

October 12–14, 2026
IDA Conference Centre | Copenhagen, Denmark

Biocompatibility Insights 2026



TRAINING DAY

Monday, October 12

- 9.00–10.00: Registration
- 10.00–12.30: **ISO 10993-1:2025: Combining Practical Case Studies with Interactive Discussions to Support Real-World Application**
Veranex Biocompatibility & Toxicology Team
- 12.30–13.30: Lunch at IDA Conference Centre
- 13.30–15.00: **ISO 10993-3 Genotoxicity Assessment – When You Need It and How to Do the Evaluation**
Phil Clay, UKRT, ERT, Senior Principal Toxicologist, Chorley Consulting UK
- 15.00–15.30: Coffee Break
- 15.30–16.45: **AI in Toxicology & Biocompatibility: Gamechanger or Risk Factor or Both?**
Veranex Biocompatibility & Toxicology Team
- 16.45–17.00: Q&A
- 17.00: Come Together Event at the IDA Conference Centre

CONFERENCE DAY 1

Tuesday, October 13

- From 8.00: Registration (*coffee and tea available*)
- 9.00: Welcome from Hosts Veranex and Introduction to Day 1

KEYNOTE Emerging Trends – Biocompatibility Insights from Copenhagen '22, Annapolis '23, Copenhagen '24 and '26, with a View Forward
Ron Brown, Principal Toxicologist, Risk Science Consortium, US

SESSION 1 RISK-BASED APPROACH FORWARD WITH THE NEW ISO 10993-1

The New ISO 10993 Part 1 – Challenges and Opportunities: A Risky Conversation?
Arthur Brandwood, Biomaterials expert, former senior regulator, Project lead for revision of ISO 10993-1:2025 and Thor Rollins Vice President, Global Market Segment Leader, Nelson Labs—Medical Device Convenor of TC 194 WG1

COFFEE BREAK

Consideration of Reasonably Foreseeable Misuse in a Biological Evaluation – Perspective from the WG1 Project Leader
Gemma Walton, Director of Biocompatibility at Smith & Nephew, UK; Project Leader ISO/TC 194 WG1 - Reasonably Foreseeable Misuse

A Notified Body's Perspective on the New ISO 10993-1:2025 Standard: Changes, Impact, and Challenges
Andrea Loro, Biocompatibility and Animal Origin Reviewer, auditor ISO 13485 and ISO 9001, Customer Specialist, TÜV SÜD, Italia

Introduction to Panel – Part 1 Revision: The Industrial Perspective Through the Eyes of Consultants
Elisabeth Hirth & Cornelia Fiuza List, Veranex Biocompatibility & Toxicology Team

Panel Discussion: Industry and Regulators – Practical Implementation of the New Part 1
Led by Arthur Brandwood & Thor Rollins

LUNCH

SESSION 2 CLINICAL RELEVANCE OF MATERIAL CHARACTERIZATION – ENOUGH AND RELEVANT?

Overextraction and Clinical Relevance?
Jianwei Li, PhD, Chemistry Characterization Consultant and Technical Writer, Chemical Characterization Solutions, LLC (USA)

Fit-for-Purpose Chemical Characterization Studies for Medical Devices: A Practical Approach
Sandi Schaible, Founder & President, Scientific Consulting & Strategy | Bonded in Science

COFFEE BREAK

Technical Specifications for Chemical Characterization
Chris Waine, Principal Toxicologist and Director, Bibra Toxicology Advice Consulting – Convenor, ISO/TC 194/WG14 on Material Characterization of Medical Devices

Q&A SESSION CLINICAL RELEVANCE OF MATERIAL CHARACTERIZATION

- 16.30: End of Day 1
- 19.00: Conference Dinner at IDA Conference Centre

CONFERENCE DAY 2

Wednesday, October 14

8.30: Introduction to Day 2

SESSION 3 TOXICOLOGICAL RISK ASSESSMENTS

Toxicological Risk Assessment – Challenges and Future Directions

Sherry Parker, Toxicology Consultant, Co-Chair of the AAMI/ Biological Evaluation (AAMI/BE) Committee (US Mirror committee for TC 194/ISO 10993), and an ISO expert of the working groups for ISO 10993-1 and ISO 10993-17. SParker Consulting, US)

Toxicological Assessment With Considerations for Sensitive Patient Populations

Kimberly Ehman, PhD, DABT, Head of Regulatory Toxicology, Eurofins Medical Device Services

Q&A SESSION TOXICOLOGICAL RISK ASSESSMENTS

COFFEE BREAK

Is It Necessary to Account for Bioaccumulation When Assigning a Device to an Exposure Duration Category?

Ron Brown, Principal Toxicologist, Risk Science Consortium, US

Q&A SESSION BIOACCUMULATION

Interactive Discussion: Risks and Opportunities of AI in Toxicological Risk Assessment

Neeru Mittal & Carl-Johan Zettervall, Veranex

SESSION 4 CLINICALLY RELEVANT EFFECTS AND RELEVANT TESTING

Emerging Medical Device Allergens – An Update From a Clinical Perspective

Cecilia Svedman, professor of Occupational and Environmental Dermatology IKVM, University of Lund, Sweden, Head of Department of Occupational and Environmental Dermatology, VO HRÖ, SUS Malmö, Sweden. Martin Mowitz, chemist at the Department of Occupational and Environmental Dermatology at Skåne University Hospital, Lund University in Malmö, Sweden with nearly two decades of experience of contact allergy investigations and research.

LUNCH

Industry Perspective/Case Study – Use of In Vitro Methods

Andy Forreryd, Key Account Manager & Scientific Liaison, Senzagen

Practical Challenges to the Use of NAMs for Medical Devices – When State-of-the-Art Science Is Not Enough

Janine Townsend, Director, Chorley Consulting Ltd., UK

COFFEE BREAK

Beyond Biocompatibility: Integrating Clinical Evidence Into Biological Evaluation Across the Medical Device Lifecycle

Jose Pablo Morales, MD, Chief Medical Officer, Veranex

Introduction to Panel – What Information Can Be Used to Make a Risk Assessment Supporting a Stepwise Approach?

Phil Clay, Senior Principal Toxicologist, Chorley Consulting Ltd., UK

Panel Discussion – Is the Science Ready to Support Changes in How We Perform Biological Evaluation?

Panel Discussion Led by Phil Clay

CLOSING PLENARY WAY FORWARD

Conference Summary and Learnings

Arthur Brandwood

16.00: End of Conference – *Thank You!*

