SWISS MEDTECH

PROGRAMME

NATIONAL REGULATORY CONFERENCE 2026



29 October 2026 | Festhalle BernExpo | Bern

Morning Programme

Plenary Session 1: Swiss Politics and Regulatory Framework

09.15	Programme start
09.20	**Global Development and Trade Policy: how do they affect Switzerland as a Medtech business location?** Damian Müller, President, Swiss Medtech
09.30	**FDA Recognition, Regulatory Fees and the Role of Swissmedic for the Swiss Medtech Sector** Vincenza Trivigno, Director, Swissmedic
09.50	**Opportunities and Risks for Switzerland as a Medtech Location: Insights from the Swiss Medtech Industry Study** Adrian Hunn, Director, Swiss Medtech
10.05	**Switzerland's Innovation Ecosystem under Pressure: Where Does the Medtech Industry Stand?** Martin Wörter, Head of Innovation Economics, KOF Swiss Economic Institute
10.25	**MDR Revision: Quo Vadis?** Dr Christina Ziegenberg, Head of Regulatory Affairs, BVMed
10.45	Coffee Break

Breakout Sessions

11.15	**Session 1**	**Smarter Regulatory Workflows: AI in Medtech Practice**	>> Details
11.15	**Session 2**	**MDR in Practice: Revision and Its Implications and Challenges in Switzerland**	>> Details
11.15	**Session 3**	**Navigating Changing Requirements: Sustainability Reporting in Practice**	>> Details
12.30		Lunch Break	
13.45	**Session 4**	**Cybersecurity Compliance under MDR**	>> Details
13.45	**Session 5**	**FDA's Introduction of the Quality Management System Regulation – First Live Experiences**	>> Details
13.45	**Session 6**	**Designing Compliant and Marketable Medtech Products**	>> Details
15.00		Afternoon Break	

Afternoon Programme

Plenary Session 2: Regulatory Readiness in Practice

15.30	Programme start
15.35	**Ready for Swissdamed?** Susanne Wydenkeller Hinder, Head of Division Medical Devices Operations & Development, Swissmedic
15.45	**Clinical Research and Studies in Switzerland: Strengths, Weaknesses and Future Potential** Claudia Becherer, Team Leader Regulatory Affairs for Clinical Trials, Swiss Clinical Trials Organisation
16.00	**Success Story: Using AI to Navigate Regulatory Complexity – Practical Insights** Kübra Kabak, Regulatory Affairs Manager, Oertli Instrumente
16.20	**Pitch Session: Digitalisation in Medtech – Go Digital or Die** • Ralf Thür, CEO, Avasis • Arlette Schilter, CEO, ColabON • Thierry Rietsch, CEO, Nakamo • Anna-Marie Makarova, CEO, RegCheck
16.40	**Looking Ahead to 2027: What to Expect from Medtech Regulation** Carina Schaller, Head of Public Affairs, Swiss Medtech
16.50	**Event Closing** Adrian Hunn, Director, Swiss Medtech

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Breakout Sessions



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Breakout Session 1 – AI-enabled Compliance

Smarter Regulatory Workflows: AI in Medtech Practice

AI is transforming regulatory work across the healthcare sector. This session explores practical AI applications, from supporting ethics committee submissions and answering regulatory questions to discussing the evolving role of human expertise in an AI-enabled workplace.

- **Lost in Ethics, Stuck in Regulation - An AI Supported Approach to Preparing and Submitting Ethics Committee Applications**
  Marinja Principe, University of Zurich
- **AI in Action - Turning Regulatory Questions into Trusted Answers**
  Thierry Rietsch, Nakamo
- **Panel Discussion: Beyond Productivity - Human Expertise in the Age of AI**
  Pavel Kraus and Jessica Wyler, Swiss Knowledge Management Forum

Key Takeaways
Participants will gain insights into current opportunities, challenges, and future perspectives for AI in regulatory affairs and compliance.

Moderated by
Bernhard Bichsel, ISS AG Integrated Scientific Services

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Breakout Session 2 – MDR Revision

MDR in Practice: Revision and Its Implications and Challenges in Switzerland

How will the MDR revision affect Swiss medtech companies in practice? This session examines which proposed simplifications could reduce regulatory burden, how future EU–Switzerland relations may influence market access, and how companies can manage ongoing challenges when working with Notified Bodies.

