2024 Bi Biocompatibility Insights

October 15–17
Copenhagen, Denmark

Biocompatibility Insights 2024

Full Program

October 15th – 17th

veranex.com/biocompatibility-insights-2024

The Biocompatibility Insights Conference

This is a global, three-day conference and training event at the IDA Conference Center in Copenhagen, geared toward Biocompatibility experts and scientists in the medical device industry looking to get inspiration, education, and build connections.

The Third Annual Event

This event, hosted by Veranex's biocompatibility experts, brings together our exceptional program advisory Board: Arthur Brandwood, Lars-Magnus Bjursten, Philip Clay, Ron Brown, Sherry Parker, and Ted Heise.

Training Day by Veranex and Nelson Labs, October 15th – Morning	
9:00	Welcome to the Veranex training day!
9:10 – 13:00	Training by Veranex Biocompatibility and Toxicology team (1/2 hour Coffee Break included)
9:10 – 10:00	**Understand the new concepts of the 2024 version of the ISO 10562 standard series** ▪ What do you need to think of at biocompatibility evaluation of breathing gas pathway devices? ▪ What are the potential hazards ▪ Evaluation process ▪ Focus on main updates in the 2024 versions and their impact ▪ Q&A

10:00 – 12:00	**Understand the new concepts of ISO 10993-17: 2023**
	▪ Explanation of changes in the standard with focus on the new concepts
	▪ Group exercise based on case studies including discussions. Focus on tricky cases, such as:
	  ▪ Children / neonates
	  ▪ Carcinogenic substances
	▪ Q&A

12:00 – 13:00	**New Approach Methodologies (NAMs), when can we use these tools and what are the hurdles for regulatory acceptance** ▪ Emerging NAMs with focus on in vitro methods ▪ Current global regulatory acceptance for NAMs ▪ Case studies ▪ Q&A
13:00 – 14:00	Lunch

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Training Day by Veranex and Nelson Labs, October 15 – Morning	
8:00	**Arrival and Check-In (Coffee and Tea available)**
9:00	**Welcome to the Veranex training day!**
9:10–13:00	**Training by Veranex Biocompatibility and Toxicology team** **(Coffee Break included, approx. 11:00–11:30)**
9:10–10:00	**Understand the new concepts of the 2024 version of the ISO 18562 standard series** • What do you need to think of at biocompatibility evaluation of breathing gas pathway devices? • What are the potential hazards • Evaluation process • Focus on main updates in the 2024 versions and their impact • Q&A

10:00–12:00	**Understand the new concepts of ISO 10993-17: 2023**
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	  • Children / neonates
	  • Carcinogenic substances
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12:00–13:00	**New Approach Methodologies (NAMs), when can we use these tools and what are the hurdles for regulatory acceptance** • Emerging NAMs with focus on in vitro methods • Current global regulatory acceptance for NAMs • Case studies • Q&A
13:00–14:00	**Lunch**



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Training Day by Veranex and Nelson Labs, October 15 – Afternoon	
14:00–17:00	**Training by Nelson LABs (Coffee Break included, approx. 15:15–15:45)**
14:00–14:15	**Introduction to reusable devices and reprocessing** • Single-use versus reusable devices and why they require different approaches • High-level overview of reprocessing for reusable medical devices and validation requirements
14:15–15:15	**Cytotoxicity testing** • One test for many applications: How to design cytotoxicity test depending on what you want to evaluate and how to interpret results? • As a biocompatibility endpoint • As part of a reprocessing validation • As part of an End-of-Life cycle evaluation • How to handle failures • Is there a real risk to the patient versus the sensitivity of the assay? • Case study
15:45–17:00	**End-of-Life cycle evaluation** • How to approach End-of-Life cycle evaluations? What should be evaluated? • General strategy & endpoints to evaluate (biocompatibility, soil build-up, functionality, …) • Single-use versus reusable medical devices • EU versus US (MDR versus FDA) • Case study

Networking event at IDA Saloon

Directly after the training, all conference and training day participants are invited to our networking event at IDA Saloon, by the canals at Kalvebod Brygge in Copenhagen. We look forward to welcoming you to this event and hope you will take advantage of this opportunity to connect with other attendees, speakers and sponsors.



