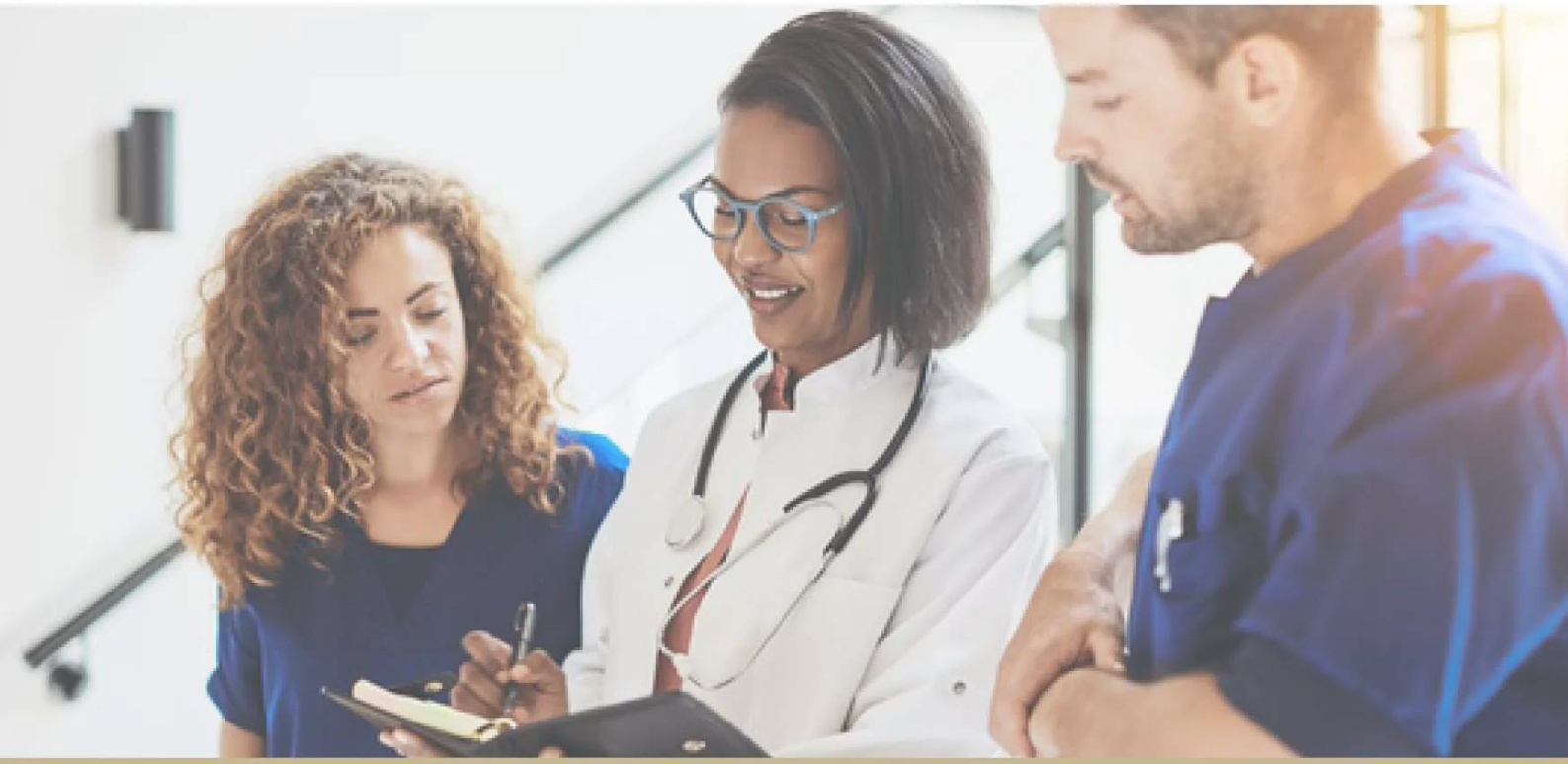
EFFECTUM MEDICAL

YOUR START-UP TO MARKET



We make innovation happen!

