CONFERENCE PROGRAM

BIOCOMPATIBILITY MATTERS 2022

2022 Bm Biocompatibility Matters Copenhagen

CONFERENCE DAY 1 October 5, at 9 am – 5 pm

WELCOME TO OUR WORLD – THE CURRENT STATE OF ISO 10993

- The ISO 10993 family – and use in regulation
  Jeremy Tinkler (Chair, ISO TC 194)
- Strengths and weaknesses of ISO 10993 as a regulatory tool
  Michelle Kelly (NAMSA, UK)

UNDERSTANDING YOUR DEVICE – WHEN AND HOW TO "DO CHEMISTRY"

- Notified body perspectives on chemical characterization and MDR rule 21 ADME requirements
  Christoph Lindner and Christiana Hoffmann (TUV Sud, DE)
- Establishing a Practical Analytical Evaluation Threshold (AET)
  Ted Heise (MED Institute, US)
- Minimizing "Unknown" Compounds - Best Analytical Practices
  Dries Cardoen (Nelson Laboratories, EU)
- Chemical Characterisation Q&A
  Moderator: Ted Heise

NEW SCIENCE IN BIOLOGICAL EVALUATION

- Working with the regulator to do things differently
  Ron Brown (Risk Science Consortium, US)
- New approaches to in vitro sensitization - *regulatory* acceptance
  Rose-Marie Jenvert, (Senzagen, SE)
- In vitro thrombosis testing
  Miki Giffin (Nelson Laboratories, US)
- Standardization of new science: in vitro irritation as a case study
  Christian Pellevoisin (Urbilateria Conseil, FR)

US FDA EXPECTATIONS

- Evaluation, testing and new approaches: US FDA expectations
  Jennifer Goode (US FDA)

TOWARDS A NEW BIOLOGICAL EVALUATION PARADIGM

Panelists: Michelle Kelly, Ron Brown, Sherry Parker, Philip Clay, Jeremy Tinkler

CONFERENCE DINNER AT IDA CONFERENCE CENTER

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CONFERENCE DAY 2 October 6, at 8.30 am – 4 p

SPECIAL CASES – BEYOND TABLE A1

- Updates to ISO 18562 for breathing gas pathways - a manufacturer perspective
  Paul Dixon (Vyair, UK)
- Implantation studies for biomaterials - 10993-6, in general and effects of degradation
  Wim de Jong (RIVM, NL)
- Endocrine Disruptors: Regulations, Guidance and NAMs
  Hedwig M Braakhuis (RIVM, NL)

TOXICOLOGICAL RISK ASSESSMENTS– USING PART 17

- New Concepts in Toxicological Risk Assessments
  Sherry Parker (WuXi AppTec, US)
- Toxicological Screening Limits – Derivation and Case Study
  Todd Kennedy (WL Gore, US)
- How low should you go? An Analysis of the Lowest Effective Dose in Genotoxicity testing
  Paul Rawlinson (Gentronix, UK)
- Tools and best practices for Read-Across in Toxicological Risk Assessment of Medical Devices
  Joel Cohen (Gradient, UK)
- Manufacturer case studies in Tox Risk Assessment
  Philip Clay (Chorley consulting, UK)

RISKS, RETURNS AND REGULATION. CLOSING PLENARY AND FORUM

- Risks and Rewards – Where next for ISO 10993-1?
  Arthur Brandwood (Project Leader – revision of ISO 10993-1)
- New science and better standards for risk-based regulation
  Moderators: Lars Magnus Bjursten, Ted Heise, and Jeremy Tinkler

Questions about the program? contact Monica Grekula at monica.grekula@limulusbio.com or +46 (0)70 280 86 21
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** Please note that Limulus Bio reserves the right to adjust the program*