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ON-SITE WORKSHOP

STREAMLINED RISK MANAGEMENT: ADAPTING TO NEW ISO/FDIS 10993-1 REQUIREMENTS

Speakers: Marcel Dörkes & Jana Osterritter

29. October 2025

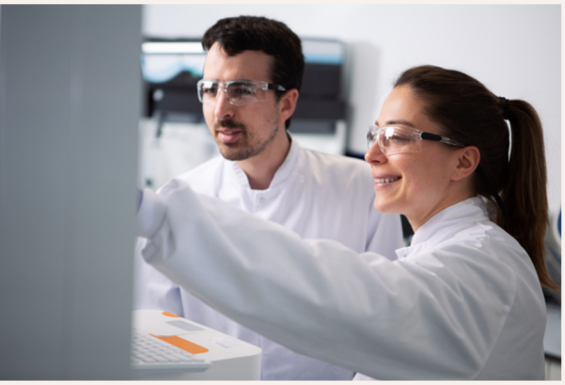
9:00 - 17:00 CET

with Lunch

WORKSHOP LANGUAGE: ENGLISH

WORKSHOP LOCATION

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



INTRODUCTION

This workshop presents the latest changes to the ISO/FDIS 10993-1 standard for the biological evaluation of medical devices. These changes have significant implications for the biological safety assessment of all medical devices. The focus will be on the essential adjustments required to address these new challenges. Participants will learn how to implement these changes, identify biological risks, and apply the relevant testing and evaluation methods. The workshop will also cover the practical application of ISO 14971 principles for risk analysis and management, providing professionals with the knowledge needed to ensure the safety of medical devices and efficiently apply the standards in practice.

WORKSHOP REGISTRATION

Register via the following link:
https://form.jotform.com/251884142688468

SPEAKERS & EXPERTS

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. Marcel Dörkes' expertise includes the biological safety assessment of medical devices and related toxicological issues including strategy planning, chemical characterization 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.

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 and introduction**
09.15 - 10.30	**ISO/FDIS 10993-1 Biological Evaluation of Medical Devices – Theoretical Part** • Implemented Changes: An overview of the key changes in the standard and their significance for practice. • Identifcation of Biological Effects: How biological risks associated with medical devices must be identified and assessed. • Identification of the Scope: Determining the relevant testing and evaluation methods as well as the necessary criteria for a complete assessment.
10.30 - 10.50	**Coffee break**
10.50 - 12.30	**Application of ISO 14971 Principles – Theoretical Part** • Requirements for risk analysis • Identification of the necessary data • Biological risk control: How biological risks are managed and controlled throughout the lifecycle of a medical device • Activities of the risk management process and their documentation.

AGENDA

12.30 - 13:15	**Lunch**
13:15 - 14:45	**ISO/FDIS 10993-1 Biological Evaluation of Medical Devices – Practical Part** • The new changes and their implications in practice • How to handle the changes effectively • The conclusions that can be drawn from the tables for the biological risk analysis • The impact of these changes for the Biological Evaluation Plan
14.45 - 15.00	**Coffee break**
15.00 - 16.30	**Application of ISO 14971 Principles – Practical Part** • Intended use and reasonably foreseeable misuse • Identification of safety-relevant characteristics • Identification of hazards and hazardous situations • Risk estimation
16.30 - 17.00	**Wrap-up**

BRIEF DESCRIPTION OF THE PRESENTATIONS

ISO/FDIS 10993-1 Biological Evaluation of Medical Devices – Theoretical Part

This workshop covers the latest changes included in the ISO/FDIS 10993-1 standard for the biological safety evaluation of medical devices. An overview of the key changes that are going to be implemented will be provided, along with an explanation of their practical significance. A major focus will be on the identification and assessment of biological risks associated with medical devices and the general outline and procedure of the biological risk assessment as described in the new version of the standard. Participants will gain a solid foundation for successfully applying the revised standard in practice.

ISO/FDIS 10993-1 Biological Evaluation of Medical Devices – Practical Part

In this session, the latest changes to the ISO/FDIS 10993-1 standard for the biological evaluation of medical devices will be covered in detail. We will discuss the practical implications of these changes and how to handle them effectively. We will explain what procedures shall be followed for different devices and certification phases and how the impact on available biological safety documentation can be handled.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Application of ISO 14971 Principles – Theoretical Part

This section covers the key requirements for conducting a risk analysis, focusing on the identification of relevant data to be considered. It also addresses the management and control of biological risks throughout the lifecycle of a medical device. Furthermore, the activities involved in the risk management process will be discussed, along with the necessary documentation to ensure proper traceability and compliance with ISO 14971.

Application of ISO 14971 Principles – Practical Part

This section covers the practical procedure during implementation of risk management in accordance with ISO 14971. It covers the intended use of a medical device and reasonably foreseeable misuse. It also includes the identification of safety-relevant characteristics, as well as the identification of hazards and hazardous situations. Finally, the process of risk assessment will be discussed, focusing on evaluating the potential risks associated with the device throughout its lifecycle.

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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://form.jotform.com/251884142688468

GENERAL TERMS AND CONDITIONS:

IN THE EVENT OF CANCELLATION BEFORE SEPTEMBER 29, 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.

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