Our Plug-and-Play QMS

Service Overview

05-12-2022

Our Plug-and-Play QMS

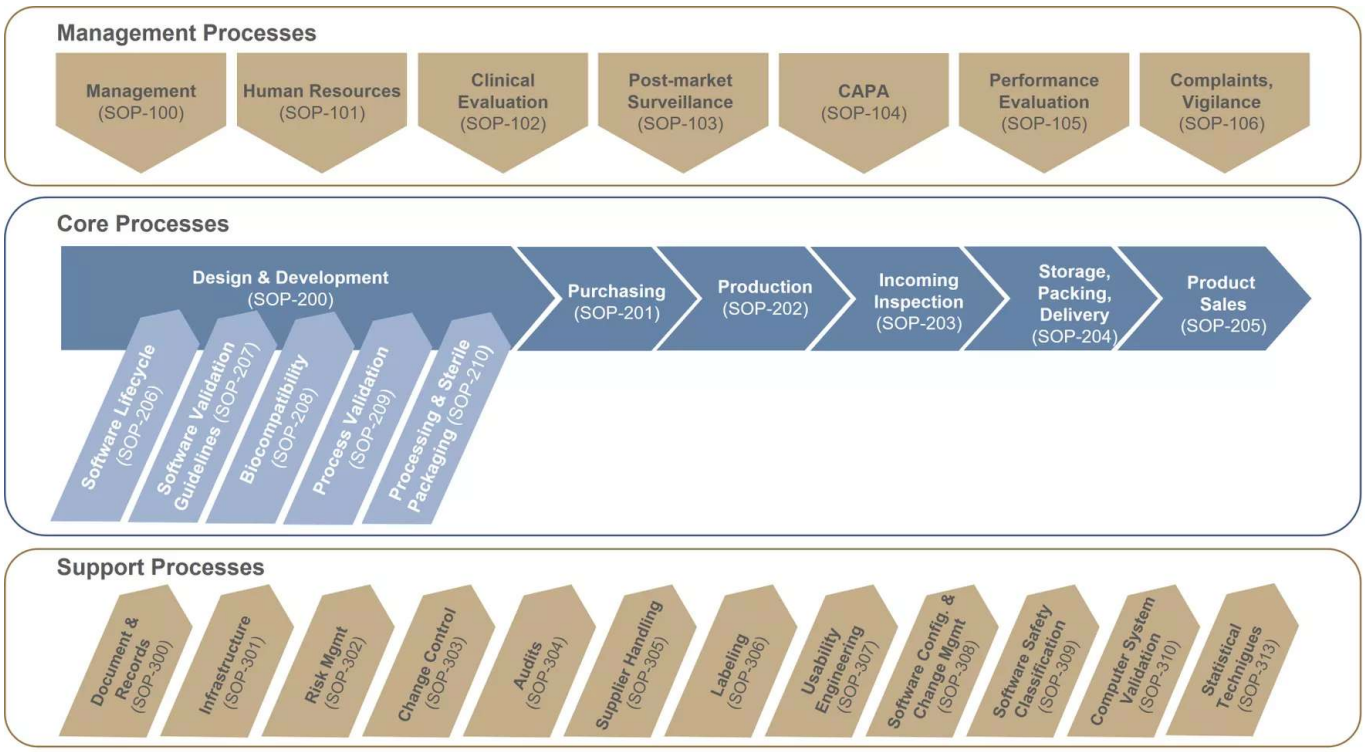
We offer an actively applied and maintained and certified Quality Management System. Our QMS covers more than "just" ISO 13485: **we offer a QMS according to ISO 13485, MDD/MDR, IVDD/IVDR and FDA standards**, with > **40 norms implemented** (see "Appendix: List of Norms considered in our QMS"). The **Plug-and-Play QMS packages include 30 Standard Operating Procedures (SOP's) and 150 templates**.

What makes the quality standard of our QMS unique, is that we are ourselves using the same framework for our legal manufacturer services and it's being applied daily for medical devices, medical software and IVD products. We are continuously enhancing it to ensure optimal workflows and it is regularly audited by notified bodies and customers. Thus, you can trust that **our QMS is up to date at all times** and that we provide a **state-of-the art solution**.

Once you decide for our plug-and-play QMS you can **start working with the QMS** and preparing documents **within a few days** rather than spending several weeks or even months with establishing a QMS from scratch. This saves not only costs, but also shortens your time to market

We accompany you throughout your journey to obtain your own company certification – be it ISO 13485, MDR or IVDR certification – and give you a hand with establishing the technical documentation for product certification.

