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ON-SITE WORKSHOP

ENTERING THE MEDICAL DEVICE INDUSTRY: A PRACTICAL GUIDE FOR RAW MATERIAL & COMPONENT SUPPLIERS

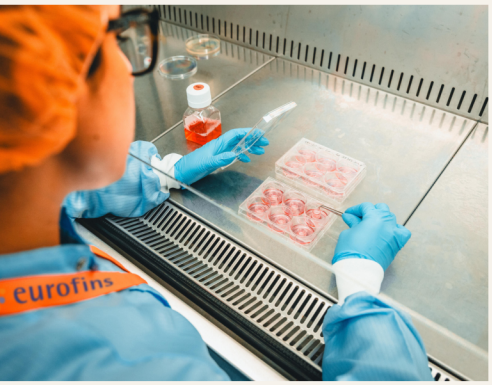
Speaker: Kristin Rödig, Dr. Maria-Fatima Tepedino, Dr. Torben Gehring & Jana Osterritter

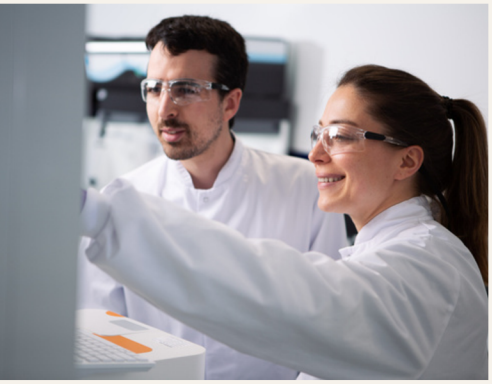
25. November 2025

9:00- 17:00 CET (with lunch)

Eurofins BioPharma Services Consulting Munich
Robert-Koch-Straße 3a,
82152 Planegg/Munich, Germany

WORKSHOP LANGUAGE ENGLISH





INTRODUCTION

The medical device industry is known for its stringent standards, continuous innovation, and strong potential for growth. As regulatory requirements evolve, both new and established suppliers must remain agile to maintain compliance and a competitive edge.

This full-day workshop is designed for suppliers of raw materials and components who are either entering the medical device sector or seeking to strengthen and update their existing quality and regulatory systems.

Participants will gain practical insights into:

- Transitioning or aligning from ISO 9001 to ISO 13485
- Understanding the upcoming changes to USP Class VI
- Applying risk-based strategies for biocompatibility and chemical testing
- Meeting evolving regulatory and quality system requirements

Led by experienced industry professionals, the workshop offers a structured, hands-on approach to navigating the complexities of medical device regulations. In addition to foundational content for newcomers, dedicated sessions will focus on current updates, trends, and best practices for experienced suppliers.

Whether you are exploring new opportunities within healthcare or looking to refresh and optimise your existing processes, this workshop will provide you with the tools and knowledge to ensure continued compliance, product safety, and long-term success in the medical device market.

WORKSHOP REGISTRATION

Register via the following link:

https://eu.jotform.com/form/252683895233467

SPEAKERS & EXPERTS

KRISTIN RÖDIG

Kristin Rödig has over 20 years of experience in in vitro toxicology, pharmacology, and biological safety assessment. Since March 2005, she has been part of Eurofins BPT, where she served as a Study Director, overseeing a broad spectrum of in vitro studies. Her expertise spans genotoxicity, cytotoxicity, and alternative testing methods such as irritation and sensitisation.

In September 2022, she transitioned to the role of Consulting Specialist at Eurofins Medical Device Consulting. 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 has been working in the field of analytical chemistry since completing her doctorate in bioinorganic chemistry. During the first four years of her career, she specialised in clinical chemistry, where she was deeply involved in method development and validation.

Since October 2019, she has held the position of Study Director at Eurofins Medical Device Testing, where she is responsible for overseeing studies in chemical characterisation. In April 2024, she additionally took on the role of Group Leader in chemical characterisation, managing both technical responsibilities and team coordination.

SPEAKERS & EXPERTS

DR. TORBEN GEHRING

Dr. Torben Gehring is the head of the haemocompatibility and cytotoxicity group in the in vitro pharmacology and toxicology department at Eurofins Medical Device Testing in Munich. He completed his PhD at the Helmholtz Centre Munich, at the Institute of Molecular Toxicology and Pharmacology. He joined Eurofins Munich in 2020 as Head of Haemocompatibility Testing, taking over as Group Leader of Cytotoxicity in early 2022. He also took over as head of the haemocompatibility group in mid-2023 and has been responsible for both groups ever since.

