



in collaboration with

siteminsel

SWISS MEDTECH

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UNIVERSITÄT
BERN

sitem-insel School – Symposium 2021

Date: Thursday, 27 May 2021, 13.30 - 18.10

Regulation of Medical Devices: From Innovation to Application

Agenda

- 13:30 – 13:40 **Welcome and introduction to MDRQ* study program, University of Bern**
Jürgen Burger, sitem-insel AG & University of Bern
- 13:40 – 13:50 **Increasing regulation and new technologies: Can SME and Startups even succeed?**
Beni Hirt, Decomplix
- 13:50 – 14:40 **Keynote lecture: Journey and lessons learnt by the first company to achieve a certification of their QMS system and product against the EU MDR**
Mike Wallenstein, Novartis Pharma AG
- 14:40 – 15:10 **MDR: Career prospects in the MedTech industry**
Elena Kyria, Elemed
- 15:10 – 15:40 Break
- 15:40 – 16:10 **Practical aspects of Medical Device Regulations and Approvals: a RnD and Radiology point of view**
Tobias Kober, Siemens Healthineers
- 16:10 – 17:10 **Round table discussion with impulse lecture**
Impulse lecture by Daniel Delfosse, Swiss Medtech:
“Regulatory uncertainties and their effect on the Swiss medtech industry”
Round table discussion lead by Daniel Delfosse, Swiss Medtech and
Elena Kyria, Elemed
Michael Maier, RAPS Switzerland
Beni Hirt, Decomplix
Mike Wallenstein, Novartis Pharma AG
Tobias Kober, Siemens Healthineers
Juergen Burger, sitem-insel AG & University of Bern
- 17:10 – 18:10 **Industry Based Learning in the MDRQ Study Program - Questions & Answers**

*MDRQ:

Medical Device Regulatory Affairs and Quality Assurance
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Please sign up by 25.05.2021 at
[Registration for the MDRQ Minisymposium 2021](#)