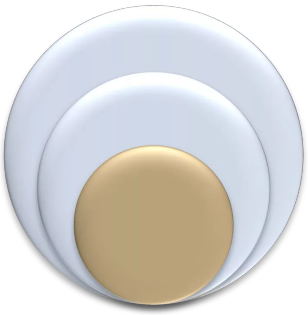
Our process landscape & scope of QMS



From Full Fledged eQMS to basic QMS - You Choose Depending on Your Needs

Depending on your personal needs you can choose from our QMS options ranging from a full-fledged eQMS to a basic version limited to the minimum required to prepare the technical documentation for product certification or to obtain company certification according to ISO 13485 and MDR or IVDR.

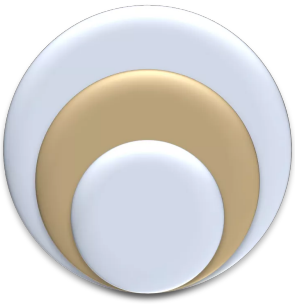
You can choose the QMS scope depending on your preference:



QMS Technical Documentation

Our "QMS Technical Documentation" covers all SOPs and templates required to

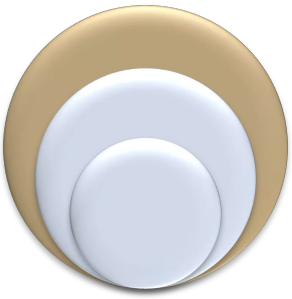
- prepare a compliant technical documentation and
- get your product certified according to the MDR or IVDR



QMS All - Basic

Our "QMS All - Basic" is a full QMS, but limited to the minimum required. It covers all SOPs and templates required to

- prepare a compliant technical documentation
- get your product certified according to the MDR or IVDR
- obtain company certification according to ISO 13485 and MDR or IVDR
- Maintain product certification after product launch
- note: only available as SharePoint version



QMS All

Our "QMS All" covers all SOPs and templates required to

- prepare a compliant technical documentation
- get your product certified according to the MDR or IVDR
- obtain company certification according to ISO 13485 and MDR or IVDR
- Maintain product certification after product launch

Benefits of working with an eQMS

With our SharePoint based QMS you get access to the SOPs and templates as editable documents (MS Word, Excel, etc.). You can then transfer the documents to your proprietary SharePoint or whatever system you are using. If you would like to benefit of working with **digitalized work streams** for document management, managing quality events, and training management and **save time and costs**, you can opt for our Qualio based eQMS.

There are numerous benefits of working with an eQMS

Cost Savings

Cost **savings** are estimated to sum **up to 40'000 € per year** ccording to an ROI study for implementing an eQMS in an SME with 10-50 empolyees with an average salary of 50'000 €, ("The return on investment of an electronic quality management system (eQMS)" by Qualio, 2022).

100% of the cost and effort of maintaining your system is carried by the cloud vendor. ("Why cloud-powered quality management is the future" by Qualio)

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Increased security

Cloud-based software systems run on their own servers maintained and hosted by the vendor, not you. And any reputable vendor with a functioning QMS of their own will be entirely dedicated to keeping that system secure and bug-free at all times. Small problems and weaknesses therefore don't get the chance to snowball and threaten your information security as they would in an in-house system. Furthermore, physically separate data centers eliminate the risk of disaster and disruption. ("Why cloud-powered quality management is the future" by Qualio)

Higher compliance

Here some facts underlining the increase compliance with an eQMS:

- 7.5% of paper documents get lost and 3% get misfiled every year
- The average document gets copied 19 times, with each copy reducing data accuracy and integrity
- Hard documents and uncontrolled Dropbox and email documents are up to 5 times more likely to be lost or stolen than documents in a controlled digital repository

Scalability

The scalability and agility of cloud systems ensures your QMS is flexible and malleable enough to keep pace with your organization and help it grow, from seed stage to full-on market expansion. Cloud systems can be quickly shaped, updated and integrated with your other business tools and adding new users, roles and responsibilities takes a matter of minutes. ("Why cloud-powered quality management is the future" by Qualio)er.

