



We make
innovation
happen!

The Effectum Medical team owns **in-depth knowledge** and provides **daily hands-on support** for **regulatory affairs** and **quality management** of **medical devices**, **medical software** and **in-vitro diagnostic products**. Our team is delighted to serve you on your venture's journey!

Plug & Play (e)QMS Bootcamp October / November 2024

1. **Get to know our process experts** and take the opportunity to ask your questions to the (e)QMS Management and your journey from Technical Documentation until CE certification and Post Market Surveillance.
2. **Receive training** including a training certificate on Effectum's (e)QMS and get to know how the SOP's and templates work. This will greatly facilitate your path to certification.
3. **Get 6-months free access to Effectum's e-learning platform** to update your know-how when it is needed.
4. Join 6-months free our **monthly online lunch sessions** held by **Effectum's team members and key partners** to share best practices, trends and latest insights on relevant topics for your venture's journey.
5. **Enjoy interactive workshops** spread over four weeks and meet with like-minded medical device start-ups.



Contact us for prices. Register until September 23rd, 2024!

→ Qualio eQMS: Sign up until August 31st 2024 to ensure your eQMS is ready at the start of the Bootcamp!

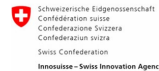
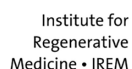
Early Bird discount until July 15th 2024

Join our Effectum eQMS workshop sessions which will be held hybrid (virtual and physical).

Topic	Dates 2024
Qualio eQMS Intro*	October 14, 14h00-16h00
QMS – General quality manual, management responsibilities, document management, human resources, training, internal audits, CSV etc.	October 16, 09h00-12h00
QMS: Design & Development - Part I design & development process / technical documentation (TD) / verification & validation; product classification, applicable regulatory requirements, software lifecycle process	October 21, 13h00-17h00
QMS: Design & Development - Part II risk management, clinical evaluation (MD) vs. performance evaluation (IVD)	October 23, 08h30-12h30
QMS: Design & Development - Part III usability engineering, labelling requirements/UDI, design review meetings, TD management, change management, TD submission EU/CH/USA & Launch Phase	October 28, 13h30-16h00
QMS: Supplier Management and Product Release supplier handling & control, quality agreements, purchasing, incoming inspection, production, storage, packing, process validation, product release	October 29, 08h30-12h00
QMS: Non-Conformities and PMS corrective and preventive actions, complaints, post market surveillance (PMS), vigilance	November 04, 13h00-16h00
Qualio eQMS Management*	November 06, 10h00-12h00

* Only for participants who use Effectum's **Plug & Play eQMS**.

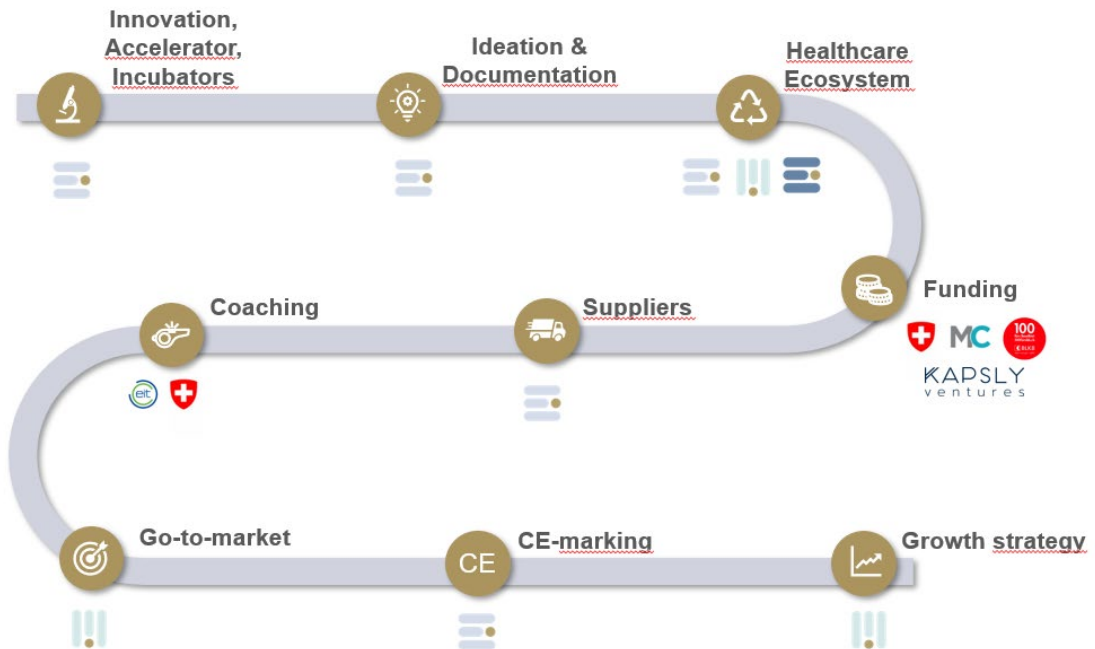
If you are part of one of the below programs, please reach out to us to learn more about or partnership offering.



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Benefit from our expertise and network along the entire value chain



EFFECTUM MEDICAL

Buy or lease a quality management system



Effectum CH-REP

Swiss Authorized Representative



MEDICALBOARD

Insight analysis, business coaching and interim management

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