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WORKSHOP

MEDICAL DEVICE SOFTWARE: FROM REGULATION TO READY FOR MARKET

23 JUNE 2026
09:00 - 17:00 CET

PLANEGG/MUNICH, GERMANY

SPEAKERS

Ruthy Spitzer,
Business Development Consulting and Testing for Medical Device

Amit Hananel,
Regulatory Affairs & Quality Leader

Lisandro Acosta,
Regulatory and Quality Expert

Limor Levinsky,
Project and Product Manager
Software Expert

For more information:

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WORKSHOP TOPICS:

- **Medical Device, Wellness, or Borderline?** Classifying Software Products Under FDA and EU MDR.
- **From Code to Compliance: IEC 62304, FDA & EU MDR** Software Requirements and the Deliverables
- **Cybersecurity Management, Threat Modeling, SBOM & AI/ML Risk -** What FDA and EU MDR Expect Today
- **End-to-End Software Traceability: From Requirements to Outputs -** What Regulators Expect and How to Deliver It
- **Quality-Driven Software Excellence:** SW development as Best Practice

INTRODUCTION

This workshop is designed specifically for medical device companies developing software who need to translate regulatory requirements into practical, defensible, and audit-ready implementation.

Through expert-led, real-world sessions, participants will gain clarity on software classification including medical device, wellness, and borderline products, understand how to correctly implement IEC 62304 across the software lifecycle, and learn how regulators expect manufacturers to address today's most critical topics.

The agenda focuses on what regulators actually review during audits and technical file assessments, helping teams reduce findings, avoid common compliance pitfalls, and accelerate time to market.

What sets this workshop apart is its hands-on, end-to-end approach. Participants are guided from intended use and user needs through system and software requirements, architecture, development, risk management, and all the way to verification, validation, and post-market considerations. The program goes beyond theory to show how to build a coherent, defensible software file that stands up to regulatory scrutiny. The workshop is further enhanced by one-on-one meeting with experienced regulatory and software experts.

WORKSHOP REGISTRATION

Register via the following link:
https://form.jotform.com/260878662793475

AGENDA

09.00 - 09.30	**Arrival, registration, welcome**
09.30 - 09.45	**Opening & objectives** *Ruthy Spitzer*
09.45 - 10.20	**Medical Device, Wellness, or Borderline? Classifying Software Products Under FDA and EU MDR** *Amit Hananel*
10.20 - 11.20	**From Code to Compliance: IEC 62304, FDA & EU MDR Software Requirements and the Deliverables** *Lisandro Acosta*
11:20 - 11.50	**Coffee Break**
11.50 - 12:50	**Secure by design - Cybersecurity Management, Threat Modeling, SBOM & AI/ML Risk - What FDA and EU MDR Expect Today** *Amit Hananel*
12:50 - 14:00	**Lunch**
14:00 - 14:45	**End-to-End Software Traceability: From Requirements to Outputs - What Regulators Expect and How to Deliver It** *Lisandro Acosta*
14:45 - 15:00	**Short Coffee Break**
15:00 - 16:00	**Quality-Driven Software Excellence: SW development as Best Practice** *Limor Levinsky*
16:00 - 16:10	**Closing remarks** *Ruthy Spitzer*
16:10 - 17:00	**Ask the Expert – 1:1 Consultancy Sessions** Get expert insights and practical solutions in exclusive one-to-one consultancy sessions.

SPEAKERS

RUTHY SPITZER

Ruthy Spitzer is a Business Development at Eurofins Li-Med supporting medical device and IVD companies with tailored end-to-end consulting and testing solutions across the product lifecycle.

AMIT HANANEL

Amit Hananel is a senior RA/QA professional with more than 15 years of experience across the medical device and IVD sectors. He bridges science and regulation to enable compliant products and successful FDA and EU MDR submissions. His expertise includes harmonizing quality management systems with ISO 13485, ISO 14971, and IEC 62304, implementing cybersecurity frameworks, and leading AI/ML dataset-quality initiatives to meet regulatory compliance.

