



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**. In addition, the company unites MedTech business and management experience and provides access to a unique network of experts along the entire value chain.

Our team is delighted to serve you on your venture's journey!

Plug & Play (e)QMS Bootcamp October/November 2023

1. **Get to know our comprehensive team of medical device experts who accompanies our customers on a daily basis** through their journey from Technical Documentation until CE certification and Post Market Surveillance.
2. **Experience all details** about Effectum's Quality Management System (QMS) - SOP's and templates are actively maintained, yearly audited and meet MDR, IVDR and FDA requirements.
3. **Get 1-year free access to Effectum's e-learning platform** to update your know-how when it is needed.
4. Join afterwards 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 short interactive workshops** spread over four weeks and meet with like-minded medical device start-ups.

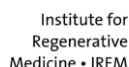
[Contact us](#) for prices. Secure your early-bird ticket until August 15, 2023!

Join our modular concept of six fixed and four optional sessions which will be held hybrid (virtual and physical).

Topic	Dates 2023
Qualio eQMS Intro*	Oct 20, 9 – 12 am
Regulatory Strategy & Product classification** Individual workshop	On demand
QMS – General quality manual, management responsibilities, document management, human resources, training, internal audits, CSV etc.	Oct 31, 8 – 12 am
QMS: Design & Development - Part I design & development process / technical documentation; SW lifecycle process	Nov 2, 8 – 12 am
QMS: Design & Development - Part II risk management and usability engineering, Clinical Evaluation (MD) vs. Performance Evaluation (IVD), Statistical Methods	Nov 7, 8 – 12 am
Biocompatibility & Sterile Products**	Nov 8, 11 – 12 am
QMS: Supplier Management and Product Release supplier handling & audits, quality agreements, purchasing, incoming inspection, production, storage, packing, process validation etc.	Nov 10, 8 – 12 am
QMS: Labelling & Launch preparation Labelling, marketing, sales, distributor management, product submission EU/CH/USA	Nov 13, 9 – 12 am
QMS: Non-Conformities and PMS corrective and preventive actions complaints, post market surveillance, vigilance, change management	Nov 20, 8 – 12 am
Qualio eQMS Management*	Nov 21, 9 – 12 am

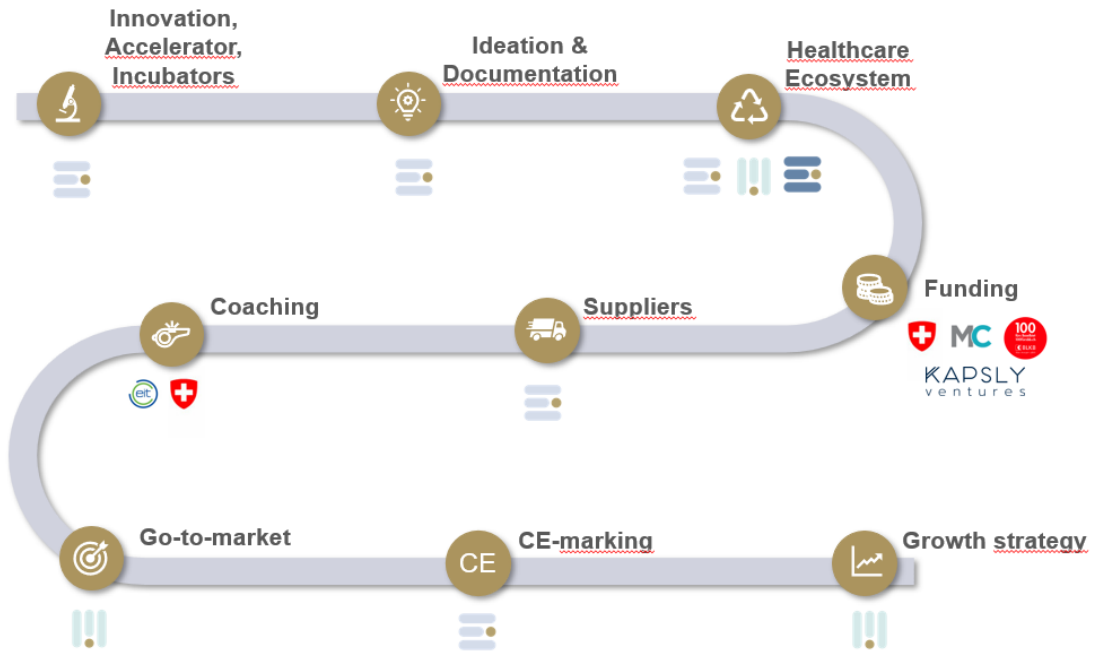
* Only for participants who use Effectum's **Plug & Play eQMS**. / ** Optional sessions. Need to be booked and paid separately.

If you are part of one of these 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 rent a quality management system



Effectum CH-REP

Swiss Authorized Representative



MEDICALBOARD

Insight analysis, business coaching and interim management

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