Unlocking Growth for Startups:

The Benefits of Outsourced Legal Manufacturing with Effectum Medical

EFFECTUM MEDICAL

“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,
Leiterin mediQ (PDAG)

What‘s In It For You?

Accelerated Market Entry:
Gain immediate access to a certified Quality Management System (QMS), cutting down your time-to-market by 9 to 15 months.

Cost Efficiency:
Share QMS maintenance and audit costs with other companies, eliminating the need for additional hires and saving on expenses that can reach up to 30,000 CHF annually.

Streamlined Certification:
Benefit from Fast Track certification, allowing your products to hit the market in as little as 5 months, with specific advantages for different product classes.

Risk Mitigation:
Access a network of pre-vetted suppliers, reducing supply chain risks and sharing maintenance costs.

Regulatory Support:
Rely on an extended team of regulatory and quality management experts to ensure compliance, freeing you from liaising with notified bodies.

Focus on Innovation:
Concentrate on your core competencies—innovation, development, and marketing—while we handle regulatory, quality, and compliance challenges.

Intellectual Property Security:
Retain full ownership of your intellectual property (IP) while benefiting from a streamlined path to market.

By partnering with Effectum Medical, you unlock growth potential, increase productivity, and reduce stress, allowing you to bring your vision to life efficiently.

Why Startups Choose Effectum Medical

Startups face unique challenges, from limited resources to navigating complex regulatory landscapes. By outsourcing your QMS management to Effectum Medical, you gain access to a certified partner that offers five key benefits:

1 Immediate Access to a Certified QMS

Setting up and certifying a Quality Management System (QMS) can take anywhere from 9 to 15 months. By outsourcing your legal manufacturing to Effectum Medical, you get immediate access to a certified eQMS, significantly reducing your time to market. You will receive the required training to perform your tasks and work in a modern eQMS, which increases efficiency and communication.

Time Savings:

Besides saving time on setting up a QMS, you will save additional time on QMS maintenance. As the legal manufacturer, Effectum Medical takes care of the yearly ISO 13485, MDR, and IVDR audits—saving you a significant amount of time every year. There is no need for you to perform many required day-to-day QMS maintenance tasks such as internal audits, regular CAPA, Non-Conformity, Change and complaints meetings, SOP updates, regulatory requirements monitoring, management reviews and much more...

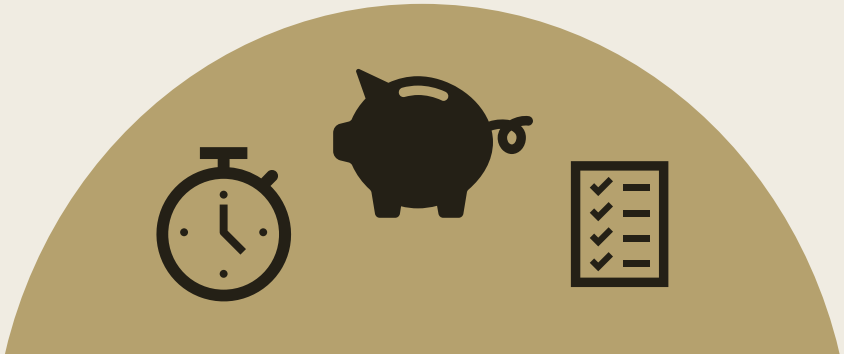
This gives you time to focus on your own priorities. We ensure the QMS remains certified and that your documentation is set up and maintained as per requirements.

Cost Benefits:

