as well as in two Notified Bodies. In these positions he published 16 scientific papers, numerous technical papers and wrote chapters of scientific books. Dr. Bos holds a position as Head of Regulatory and Clinical Affairs at BSI Healthcare. He acts as chair of the Medical Notified Body forum NB-Med in Brussels, and participates in the Notified Body Recommendation group (NBRG), the Clinical evaluation Task Force (CIE), Medical Device Expert Group (MDEG) and the MDEG workgroups on animal tissue, on MRA's, and on IVD's. He is a member of the RAPS advisory committee.

Mr. Michael FANGON – *Marketing Manager & Regulatory Affairs, Amcor Flexibles, FR*

Michael Fangon has been working for Amcor SPS since 1999. Amcor is a world leader in Packaging manufacturing and recently acquired some Alcan businesses to become a group of more than 35 000 employees. Initially Marketing and Product Manager for the Hospital Division (SPS), he also covers the regulatory field for Amcor Europe. Based in Coulommiers France, M Fangon has been appointed in 2007 as convener of the medical packaging working group in AFNOR, the French national standard committee. He also represents France as "medical packaging" expert for both CEN and ISO committees. For the last 10 years M Fangon was involved in many packaging developments and innovations for sterilization packaging like Integrapak, a new type of pouch which was rewarded as best innovation in 2007 by hospital users.

Dr. Christian GIANINAZZI - *Laboratory Manager, Medistri SA, CH*

ChristianGianinazzi has a PhD degree in biology. He has been working in research in the field of infectious diseases and parasitology, with the focus on the central nervous system. He has published several scientific articles in peer-reviewed journals, and was also involved as co-worker in national and international research projects including universities, cantonal laboratories, and national institutions. He has actively participated in national and international meetings, and has given lectures and courses for the University of Bern (CH) and Monastir (TUN). Since 2009, he is the laboratory manager at Medistri.

Dr. Karen HEATON - *Laboratory Manager (Keele), Anderson Caledonia, UK*

BSc (Hons) – Biological Science, MSc- Environmental Sciences, PhD – environmental Aquatic Microbiology
Dr Heaton runs the Andersen Caledonia Keele contract testing laboratory. This laboratory operates to ISO17025 and provides environmental monitoring services to hospitals and medical device companies across England, Wales and internationally. Much of the work performed relates to testing of water samples. Dr Heaton has 12 years experience of researching the formation and rheology of biofilms under flow conditions and the isolation and characterization of bacteria from suspension and surfaces from numerous environments such as food, fresh water, sewage treatment works, factories and hospitals. Dr Heaton undertook a 4 years research project investigating microbial community interactions on ureteric stents manufactured from biomaterial Percuflex post removal from the body in relation to the role microbes play in the formation of struvite and hydroxypatite encrustations.

Mr. Gary MITCHEL - *Senior Fellow, Johnson & Johnson, Sterile Process Technology, US*

Gary Mitchel has B. S. and M. S. degrees and Chemical Engineering and is a Registered Professional Engineer in the State of California. He is a Senior Engineering Fellow of Sterile Process Technology; a corporate function of Johnson & Johnson. He has 35 years of experience in sterilization of parenteral solutions, pharmaceuticals, medical devices and consumer products. He has been responsible for design, installation, start-up and validation of sterilization facilities for Cutter Laboratories and Johnson & Johnson affiliate companies. As a member of Sterile Process Technology he is involved in sterilization cycle development and optimization as well as developing novel approaches to modeling ethylene oxide and radiation sterilization. He represents Johnson & Johnson on ANSI/AAMI/ISO working groups for Dry Heat, Moist Heat and Ethylene Oxide.

Mrs. Sandra SONIEC - *Managing Director, Meditec Consulting GmbH, CH*

Sandra Soniec has a background in biomedical engineering and more than 10 years experience in Regulatory Affairs and Quality Management for medical devices. In her former position she was working for five years as Manager Regulatory Affairs for a Swiss based drug device delivery company. Since February 2004 she is owner and managing director of Meditec Consulting, Switzerland; an independent consultancy company specialized in Regulatory Affairs and Quality Management Services for medical device manufacturers and associated industries.

Mr. Pierre-Alain SOMMER – *Managing Director, Geskal, CH*

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. Beat STEFFEN, *Managing director, Confinis AG, CH*

MSc in electrical engineering, executive MBA. 15 years of experience in medical device development and manufacturing, from software and hardware design to project management. Worked for Disetronic and Ypsomed and was responsible for a number of development projects from the first idea to successful registration and commercialization as well as infrastructure projects. His client's portfolio included Pfizer, Sanofi-Aventis, Eli Lilly & Company, Genentech and Amylin Pharmaceuticals. He built up and spear-headed the project management & risk management department at Ypsomed. He founded Confinis in 2005. Besides providing professional services and advises to clients in medical device, pharmaceutical, diagnostics and biotech field he works as a freelance auditor regarding ISO 13485 and MDD 93/42/EEC for the Swiss Association for Quality and Management Systems (SQS). Furthermore he is a certified auditor for the Canadian Medical Device Regulation under CMDCAS.

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

Markus Zobrist graduated from ETH Zürich in natural science and received his PhD from the University of Fribourg. He was a quality manager in industry until 1991 when he joined the Swiss Competent Authority for Therapeutic Products. He was involved in setting up the medical devices legislation and he was responsible for the market surveillance, auditing and for the designation of conformity assessment bodies. He was member of ISO TC 210 WG1 developing ISO 13485:2003 from 2000 to 2003. From 2006 until his retirement in May 2008, he chaired the Global Harmonization Task Force Study Group 4 which is developing the international guidelines for auditing medical devices manufacturers.

Seminar Details:

Seminar Location	Radisson Blu Hotel, 8058 Zürich Airport, in walking distance from the gates, or parking # 1, then elevator to floor -1	
Language	English	
Schedule	From 08:00	Registration and welcome coffee
	09:00	Opening
	13:00	Lunch - networking
	14:15	Continuation
	18:10	End of seminar
Fees	Fee per person is CHF 450. – 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 10th August 2010. Nevertheless, a registrant can designate a substitute attendee.	
Accommodations	For overnight staying, attendees can contact directly the Radisson SAS Hotel, Zürich 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 Mrs. Shoko Nilforoushan, +41 (0) 26 676 90 80 or info@medbraid.com For any questions regarding the booking of a hotel room, please contact Mrs. Nadine Drexler at Radisson Blu Hotel, Zürich Airport: +41 (0) 44 800 44 43 or nadine.drexler@radissonblu.com	

Registration Form

Sterilization of Medical Devices
6th September Radisson Blu Hotel, 8058 Zürich Airport 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
Medistri SA
Medbraid 2010 (to put in reference)
Banque cantonal de Fribourg
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IBAN : CH71 0076 8250 1217 8990 2

Signature: Date:

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

The organizer keeps 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 Organizer doesn't assume financial losses incurred in travel tickets or cancellation of hotel rooms. Any speaker or subject of presentation can be changed without notification.

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

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