



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 are actively maintained, audited and meet MDR, IVDR and FDA requirements.
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!**

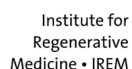
→ Qualio eQMS: Sign up until August 31<sup>st</sup> 2024 to ensure your eQMS is ready at the start of the Bootcamp!

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

Topic	Dates 2024
<b>Qualio eQMS Intro*</b>	October 14, 14h00-16h00
<b>QMS – General</b> quality manual, management responsibilities, document management, human resources, training, internal audits, CSV etc.	October 16, 09h00-12h00
<b>QMS: Design &amp; Development - Part I</b> design & development process / technical documentation; SW lifecycle process	October 21, 13h00-16h00
<b>QMS: Design &amp; Development - Part II</b> risk management and usability engineering, Clinical Evaluation (MD) vs. Performance Evaluation (IVD), Statistical Methods	October 23, 09h00-12h00
<b>QMS: Supplier Management and Product Release</b> supplier handling & audits, quality agreements, purchasing, incoming inspection, production, storage, packing, process validation etc.	October 28, 13h00-16h00
<b>QMS: Labelling &amp; Launch preparation</b> Labelling, marketing, sales, distributor management, product submission EU/CH/USA	October 29, 09h00-12h00
<b>QMS: Non-Conformities and PMS</b> corrective and preventive actions complaints, post market surveillance, vigilance, change management	November 04, 13h00-16h00
<b>Qualio eQMS Management*</b>	November 06, 10h00-12h00

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

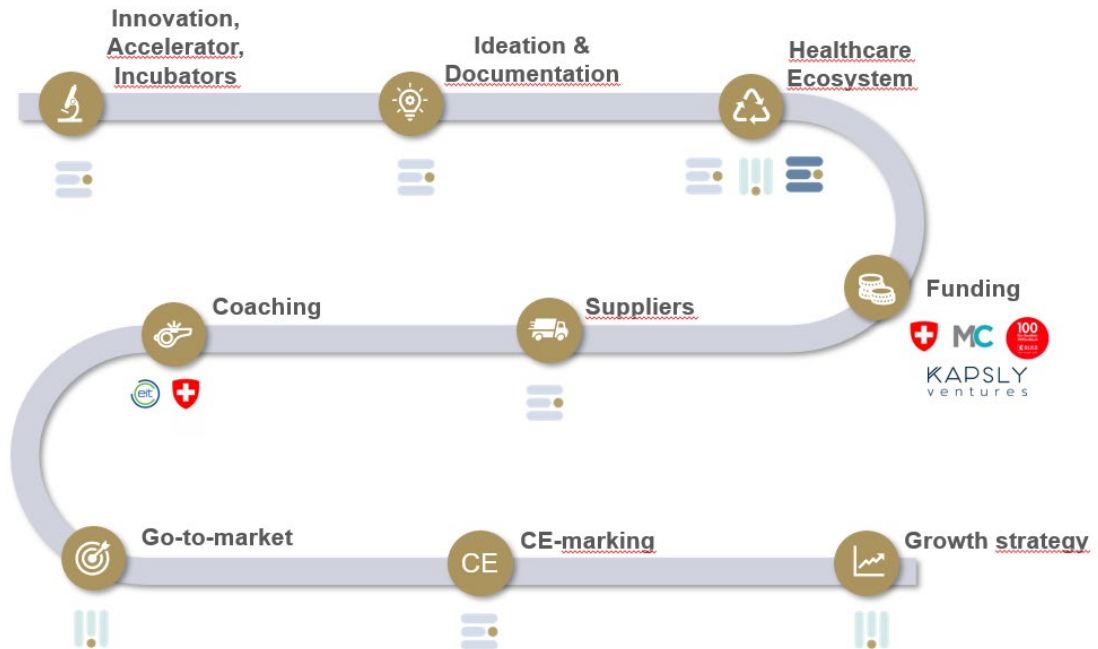
If you are part of one of the below programs, please reach out to us to learn more about or partnership offering.



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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

For more information contact:



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