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Conference Day 1, October 16

Co-chairs Arthur Brandwood, Project Leader revision of ISO 10993-1, AU & Sherry Parker, SParker Consulting, US

8:00	**Arrival and Check-In** (coffee and tea available)
9:00	**Welcome from hosts Veranex**
	Emerging Trends – Biocompatiblity Insights from Copenhagen '22, Annapolis '23 and Copenhagen '24 *Ron Brown (Risk Science Consortium, US)*
	Knowing Me, Knowing You: Toxicity Data Quality
	Demystifying REACH: Overview of Database and Data Quality *Erwin Annys (ECHA, Finland)*
	Deriving Tolerable Intake (TI) from REACH, Including Read Across *Chris Waine (Bibra toxicology advice & consulting, UK)*
	Q&A Session
10:45–11:15	**Coffee Break**
	No Doubt About It: Evidence and Uncertainty in Chemical Characterization
	Considerations on Simulated Use Extraction, Device Degradation, and CDRH Chemical Analysis Guidance. *Ted Heise (Convenor 10993-18, MED Institute, US)*
	How the CLAP-List May Be Used to Address Some Recent FDA Recommendations (Draft FDA Guidance; 2024) in Developing and Optimizing Chemical Characterization Studies *Piet Christiaens (NelsonLabs, BE)*
	Q&A Session
12:30–13:50	**Lunch**
	When All is Said and Done: Clinical Relevance of Biocompatibility Tests
	Clinical Risk in the Real World — Experience from 20000 Implantable Devices *Lars Magnus Bjursten (Convenor ISO 18562, Senior Professor of Bioimplant Research, SE)*
	Medical Devices: Adverse Events, the Skin and Real-World Data *Cecilia Svedman and Martin Mowitz (Skåne University Hospital Malmö, SE)*
	Clinical Relevance of Extractions in Biological Tests *Bob Przygoda (Adventure Biocompatibility Consulting, US)*
15:20–15:50	**Coffee Break**
	The Name of the Game: Science and Evidence in Biocompatibility
	KEYNOTE: Evidence-Based Toxicology for Safety Assessment of Medical Devices, MMP as an Example *Thomas Hartung (Johns Hopkins Bloomberg School of Public Health, US)*
	Expert Panel: So the Results Are In — What Does it All Mean?
17:00	**Hasta Mañana: Day 1 Closing Summary**
19:00	**Conference Dinner at IDA Conference Center (Dinner ticket required)**

Conference Day 2, October 17 Co-chairs Arthur Brandwood, Project Leader revision of ISO 10993-1, AU & Sherry Parker, SParker Consulting, US	
8:30	**The Visitors: Leveraging Approaches from Other Fields of Regulatory Toxicology**
	Introduction – Day 2 *Philip Clay (Chorley Consulting, UK)*
	KEYNOTE: Using NAMs to Improve Clinical Relevance of Biological Tests *Helena Kandarova, (Institute of Experimental Pharmacology and Toxicology, CEM, Slovak Academy of Sciences, Slovakia)*
9:25–9:50	**Coffee Break**
	Yes, you can replace the animal studies: cross-sector opportunities for medical device safety assessment *Jeffrey Brown (PETA, Germany)*
	Expert Panel: Learning from Others — What is the State of the Art? *Moderator: Phil Clay* *Participants: Kelly Coleman, Helena Kanadrova, Jeffrey Brown*
	I do, I do, I do, I do, I do: Current Challenges and Regulatory Acceptance
	Hydrogels, Dressings, and Soft Polymers: Testing and Evaluating Devices Not Compatible with 10993-12 *Beau Rollins (Convatec, US)*
	Q&A, including follow up from the Veranex Biocompatibility Coffee Break on September 26
11:30–13:00	**Lunch**
	ISO 10993-17, US FDA Expectations for TRAs, and Potential Impact of Draft Chemical Characterization Guidance *Sherry Parker (SParker Consulting, US)*
	Applying Part 17 to a Range of Data Sets: Real World Experience *Rona Middlemiss (Chorley Consulting, UK)*
	Biocompatibility Hot Topics – A New ISO 10993-17 and Legacy Devices under MDR *Katarina Weidmann (TÜV SÜD, Germany)*
	Q&A Session
14:45–15:15	**Coffee Break**
	I Have a Dream: Closing Plenary — Where to from Here?
	Conference Summary and Learnings
	ISO TC 194 Paris (21-25 Oct) Preview Including Progress on the New Part 1
	A 5-Year Plan — Biocompatibility 2029 *In Conversation: Jeremy Tinkler (Chair ISO TC 194, ICON, UK) and Arthur Brandwood (Project Leader – revision of ISO 10993-1, AU)*
15:55–16:00	**Thank You for the Music: Closing Remarks (Veranex)**