- **MDR Revision and the MRA: Cutting Through the Complexity for Swiss Medtech Companies**
  Anna Melin, Sidley
- **MDR Revision in Practice: Which Simplifications Matter Most for Swiss Medtech Companies?**
  Janett Kientopp, GS1 Switzerland
- **Working with Notified Bodies under MDR: Bottlenecks, Expectations and Practical Strategies**
  Royth P. v. Hahn, TÜV SÜD

Key Takeaways
Participants will gain a practical understanding of the MDR revision and learn how to prepare for changes affecting compliance, market access and cooperation with Notified Bodies.

Moderated by
Eva von Mühlenen, Sidley

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Breakout Session 3 – Sustainability Reporting

Navigating Changing Requirements: Sustainability Reporting in Practice

How are changing sustainability reporting requirements affecting medtech companies? This session examines the implications of the EU Omnibus package, the practical challenges faced by SMEs, and the tools available to help companies manage reporting requirements efficiently and create meaningful impact.

- **Sustainability Reporting after Omnibus: What Companies Need to Know**
  Theresa Baumstark & Lucca Kallenberger, ERM
- **Sustainability Reporting in Practice: Challenges for SMEs**
  Raphael Laubscher, Laubscher Präzision AG
- **From Requirements to Implementation: How Swiss Medtech Supports Companies with Practical Tools**
  Adrian Siegrist, Sulytics & Barbara Mettler, Swiss Medtech

Key Takeaways
Participants will gain practical guidance on changing reporting requirements and learn how SMEs can reduce complexity with targeted tools and support.

Moderated by
Sarah Vowles, Tecan

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Breakout Session 4 – Cybersecurity

Cybersecurity Compliance under MDR

How can medtech companies meet cybersecurity requirements throughout the product lifecycle? This session examines the practical implementation of MDR Annex I, the regulatory management of software updates and vulnerabilities, and the documentation needed to demonstrate compliance during audits.

- **Cybersecurity under MDR: Practical Implementation of Annex I Requirements**
  Richie Christian, Congenius AG
- **Managing Software Updates, Vulnerabilities and Versioning under Regulatory Oversight**
  Paul Gardner, Ypsomed AG
- **Cybersecurity Documentation and Audit Readiness: What Notified Bodies Expect**
  Aleksander Kowalski, TÜV SÜD

Key Takeaways
Participants will gain practical guidance on implementing cybersecurity requirements, managing software changes and preparing documentation that meets regulatory and Notified Body expectations.

Moderated by
Stephen Ranjan, Congenius AG

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Breakout Session 5 – FDA's QMSR

FDA's Introduction of the Quality Management System Regulation

The FDA significantly increased its inspection activities for manufacturers and contract manufacturers in Switzerland in 2025. At the same time, the transition from the former QSR to the ISO 13485-aligned QMSR was underway. As of 2 February 2026, the QMSR is fully implemented, and FDA inspections worldwide are conducted under the new framework.

In this breakout session, practical, hands-on experience from QMSR inspections will be shared. What is new? What has changed? How can companies prepare?

- **QMSR and the New Inspection Guideline: Main Changes Compared to QSR and QSIT**
  Thomas Vogl-Dibbern, Confinis
- **FDA Inspection Strategies and Preparation: The Perspective of a Translator and Facilitator**
  Daniel Helbling, Axxos
- **FDA Inspection – the practical side**
  Roger Bill, BBC Cellpack Technology

Key Takeaways
Participants will understand how QMSR changes FDA inspections and gain practical insights into preparation, facilitation and successful implementation.

Moderated by
Markus Wipf, Axxos

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Breakout Session 6 – Sustainability Product Regulation

Designing Compliant and Marketable Medtech Products

How do new sustainability requirements affect the design, packaging and lifecycle of medical devices? This session examines upcoming packaging regulations in Switzerland and the EU, requirements related to electronic devices and the circular economy, and how medtech companies can develop competitive products within an increasingly complex regulatory framework.

- **Packaging Requirements under the PPWR and Swiss Regulation: What Medtech Companies Need to Prepare For**
  Roland Bäge, Icotec & Uriel Zemp, ISS AG, Integrated Scientific Services
- **Swiss Ordinance on the Return, Taking Back and Disposal of Electrical and Electronic Equipment: Implications for Circular Medtech Products**
  Pasqual Zopp, SENS eRecycling
- **From Compliance to Market Success: Designing Medtech Products within a Complex Regulatory Framework**
  Lucas Pianegonda, Gradical

Key Takeaways
Participants will understand how product-level sustainability regulations affect packaging, product design and lifecycle management, and how compliance can support market-ready and competitive solutions.

Moderated by
Elena Lucano, Veranex

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Full schedule & speaker information