eurofins | Medical Device Services

WORKSHOP

MASTERING MEDICAL DEVICE REPROCESSING: REGULATORY EXPECTATIONS, VALIDATION AND PRACTICAL SOLUTIONS

6 OCTOBER 2026
09:00 – 16:45

AT EUROFINS MEDICAL DEVICE TESTING IN PLANEGG / MUNICH

SPEAKERS

Kristin Rödig,
Eurofins Medical Device Consulting Germany

Dr. Stefan Holzmayr,
Eurofins Medical Device Testing Germany

Jessica Jankowski,
Eurofins Medical Device Testing Germany

Sophia Beck,
Eurofins Medical Device Testing Germany

Dr. Laura-Marie Ammer,
Eurofins Medical Device Testing Germany

WORKSHOP TOPICS:

- Categorisation, differences in European and FDA requirements, validation of processing steps, and life cycle evaluation.
- Best practices for cleaning, disinfection, sterilisation, and reprocessing life cycle evaluation
- Preventive measures, project coordination, and compliance requirements
- Reproccessing Lab Tour
- Key guidelines, test strategies, and methodological insights
- One-to-One meetings

Register now

For more information:
Medical-Device@mds.eurofinseu.com

INTRODUCTION

This on-site workshop provides a comprehensive journey through the regulatory and practical aspects of medical device reprocessing and reprocessing validation. Participants will be guided through current European and FDA requirements, including key standards such as ISO 17664 and ISO 10993, while gaining valuable insights into cleaning, disinfection, sterilisation, and lifecycle evaluation of reusable medical devices.

Through expert-led presentations, practical examples, and real-world case studies, attendees will learn how to develop compliant reprocessing strategies, overcome common validation challenges, and successfully navigate regulatory expectations.

The workshop also includes an exclusive laboratory tour, providing insights into test strategy development, sample preparation, and test execution. Interactive discussions and one-to-one expert consultations will help participants translate theory into practice, equipping them with the knowledge required to design scientifically sound and regulatory-compliant reprocessing programs for reusable medical devices.

WORKSHOP REGISTRATION

Register via the following link:
https://form.jotform.com/262114207496455

AGENDA

09:00 – 09:30	**Welcome & Introduction** *Nitesh Bihani*
09:30 – 10:15	**Reprocessing Medical Devices: Where EU Meets FDA – and Where Life Ends** *Kristin Rödig*
10:15 – 10:30	**Coffee Break**
10:30 – 11:15	**Reprocessing Validation - Principles and Requirements Cleaning, Disinfection and Sterilisation** *Dr. Stefan Holzmayr*
11:15 – 12:00	**How to Overcome Pitfalls in Reprocessing - Your Way to Success** *Jessica Jankowski*
12:00 – 12:45	**Lunch**
12:45 – 14:00	**Reproccessing Lab Tour – From Test Strategy to Execution**
14:00 – 14:45	**Method Details and Case Study** *Sophia Beck*
14:45 – 15:00	**Coffee Break**
15:00 – 15:45	**Cytotoxity and Checmical Characterisation Overview** *Dr. Laura-Marie Ammer & Dr. Stefan Holzmayr*
15:45 – 16:30	**Wrap-Up & Next Steps**
16:30 – 16:45	**Ask 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: **medical-device@mds.eurofinseu.com**

SPEAKERS

KRISTIN RÖDIG

Kristin Rödig has more than 20 years of experience in *in vitro* toxicology/pharmacology and biological safety assessment. Since March 2005, she has worked for Eurofins BioPharma Product Testing Munich GmbH (formerly BSL Bioservice GmbH). In this role, she supervised a wide range of *in vitro* studies as a Study Director, including studies in the fields of genotoxicity, cytotoxicity, as well as alternative methods such as irritation and sensitisation studies, and *in vitro* assays for the detection of endocrine disruptors. Since September 2022, she has been working as a Consulting Specialist at Eurofins BioPharma Services Consulting Munich GmbH. Ms. Rödig holds a degree in Biotechnology Engineering (Diplom-Ingenieurin) from the University of Applied Sciences Weihenstephan.

DR. STEFAN HOLZMAYR

Dr. Stefan Holzmayr is the Business Unit Manager for Microbiology and Analytics at Eurofins Medical Device Testing in Munich, comprising the reprocessing group. After completing a PhD in the field of food chemistry at the Technical University of Munich and working 10 years in an analytical testing laboratory in different roles, Dr. Stefan Holzmayr joined Eurofins in 2025. His expertise for medical device services ranges from chemical characterisation over routine microbiological testing to reprocessing validation.

SPEAKERS

JESSICA JANKOWSKI

Jessica Jankowski is a Study director in the Reprocessing of Microbiology at Eurofins Medical Device Testing Germany GmbH. She earned a Master of Science in Chemical Biology. Prior to joining Eurofins in October 2025, she worked as a Microbiologist in an infectious disease diagnostics laboratory.

At Eurofins, her expertise includes the supervision of reprocessing studies (GLP and non-GLP), covering manual and automated cleaning, manual and thermal disinfection, and moist heat sterilisation. She is also experienced in scientific consultation, technical project support, and customer communication, facilitating scientific discussions, and providing technical guidance to medical device manufacturers.

