MedTech Summit by informa

15 - 18 June 2026
JW Marriott Hotel Berlin
Berlin, Germany

Speaker Stories

Marina Daineko, Biocompatibility Consultant at Intrinsic Medical Group

Could you introduce yourself and give us a brief snapshot of the key topics that will be covered during this year's workshop?

I am Marina Daineko, a seasoned Biocompatibility Consultant at Intrinsic Medical Group (IMG), with an MSc in Analytical Chemistry and over 10 years of experience in the medical device industry. I have authored more than 100 Biological Evaluations and remain deeply passionate about advancing scientifically robust and regulatory-defensible biological evaluation strategies.

Beau and I will be covering the entire lifecycle of biological evaluation, but with a sharp focus on the newest "essentials" introduced in the 2025 version:

- Gap analysis to know how to evaluate your legacy 2018-based files against the reorganized standard.
- Structured Biological Evaluation development to move away from the "Table A.1 shopping list" to a risk management framework aligned with ISO 14971.
- Reasonably foreseeable misuse to integrate predictable human behavior into your device categorization and hazard identification.
- New duration calculations to transit to the "Contact Day" concept, where any contact in a 24-hour period counts as a full day.
- Defensible test strategies to justify the selection of biological effects (formerly "endpoints") using a weight-of-evidence approach.

Who should join? What can attendees expect to gain from participating?

Anyone responsible for making sure a medical device is not just innovative but biologically safe and regulatorily defensible.

This includes Biocomp experts, RA/QA professionals, R&D engineers, toxicologists, and decision-makers who carry accountability for ISO 10993-based biological evaluation.

What top challenges do professionals face when adapting to the latest revision of ISO 10993-1, and how will the workshop address these?

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What top challenges do professionals face when adapting to the latest revision of ISO 10993-1, and how will the workshop address these?

The 2025 revision presents several significant hurdles for even seasoned professionals. One of the biggest challenges is the new requirement for genotoxicity evaluation for nearly all prolonged contact devices (except intact skin), which will hit legacy devices particularly hard. 😊

Many professionals struggle with the shift from adding up minutes/seconds to the "Contact Day" rule, which often bumps "limited" devices into the "prolonged" category. Additionally, agencies now require documented CVs for BEP/BER authors & reviewers to prove they are "knowledgeable and experienced professionals".

Our workshop addresses these challenges directly through practical exercises. We will walk you through real-world scenarios to calculate contact duration correctly and show you how to structure your qualifications to meet the new "Competent Personnel" requirements.

How do you see the field of biocompatibility evolving in the next 5–10 years, and what role does this workshop play in preparing professionals for future changes?

In the next decade, I see biocompatibility evolving into a field that is 90% chemistry and risk assessment and 10% confirmatory testing. We are seeing a massive global push toward the 3R principles (Replace, Reduce, Refine), where New Alternative Methodologies (NAMs) and in vitro models will replace traditional animal tests.

For instance, Material-Mediated Pyrogenicity (MMP) is already being phased out for common materials, a trend that will likely continue for biological effects like irritation and sensitization. 😊

This workshop prepares you for this future by teaching you how to become a "Biological Risk Manager" rather than a "Test Coordinator". We provide you with the tools to justify scientific gaps using existing data, literature reviews, and chemical characterization (ISO 10993-18), ensuring you are ready for a world where animal testing is the absolute last resort

Intrinsic Medical Group will be joining us at MedTech Summit this June in Berlin. Register Now.