LISANDRO ACOSTA

Lisandro Acosta is a QA/RA consultant specializing in medical device and IVD software design controls. He supports companies in applying IEC 62304 across the software development lifecycle, from requirements and architecture to verification, change control, and audit readiness. Lisandro brings hands on expertise with a clear focus on traceability across the medical device system and practical, scalable software processes.

SPEAKERS

LIMOR LEVINSKY

Limor Levinsky is an experienced project and product leader with a strong engineering background and over two decades of hands-on experience across medical devices, digital health, and complex regulated systems. She specializes in guiding companies from early concept and intended use definition through design, development, verification, validation, and regulatory submission. Her expertise spans regulatory strategy for FDA and EU markets, IEC 62304 software lifecycle compliance, ISO 13485 quality systems, risk management per ISO 14971, usability engineering, and design controls across hardware-software systems. Limor brings a pragmatic, end-to-end approach—bridging product management, engineering, QA/RA, and clinical stakeholders—to build defensible technical documentation, support audit readiness, and accelerate time to market while maintaining regulatory and quality excellence.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Medical Device, Wellness, or Borderline? Classifying Software Products Under FDA and EU MDR

Amit Hananel, Regulatory Affairs & Quality Leader

This presentation provides an overview of how software-based healthcare products are classified under US and EU regulatory frameworks - covering the spectrum from SaMD and SiMD to IVD software, Clinical Decision Support, borderline products, and general wellness applications. Through real-world case studies and a side-by-side comparison of FDA and EU MDR/IVDR/AI Act requirements, participants learn how intended use claims, labeling language, and user population drive classification outcomes - and why getting this right early is one of the most consequential business decisions in digital health product development.

Cybersecurity Management, Threat Modeling, SBOM & AI/ML Risk - What FDA and EU MDR Expect Today

Amit Hananel, Regulatory Affairs & Quality Leader

This presentation focuses on how to build cybersecurity, threat modeling, Software Bill of Materials (SBOM), and AI/ML compliance into a medical device from day one, emphasizing an early, integrated approach to regulatory and security requirements in order to support safer designs, more efficient regulatory submissions, and long-term compliance throughout the product lifecycle.

BRIEF DESCRIPTION OF THE PRESENTATIONS

From Code to Compliance: IEC 62304, FDA & EU MDR Software Requirements and the Deliverables

Lisandro Acosta, Regulatory and Quality Expert

This presentation explores of IEC 62304 as the foundational standard for medical device software development, while emphasizing that it does not operate in isolation, as additional expectations are introduced through the FDA's 2023 guidance on software functions and the EU MDR Annex I General Safety and Performance Requirements (GSPRs); it highlights the importance of understanding where these frameworks align and where they diverge in order to build a defensible technical file rather than one that results in regulatory findings, and it also addresses key validation topics, including the packaging validation process, testing methods used in packaging validation, and the related documentation requirements.

End-to-End Software Traceability: From Requirements to Outputs - What Regulators Expect and How to Deliver It

Lisandro Acosta, Regulatory and Quality Expert

This presentation takes a hands-on approach by presenting a set of examples that walk participants through the complete software traceability chain, starting from user needs and intended use, and continuing through system and software requirements, risk management, architectural and detailed design, implementation, and ultimately verification and validation outputs.

BRIEF DESCRIPTION OF THE PRESENTATIONS

Quality-Driven Software Excellence
Best Practices and Tools for Regulated Medical Device Development

Limor Levinsky, Project Manager & Product Consultant

This presentation provides a practical overview of best practices, operating models, and tools used to successfully develop medical device and digital health products in regulated environments, focusing on effective team structures, streamlined processes, and simple audit-ready execution.

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REGISTRATION FEE : 195 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://form.jotform.com/260878662793475

GENERAL TERMS AND CONDITIONS:

IN THE EVENT OF CANCELLATION BEFORE MAY 30TH, 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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