Biocompatibility Matters 2022

Copenhagen, Denmark

October 4th Training day

October 5-6th Conference days

2022 Bm Biocompatibility Matters Copenhagen

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TRAINING DAY **BIOCOMPATIBILITY MATTERS 2022**

2022 Bm Biocompatibility Matters Copenhagen

TRAINING DAY, October 4th, at 9 am – 5 pm

SESSION 1 – ISO 10993-1LED BY LIMULUS BIO

In this session, the instructors will discuss the importance of a risk based approach for biological evaluations, as well as ideas on how to connect to the risk analysis and overall risk management process. This workshop will include group discussions and hands-on exercises guided by experienced Limulus Bio instructors.

Upon completion, attendees will be able to:

- Understand how ISO 10993-1:2018 connects to other processes
- Get example of the structure of a a biological evaluation plan and report
- Understand what needs to be included due to the EU MDR
- Know what Endocrine Disruptors (ED) are and why they are of concern

SESSION 2 - ISO 10993-18 LED BY NAMSA

In this session, the instructor will discuss the chemical characterization of materials and the evaluation steps to examine material composition information and choose proper tests, extracts and test durations to meet the latest industry requirements. This workshop will include instruction and hands-on exercises guided by an experienced NAMSA instructor.
Upon completion, attendees will be able to:

- Discuss ISO 10993-18:2020 in a practical use format
- Develop a testing strategy for multiple device types
- Evaluate material composition information and identify possible challenges with testing implementation
- Solve problems that may occur during testing, such as a degraded sample
- Plan for challenging test articles such as liquids, gels or other soluble devices

SESSION 3 – PART 17 LED BY WUXI APPTEC

In this session, the instructor will discuss the conduct of toxicological risk assessments to evaluate chemical information, utilizing current and upcoming approaches for gathering toxicology data (both actual and predicted), estimating exposure, and evaluating toxicological risks. This workshop will include instruction and hands-on exercises guided by Sherry Parker (Senior Director of Regulatory Toxicology at WuXi AppTec), who isan experienced WuXi AppTec instructor.
Upon completion, attendees will be able to:

- Understand critical aspects of toxicological risk assessments and next steps to mitigate risk
- Learn about the upcoming changes to ISO 10993-17 (including useful tools) and the impact on current toxicological risk assessment processes
- Avoid common pitfalls, and meet regulatory expectations

Breakfast, lunch and afternoon snack are included in the training day!

CONFERENCE PROGRAM **BIOCOMPATIBILITY MATTERS 2022**

2022 Bm Biocompatibility Matters Copenhagen

CONFERENCE DAY 1, October 5th, at 8.30 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 regulators 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 (Medtronic, US)
- Standardization of new science: in vitro irritation as a case study
  Christian Pellevoisin (Mattek Life Science, FR)

US FDA EXPECTATIONS

- Evaluation, testing and new approaches: US FDA expectations
  Jennifer Goode (Biocompatibility Program Advisor, OPEQ FDA, CDHR)

TOWARDS A NEW BIOLOGICAL EVALUATION PARADIGM

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

CONFERENCE DINNER AT IDA CONFERENCE CENTER

Breakfast, lunch, and afternoon snack are included in the conference days!
Dinner ticker are included in the package deal our bought separately.

CONFERENCE PROGRAM **BIOCOMPATIBILITY MATTERS 2022**

CONFERENCE DAY 2, October 6th, at 8.30 am – 4 pm

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, US)
- 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

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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*