eurofins | Medical Device Services

WORKSHOP

FROM DESIGN TO VALIDATION: STERILE BARRIER PACKAGING VALIDATION AND STABILITY STUDIES FOR MEDICAL DEVICES WORKSHOP

30 JUNE 2026
10:00 - 16:00

EUROFINS MEDICAL DEVICE SERVICES – VIMODRONE, (MI), ITALY

WORKSHOP TOPICS:

- **End-to-end sterile packaging design and development**, including key design drivers, solution selection, and real project case studies.
- **Regulatory framework for medical device packaging** validation, outlining applicable standards, compliance expectations, and documentation requirements.
- **Packaging validation process** according to ISO 11607-2
- **Testing methods** used in packaging validation to ensure package integrity, sterility maintenance, and product protection throughout the lifecycle.
- **Stability studies** for medical devices, including regulatory context, required parameters

SPEAKERS

Martina Danesi
Eurofins Medical Device Consulting – Event Moderator

Steffen Lindenmeier,
Eurofins Sterile Packaging

Leonela Tita Gallo,
Eurofins Medical Device Consulting

Lisa Heilemann,
Eurofins Sterile Packaging

Elena Bizzotto
Eurofins Medical Device Consulting

For more information:

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INTRODUCTION

This workshop will provide a practical and comprehensive overview of sterile packaging for medical devices, following the product lifecycle from design and development, through validation and stability assessment.
It will begin by exploring how sterile packaging systems are designed using an end-to-end approach, highlighting the main design drivers, material and system selection, and how regulatory, functional, and operational requirements influence packaging decisions. Real project examples will be used to show how these principles are applied in practice.
The workshop will then focus on the regulatory context governing packaging validation, explaining the relevant standards and expectations, particularly those related to ISO 11607.

Participants will be guided through the packaging validation process, including process qualification, risk-based testing strategies, and appropriate sampling approaches. Common testing methods used to demonstrate packaging integrity, sterility maintenance, and product protection will be discussed in detail, supported by practical case studies.

The session will conclude with real-world case studies that illustrate how stability and packaging validation activities are aligned to ensure compliance, product safety, and market readiness.

WORKSHOP REGISTRATION

Register via the following link:
https://form.jotform.com/260610820217446

AGENDA

10.00 - 10.15	**Arrival, registration, coffee**
10.15 - 10.30	**Opening & objectives** ***Martina Danesi*** **- Italian**
10.30 - 11.15	**Design & Development: Sterile Packaging in Practice** ***Steffen Lindenmeier*** **- English**
11.15 - 11.30	**Coffee break**
11.30 - 12.15	**Regulatory Framework and Packaging Validation for Medical Devices** ***Leonela Tita Gallo*** **- Italian**
12:15 - 13.00	**Packaging Validation According to ISO 11607-2: Process, Testing, and Case Studies** ***Lisa Heilemann*** **- English**
13.00 - 14:00	**Lunch**
14:00 - 15:00	**Medical Device Stability: Regulatory Context, Testing, and Case Studies** ***Elena Bizzotto*** **- Italian**
15:00 - 16:00	**Ask the Expert – 1:1 Consultancy Sessions** One-to-one meetings will give you the opportunity to discuss your projects with our experts.

SPEAKERS

MARTINA DANESI

Martina has been an expert in biocompatibility since 2021, having started her career as an RA Specialist and subsequently joining the Eurofins Group in 2022, where she is part of the medical device consulting team. With solid experience in the field, Martina specializes in performing biological evaluations and literature reviews to support preclinical data for medical devices. She has successfully completed more than 200 biocompatibility assessments, making a significant contribution to the safety and regulatory compliance of medical devices.

STEFFEN LINDENMEIER

Steffen has been part of Eurofins Sterile Packaging since 2024, working at the interface of Business Development and Project Management with a focus on sterile packaging and sterilization processes. He supports medical device manufacturers from early product development, defines ISO 11607-compliant packaging solutions, and contributes to the implementation of complete processes including cleaning, assembly, packaging and terminal sterilization, always considering product-specific and regulatory requirements.

