

WORKSHOP



CARDIOVASCULAR DEVICE TESTING & STATE-OF-THE-ART STRATEGIES

FULL-DAY WORKSHOP DEDICATED TO THE LATEST REGULATORY UPDATES, STRATEGIES AND PRACTICAL CASE DISCUSSIONS IN CARDIOVASCULAR DEVICE EVALUATION AND HEMOCOMPATIBILITY TESTING

29 APRIL 2026

9:00 - 17:00

AT EUROFINS MEDICAL DEVICE
TESTING IN PLANEGG / MUNICH

SPEAKERS

Marcel Dörkes,
Eurofins Medical Device Consulting Germany

Dr. Torben Gehring,
Eurofins Medical Device Testing Germany

Jan Roggenkamp,
Eurofins Medical Device Testing Germany

Register now

For more information:

Medical-Device@mds.eurofinseu.com

WORKSHOP TOPICS:

- Jumping in the beautiful world of biocompatibility assessment: Updates, Impact, Outlook ISO 10993-1 and Introduction ISO 10993-4
- Setting the Benchmark for Hemocompatibility: Advanced Testing for Cardiovascular Device according to ISO 10993-4
- Challenges in *in-vitro* studies for performance characterisation and product approval: Strategies, project planning, costs, market-related and technical risks. Examples from the laboratory's perspective - heart valves, oxygenators, cannulas
- Lab Tours: On-Site Hemocompatibility Centre of Excellence Tour & Virtual Cardiovascular Performance Testing Lab Showcase

INTRODUCTION

This workshop provides a concise yet comprehensive introduction to current best practices in the biological and functional assessment of cardiovascular medical devices. Participants will gain insight into the latest updates of ISO 10993-1 and an applied overview of ISO 10993-4, with a clear focus on evaluating blood-contacting devices and establishing a scientifically robust hemocompatibility assessment.

The second part of the workshop addresses the practical challenges of in-vitro performance testing for cardiovascular technologies such as heart valves, oxygenators and cannulas. Using real laboratory case studies, the session highlights typical technical and regulatory obstacles, effective project planning, cost considerations and strategies to mitigate market-driven and technical risks.

By combining regulatory expectations with hands-on laboratory experience, this workshop equips attendees with the essential knowledge to design efficient, compliant and scientifically sound testing strategies that support successful product development and approval in the cardiovascular device field.

WORKSHOP REGISTRATION

Register via the following link:

<https://eu.jotform.com/form/260610319101441>



AGENDA

09.00 - 09.15

Arrival, registration, coffee

09.15 - 09.30

Opening & objectives

09.30 - 10.30

**Jumping in the beautiful world of biocompatibility assessment: Updates, Impact, Outlook
ISO 10993-1 and Introduction ISO 10993-4**

10.30 - 10.45

Coffee break

10.45 - 11.45

Setting the Benchmark for Hemocompatibility: Advanced Testing for Cardiovascular Device according to ISO 10993-4

11.45 - 12.00

Brief Q&A and Wrap-Up of the First Half

12:00 - 13.00

Lunch

13.00 - 13.45

Challenges in *in-vitro* studies for performance characterisation and product approval: Strategies, project planning, costs, market-related and technical risks. Examples from the laboratory's perspective - heart valves, oxygenators, cannulas

13.45 - 14.15

Virtual Lab Showcase: Cardiovascular Performance Testing

14.15 - 14:30

Coffee break/ transition

14:30 - 15:45

On-Site Laboratory Tour: Hemocompatibility Centre of Excellence

15.45 - 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

16.45 - 17.00

Wrap-up & next steps

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.



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.

SPEAKERS



JAN ROGGENKAMP

Jan holds a degree in mechanical engineering (Dipl.-Ing.) from RWTH Aachen University, Germany. With over 16 years of experience in the medical device field, he is an expert in in-vitro testing methods and related strategies. As Head of Operations at the Eurofins Medical Device Services laboratory in Aachen, Jan offers standardised and customised solutions for performance testing to customers worldwide. His expertise includes applications for heart valve testing, blood testing with oxygenators, blood pumps, cannulas, and numerous other devices, as well as the development of customised testing procedures. Jan is also a member of the ISO TC 150 standards committee, which develops international standards for heart valve prostheses and repair devices.

BRIEF DESCRIPTION OF THE PRESENTATIONS



Jumping in the beautiful world of biocompatibility assessment: Updates, Impact, Outlook

ISO 10993-1 and Introduction ISO 10993-4

Marcel Dörkes, Eurofins Medical Device Consulting Germany

This presentation provides an overview of common risks and challenges associated with in vitro studies for performance specifications and product approval. Using various case studies from the daily laboratory practice, it highlights the importance of appropriate project planning, testing strategies, modeling, and related topics. In addition, the presentation provides insights into general and product-related standard requirements for in-vitro testing and the corresponding implementation of test methods. The aim of this presentation is to give participants a general understanding of how risks and challenges in in vitro performance testing can be addressed in order to make laboratory studies successful. able biological safety documentation can be handled.

BRIEF DESCRIPTION OF THE PRESENTATIONS



Setting the Benchmark for Hemocompatibility: Advanced Testing for Cardiovascular Device according to ISO 10993-4

Dr. Torben Gehring, Eurofins Medical Device Testing Germany

This presentation highlights state-of-the-art in-vitro hemocompatibility testing strategies for cardiovascular medical devices in alignment with ISO 10993-4. It examines how advanced laboratory models and controlled assay systems can reliably evaluate key blood-interaction endpoints such as thrombogenicity, coagulation and platelet activation, hemolysis, and complement activation. The session will gain insight into scientific principles behind these in-vitro techniques and provides clear guidance for device developers and regulatory professionals aiming to design efficient, high-quality hemocompatibility tests tailored to their products raising the regulatory acceptance.

BRIEF DESCRIPTION OF THE PRESENTATIONS



Challenges in *in-vitro* studies for performance characterisation and product approval: Strategies, project planning, costs, market-related and technical risks. Examples from the laboratory's perspective - heart valves, oxygenators, cannulas

Jan Roggenkamp, Eurofins Medical Device Testing Germany

This presentation provides an overview of common risks and challenges associated with *in-vitro* studies for performance specifications and product approval. Using various case studies from the daily laboratory practice, it highlights the importance of appropriate project planning, testing strategies, modeling, and related topics. In addition, the presentation provides insights into general and product-related standard requirements for *in-vitro* testing and the corresponding implementation of test methods. The aim of this presentation is to give participants a general understanding of how risks and challenges in *in vitro* performance testing can be addressed in order to make laboratory studies successful.

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/260610319101441>



GENERAL TERMS AND CONDITIONS:

IN THE EVENT OF CANCELLATION BEFORE MARCH 29, 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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