



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

REGULATORY OPINION



REGULATORY OPINION

Expert Regulatory Insights for Your Success

Navigating regulatory affairs can be complex, but our expertise keeps you ahead. We provide **tailored regulatory opinions**, backed by decades of experience, to help you meet compliance standards and optimize market access across **Switzerland, the EU, UK and the USA**.

Why Choose Us?

- **Proven Expertise:** Decades of hands-on experience in regulatory affairs across multiple regions.
- **Customized Solutions:** We adapt our advice to your specific product and market needs.
- **Reliable Guidance:** Stay proactive and informed in an ever-changing regulatory landscape.

Our clients receive a report identifying applicable medical device regulations and classification as well as sketching possible regulatory pathways. The report is an **essential tool for internal alignment and external compliance**. Whether launching a new product or maintaining compliance, our Regulatory Opinions provide the clarity and direction you need.

Over 35 Regulatory Opinions delivered—partner with us for success!



Camilla Messerli

Head Quality Management & Regulatory Affairs
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REGULATORY SUCCESS: CLIENT TESTIMONIALS

A great example of how successful collaboration can lead to a positive regulatory opinion.

“I had the pleasure of meeting Karina during a coaching session in the Venturelab Start-up Training Business Creation course. Later, while participating in Venture Kick, we chose to work with Effectum Medical to tackle our regulatory questions, and were assigned to Annalisa.

Her support was invaluable, especially with her hands-on experience in both startup and corporate environments. Effectum Medical didn't feel like a typical consultancy; they felt like an extension of our team, an extra set of hands helping us achieve more in less time. Their guidance gave us the confidence to establish a clear roadmap for regulatory approval, which we took into our Venture Kick Stage III pitch—and won.

I would wholeheartedly recommend Effectum Medical to any startup facing regulatory challenges.”

Gian Nutal Schädli, CEO of CompagOs AG



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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](https://www.effectummedical.com) for details.

For more information visit: www.effectummedical.com



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