Effectum Medical AG

assists in the development of innovative medical devices and technologies throughout the certification and life cycle management process. Acting as legal manufacturer and by offering our Plug & Play (e)QMS, we speed up your time to market and ensure compliance and excellence in every stage of development.

EFFECTUM
MEDICAL

PLUG & PLAY (e)QMS BOOTCAMP

OVERVIEW ALL SERVICES

PLUG & PLAY (e)QMS BOOTCAMP OVERVIEW

Plug and Play (e)QMS Bootcamp

Enhance your (e)QMS management and technical documentation skills with our Plug & Play (e)QMS Bootcamp. Choose between our hybrid Spring 2025 Bootcamp or the self-study option for flexible learning at your own pace. Our Bootcamp is ideal for companies using or planning to purchase our Plug & Play (eQMS) SOP Packages.

Self-Study Bootcamp Includes:

- **Self-Study Modules:** Five detailed modules to build your QMS expertise.
- **1-on-1 Q&A Sessions:** Schedule an hour with an expert after each module.
- **12 Months Free Access:** Revisit content anytime with access to Effectum's e-Learning platform and additional training videos.

Spring 2025 Hybrid Bootcamp Includes:

- **Expert-Led Modules:** Six workshops (2-4 hours each) over three weeks.
- **Flexible Participation:** Join workshops on-site or remotely and network with other companies.
- **Six Months Free Access** to additional training materials.

Earn a certificate upon completion. Connect, learn, and grow with Effectum's Plug & Play (e)QMS Bootcamp!

Camilla Messerli
Head Quality Management & Regulatory Affairs
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PLUG & PLAY (e)QMS BOOTCAMP SPRING 2025

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. Enjoy 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. **Join interactive workshops over three weeks,** connecting with like-minded medical device start-ups. Attend on-site at Effectum Medical in Olten, Switzerland, or remotely.

This Bootcamp is designed for companies having purchased our QMS SOP package.

Sign up for Qualio eQMS by January 31st, 2025 to be ready for the Bootcamp!

If you are part of one of our parntner programs, please reach out to us to learn more about or partnership offering. (Our partner:www.effectummedical.com/partners/)

☀ **Early Bird Discount!** ☀

Register by December 31st, 2024, and save with our exclusive offer! **Contact Us for Pricing!**

PLUG & PLAY (e)QMS BOOTCAMP
SPRING 2025 TRAINING SCHEDULE

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

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

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SELF-STUDY
PLUG & PLAY (e)QMS BOOTCAMP

Join Our Self-Study Plug and Play QMS Bootcamp!

1. Learn at your own pace and dive into the various aspects of (e)QMS management. Our Bootcamp consists of five comprehensive modules, each designed to enhance your understanding and skills in quality management systems.
2. After completing each module, you can schedule a 1h Q&A session with the respective expert to clarify any questions and deepen your insights.
3. Enjoy **twelve months of free access to Effectum's e-Learning platform**, allowing you to update your knowledge whenever needed and allowing you to access some other videos, not directly part of the Bootcamp.
4. Additionally, participate for six months in our **monthly online lunch sessions** hosted by Effectum team members and key partners. These sessions are a great opportunity to exchange best practices, trends, and the latest insights on relevant topics for your business.
5. Upon completion of the Bootcamp, you will receive a **certificate and course confirmation to showcase** your achievement.

Unlock your potential in quality management with us—enroll today!

This Bootcamp is designed for companies having purchased our QMS SOP package.

Price (excl documents): 2000.- CHF per user, every additional user of your company gets a 50% discount if they sign up at the same time and the Q&A sessions are performed together!

SELF-STUDY PLUG & PLAY (e)QMS BOOTCAMP TRAINING SCHEDULE

Description	SOPs covered
QMS – General - Elevate Your Quality Management System The workshop discover the importance of a QMS and its regulatory framework. You'll learn about: ▪ **QMS Basics**: Overview of the QMS setup and its significance. ▪ **SOP Training**: Essential SOPs on management responsibilities, document management, and more. ▪ **HR Insights**: Key aspects of employee training and qualifications. ▪ **Audit Overview**: Understanding the audit process for compliance. ▪ **CSV Requirements**: Essential practices for computer system validation. ***Expert: Camilla Messerli***	• Quality Manual (QM) • SOP-4 Management • SOP-5 Human Resources • SOP-19 Document & Records • SOP-23 Audits • SOP-27 Computer System Validation (CSV)
QMS: Design & Development Process Learn about the Design & Development process, including software projects. We will cover: ▪ **Milestones**: Key stages in the development cycle. ▪ **Hot Topics**: Most important parts of each processes ▪ **Review Meetings**: Their importance for project success. ▪ **Risk Management:** Learn the key concepts of risk management ▪ **Design Engineering:** Discover how design engineering is performed effectively ▪ **Change Control**: Learn how to control the design and the important steps thereof We'll also connect this process to usability engineering and risk management, which will be reviewed in the second workshop. ***Expert: Rolf Kaufmann / Séverine Cranz***	• SOP-2 Performance Evaluation (IVD) • SOP-6 Clinical Evaluation (MD) • SOP-8 Design and Development process • SOP-13 Product Sales • SOP-14 Software Lifecycle Management • SOP15 Biocompatibility • SOP-21 Risk management • SOP-22 Change Control • SOP-25 Labelling • SOP-26 Usability engineering • SOP-29 Statistical Methods
QMS: Supplier Management and Product Release This workshop provides essential training on the processes involved in Supplier Management and Product Release. Participants will learn about: ▪ **Individual Processes**: An overview of the key processes in supplier management and product release. ▪ **Template Usage**: Explanation of how and when to use relevant templates to streamline these processes. ***Expert: Judith Oriwal / Marius Wiederkehr***	• SOP-9 Purchasing • SOP-10 Production • SOP-11 Incoming Inspection and Quality Inspection • SOP-12 Storage & Transport • SOP-16 Process Validation • SOP-17 Processing and Sterile Packaging SOP-20 Infrastructure • SOP-24 Supplier Management a general introduction to QAA
QMS: Non-Conformities and Post-Market Surveillance (PMS) This workshop provides essential training on Non-Conformities and Post-Market Surveillance processes. Participants will learn about: ▪ **Key Processes**: Overview of non-conformities, complaints, vigilance and PMS. ▪ **Template Usage**: Guidance on relevant templates. ***Expert: Camilla Messerli***	• SOP-1 CAPA, • SOP-3 Complaints & Vigilance, • SOP-7 Post-Market Surveillance

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SUPPORT OPTION

Outsourced Legal Manufacturer:
Streamline market access and compliance with our trusted legal manufacturer services. Need speed? Ask about our fast-track option!

Plug & Play (e)QMS:
Accelerate your launch with a ready-made EN ISO 13485, MDR/IVDR, and FDA-compliant quality management system.

Plug-and-Play eQMS Bootcamp:
Flexible training to empower self-management of your QMS.

Rent an Expert:
Add quality management and regulatory expertise to your team as needed.

Regulatory Opinions:
Access expert insights for global compliance and market strategy.

AI/ML Device Certification:
Certification services for AI and machine learning-based medical devices.

CH-REP (Swiss Authorized Representative):
Facilitate Swiss market access with local representation. Visit Effectum CH-REP AG for details.

For more information visit: www.effectummedical.com

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