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WORKSHOP

DENTAL PRODUCT TESTING & SAFETY: BRIDGING SCIENCE, RISK & REGULATION

7 JULY 2026
09:00 – 16:45

AT EUROFINS MEDICAL DEVICE TESTING IN PLANEGG / MUNICH

SPEAKERS

Kristin Roedig,
Eurofins Medical Device Consulting Germany

Dr. Maria-Fatima Tepedino,
Eurofins Medical Device Testing Germany

Dr. Torben Gehring,
Eurofins Medical Device Testing Germany

Dr. Helge Gehrke,
Eurofins Medical Device Testing Germany

Lisa Heilemann
Eurofins Sterile Packaging

WORKSHOP TOPICS:

- Overview of dental product testing from both scientific and regulatory perspectives
- Latest updates and evolving requirements of ISO 10993-1 and ISO 7405
- Design and implementation of risk-based biological evaluation strategies
- Chemical characterization: key principles and sample preparation approaches
- Practical testing workflows illustrated through real laboratory case studies
- Packaging validation, including sterilization methods, shelf life considerations, and regulatory implications
- Integration of scientific evidence, risk assessment, and regulatory expectations to support compliant testing strategies

Register now

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

INTRODUCTION

This workshop provides key scientific and regulatory aspects of dental product testing, combining current ISO requirements with practical laboratory experience. The sessions will explore how to design and implement risk-based biological evaluation strategies, addressing the latest expectations from ISO 10993-1 and ISO 7405.

We will also examine the role of chemical characterization in defining testing approaches, including how material properties influence sample preparation and test design. Building on these foundations, the workshop will cover how to assess biological risks and select appropriate testing strategies, supported by real laboratory examples.

Special attention will be given to emerging topics such as the characterization and risk assessment of nanoparticles in dental materials, as well as to critical regulatory elements like sterile packaging, including sterilization methods, shelf-life considerations, and validation requirements.

Overall, the workshop aims to provide a comprehensive and practical understanding of how to integrate scientific evidence, risk assessment, and regulatory expectations to develop efficient, compliant, and robust testing strategies for dental products.

WORKSHOP REGISTRATION

Register via the following link:
https://eu.jotform.com/form/260610319101441

AGENDA

09:00 – 09:30	**Opening & objectives**
09:30 – 10:15	**Risk-Based Biological Evaluation of Dental Products: From ISO Requirements to Practical Case Studies** *Kristin Roedig*
10:15 – 10:30	**Coffee break**
10:30 – 11:15	**Chemical Characterization & Test Requirements for Dental Products: From Material to Sample Preparation** *Dr. Maria-Fatima Tepedino*
11:15 – 12:00	**Biological Effects Testing for Dental Products: From Chemical Risk Assessment to Biological Evaluation** *Dr. Torben Gehring*
12:00 - 12:45	**Lunch**
12:45 - 14:00	**Lab Tour: From Test Strategy to Practice – Laboratory Insights into Sample Preparation and Characterization**
14:00 - 14:45	**Nanoparticles in Dental Materials: From Characterization to Risk and Regulatory Requirements** *Dr. Helge Gehrke*
14:45 -15:00	**Coffee break**
15:00- 15:45	**Sterile Packaging for Dental Devices: From Approval Requirements to Sterilization and Shelf-Life** *Lisa Heilemann*
15:45 - 16:30	**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**
16:30-16:45	**Wrap-up & next steps**

SPEAKERS

KRISTIN RODIG

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 sensitization 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. MARIA-FATIMA TEPEDINO

Dr. Maria-Fatima Tepedino is a Group Leader and Study Director in Chemical Characterization at Eurofins BioPharma Product Testing Munich GmbH. She has extensive experience in the evaluation of medical and dental devices, with a strong focus on chemical characterization, mass spectrometry, and regulatory-driven testing strategies.

Over the course of her career at Eurofins, she has held roles of increasing responsibility, including Study Director and Team Leader, developing deep expertise in analytical chemistry and supporting product compliance through tailored testing approaches.

Maria Tepedino holds a Ph.D. in Chemistry and has a solid academic and professional background in analytical sciences. She regularly contributes her expertise to the development of scientifically robust and regulatory-compliant evaluation strategies for complex materials.

