Biocompatibility Insights Training Day

26 September 2023

Course Leaders: Ron Brown (Risk Science Consortium) & Senior consultants from Veranex

Time	Topic
8.30 – 9.00	Registration, coffee & networking
9.00 - 9.05	Welcome and housekeeping
9.05 – 10.00	The EU MDR from a biological safety perspective • Substance based devices • Particles • CMR/ED • Some of our experiences so far •
10.00-10.30	What the toxicologist needs to know about chemical characterization
10.30-11.00	Coffee Break
11.00-13.00	Introduction to computational approaches for the safety assessment of extractable and leachable compounds including case studies **–** *Use of QSAR Models and Read Across Approaches*
13.00-14.00	Lunch
14.00 -15.15	An overview of new concepts discussed in the FDIS/ISO 10993-17 standard with group exercises and case studies
15.15-15.45	Coffee break
15.45-16.45	Group exercises and case studies (continued)
16.45-17.00	Summary of the day and what to expect for the future End of training and farewell

Please note, we reserve the right to adjust the program.

Q&A and short breaks included during the day.

Moderated by: Senior consultants from Veranex
Location: Annapolis Waterfront Hotel

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 last year's conference, Biocompatibility Matters 2022? *Jeremy Tinkler (Chair ISO TC 194, ICON, UK)*
The role of Chemistry in evaluation of Medical Devices
Common Challenges in chemical analysis and strategies when seeking feedback from the US FDA *Joshua Young (US FDA CDRH, US)*
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
Overview of Changes to ISO 10993-17 *Sherry Parker (SParker Consulting, US)*
Case studies addressing identification and assessment of potentially carcinogenic substances in medical devices, cohort of concern, and common medical device degradation products *Joel Cohen (Gradient, US)*
Coffee Break
Use of simulated-use extractable studies to refine exposure estimation for toxicology risk assessment *Kimberly Ehman (WuXi AppTec, US)*
Panel discussion
" Is the future in chemistry? Advantages and limitations" *Moderator: Sherry Parker*

Mingle and Conference 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 *Ron Brown (Risk Science Consortium, US)*
Q/A Implantation
Coffee Break
New risk assessment approaches to evaluate skin sensitization
Update on WG8 (ISO 10993-10) 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 (Veranex, 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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