EFFECTUM
MEDICAL

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 March / April 2025

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 access to 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 three weeks and meet with like-minded medical device start-ups.

Contact us for prices. Register until February 14th, 2025!

➔ Qualio eQMS: Sign up before January 31st 2025 to ensure your eQMS is ready at the start of the Bootcamp!

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

Topic	Dates 2025
Qualio eQMS Intro*	March 26, 10h00-12h00
QMS – General quality manual, management responsibilities, document management, human resources, training, internal audits, CSV etc.	March 26, 13h00-16h00
QMS: Design & Development - Part I design & development process / technical documentation (TD) / verification & validation; product classification, applicable regulatory requirements, software lifecycle process	March 27, 13h00-17h00
QMS: Design & Development - Part II risk management, clinical evaluation (MD) vs. performance evaluation (IVD)	March 31, 13h00-17h00
QMS: Design & Development - Part III usability engineering, labelling requirements/UDI, design review meetings, TD management, change management, TD submission EU/CH/USA & Launch Phase	April 03, 09h00-12h00
QMS: Supplier Management and Product Release supplier handling & control, quality agreements, purchasing, incoming inspection, production, storage, packing, process validation, product release	April 09, 08h30-12h00
QMS: Non-Conformities and PMS corrective and preventive actions, complaints, post market surveillance (PMS), vigilance	April 11, 09h00-12h00
Qualio eQMS Management*	April 11, 13h00-15h00

* 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.

healthtechpark · Institute for Regenerative Medicine • IREM · SitenStartUp Club · Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra Swiss Confederation Innosuisse – Swiss Innovation Agency · Swiss Healthcare Startups · USZ Health Innovation Hub

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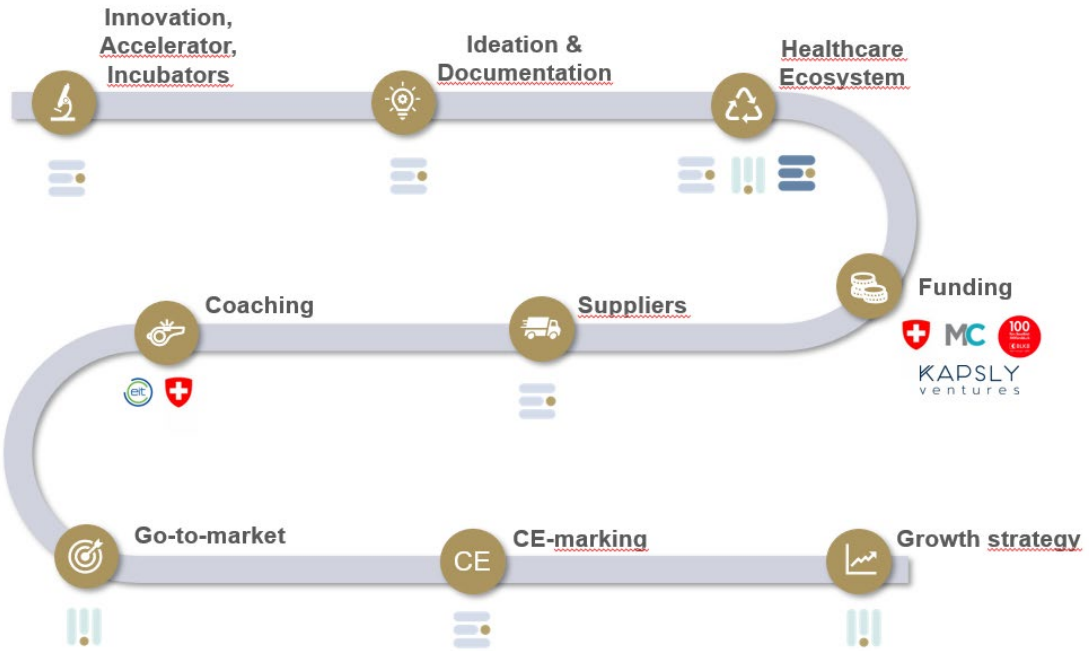
Benefit from our expertise and network along the entire value chain



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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