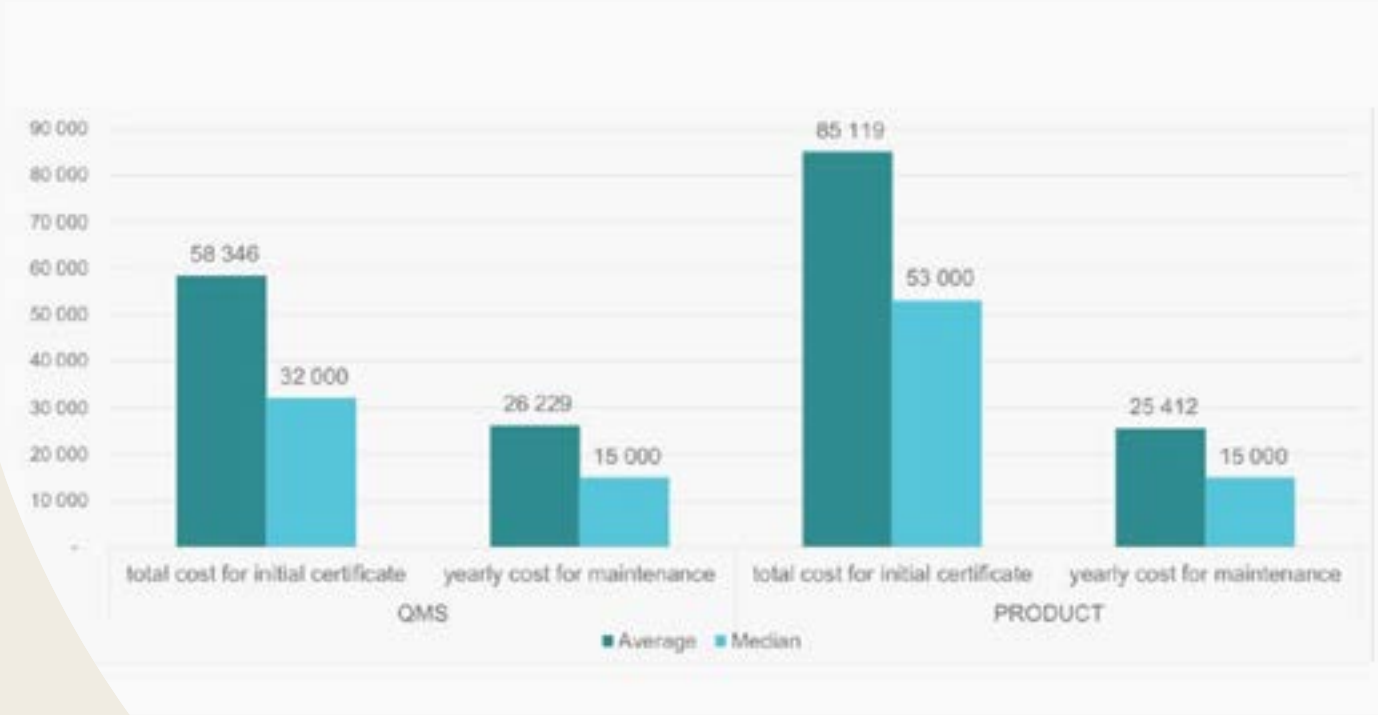
Outsourcing the Legal Manufacturing Services will also lead to cost benefits, as the eQMS, QMS maintenance, and audit costs are shared between several companies. Furthermore, there is no need to hire a PRRC or a (Quality) Management Representative, as we cover this part for you. QMS audits alone can cost up to 30,000 CHF annually, excluding the salaries of the team needed for preparation, participation, and follow-up with notified bodies.

No Notified Body Shortage & Uncertainty:

There is no uncertainty around costs, timelines, and regulatory predictability with Notified Bodies, as we have contracts with IVDR and MDR accredited notified bodies and are part of their existing customer pool. New products are immediately dealt with and do not have to go through the notified body onboarding process first.



Average costs for MDR / IVDR compliant QMS (€)



Reference: Study supporting the monitoring of availability of medical devices on the EU market - European Commission

Included

This Graph represents only the notified bodies costs for audits and assessments leading to the initial certification as well as follow-up costs for the notified body activities required by the Regulations to maintain the validity of certificates per year

(i.e. fees for surveillance activities like annual audits, unannounced audits, evaluation of periodic safety update reports (PSUR), evaluation of summary of safety and clinical performance (SSCP))

Not Included

Internal cost as well as other external costs (e.g. costs of clinical investigations, consultant costs for helping with upgrading the QMS system and existing technical documentation to become MDR compliant or to prepare applications) are not included.

2 Fast Track Product Certification in Switzerland and Europe

By leveraging our existing QMS and product certifications, companies can avoid the lengthy setup, audit, and review processes typically required. While the standard certification process can take 6 to 24 months (or even longer), with Fast Track certification, products can reach the market in only a few months!

Over the years, we have successfully launched various products and can now offer Fast Track Certification for the below-listed codes (As of 04/2025). With our Fast Track process, eligible products can be marketed immediately after completing the Technical Documentation and Declaration of Conformity — without a technical file review by the notified body.

Covered Codes at a Glance

We hold MDR certificates for several product groups (Class Is and IIa).

MDN 1202
Non-active non-implantable devices for administration, management and removal of substances including dialysis products (class Is)

MDA 0308
Active non-implantable devices for wound and skin care (class IIa)

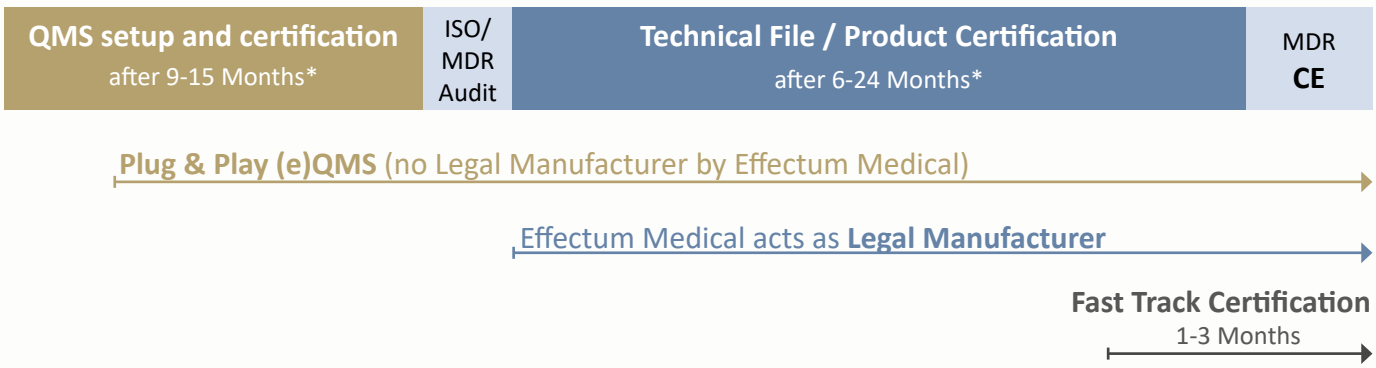
MDA 0204
Other active non-implantable devices for monitoring and/or diagnosis (class IIa)

