



Medical Device
Services

WORKSHOP



NAVIGATING THROUGH THE JUNGLE OF BIOCOMPATIBILITY AND BEYOND

23 APRIL 2026

8:30 - 16:00

VAN DER VALK HOTEL UTRECHT,
WINTHONTLAAN 4-6, 3526 KV
UTRECHT, NETHERLANDS

WORKSHOP TOPICS:

- Biological Evaluation in 2025: Implications of the Updated ISO 10993-1
- From Standard to Practice: Implementing ISO 10993-1:2025 in Biocompatibility Strategies
- Navigating Non-Harmonised FDA and EU Requirements with a Global Biocomp Strategy
- Biocompatibility 2.0: Advancing Beyond ISO 10993-1 with Insights into ISO and USP Revisions and how to deal with changes in general
- Navigating through the jungle of 11607 – How to proceed with Packaging Validation and Shelf-Life Assessment



SPEAKERS

Marcel Dörkes,
Eurofins Medical Device Consulting

Georgina Targa Fabra
Eurofins Medical Device Consulting

Hicham Saaid,
Eurofins Medical Device Consulting

Lisa Heilemann,
Eurofins Sterile Packaging

Register now

For more information:

Medical-Device@mds.eurofinseu.com

INTRODUCTION

This on-site workshop provides a clear and practical overview of the current biocompatibility and packaging-validation landscape. Participants will be guided through the key updates in ISO 10993-1:2025, global regulatory expectations from FDA and EU authorities, recent developments across ISO and USP standards, and effective approaches for risk-based biological evaluations.

Real-world case studies support the transition from theory to practice, and the workshop concludes with an in-depth look at packaging validation and shelf-life assessment in accordance with ISO 11607, ensuring participants are fully equipped to implement compliant and scientifically robust strategies for their medical devices.

WORKSHOP REGISTRATION

Register via the following link:

<https://eu.jotform.com/form/260610164385453>



AGENDA

08.30 - 09.00

Welcome / Arrival

09.00 - 09.45

Biological Evaluation in 2025: Implications of the Updated ISO 10993-1

09.45 - 10.00

Coffee break

10.00 - 10.45

From Standard to Practice: Implementing ISO 10993-1:2025 in Biocompatibility Strategies

10:45 - 11.45

Navigating Non-Harmonised FDA and EU Requirements with a Global Biocompatibility Strategy"

11.45 - 13.00

Lunch

13.00 - 14.00

Biocompatibility 2.0: Advancing Beyond ISO 10993-1 with Insights into ISO and USP Revisions and how to deal with changes in general

14.00 - 14:15

Coffee break

14:15 - 15:15

Navigating through the jungle of 11607 – How to proceed with Packaging Validation and Shelf-Life Assessment

15.15 - 15.45

Meet the Expert – 1:1 Consultancy Sessions

One-to-one meetings will give you the opportunity to discuss your projects with our experts. To book an individual meeting, please contact us before the workshop to reserve your slot:

mdmarketing@mds.eurofinseu.com

15.45 - 16:00

Wrap up

SPEAKERS



MARCEL DÖRKES

Marcel has an academic degree (MSc) in molecular biology and an advanced toxicological expertise by further training. Marcel has been working in the field of evaluating the biological safety of medical devices since February 2018 and is now the Head of Medical Device Consulting in Germany and Benelux. Marcel Dörkes' expertise includes the biological safety assessment of medical devices and related toxicological issues including strategy planning, chemical characterisation procedures and overall biological risk assessments. Marcel is member of ISO TC 194 and involved in several working groups including ISO 10993-1, ISO 10993-17 and ISO 10993-18.



GEORGINA TARGA FABRA

Georgina holds a BSc in Biomedical Sciences and an MSc in Translational Medicine. With a background in orthopaedic medical device research, she joined Eurofins in 2023 as a consultant. Her current role focuses on biological evaluations and the development of biocompatibility testing strategies for a wide range of medical devices. Her work ensures compliance with international standards to support global regulatory submissions.

SPEAKERS

HICHAM SAAID

Hicham holds a PhD in Biomedical Engineering, specializing in cardiovascular implants. He has broad experience in biofluid mechanics testing, with expertise in risk assessment and V&V. Since November 2022, he has been a consultant at Eurofins Belgium, leading biological and toxicological risk assessments across all stages of the product lifecycle. He also assists in addressing deficiencies raised by the FDA and other regulatory agencies and develops biocompatibility testing strategies aligned with ISO 10993, FDA, MHLW, and EU MDR requirements.



LISA HEILEMANN

Lisa Heilemann completed a Master's degree in Biological Sciences in 2016. Since then, she has conducted validations of medical devices in accordance with ISO standards 19227, 11135, 11137 and 11607 for cleaning, sterilisation and packaging at Eurofins Inpac. Her core areas of focus include packaging and transport validation, ageing studies, gamma and EO sterilisation, regulatory processes, and quality management. As a long-term employee of the validation and quality assurance department, she has excellent qualifications. Since 2021, she has been one of two heads of validation. As of 2025, she has taken on the role of sole Head of Validation and Quality Management and Quality Management Representative (QMR). Since 2022, Lisa Heilemann has been a member of the DIN standards committee for the packaging and sterilisation of medical devices, where she shares her expertise and skills with other experts.