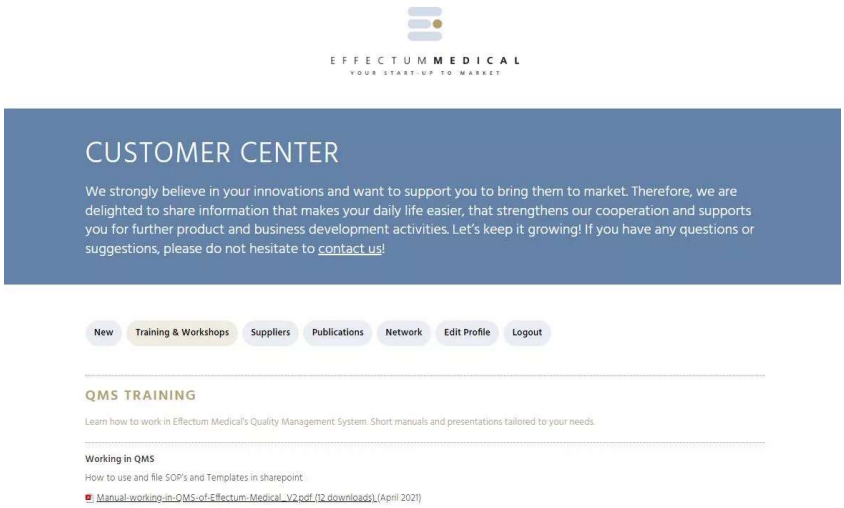
By choosing our Qualio-based eQMS you also can benefit of access to **extensive training material** such as playbooks and checklists to prepare for an ISO 13485 audit.

A modular concept - pick and choose required services

Our **QMS is modular**, meaning that you can pick and chose the services that you require. We offer various optional packages that you can select from:

Maintenance up-date & customer center

- You can book this service additionally to the Plug-and-Play QMS, if you would like to **receive regular up-dates on the changes, amendments, and additions that we make to our QMS**
- We also **update** and provide you our **regulatory and normative requirements list** annually.
- Further, you receive **access to our customers center** which is your access point to our own ecosystem and network within the Medical Device Industry, across Europe. You find basic **training information, useful tips & tricks that goes beyond our QMS and gives you access to key contacts and partners, e.g. suppliers, clinical studies and much more.**



Support package covering additional/further support as needed

- **Individual coaching / guidance** through the product development process, **Q&A sessions**
- **Review of documents** - technical documentation
- Adaptation of QMS to your specific needs - **Customization of QMS & adaptation of SOPs and templates**
- **PRRC - training** throughout a year on the topic of PRRC after which you can act as PRRC yourself

Computer System Validation & Supplier Qualification

- In order to get your company certification, you have to validate your own instance. We establish a **plan** for the required **computer system validation**, perform all necessary **testing** and provide you with a **report**.
- Furthermore, you have to **qualify Qualio as a supplier**. We perform the qualification for you and provide you with all necessary documentation.

Contractual Framework

- Receive a **set of contract templates** in line with your QMS to es**tablish your contractual framework with your suppliers and partners**. Select the full set or choose individual templates.
- The set includes a **Quality Assurance Agreement (QAA)** and **Purchasing Agreement**.,
- The contract templates have been reviewed by our legal advisors. However, we do not provide any legal advice by making the templates available.

Training Platform (coming soon)

Not sure how to fill-in the intended use statement or the risk management file? You would like to qualify a new supplier and do not know where to start?

- Our library with **presentations and videos on quality management, regulatory affairs, technical documentation, clinical affairs, and supplier management can support** you with training yourself and your team and bring everybody up-to speed.
- **On-demand**: You can watch the trainings when it suits you best and/or when you are about to fill the templates.
- If you have questions after a training session, we are happy to answer them in a **1:1 Q&A session**.

If you want to be part of the pilot project of our training platform, you can sign-up and can profit of our **reduced pilot fee**.