MDA 0313
Active, non-implantable protheses and devices for rehabilitation (class IIa)

MDA 0315
Software (class IIa)

Time Requirement

Fast Track Certification vs. Regular Certification



*The specified time periods are based on our experience and are non-binding.
Liability is excluded. They also do not include the writing of technical documentation.

3 Expert Supplier Management

Effectum Medical provides access to a strong network of qualified and approved suppliers, giving you flexible options to choose from. Additional suppliers are reviewed and qualified by our teams. In summary, we take care of supplier management, ensuring that all necessary qualifications and contracts are in place for production and supply chain efficiency. We also take care of supplier monitoring by performing regular performance assessments, periodic reviews, certificate updates, and, as required, supplier audits.
In general, we can take care of the entire purchasing process for you, which again, allows you to focus on other activities.

Risk Mitigation:

Pre-vetted suppliers ensure compliance and reliability. Qualification, management, and monitoring by an expert team enable the reduction of supplier-related risks in the supply chain.

Cost Reduction:

If one of our previously qualified suppliers is used, then the costs of supplier maintenance and audits are shared between several companies.

Streamlined Operations:

Focus on product development while we manage supplier relations, approvals, and maintenance.

4 Extended Regulatory Affairs & Quality Management Team

Working with Effectum Medical means you gain access to an extended team of regulatory, technical documentation, and quality management experts. We also provide the legally required “Person Responsible for Regulatory Compliance” (PRRC), ensuring conformity with EU requirements under MDR and IVDR. Furthermore, there is no need for you to liaise with notified bodies or authorities, nor to prepare and participate in audits, as we take over all official communication and ensure that the QMS remains certified.

Regulatory Expertise:
Full support from seasoned professionals in medical devices, software, and IVD.

Comprehensive Documentation:
Assistance with technical documentation creation ensures accuracy and efficiency. A PRRC review of the technical documentaiton ensures compliance.

5 Focus on Core Competencies

Perhaps the most significant benefit of outsourcing legal manufacturing services is that companies can focus on what they do best—innovating, developing, and marketing their products. Effectum Medical takes care of the regulatory, quality, and compliance challenges, freeing up your team to concentrate on product development and growth. Of course, innovators retain full ownership of their IP while benefiting from a streamlined path to market.

- **Increased Productivity:** More time to focus on product lifecycle management, marketing, and sales.
- **Reduced Stress:** Let the experts handle compliance, so you can focus on bringing your vision to life.

biospectal

Key Learnings:

„Effectum Medical guided us through the regulatory landscape, enabling us to work efficiently under a Quality Management System (QMS) despite initial inexperience. Their eQMS significantly improved accuracy, reduced errors, and saved time. Most importantly, we accelerated time-to-market by bypassing the need for our own Notified Body relationship and internal resources. Our successful launch, even without reimbursement, proves that patients are willing to pay out-of-pocket.“

— Frederic Fappereau, Head of Product @ Biospectal

Glossar

QMS ..... Quality Management System

MDR ..... EU Regulation 2017/745 on Medical Devices; see Regulation - 2017/745

IVDR ..... EU Regulation 2017/746 on in vitro diagnostic medical devices; see Regulation - 2017/746

IVD ..... In-vitro diagnostic

EM ..... Effectum Medical

LM ..... Legal Manufacturing

MD ..... Medical device

PRRC ..... Person Responsible for Regulatory Compliance according to Article 15 of MDR/IVDR

MDN/MDA ..... See details in MDCG 2019-17

FDA ..... US Food and Drug Administration

IvDO ..... Ordinance on In Vitro Diagnostic Medical Devices SR 812.219

MedDO ..... Medical Device Ordinance; see SR 812.213

EN ISO 13485.... Medical devices – Quality management systems — Requirements for regulatory purposes

Ready to Transform
our Startup's Potential?

If you're interested in learning more about our legal manufacturing services and how they can benefit your startup, reach out to **Marius** by email (**marius.wiederkehr@effectummedical.com**) or book an exploratory call with him.

Let Effectum Medical be your partner in innovation and success!

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MEDICAL

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