Aug 24, 2017

2nd Symbioteq Biocompatibility of Medical Devices Conference 2017

Join us for a multidisciplinary event that gives you the opportunity for learning the latest news within biocompatibility. An excellent occasion to network with global Medical Devices Biocompatibility Professionals, share and discuss experience with colleagues and friends. Whether you are a specialist or beginner within biocompatibility, work with R&D, QA or Regulatory, we are certain that you will have a rewarding few days in Gothenburg, Sweden. A not-to-be-missed-event!

Discounts for groups registered and invoiced together. *Check the web-site for continuous updates - stay tuned!*

DAY 1
Chairman: Henry Sibun, Henry Sibun Associates Ltd, and External Auditor/Reviewer for TüV SüD Product Service GmbH, UK

A quarter-century with ISO 10993 - from simply toxicology to risk-based evaluation, a personal view
Karl-Gustav Strid, PhD, Professor, Senior medical device expert, SP Certification (RISE), Sweden

Update on the ISO 10993 standard series (what has happened since the last conference October 2014) – Status and upcoming changes.
Dr. Albrecht Poth, Dr. Knoell Consult GmbH, Germany

Standardization – a powerful tool!
Lena Morgan, Swedish Standards Institute, Sweden

Notified Body perspective on biocompatibility, with the new Regulation in mind.
Dr. Julian Kirch, TÜV SÜD Product Service GmbH, Germany

Biocompatibility, risk management and the QMS.
Henry Sibun, Henry Sibun Associates Ltd, UK

Global submission expectations regarding ISO 10993-1 – a manufacturer of active implantable devices' perspective.
Gerhard Marini, MED-EL, Austria

Hemocompatibility ISO 10993-4, with industry examples from a global perspective.
Barbara Musi, PhD, Baxter Healthcare Corporation, Sweden

Are the current medical device extraction procedures sufficient for genetic toxicity hazard identification?
Robert Przygoda, PhD, Johnson & Johnson, USA

Development of an in-vitro testing battery to assess biocompatibility of medical devices.
DI Elisabeth Mertl, OFI Technology & Innovation GmbH, Austria

Sterilization and Microbiology, impact on biological safety? Sterilization area in general and reprocessing of reusable instruments.
Dr. Hana Hofman-Hüther, Professional Scientific Services, Germany

DAY 2
Chairman: Albrecht Poth – Chairman ISO TC 194 and of the German National Mirror Committee, Convenor of ISO 10993-3, Dr. Knoell Consult GmbH, Germany

Current development and future trend of ISO 10993 standards in China.
Director Chenghu Liu of the Biological evaluation department at China FDA-Shandong Quality Inspection Center For Medical Devices, China

Toxicological considerations on the biological evaluation of implantable medical devices: perspectives and case studies of a toxicologist from the manufacturer.
Sharlene Dai, Medtronic, USA

Presentation on non-clinical wound-healing studies.
Trine Starostka, DVM, CiToxLAB Scantox A/S, Denmark. Co-chair Andy Makin, Scientific Director, CiToxLAB Scantox A/S.

Chemical characterization, extraction/leaching conditions and biological testing in relation to the TTC concept (Threshold of Toxicological Concern).
Ulrika Carlander, PhD, SoundAdvice AB and Lars Magnus Bjursten, Professor Bioimplant Research, Lund University, Sweden

The ISO 18562 series "Biocompatibility of breathing gas pathways in healthcare applications" is now released - what does it contain and why?
Lina Burman, PhD, Consultant, Symbioteq, Sweden

Toxicological Risk Assessment of medical devices based on extractable and leachable data – Lessons learned.
Dr. Anja Rämisch, Dr. Knoell Consult GmbH, Germany

When Drug meets Device - New challenges for Drug Stability and Material characterization of Combination products.
Dr. Ir. Lise Vanderkelen, Toxikon Europe nv, Belgium

Global harmonization - Stephan Buttron, Principal Medical Research Manager Regulatory Affairs, NAMSA, Germany

TBD - FDA's experience following their new guidance document.
Jennifer Goode, Biocompatibility Program Advisor, FDA, US (Remote presentation)

Monica Grekula and the Conference Team

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