5420 Wade Park Blvd Suite 204,
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Biocompatibility Insights 2026 - October 13-14

Day 1

Chairman: Sherry Parker, Toxicology Consultant, SParker Consulting, US. 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.

TBA = To be announced

From 8.00 Registration (Coffee and tea available)
9.00 Welcome from hosts Veranex and Introduction Day 1
KEYNOTE: Emerging Trends – Biocompatibility Insights from Copenhagen '22, Annapolis '23 and Copenhagen'24, and '26, with a view forward *Speaker: 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? This session will be a dialogue between the presenters – and with the audience: focussing on the new concepts and new opportunities presented by ISO 10993-1 2026. We will also explore the work still to be done including development of additional guidance's and explore how the new standard provides the opportunity to apply the latest science for more efficient assessment and safer devices. *Speakers: 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 (sandwiches or pastries)
Title TBA *Speaker: TBA*
A Notified Body's perspective on the new ISO 10993-1:2025 standard: changes, impact and challenges • Highlights on the main changes between the 2018 and the 2025 version of the standard • Impact of the changes and related challenges for manufacturers in preparing the biological evaluation. • Challenges for NB biocompatibility reviewers in evaluating the manufacturer's biological assessment *Speaker: 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 *Speaker: Elisabeth Hirth & Cornelia Fiuza List, Veranex Biocompatibility & Toxicology Team*
Panel Discussion "Industry and Regulators: Practical implementation of the new Part 1" We bring together our speakers to ask, "How to be brave?" - how both regulators and industry can take full advantage of the opportunities offered by the new standard to focus on the real risks, use modern techniques, eliminate unnecessary testing and drive regulatory reviews which use the latest science. *Panel Discussion Lead by: Arthur Brandwood and Thor Rollins*
Lunch
SESSION 2: Clinical relevance of material characterization - Enough and relevant?

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Overextraction and clinical relevance? • What are the major scientific issues in chemical characterization of medical devices (ISO 10993-18) today? • How do solvent choices affect uncertainties of identification and quantification? • Why is "overextraction" the key issue? • What are the extraction powers of human tissues? • How to streamline extraction solvents based on power of biological tissues? *Speaker: 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 • Risk-Based Decisions on Chemical Characterization • Determining when new testing adds value and when existing evidence is sufficient. • Focusing Effort Where It Matters Most • Aligning analytical rigor with the uncertainties that influence patient risk. • Maximizing the Value of Chemistry Data • Leveraging ISO 10993-17 and -18 to support biocompatibility assessment and reduce biological testing requirements *Speaker: Sandi Schaible, Founder and President Scientific Consulting & Strategy I Bonded in Science*
Coffee Break

Technical specifications for chemical characterization
• ISO 10993-18 defines the process for material characterisation
• TC 194/WG 14 considered that additional technical guidance was required to ensure the consistency of chemical characterisation data used for biological evaluation
• This presentation will present an update on the progress of the various draft Technical Specification documents being prepared in WG14, covering:
  ○ Identification of extractables and leachables
  ○ Quantification of extractables and leachables
  ○ Generation of extracts and issues relating to extract viability
  ○ Guidance on commissioning chemical characterisation testing
Speaker: 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 Center

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Day 2

Chairman: Arthur Brandwood, Biomaterials expert, former senior regulator, Project lead for revision of ISO 10993-1:2025

8.30 Introduction Day 2
SESSION 3: Toxicological risk assessments
TRA Challenges and Future Directions *Speaker: 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 • Evaluation of developmental and reproductive toxicity (DART) in ISO/FDIS 10993-3 • Approaches to evaluating DART endpoints in the TRA • Case studies for selection of a point of departure *Speaker: 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? • The ISO 10993-1:2025 instructs users to assign short-term exposure devices that contain compounds expected to bioaccumulate to a longer-term exposure category. • Using a pharmacokinetic model, we were able to show that compounds with the potential to bioaccumulate do not reach levels associated with toxicity following their release from intermittently used devices. • As a result, we recommend that this section of the standard be deleted. *Speaker: Ron Brown, Principal Toxicologist, Risk Science Consortium, US*
Q&A session - Bioaccumulation
Interactive Discussion: Risks and Opportunities of AI in Toxicological Risk Assessment *Discussion Leaders: Neeru Mittal and Carl-Johan Zettervall, Veranex*
SESSION 4: Clinically relevant effects and relevant testing
Emerging medical device allergens - an update from a clinical perspective • Emerging allergens and related exposures • Contact allergy to medical adhesive tapes within the military forces • Clinical implications of medical device-related contact allergies • How can we learn from the past to develop safer products in the future *Speaker: 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 • This presentation will provide an update on the application of non-animal testing approaches for the biological evaluation of medical devices, with a particular focus on skin irritation and sensitization. • The talk will explore the industry perspective, highlighting how these methods can be applied in regulatory submissions and used to support decision-making throughout product development.

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• Case studies will be presented, and key challenges and opportunities associated with their implementation will be discussed. *Speaker: Andy Forreryd, Key Account Manager & Scientific Liaison Senzagen*
Title TBA *Speaker: Janine Townsend, Director at Chorley Consulting Ltd, UK*
Coffee Break
Beyond Biocompatibility: Integrating Clinical Evidence into Biological Evaluation Across the Medical Device Lifecycle • Explore how clinical data can strengthen biological evaluations throughout the entire medical device lifecycle, from development through post-market surveillance. • Discuss the evolving role of clinical evidence in complementing traditional biocompatibility and toxicological assessments. • Examine the relationship between preclinical biological testing and real-world clinical outcomes, including the limitations of predicting clinical performance solely through laboratory testing. • Review how post-market surveillance (PMS) and clinical experience can provide valuable insights into biological safety and device performance over time. • Highlight the importance of clinical judgment in interpreting biological risks within the context of the device's intended use, patient population, and available treatment alternatives. • Consider how benefit-risk assessment supports decision-making when biological risks must be balanced against significant clinical needs, particularly for life-threatening conditions. • Discuss challenges in linking patient symptoms and adverse events directly to device-related biological effects and how clinical evidence can help bridge these gaps. • Review emerging regulatory perspectives and lifecycle-focused approaches, including increased emphasis on integrating clinical and biological evidence throughout a device's market journey. *Speaker: 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? *Speaker: Phil Clay, Senior Principal Toxicologist at Chorley Consulting Ltd, UK*
Panel discussion - Is the science ready to support changes in how we perform biological evaluation? We are pushing, and being pushed, very hard to move away from the traditional *in vivo* experiments we have relied on for a long time as the basis of biocompatibility assessments. Many alternative and replacement approaches are available, but is the science ready to give the confidence to move away from our reliance on animal studies? A panel of distinguished scientists, never afraid to offer an opinion, will explore real-world experience and successes with NAM-based approaches, including key hurdles, both scientific and regulatory *Panel Discussion Led by: Phil Clay*
CLOSING PLENARY – Way forward
Conference Summary and Learnings *Speaker: Arthur Brandwood*
16.00 END OF CONFERENCE – Thank you!