Overview of our Plug & Play QMS Service Offering

Package	mandatory	optional	coming soon	SharePoint			eQMS	
				TD	All	All Basic	TD	all
Set of SOPs & Templates	✓	▪	▪	✓	✓	✓	✓	✓
Qualio software licenses	✓	▪	▪	n/a	n/a	n/a	✓	✓
Onboarding/setup Qualio	✓	▪	▪	n/a	n/a	n/a	✓	✓
Onboarding/setup Effectum Medical	✓	▪	▪	n/a	n/a	n/a	✓	✓
Computer System Validation & Supplier Qualification	✓	▪	▪	✓	✓	✓	✓	✓
Set of contract templates: QAA & Purchasing Agreement	▪	✓	▪	✓	✓	✓	✓	✓
Support packages: 10, 20, 40, 80 hours	▪	✓	▪	✓	✓	✓	✓	✓
Maintenance & up-dates & Customer Customer Center	▪	✓	▪	✓	✓	✓	✓	✓
Customer center	▪	✓	▪	✓	✓	✓	✓	✓
MDSAP	▪	▪	☐	☐	☐	☐	☐	☐
Company tool-box	▪	▪	☐	☐	☐	☐	☐	☐
Electronic signature expansion	▪	▪	☐	☐	☐	☐	n/a	n/a
Training plattform	▪	▪	☐	☐	☐	☐	☐	☐

Our proven process

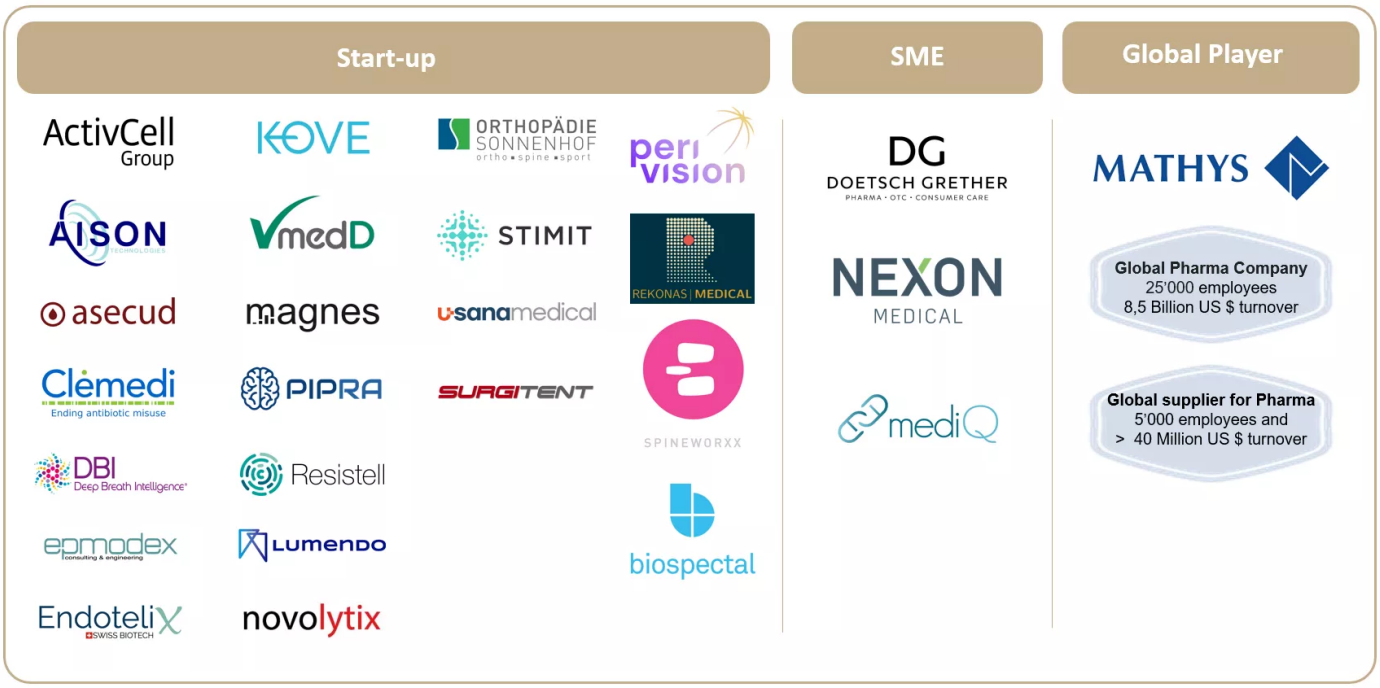
Once you have decided for our Plug-and-Play QMS, we initiate your on-boarding starting off with an Introductory training to gain an understanding of the elements and aspects of a QMS according to ISO 13485, MDR and IVDR standards and how to work with such a QMS. You can **start working with the QMS and preparing documents within only a few days**.

