



Swiss Network for
Digital Medical Regulation

Digital Transformation in Regulation

Dr. Niklaus Bühler, September 2025

SNMDR Continuing Education Event 2025

«A Guide Through MedTech Regulation for Startups and Student Innovators»

Wednesday, November 5th, 13.45-18.00h

ZHAW, Dept. Gesundheit/MG, Meeting Room EO.088

Katharina Sulzer Platz 9, Winterthur



Organised by:

Dr. Niklaus Bühler, Managing Director SNMDR
Prof. Martina Spiess, ZHAW

Location:

“Haus Adeline Favre”, ZHAW, Katharina Sulzer Platz 9, Winterthur
Room EO.088

Date:

5. November 2025, 13.45-18.00h, followed by a reception

Target Audience:

Start-ups, students, researchers, other young innovators from Swiss Universities

Sponsors and Partners:

Zürcher Hochschule
für Angewandte Wissenschaften



The People Behind the Event: Organizers and Presenters



With more than 20 years of experience in developing medical technology products, **Prof. Dr. Roger Abächerli** applies his expertise to advancing innovative digital health solutions. His knowledge spans technical aspects as well as the integration of artificial intelligence into medical devices. He also brings in-depth expertise in medical device regulations, including qualification and classification issues, as well as general regulatory requirements.



Dr. Daniel Delfosse is Vice Director and Head of Regulation & Innovation at Swiss Medtech, the industry association representing and promoting the Swiss medical technology sector. In this role, he works to maintain Switzerland's position as a leading hub for MedTech. For nearly two decades, he headed R&D at a Swiss orthopedics company, operating at the intersection of regulation and innovation.



With more than 20 years of experience in the medical technology industry, **Dipl. Ing. ETH Arlette Schilter** founded Colabon in 2020 with the mission of empowering MedTech innovation by simplifying complex compliance requirements. As CEO, she brings extensive expertise in the development of digital health products. She has a particular interest in complex systems and challenges, where she can apply her broad experience to create effective solutions.



Dr. Reinhold Sojer has extensive experience in standardization, semantic interoperability, and knowledge-based systems in medicine. As a bridge builder between technology and users, he has worked across research, startups, SMEs, federal administration, and associations. He combines a deep understanding of healthcare professionals' needs with hands-on involvement in pioneering projects for the healthcare sector.



Dr. Niklaus Bühler studied chemistry at ETH Zurich and worked in industry for 35 years in various research management positions at Ciba-Geigy, Novartis, and Ciba Specialty Chemicals. He founded the Industry Relations group at ETH Zurich and taught Materials Science at ETH Zurich and the University of Neuchâtel for 20 years. In 2022, he established the "Swiss Network for Digital Medical Regulation," where he now serves as Managing Director.



Prof. Dr. Martina Spiess leads the Rehabilitation Technology Research Group at the Institute of Occupational Therapy, ZHAW School of Health Sciences in Winterthur. Her research focuses on how new technologies can best support optimal outcomes for clients through an interdisciplinary approach involving data scientists, engineers, clinicians, patients, and other stakeholders. She teaches in clinical and engineering programs and is a guest lecturer at the Bern University of Applied Sciences, the University of Texas at El Paso, and ETH Zurich.

Programme:

13.45	Welcome and Introduction of the Keynote Speakers and Focus Topics Plenum room EO.088 Martina Spiess and Niklaus Bühler	
14.00	Key Notes (15 minutes each) Plenum room EO.088 <ul style="list-style-type: none"> • Roger Abächerli: MDR or FDA? - That is the Question. • Reinhold Sojer: The Digitalisation of Regulatory Laws • Daniel Delfosse: How to Innovate Within the Boundaries of Medical Device Regulation • Arlette Schilter: A recipe for QMS 	
15.00	Workshop 1: Recipes for Using Digital Tools in Regulation Moderation: Roger Abächerli, Arlette Schilter, Reinhold Sojer Meeting room O1.142, group rooms O1.067 and O1.070 <ul style="list-style-type: none"> - Presentation of the task - Group work (three groups) - Preparation of a work plan for presentation to the plenum 	Workshop 2: Choosing between MDR and FDA Moderation: Daniel Delfosse, Martina Spiess, Niklaus Bühler Meeting room O1. 143, group rooms O1.076 and O1.077 <ul style="list-style-type: none"> - Presentation of the task - Group work (three groups) - Preparation of a work plan for presentation to the plenum
16.30	Presentations to the Plenum from the Working Groups Plenum room EO.088	
18.00	Conclusions followed by an Apéro/Reception Forum in front of EO.088	

Registration:

You can find the [registration platform here](#) or through the QR code.

Registration Fees:

Students: free of charge
Others: CHF 100



Students must provide proof of enrolment upon check-in to the event. Non-students will receive an invoice for the registration fee after completing their registration.

We are looking forward to seeing you at ZHAW on Nov. 5th 2025!

Please direct any questions regarding the event to:

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