Program Biocompatibility Insights 2023

"The Science Behind the Regulations"

"Addressing Challenges in Medical Device Toxicology"

Chairmans: Sherry Parker and Arthur Brandwood

Day 1 September 27
Registration and networking
Welcome/Housekeeping and words from chairman
Welcome to our world – the current state of ISO 10993
Setting the scene - Challenges that we currently face in medical device toxicology *Ron Brown (Risk Science Consortium, US)*
Keynote speaker: New standards and ongoing development – what happened since BM2022? *Jeremy Tinkler ((Chair ISO TC 194, ICON, UK)*
The role of Chemistry in evaluation of Medical Devices
TBC
Coffee Break
Challenging in navigating laboratory studies and regulatory submissions in the changing environment of Chemical characterization *Eric Sussman ((MCRA, US)*
Aspects of extractions
Use of simulating solvents in medical devices and adjacent disciplines *Ted Heise (Convenor 10993-18, MED Institute, US)*
Substance release – Implications for Extractables/leachables *Jianwei Li (Chemical Characterization Solutions, US)*
Q/A Chemistry sessions
Lunch
Toxicological Risk Assessments
Intro/Overview of Changes to ISO 10993-17 *Sherry Parker (SParker Consulting, US)*
Identification and assessment of potentially carcinogenic substances in medical devices, Cohort of concern, and common medical device degradation products incl case study *Joel Cohen (Gradient, US)*
Coffee Break
Use of simulated-use extractable studies to refine exposure estimation for toxicology risk assessment *(TBC)*
Panel discussion How to evaluate medical devices using chemistry and TRA – pros and cons compared to historical methods *Moderator: Sherry Parker*
Mingel and Dinner

Day 2 September 28
Welcome / Housekeeping
Introduction to day two - Emerging approaches for the safety assessment of medical devices *Philip Clay (Chorley consulting, UK)*
The case of implantation - When and why are implantation studies really relevant?
When and why are implantation studies really relevant? *Lars Magnus Bjursten (Convenor ISO 18562, Sen Prof Bioimplant Res, SE)*
Quantitative In Vitro In Vivo Extrapolation of Nickel Toxicity to Tissues Adjacent to a Metallic Implant. (*TBC*)
Q/A Implantation
Coffee Break
New risk assessment approaches to evaluate skin sensitization
Introduction to the session *Ron Brown (Risk Science Consortium, US)*
Update on WG8 round robin and Thresholds for sensitization *Kelly Coleman (Medtronic, US)*
Prediction of Sensitization Hazard for Chemical Substances Released From Medical Devices: PreS/MD and other tools *Alex Tropsha (UNC-Chapel Hill, US)*
Q/A Sensitization
Lunch
Safety assessment addressing inhalation
ISO 18562 – Evaluation, testing and new approaches, incl. Physics and Measurement of VOCs *Lina Burman (Limulus Bio, SE) and Jianwei Li (Chemical Characterization Solutions, US)*
In vitro methods to assess inhalation toxicity *Amy Clippinger (PETA Science Consortium International, US)*
Q/A Inhalation
Coffee Break
Closing plenary
Reflection of the conference – where are we going *Arthur Brandwood (Project Leader – revision of ISO 10993-1, AU)*
Panel discussion Where are we going?
Closing remarks

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