BRIEF DESCRIPTION OF THE PRESENTATIONS



Biological Evaluation in 2025: Implications of the Updated ISO 10993-1

Georgina Targa Fabra, Eurofins Medical Device Consulting

This session explores how the new standard reframes biocompatibility expectations for modern medical devices. An overview of the key changes introduced in ISO 10993-1:2025 will be given, with a clear focus on how they impact biological evaluation strategies for medical devices. Participants will learn how the updated standard strengthens the risk-based approach and clarifies expectations for toxicological assessments.

From Standard to Practice: Implementing ISO 10993-1:2025 in Biocompatibility Strategies

Georgina Targa Fabra, Eurofins Medical Device Consulting

Through hands-on case studies, the session illustrates how these concepts apply to real-world device scenarios. This talk examines how ISO 10993-1:2025 moves from written guidance to actionable biocompatibility strategies rooted in risk-based thinking.

Navigating Non-Harmonised FDA and EU Requirements with a Global Biocomp Strategy

Hicham Saaid, Eurofins Medical Device Consulting

This talk outlines the latest global biocompatibility expectations and how they diverge between FDA and EU Notified Bodies. Attendees will learn how to integrate these new requirements into their biological evaluation plans and documentation processes. The session also covers effective deficiency-handling strategies—showing how to respond to regulatory questions, address data gaps, and demonstrate compliance through scientifically robust explanations and comprehensive risk assessments.



BRIEF DESCRIPTION OF THE PRESENTATIONS



Biocompatibility 2.0: Advancing Beyond ISO 10993-1 with Insights into ISO and USP Revisions and how to deal with changes in general

Marcel Dörkes, Eurofins Medical Device Consulting

This presentation provides an overview of recent developments in the field of biocompatibility, focusing on key revisions in ISO and USP standards that extend beyond the latest ISO 10993-1 requirements. In addition, it outlines practical approaches for implementing effective change assessment strategies to ensure continued compliance and robust biological safety evaluations in an evolving regulatory landscape.



Navigating through the jungle of 11607 – How to proceed with Packaging Validation and Shelf-Life Assessment

Lisa Heilemann, Eurofins Sterile Packaging

Packaging validation for terminally sterilised medical devices is performed in accordance with ISO 11607-1 and -2, with key requirements such as sterilisation compatibility, biocompatibility, shelf life, and aseptic presentation considered already during packaging development. This presentation gives you insights into the validation procedure and process performance using statistically justified tests. We keep an eye as well on the integrity of the sterile barrier system after sterilisation, transport simulation and aging to confirm package performance over distribution and storage.

REGISTRATION FEE : 250 EUROS, VAT EXCLUDED
WORKSHOP LANGUAGE: ENGLISH

THE PRICE INCLUDES: PARTICIPATION IN THE WORKSHOP, LUNCH AND REFRESHMENTS.
YOU WILL RECEIVE CONFIRMATION, PAYMENT AND INVOICING DETAILS BY EMAIL AFTER SUBMISSION.
THE REGISTRATION FEE IS PAYABLE IN ADVANCE BY BANK TRANSFER.

Registration link | <https://eu.jotform.com/form/260610164385453>



GENERAL TERMS AND CONDITIONS:

IN THE EVENT OF CANCELLATION BEFORE MARCH 23, 50% OF THE FEE WILL BE REFUNDED. CANCELLATIONS RECEIVED AFTER THIS DATE WILL NOT BE REFUNDED.

EUROFINS MEDICAL DEVICE SERVICES RESERVES THE RIGHT TO CANCEL OR CHANGE THE PROGRAMME, SPEAKERS, DATE OR VENUE. IF THE EVENT HAS TO BE CANCELLED, REGISTRANTS WILL BE NOTIFIED AS SOON AS POSSIBLE AND WILL RECEIVE A FULL REFUND OF FEES PAID. EUROFINS MEDICAL DEVICE SERVICES IS NOT RESPONSIBLE FOR AIRFARE, HOTEL OR OTHER EXPENSES INCURRED BY PARTICIPANTS.



ONE STOP-SHOP SOLUTION FOR YOUR MEDICAL DEVICE NEEDS

CONSULTING

CE, FDA, ROW Regulatory Submission
QA/RA Management • Technical Documentation
Quality Management System • Training
Design Validation • Usability/Human Factor
Biocompatibility & Preclinical Safety (Biological
Evaluation - Toxicological Risk Assessment)
Clinical Evaluation • PMS/PMCF/PSUR
ISO 13485 Certified • Certified auditors

TESTING

Biocompatibility & Toxicology
Cleaning & Reprocessing Validations
Chemical & Physical Analysis
Distribution & Package Integrity • Electrical Safety
Human Factors & Usability
Microbiology & Sterility • Mechanical &
Functionality • Viral Safety

STERILE PACKAGING

Cleaning • Assembly •
Packaging (Materials & Design) •
Sterilisation • Validations • Documentation
Procurement Management

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