SPEAKERS

DR. TORBEN GEHRING

Dr. Torben Gehring is group leader of Hemocompatibility and Cytotoxicity testing in the department in vitro pharmacology and toxicology at Eurofins Medical Device Testing in Munich. Torben Gehring completed his PhD in the field of Immunology and B cell lymphoma at the Helmholtz Center Munich in the Institute of Molecular Toxicology and Pharmacology. In 2020, Torben Gehring started as a study director in the group of Hemocompatibility Testing at Eurofins Munich. Start of 2022, he took over the Group Leader position of Cytotoxicity testing and has been Group Leader of Hemocompatibility and Cytotoxicity since mid of 2023.

DR. HELGE GEHRKE

Dr. Helge Gehrke is a Senior Scientific Director for in vitro Toxicology / Alternative Methods and a European Registered Toxicologist (ERT), holding a PhD in Nanotoxicology. He has been involved in the field of toxicology for more than 14 years and has a broad expertise in the areas of genetic toxicology, alternative methods, 3D cell culture models, cytotoxicity, hemocompatibility and nanotoxicology. As a toxicologist, he actively promotes the development the establishment of current alternative methods for the evaluation of biological safety within the Eurofins network but also in the context of international committees (NETVAL) and is an expert member of several working groups of ISO WG TC/194.

SPEAKERS

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

Risk-Based Biological Evaluation of Dental Products: From ISO Requirements to Practical Case Studies

Kristin Roedig, Eurofins Medical Device Consulting Germany

This session will explore the principles and practical application of risk-based biological evaluation for dental products in accordance with ISO 10993-1 and ISO 7405. It will provide insights into recent updates to ISO 10993-1 and their implications for dental devices, as well as specific requirements outlined in ISO 7405.

Participants will gain an understanding of how to translate regulatory expectations into effective and compliant testing strategies. The session will also demonstrate how theoretical frameworks can be applied in practice through real-life case studies, illustrating decision-making processes and optimized evaluation approaches.

Chemical Characterization & Test Requirements for Dental Products: From Material to Sample Preparation

Dr. Maria-Fatima Tepedino, Eurofins Medical Device Testing Germany

This session will focus on the key principles of chemical characterization for dental devices, in line with ISO 7405 and ISO 10993-18. It will provide an overview of regulatory expectations and explain how different material types influence sample preparation, test design, and overall evaluation strategies.

Participants will gain practical insights into defining appropriate test item specifications and ensuring compliance with current standards, supporting the development of scientifically sound and regulatory-aligned testing approaches.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Biological Effects Testing for Dental Products: From Chemical Risk Assessment to Practical Evaluation

Dr. Torben Gehring, Eurofins Medical Device Testing Germany

This session will build on chemical characterization results to explore how to define and perform biological effects testing based on identified risks. It will outline the process of selecting appropriate biological endpoints and designing studies tailored to specific product profiles.

Participants will gain practical insights into the execution of biological testing, supported by real laboratory examples and case studies that illustrate effective evaluation strategies and decision-making approaches.

Nanoparticles in Dental Materials: From Characterization to Risk and Regulatory Requirements

Dr. Helge Gehrke, Eurofins Medical Device Testing Germany

This session will address the growing importance of nanoparticles in dental materials, with a focus on the key principles and analytical approaches used for their characterization and assessment. It will explore how the unique properties of nanomaterials can influence their behavior, performance, and potential biological interactions within dental applications.

The session will also provide an overview of potential health risks associated with nanoparticles, along with the evolving regulatory expectations governing their use in medical and dental devices.

Participants will gain practical insights into how to effectively integrate nanoparticle considerations into a comprehensive and compliant testing and evaluation strategy.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Sterile Packaging for Dental Devices: From Approval Requirements to Sterilization and Shelf Life

Lisa Heilemann, Eurofins Sterile Packaging

This session will provide a comprehensive overview of the role of sterile packaging in the approval of dental devices, highlighting key regulatory expectations and validation requirements. It will explore how packaging systems contribute to product safety and compliance, particularly in relation to maintaining sterility throughout the product lifecycle.

The session will cover different sterilization methods and their impact on packaging materials, as well as important considerations for shelf-life determination and stability. Participants will also gain insights into common challenges associated with sterile packaging and how to address them effectively.

Practical case studies will be used to illustrate real-world scenarios, offering a clear understanding of how to develop robust, compliant packaging strategies that meet both scientific and regulatory requirements.

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REGISTRATION FEE : 250 EUROS, VAT EXCLUDED
WORKSHOP LANGUAGE: GERMAN/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/261412173354450

GENERAL TERMS AND CONDITIONS:

IN THE EVENT OF CANCELLATION BEFORE JUNE 7, 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

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Quality Management System • Training
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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 •
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