JANA OSTERRITTER

As a biomedical engineer, Jana Osterritter has been involved in the development and approval of medical devices for several years.

At Eurofins Medical Device Consulting, she offers consulting services to clients in the field of quality management and technical documentation, but also regarding general regulatory issues relating to medical devices.

AGENDA

09:00 - 09:15	**Welcome & Introduction**
09:15- 10:45	**The End of USP Class VI – A Shift Toward Risk-Based Biocompatibility Assessment** Kristin Rödig
10:45- 11:05	**Coffee Break**
11:05 - 12:05	**Opportunities and challenges arising from chemical characterisation for raw material and component suppliers** Dr. Maria-Fatima Tepedino
12:05- 13:05	**Lunch**
13:05 - 14:05	**In vitro tests with cell cultures for assessing the biological reactivity of materials** Dr. Torben Gehring
14:05 - 14:25	**Coffee Break**
14:25 - 15:55	**From ISO 9001 to ISO 13485: Key Steps and Challenges** Jana Osterritter
15:55- 16:10	**Wrap-Up & Key Takeaways**
16:10- 17:00	**Individual Meet the Expert Sessions & Networking** At the end of the workshop, you will have the opportunity to book a 15-minute one-on-one conversation with our experts to discuss your individual challenges.

BRIEF DESCRIPTION OF THE PRESENTATIONS

KRISTIN RÖDIG

The End of USP Class VI – A Shift Toward Risk-Based Biocompatibility Assessment

The United States Pharmacopeia (USP) has moved away from traditional Class VI testing. Once regarded as the gold standard for material safety, USP Class VI is now recognised as offering limited insight and must be incorporated into a comprehensive, risk-based evaluation strategy aligned with ISO 10993.
This session explores:

- Replacement of USP Class VI and shift to a risk-based approach
- Upcoming changes for USP <87> and <88> chapters
- Revised USP chapter <1031>

DR. MARIA-FATIMA TEPEDINO

Opportunities and challenges arising from chemical characterisation for raw material and component suppliers

Extractability and leachability studies are an essential part of testing new products or their raw materials for safety in everyday use. They enable a decisive deepening of material knowledge and thus provide the basis for a subsequent assessment of material risks and identification of the best possible application.
Material analysis is carried out as part of chemical characterisation in accordance with ISO 17025, ISO 10993-12 and -18.

An important aspect of chemical characterisation is flexibility with regard to the materials to be tested and the ability to constantly adapt to new challenges. It is therefore an indispensable tool for innovation, safety and sustainable market positioning. In this session, you will learn which validated screening methods can be used to identify substances.

BRIEF DESCRIPTION OF THE PRESENTATIONS

DR. TORBEN GEHRING

In vitro tests with cell cultures for assessing the biological reactivity of materials

In vitro tests with cell cultures are an essential part of the biological safety assessment of medical devices. They enable precise and animal-free analysis of material compatibility, especially for products that come into direct contact with patients. Compared to traditional animal testing in accordance with USP <88>, these methods offer greater relevance and significance. These modern in vitro methods make a decisive contribution to the safety of medical devices – efficiently, ethically and scientifically established.

This session will focus on the test strategies listed in USP <87>, including:

- Cytotoxicity tests such as the direct contact test, elution test and neutral red uptake (NRU) test, which detect cell-damaging effects at an early stage.
- Advanced testing methods as needed, such as genotoxicity tests (Ames test, chromosome aberration test, gene mutation test, micronucleus (MNvit) test) to evaluate possible mutagenic effects.
- New addition: the Skin Irritation Test, which reliably identifies skin irritation caused by materials.

JANA OSTERRITTER

From ISO 9001 to ISO 13485: Key Steps and Challenges

Transitioning from ISO 9001 to the medical device sector's ISO 13485 involves more than just adapting documentation—it requires a fundamental shift in mindset, processes, and regulatory understanding. In this session, we will explore:

- The key differences between ISO 9001 and ISO 13485
- Regulatory and quality management implications of the transition
- Common challenges and pitfalls during implementation
- Practical strategies for a smooth and compliant migration

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REGISTRATION FEE : 250 EUROS, VAT EXCLUDED
WORKSHOP LANGUAGE: ENGLISH
ON-SITE WORKSHOP

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/252683895233467

GENERAL TERMS AND CONDITIONS:

IN THE EVENT OF CANCELLATION BEFORE OCTOBER 25, 2025, 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
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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