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Thursday March 16, 2023

## Balgrist Campus Seminar Series

**SWISS MEDTECH**



## Medical Device Regulation – a reality check” by Dr. Daniel Delfosse

### Dear colleagues

We are pleased to invite you to our 11th Balgrist Campus Seminar Series. Our guest is **Dr. Daniel Delfosse**, Head of Regulation & Innovation of Swiss Medtech.

The implementation of the European Medical Device Regulation (MDR) has proven to be more difficult than anticipated. As a result, medical device manufacturers seem to favour first certification no longer under EU-rules (CE-mark) but rather under US-rules (FDA approval). To complicate things further, Switzerland became a third country to the EU on 26 May 2021 when the MDR came into force and the Swiss-EU Mutual Recognition Agreement (MRA) failed to be updated. In response, on 28 November 2022, the Swiss parliament decided to adapt national laws so that medical devices with FDA approval shall also be recognised in Switzerland.

What strategy should you as a Swiss start-up or established manufacturer adopt to bring your medical devices on the market? Daniel Delfosse from Swiss Medtech, the industry association, will try to shed some light on the history and give you a perspective of how to navigate in these murky regulatory waters.

### Date

Thursday, March 16, 2023

### Time

11:30 – 13:30 h

### Place

Auditorium Christian Gerber  
Balgrist University Hospital

### Seminar Chair

Prof. Jess Snedeker,  
Chief Scientific Officer

### Agenda

- \_ Welcome and Introduction
- \_ **Medical Device Regulation - a reality check”**  
A lecture by Dr. Daniel Delfosse
- \_ Q&A
- \_ After the lecture, sandwiches and drinks will be served in the Foyer of the Auditorium

The presentation will be recorded and made available on the Balgrist Campus intranet for review.

Registration by e-mail to [info@balgristcampus.ch](mailto:info@balgristcampus.ch).