With access to our SOP's and templates you can get started, running through **our proven process**:

Implementïon of Plug-and-Play QMS at Company	Establishment of Technical Documentation	Review and approval by the Company	Certification of the Company	CE certification of the product	Post-CE phase
Optional training on QMS and support for implementation by Effectum Medical	The project team works on the technical documentation as part of the development process. *Optional support by Effectum Medical*	At the end of a project phase, review of documentation is closed after a review meeting to enter the next project phase. *Optional review by Effectum Medical*	Company certification is optional for MDR Class I and IVDR Class A products only	The final technical documentation is submitted to the Notified Body of the Company for approval	Product sales, post market surveillance activities, market feedback, product changes, supply chain management by Company. *Optional QMS maintenance update by Effectum Medical*

We serve from start-ups to global players

Not only Startups, but also R&D, Regulatory Affairs and Quality Management teams of established MedTech companies can count on us as an external service provider.



What our customers say

"We started to work on quality management at a very early stage of the company development. Thanks to the collaboration with Effectum Medical we could address the quality aspects, which were important at the time, without extensive investment in QM. 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.

We benefited from all the experience that Effectum Medical had in complying with standards and other regulations, starting from trainings and advice, and ending with professional document structure and templates. We could truly focus on the validation of the core technology."

GRZEGORZ WIELGOSZEWSKI,
SENIOR R&D ENGINEER RESISTELL

"Effectum Medical offered us the one-stop-solution we were seeking for. We could immediately start working in their quality management systems and benefit, at the same time, from their broad experience and great know-how. It is the combination of QM infrastructure and advisory capacity what makes them unique.

We have chosen Effectum Medical as Legal Manufacturer because we liked the approach to share risk, simplify processes, reduce time-to-market by increasing efficiency. When challenges arise, the team is very solution-oriented and shows a pragmatic approach. Overall, it is a very satisfying collaboration for us, and we have not been disappointed."

EMANUELA PUFE,
HEAD OF MEDIQ (PDAG)

"Thanks for your help getting us started! It was extremely valuable. Now we are becoming more and more independent! Please do not take it personally that we are now breaking away...it only proves that your program works and that you generate strong value & impact."

RONJA BRUHN,
CEO & CO-FOUNDER OF STIMIT AG

Effectum Medical offers outsourced QMS & Legal Manufacturing

Healthcare innovation is in the heart of our co-founders' DNA and our vision is to bridge the gap between idea and implementation by offering an **outsourced quality management system (QMS)** and acting as **legal manufacturer**.

The Effectum Medical team unites hands-on MedTech business and management experience with in-depth knowledge of regulatory affairs and quality management for medical devices, medical software and in-vitro diagnostic products. In addition, we provide access to a unique network of experts along the entire value chain.

Not only Startups, but also R&D, Regulatory Affairs and Quality Management teams of established MedTech Companies can count on us as an external service provider.

Through Effectum CH-REP, a company of Effectum Medical, we give companies domiciled outside of Switzerland access to the Swiss market by acting as their Swiss Authorized representative.

More than ISO 13485

Our skin in the game

Trust in a system that

- is compliant with ISO 13485, MDD/MDR, IVDD/ IVDR and FDA standards
- covers more than 40 norms
- has a modular concept with 30 Standard Operating Procedures (SOP's) and 150 templates
- is enriched with individual service packages
- has withstood 9 Notified Body audits in the last five years

We share the risk because we

- are responsible for Post Market Surveillance, Vigilance & Complaint Handling
- take care of supplier validation and audits
- handle the operations part from production until delivery to warehouse
- keep all documentation needed to maintain product certification up to date

Our promise

- A QMS applied daily for medical devices, medical software and IVD products
- A QMS continuously enhanced to ensure optimal workfl ows
- A QMS regularly audited by notified bodies and customers
- Through our QMS 8 products have been successfully certified and more than 10 are in the pipeline
- We actively apply the same framework for our legal manufacturer services

You have the freedom to operate quickly

- Focus on innovation, product development and technical documentation
- Shorten time to market by splitting roles and responsibilities
- Avoid wasting resources on non-core activities, e.g. preparation and realization of audits
- Overcome the current shortage of Notified Bodies

Our Team

An interdisciplinary team with a broad range of competencies and many years of experience in MedTech and IVD.