Steffen holds a Bachelor's degree in Medical Engineering.

SPEAKERS

LEONELA TITA GALLO

Leonela has been part of the Eurofins Regulatory & Consultancy Services team since 2022.
She is specialized in usability evaluation in accordance with IEC 62366-1. She has successfully completed many usability evaluations, making a significant contribution to the safety and regulatory compliance of medical devices under the MDR.
Over the past year, she has further expanded her expertise by supporting clients in the set-up and validation of packaging processes for terminally sterilized medical devices, in compliance with the relevant industry standards UNI EN ISO 11607-1 and UNI EN ISO 11607-2.
She holds a Master's Degree in Pharmaceutical Chemistry and Technology and a second-level Master's Degree in Pharmaceutical Technologies and Regulatory Affairs from the University of Turin.

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.

SPEAKERS

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.

ELENA BIZZOTTO

Elena holds a master's degree in Biology Applied to Biomedical Research. In 2015, she began her experience at Eurofins Biolab as a Study Director for in vitro cytotoxicity and irritation tests. In July 2016, she became Microbiological Laboratory Manager dedicated to medical devices, managing, among other activities, stability studies. Since July 2022, she has joined the consulting group, focusing on preclinical evaluations of medical devices and completing more than 150 evaluations. Over the past two years, she has supported clients in defining stability studies by proposing targeted testing plans.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Design & Development: Sterile Packaging in Practice

Presented in English

Steffen Lindenmeier, Eurofins Sterile Packaging

This presentation explores sterile packaging design and development in practice, adopting a comprehensive end-to-end approach that spans from initial concept to final implementation. It will examine the key design drivers and criteria that guide the selection of the most appropriate packaging solutions, ensuring an optimal balance between performance, regulatory compliance, and cost. Through a practical project case study, the session will provide concrete examples of real-world challenges and demonstrate how best practices and theoretical principles are effectively applied to deliver robust and compliant sterile packaging systems.

Regulatory Framework and Packaging Validation for Medical Devices

Presented in Italian

Leonela Tita Gallo, Eurofins Medical Device Services

This presentation provides an overview of the regulatory context and framework governing packaging validation, offering participants a clear understanding of the applicable standards and requirements. It will guide attendees through the packaging validation process, outlining the key steps necessary to ensure product integrity and compliance. The session will also cover the main testing methods used in packaging validation, highlighting their purpose and application. Finally, it will address essential documentation requirements, emphasizing the importance of robust and compliant records to support regulatory submissions and audits.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Packaging Validation According to ISO 11607-2: Process, Testing, and Case Studies

Presented in English

Lisa Heilemann, Eurofins Sterile Packaging

This presentation outlines the packaging validation process in accordance with ISO 11607-2, providing a structured view of the key phases required to demonstrate system effectiveness and compliance. It will explore the main testing methods used in packaging validation, including considerations for sampling strategies to ensure reliable and representative results. Through practical case studies, the session will illustrate real-world applications, highlighting common challenges and best practices in achieving robust and compliant packaging validation.

Medical Device Stability: Regulatory Context, Testing, and Case Studies

Presented in Italian

Elena Bizzotto, Eurofins Medical Device Consulting

This presentation provides an overview of the regulatory context governing stability studies for medical devices, helping participants understand the key requirements behind demonstrating product shelf life. It will examine the essential parameters that must be considered when designing stability protocols, along with a clear comparison between real-time and accelerated studies. The session will also introduce the main testing methods used to assess stability performance. Finally, through a practical case study, participants will gain insight into real-world applications and best practices in conducting compliant and reliable stability studies.

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REGISTRATION FEE : 90 EUROS, VAT EXCLUDED
WORKSHOP LANGUAGE: ITALIAN/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/260610820217446

GENERAL TERMS AND CONDITIONS:

IN THE EVENT OF CANCELLATION BEFORE MAY 30, 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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