SOPHIA BECK

Sophia Beck is a Scientist at Eurofins Medical Device Testing in Munich. She earned a Master of Science in Industrial Biotechnology and gained experience in both academic microbiology research and pharmaceutical process development. Before joining Eurofins in 2026, she worked at Ludwig Maximilian University Munich as a scientist in microbiology and at almapharm GmbH as a process engineer and quality manager. Her expertise includes microbiology, quality management, and the testing of medical devices.

SPEAKERS

DR. LAURA-MARIE AMMER

Dr. Laura-Marie Ammer is the group leader of cytotoxicity testing within the Department of *In Vitro* Pharmacology and Toxicology at Eurofins Medical Device Testing in Munich. She obtained her PhD in the field of Neuro-Oncology at the Department of Neurology, University Hospital Regensburg. In 2024, she joined Eurofins as a study director in the cytotoxicity group. Her expertise focuses on the extraction and biological evaluation of medical devices in accordance with ISO 10993-12 and ISO 10993-5.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Reprocessing Medical Devices: Where EU Meets FDA – and Where Life Ends

Kristin Rödig, Eurofins Medical Device Consulting Germany

The reprocessing of reusable medical devices is a critical aspect of ensuring patient safety and regulatory compliance throughout a product's intended life cycle. As regulatory expectations continue to evolve globally, manufacturers must demonstrate that medical devices can be effectively cleaned, disinfected, and sterilised without compromising their performance, safety, or biocompatibility.

This presentation explores the intersection of European and U.S. regulatory approaches to reprocessing, including requirements and principles outlined in ISO 17664-1/-2 and ISO 10993-1. Participants will gain insights into how classification, processing methods, and the selection of reprocessing agents influence validation strategies and regulatory expectations. The session will further discuss how repeated reprocessing affects device durability, material integrity, and biological safety, ultimately determining the point at which a device can no longer be considered suitable for continued use.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Reprocessing Validation - Principles and Requirements Cleaning, Disinfection and Sterilisation

Dr. Stefan Holzmayr, Eurofins Medical Device Testing Germany

Reprocessing of medical devices includes all steps needed to clean, disinfect, and sterilise reusable products. The wide variety of device designs and materials creates significant challenges, such as complex geometries, limited material compatibility, and growing regulatory expectations. Effective reprocessing therefore requires risk-based planning, suitable process validation, and clear documentation. Core guidelines provide a general framework for safety and performance, though only at a high level here. A key aspect is early awareness: many issues can be avoided if manufacturers and customers consider reprocessing requirements from the beginning and clarify essential information in advance. This enables more efficient processes and opens opportunities for improved and future-oriented reprocessing solutions.

BRIEF DESCRIPTION OF THE PRESENTATIONS

How to Overcome Pitfalls in Reprocessing - Your Way to Success

Jessica Jankowski, Eurofins Medical Device Testing Germany

The topic addresses the growing challenges of safe and compliant reprocessing in an increasingly regulated and technically complex environment. Insufficient control of cleaning, disinfection, and sterilisation processes can lead to patient risk, failed validation studies, increased costs, or regulatory rejection. The focus of the workshop is on how to comply with regulatory and authority requirements, what to prepare for validation studies to save time and cost while avoiding rejection of submissions or failing validation studies. From daily practical perspective the performance of validation studies, including the identification, mitigation, and handling of critical reprocessing parameters will be presented.

Method Details and Case Study

Sophia Beck, Eurofins Medical Device Testing Germany

This session focuses on the influence of regulatory standards and guidance documents on test design and method development. Participants will explore current approaches and alternatives for cleaning, disinfection and sterilisation processes, including established parameters and potential adaptations for specific applications. Additional topics include the use of BCA and TOC methods for residue analysis, microbiological evaluation strategies, and detailed reviews of cleaning, disinfection, and sterilisation processes. The workshop also covers key process parameters and validations.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Cytotoxity and Checmical Characterisation Overview

Dr. Laura-Marie Ammer, Eurofins Medical Device Testing Germany

Dr. Stefan Holzmayr, Eurofins Medical Device Testing Germany

This presentation will explore the role of cytotoxicity and chemical characterisation in the biological evaluation of medical devices. It will discuss how cytotoxicity testing helps assess the potential impact of device materials on living cells, whilst chemical characterisation provides valuable insight into substances that may be present within or released from a device. The session will examine how these approaches work together to support biocompatibility assessments, risk management and regulatory compliance, ultimately contributing to patient safety. As regulatory expectations continue to evolve, a solid understanding of both disciplines is essential for demonstrating the safety and performance of medical devices throughout their lifecycle.

eurofins | Medical Device Services

REGISTRATION FEE : 200 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://form.jotform.com/262114207496455

GENERAL TERMS AND CONDITIONS:

IN THE EVENT OF CANCELLATION BEFORE 15 SEPTEMBER, 2026, 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

EUROFINS.COM/MEDICAL-DEVICE