



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.



E F F E C T U M
M E D I C A L

PLUG & PLAY (e)QMS



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THE PLUG & PLAY (e)QMS



Purchase and configure your own (electronic) Quality Management System

Our system is:

- **Compliant** with ISO 13485, MDD/MDR, IVDD/IVDR, and FDA, Japanese and Australian regulatory requirements
- Includes 1 Quality Manual, **28 SOPs and over 150 templates.**

Combine our Plug & Play (e)QMS with Bootcamp and support packages for extra guidance. We can assist your teams with various topics such as **QMS configuration & setup, supplier audits, PRRC services, and technical documentation.**

Contact us to learn more!



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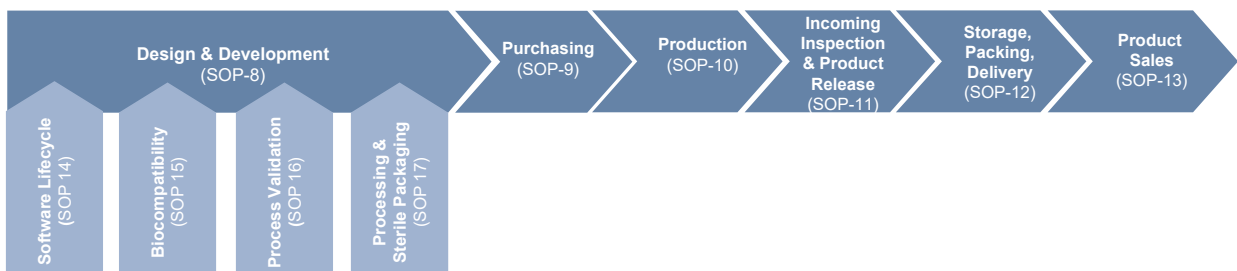


OVERVIEW OF OUR PROCESS AND SOP'S

Management Processes



Core Processes



Support Processes



This overview includes all our SOPs, part of an ISO 13485, MDR, IVDR, and FDA-compliant system that has passed over 15 audits. Our team updates these SOPs daily to meet the latest requirements.

Access Options: Available as an e-QMS via Qualio or accessible as documents on SharePoint



QUALIO – CLOUD-BASED QMS

Cloud-Based Quality Management Software

Easily integrate our QMS with ready-made SOPs and templates directly into your Qualio account.

Includes essential tools:

Design Control:
Simplify development.

Training:
Manage and track employee training.

Events:
Centralize complaints and non-conformities.

Supplier Management:
Organize supplier relationships.

Centralized document:
Creation, management and release.



Find out more about Qualio: <https://www.qualio.com/>

ID	Hazard	Hazardous Situation
RSK-14	Mechanical, Interfacing...	Crack in the tubing causing loss of damage
RSK-1	Mechanical, Interfacing...	Crack in the tubing causing loss of dosage
RSK-2	Mechanical, Electrical	Over-administration >5% over target
RSK-3	Mechanical, Electrical	Under-administration >5% under target
RSK-4	Mechanical	Patient may not be able to receive therapy
RSK-5	Cybersecurity, Electrical	Unintended parties access PHI
RSK-6	Electrical	User received electrostatic shock

Benefits: Clean document storage, automatic version history, and significant time savings.
By obtaining your Qualio license via Effectum, you will benefit from exclusive partner pricing.
Get a complete, flexible quality management solution – all in the cloud!



PLUG & PLAY QMS SUCCESS: CLIENT TESTIMONIALS

Here's what one of our clients has to say about their experience with Effectum Medical's Plug & Play QMS

„Effectum Medical's Plug & Play QMS was a great solution for us, offering a robust, time-saving foundation for implementing our own quality management system. The documentation is comprehensive, covering MDR and FDA requirements thoroughly.

Their Qualio-based QMS has a lot of advantages over paper-based systems. We extensively use the integration with JIRA; setting this up took some time, but once in place, it's very efficient. Effectum's team had also already handled the computer system validation, making our implementation faster and smoother. We would definitely recommend it to others.“

Lyle Halliday, Entrepreneur, Evoleen AG



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SUPPORT OPTIONS



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.

For more information visit:

www.effectummedical.com



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