



E F F E C T U M M E D I C A L  
YOUR START-UP TO MARKET

## Bringing your project to success while mastering the challenges of IVDR (in- vitro diagnostics)

**Goal:** The goal of this workshop is to give an overview of the regulatory landscape for in- vitro diagnostics medical devices in Europe (IVDR), the product development process, as well as the requirements regarding technical documentation. Within the IVDR-the workshop will focus on the development of medical devices and software.

- Contents:**
- The regulatory landscape for medical devices and software in Europe (IVDR)
  - The product development process and its milestones
  - Technical documentation according to IVDR 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)

**Time:** The same workshop will be held twice:

- **Thursday October 8th, 2020 at 14:00 – 16:00**
- **Monday December 7th, 2020 at 14:00 – 16:00**

**Location** Online Webinar

**Price** As we like to accelerate and support innovation in Switzerland this workshop is **free of charge for start-ups**. The fee for all other companies is 140 CHF.

**Register** Please register by sending an e-mail with the desired date to: **[workshops@effectummedical.com](mailto: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.