Karina Candrian
CEO & Co-Founder

Julia Enders
Regulatory Affairs Manager

Dr. Rolf Kaufmann
Senior Medical Device Expert

Lora Kushner
Manager Legal Affairs

Anne-Marie Joller
HR Manager & Project Coordinator

Dr. Georg Lambert
Clinical Evaluations

Dr. Annalisa Macagno
Senior Medical Device Expert

Camilla Messerli
Deputy Head QM & RA

Ulrike Neuberger
Marketing & Key Account Management

Simon Rammerstorfer
Junior PM SCM

Tom Overes
Engineering TD

Nila-Pia Rähle
Head QM & RA & Co-Founder

Claudia Reichle
Head Project Management

Jens Richter
Technology Advisor & Co-founder

Uwe Schubmehl
Senior Medical Device Expert

Markus Stohler
Head Supply Chain Management

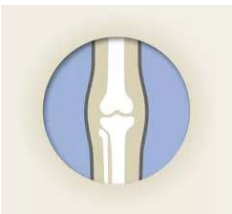
Monika Trümpler
Marketing & Management Support

Harald Züger
Finance Manager

References

Next generation software for the assessment of the interaction of combination treatments
Healthcare Service provider

- **Motivation/Scope:** Next generation software for the assessment of the interaction of combination treatments with two or more drugs, food or stimulants, considering genetic characteristics.
- **Challenge:** The database was being sold for several years, but not approved as a medical software. The customer does not have a quality management system (QMS) according to ISO 13485 in place, and therefore lacks the framework suitable to register the product as a medical software.
- **Solution:** Outsourcing of quality management (QM) and regulatory affairs (RA) to Effectum Medical. Effectum Medical acts as legal manufacturer.
- **EM-Team:** technical documentation, independent reviewer, management and alignment with 3rd party provider, responsible for the software development for preparation of technical documentation
- **Achievement:** The customer's lack of know-how in RA/QM for medical software was filled, and the project was realised in a short timeframe. Within 2 months the technical documentation was finalized, and certification obtained.

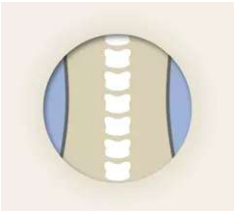


Development of instruments for an alternative arthroplasty surgical technique
Global Manufacturer for Medical Devices

- **Motivation/Scope:** Development of surgical instruments which facilitate an alternative surgical technique and are compatible with existing implants and instruments.
- **Challenge:** The Customers R&D and QA/RA teams were absorbed with transition to MDR; long milestone process for getting CE certification.
- **Solution:** Outsourcing of product development process to Effectum Medical for engineering and establishment of technical file. Effectum Medical acts as legal manufacturer. Integration into the customers QMS once the product is established in the clinical environment.
- **EM-Team:** Design Engineering, Regulatory and Quality Management, Independent Reviewer
- **Achievement:** The customer's shortage of resources was bridged, and the project was realized in a short timeframe. It took 3 months for engineering, technical documentation, manufacturing and certification.

Development of trial components for a new arthroplasty surgical technique Health Care Professionals / Clinical Research Center

- **Motivation/Scope:** Development of trial components which are compatible with an existing third-party arthroplasty system.
- **Challenge:** The customer had no internal engineering and no quality management system. It wasn't economical to implement all of it for this project.
- **Solution:** Outsourcing of engineering and quality management to Effectum Medical. Effectum Medical acts as legal manufacturer.
- **EM-Team:** Design Engineering, Regulatory and Quality Management, Independent Reviewer
- **Achievement:** Product development, certification and production was realised within 6 months and the customer could apply the new surgical technique, using the new instruments, in the OR.



Development of a spinal cage portfolio including surgical instruments Start-up - Swiss SME

- **Motivation/Scope**: Development of a new product family of spinal cages and the required reusable instrumentation.
- **Challenge:** Innovator/ investor with a product idea, but without experience in medical device development and product registration.
- **Solution:** Effectum Medical was an outsourcing partner for building a new company, developing the product portfolio, implementing a QMS, obtaining ISO certification and preparing the company for selling it to an investor.
- **EM-Team:** CEO, Design Engineering, Regulatory and Quality Management
- **Achievement:** The product idea was realized with complete development and first production followed by an exit after 18 months.

