10th Symposium of the Swiss Clinical Trial Organisation

Medical devices: Lost in translation

8 June 2021, 10:15 a.m. – 2:30 p.m. Online event
New regulations on medical devices

Following a one-year delay and the transition period, the European Union’s new Medical Devices Regulation (MDR) will become fully applicable on 26 May 2021. For reasons of consistency, Switzerland’s revised and new legislation on medical devices will enter into force in stages as well. This legislation is intended to improve patient safety and ensure that Swiss manufacturers will continue to have access to the European market.

During our symposium, we will address many interesting aspects of this topic, including the following:

- **New requirements for medical devices**: From clinical development to certification and market access
- **Focus on Switzerland**: Where do we stand in clinical development? What is the regulatory framework in Switzerland?

We will also look at medical devices from three different perspectives:

- **Patient**: A case study of patient-driven medical device development
- **User**: User-centred design and artificial intelligence
- **Academic**: Unique challenges with medical devices in translational medicine

In addition, our **breakout sessions** during the lunch break will give participants the chance to learn more about topics specific to Switzerland, for example about **access to the Swiss market** or what **training** is needed and what training is currently available in Switzerland.

Speakers will emphasise practical examples and the application of these trends and developments in the daily work of clinical researchers.

→ Presentations and Discussions will be held in English.
10.00 Online login is open for participants

10.15 Welcome address and introduction
Prof. Dr Thomas Geiser, Director of Teaching and Research at Insel Gruppe AG
Prof. Dr Christiane Pauli-Magnus, President of the SCTO
Annette Magnin, Managing Director of the SCTO

Co-moderation of the symposium
Dr Simon Rothen, CEO at sitem-insel AG
Cordula Landgraf, Director of Communications and Stakeholder Engagement of the SCTO

10.30 Keynote lecture: Setting the scene
Overview of new requirements for medical devices: From clinical development to certification and market access
Bernhard Bichsel, Senior Consultant and Member of the Management Board at Integrated Scientific Services (ISS), Biel

11.00 Coffee break

11.15 Session 1: Focus on Switzerland
Questions around clinical development and the regulatory framework: Where do we stand in Switzerland?
Dr Ottilie Zelenko, Head of Division Medical Devices Clinical Investigations at Swissmedic, Bern

11.30 Q&A for keynote lecture and session 1
Bernhard Bichsel
Dr Ottilie Zelenko

12.00 Lunch break
During the lunch break, participants may join moderated breakout sessions.

Topics of breakout sessions:

1. **Training: What is needed and what is currently available?**
   Prof. Jürgen Burger, Director of the sitem school at sitem-insel AG, Bern

2. **Regulatory requirements and market access for medical devices: Why is Switzerland different from the EU?**
   Dr Daniel Delfosse, Head Regulatory Affairs at Swiss Medtech, Bern

3. **Submission to ethics committees: New processes and synchronisation**
   Dr Susanne Driessen, President, and Dr Pietro Gervasoni, General Manager, swissethics, Bern

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13.00 **Session 2: Complementary perspectives: Patients, users, and academia**

   Patient-driven (translational) medical device development: A case study
   Derek Brandt, Diabetes Center Berne

13.15 **User-centred design: A complementary perspective on medical devices and artificial intelligence**

   Dr Sibylle Peuker, User Experience Architect at Zeix, Zurich

13.30 **Medical device translational development: An academic success story**

   Prof. Stefan Weber, CEO at CASCINATION AG, Bern

13.45 **Q&A for session 2**

   Derek Brandt
   Dr Sibylle Peuker
   Prof. Stefan Weber

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14.15 **Closing remarks**

14.30 **End of symposium**
Registration

The SCTO Symposium is an online event.

Please register for the event by Wednesday, 2 June 2021, at www.scto.ch/symposium or by e-mail at event@scto.ch.

When you are registered, you will receive further information about online participation shortly before the event.

Registration fee

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<td>Free</td>
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Organisation

Swiss Clinical Trial Organisation
Effingerstrasse 35
3008 Bern
Switzerland
Phone +41 (0)31 307 10 40
event@scto.ch, www.scto.ch