EFFECTUM MEDICAL
YOUR START-UP TO MARKET

Introduction to Product Development and Regulatory Affairs

Goal:	The goal of this workshop is to give an overview of the regulatory landscape for medical devices in Europe (MDR/IVDR) and to touch upon different aspects for USA. You will get a good understanding of the product development process, as well as the requirements regarding technical documentation. The shared insights help you to early identify the key topics of your project to be successful mid and long-term.
Contents:	▪ The regulatory landscape for medical devices and software in Europe (MDR / IVDR) ▪ The need and options to set-up and use a quality management system ▪ Technical documentation according to MDR / IVDR ▪ Product development process and its milestones ▪ Early considerations for a successful project set-up, e.g. stakeholders, timelines and costs ▪ Overview regulatory landscape USA ▪ Experience from previous projects ▪ Q & A session
Who should attend:	Start-up Founder, Start-Up Team seeking advice on regulatory affairs (medical devices and medical software and in vitro diagnostics)
Time:	**Thursday October 15th, 2020 at 13:00 – 17:00.**
Location	In the offices of Effectum Medical, 4th floor, Solothurnerstrasse 235, 4600 Olten (Usego Areal). The valid protection provision for COVID-19 are implemented.
Price	Fee for **start-ups 200 CHF** (alternatively via Innosuisse voucher), all **others 300 CHF**. Number of participants is limited to four.
Register	Please register by sending an email to: **workshops@effectummedical.com** Please note that space is limited, priority is given to start-ups.
Speakers:	**Nila-Pia Rähle**

COO and Co-Founder of Effectum Medical, a legal manufacturer for medical devices offering an outsourced quality management system (QMS) solution. Nila has been working in medical devices for nearly 20 years, for both global players and start-ups. She has broad experience along the whole value chain with a key focus on project management, regulatory affairs and quality management.