Appendix: List of Norms considered in our QMS

Norm	Description	SOP
MepV 812.213	Medizinprodukteverordnung	QM / SOP-102 / SOP-307 /SOP-103 / SOP-106 / SOP-303
Commission Regulation (EU) No 207/2012	Electronic instructions for use of medical devices	SOP-306
Council Directive 98/79/EEC	Directive on in-vitro Medical Devices (IVDD)	QM / SOP-106 / SOP-306 / SOP-307
Manufacturer Incident Report (MIR)	Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)	SOP-106
Regulation (EU) 2017/745	New Medical Device Regulation (MDR), amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	QM / SOP-101 / SOP-102 / SOP-103 / SOP-104 / SOP-106 / SOP-200 / SOP-202 / SOP-306 / SOP-307
Regulation (EU) 2017/746	New In-vitro diagnostic Device Regulation (IVDR)	QM / SOP-103 / SOP-105 / SOP-200 / SOP-306 / SOP-307
United States CFR Title 21	US Regulation for Medical Devices	QM / SOP-306 / SOP-103 / SOP-104 / SOP-106 / SOP-200 / SOP-307
EN 1041	Information supplied by the manufacturer of medical devices EN 1041:2008+A1:2013	SOP-306
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	SOP-302 SOP-307
EN 62304	Medical device software – Software life cycle processes	SOP-206 SOP-207 SOP-308 SOP-309
EN 62366-1	Medical Devices – Part 1: Application of usability engineering to medical devices	SOP-302 SOP-307
EN 868-5	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods	SOP-210
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk manamgent process	SOP-208
EN ISO 10993-17	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances	SOP-209
EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process	SOP-208

EN ISO 10993-5	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	SOP-209
EN ISO 11135	Sterilization of health care products — Ethylen eoxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	SOP-210
EN ISO 11137-2	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	SOP-210
EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019); German version EN ISO 11607-1:2020	SOP-210
EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019); German version EN ISO 11607-2:2020	SOP-210
EN ISO 11737-1	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	SOP-209
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	QM / SOP-101 / SOP-103 / SOP-104 / SOP-106 / SOP-209 / SOP-300 / SOP-305
EN ISO 14971	Medical devices – Application of risk management to medical devices	SOP-206 SOP-302 SOP-307
EN ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	SOP-306
EN ISO 17100	Translation services — Requirements for translation services	SOP-306
EN ISO 17664-1	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices	SOP-210
EN ISO 17664-2	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices	SOP-210
EN ISO 17665-1	Sterilization of health care products; Moist heat; Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	SOP-210
EN ISO 18113-1	[1] In vitro diagnostic medical devices : Information supplied by the manufacturer (labelling) : Terms, definitions and general requirements	SOP-306
EN ISO 18113-2	[2] In vitro diagnostic medical devices : Information supplied by the manufacturer (labelling) : In vitro diagnostic reagents for professional use	SOP-306

EN ISO 18113-3	In vitro diagnostic medical devices : Information supplied by the manufacturer (labelling) : In vitro diagnostic instruments for professional use	SOP-306
EN ISO 18113-4	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing	SOP-306
EN ISO 18113-5	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing	SOP-306
EN 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	SOP-307
EN 82304-1	Health software Part 1: General requirements for product safety	SOP-206
ISO 19227	Implants for surgery — Cleanliness of orthopedic implants — General requirements	SOP-209
ISO 20916	In vitro diagnostic medical devices -- Clinical performance studies using specimens from human subjects -- Good study practice	SOP-105
ISO/IEC 25010	Systems and software engineering – Systems and Software Quality Requirements and Evaluation (SQuaRE)-System and software quality models	SOP-207
ISO/TR 80002-2	Validation of software for medical device quality systems	SOP-310
ISO/TS 10993-19	Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials	SOP-209
ISO/TS 13004	Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD	SOP-210

Want to find out more?

We are happy to assist you with any further questions that you might have or if you are interested in receiving a proposal for our Plug-and-Play QMS or any of our other services.

Your contact

Karina Candrian
CEO & Co-Founder

karina.candrian@effectummedical.com