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

Please sign up by 25.05.2021 at
school@sitem.unibe.ch
Registration for the MDRQ Minisymposium 2021