



## Get Audit-Ready with a Pre-Built, on-demand Cloud-based (e)QMS

Effectum's Plug & Play QMS delivers an ISO 13485 / MDR / IVDR / FDA-compliant system with ready-to-use SOPs, templates, and software integration. It enables easy customization for the optimal fit for your company's needs.



**EFFECTUM**  
MEDICAL

# PLUG & PLAY QMS



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## PLUG & PLAY QMS

We provide a complete Quality Management System — instantly deployable and aligned with regulatory frameworks in the EU, US, Japan, and Australia. Choose between Qualio-based eQMS or SharePoint access. It enables easy customization for the optimal fit to your company needs. We can also assist you during your customization and even for the training and management of your own QMS.

### Key Services

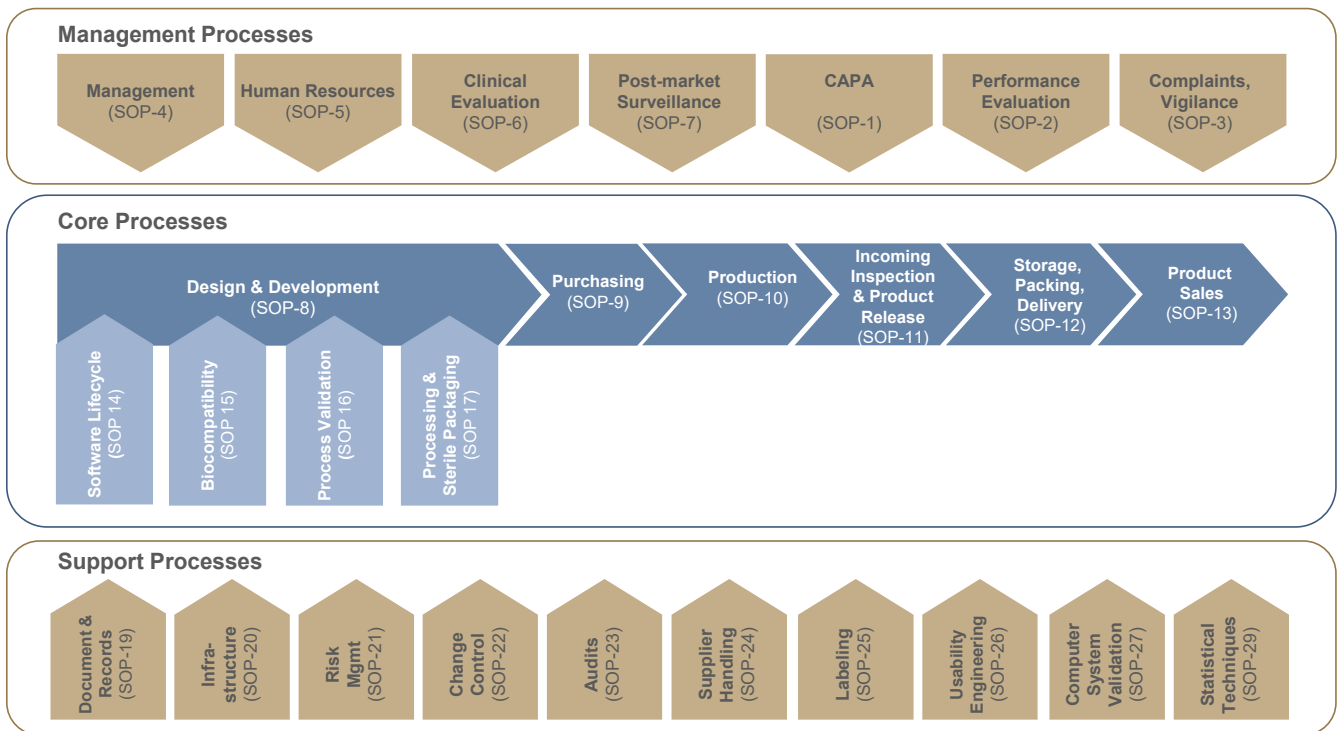
- Compliant: ISO 13485, MDR, IVDR, FDA, Japanese & Australian standards
- Audit-proven: Passed 15+ inspections
- Configurable: Use in Qualio or document-based. Also implementable in any other eQMS software tool.
- Efficient: Saves time and avoids setup delays
- Exclusive Qualio pricing: Via Effectum's Qualio partnership

### When to Choose This Service

- On-demand customization
- On-demand training
- QMS Management (incl. audits etc...)
- Documentation reviews
- PRRC / QMR services



# OVERVIEW OF OUR PROCESS AND SOP'S



This overview includes all our SOPs, part of an ISO 13485, MDR, IVDR, and FDA-compliant system that is subject to several notified body and customer audits every year. 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:

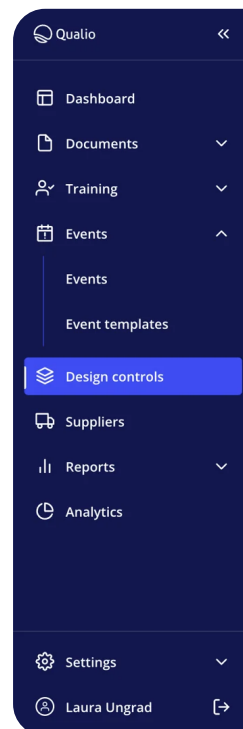
**Design Control:**  
Simplify development.

**Training:**  
Manage and track employee training.

**Events:**  
Centralize complaints and non-conformities.

**Supplier Management:**  
Organize supplier relationships.

**Centralized document:**  
Creation, management and release.



← Tertiary Infusion Smart Pump			
Open Issues	Dashboard	Requirements	Risks
ISO 14971	FMEA		
ID ^	Hazard	Hazardous Situation	
RK-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	

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

**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!



## WHAT CUSTOMERS SAY



Dr. Anjali Raja Beharelle, Co-Founder Collabree

*„We chose Effectum Medical's Plug & Play QMS because of the minimal configuration required - we simply needed to implement it. The ready-to-use documentation provided a solid foundation, which significantly accelerated our setup. It's comprehensive and saves a lot of time.“*

*„In general, the QMS documents offer excellent guidance and reflect best practices across the board. The system validation was already completed by Effectum, which saved us a lot of time and effort.“*



Gregegorz Wielgoszewski, Senior R&D Engineer, Resistell

*„We benefited from all the experience that Effectum Medical had in complying with standards and other regulations, starting from.*

*„As a result of the partnership with Effectum Medical we had access to industry-level expertise in quality management and we could acquire this knowledge from professionals.“*



## OUR SERVICES IN A NUTSHELL

### **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.

### **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.

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