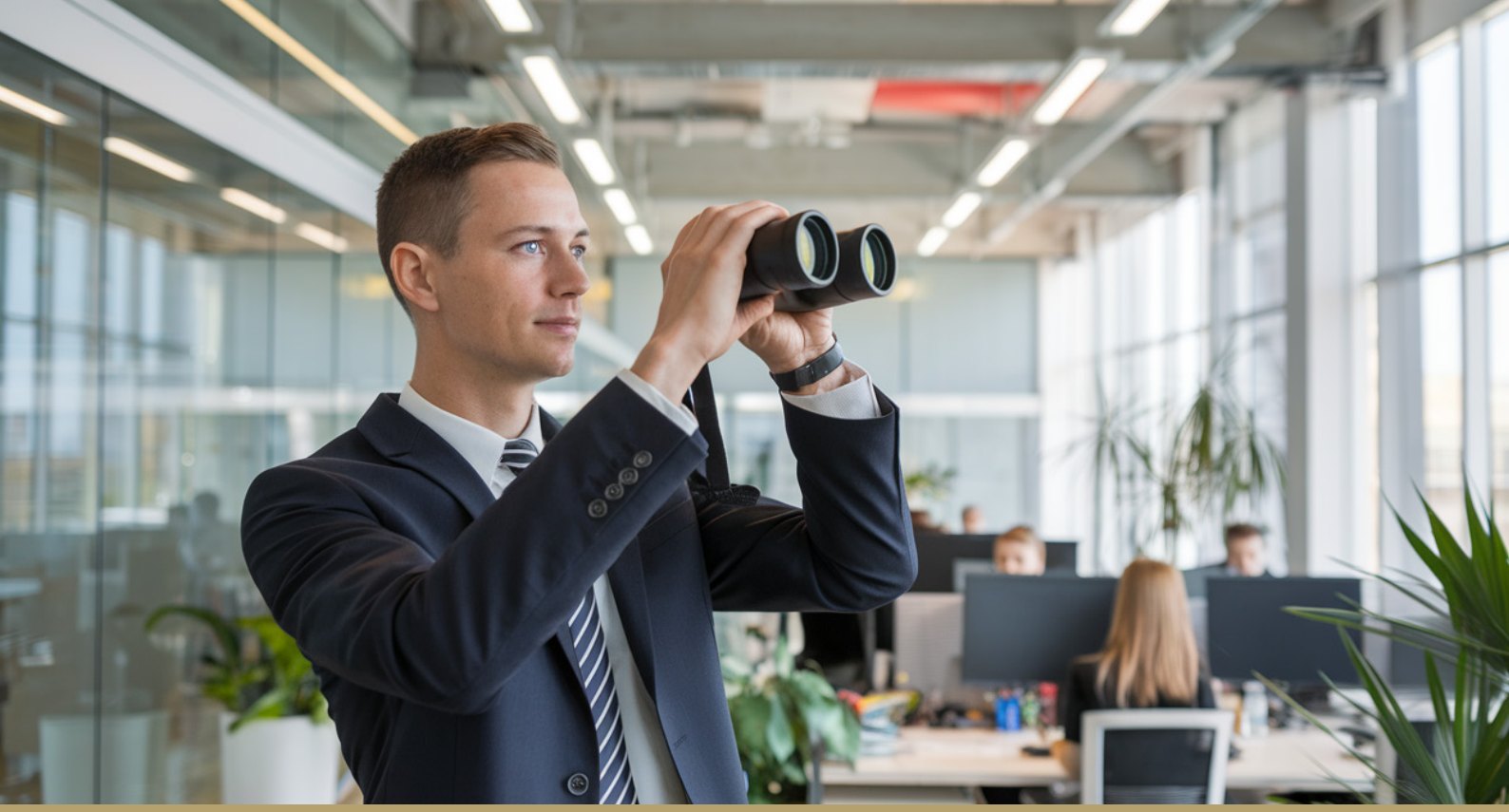
Effectum Medical AG

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.

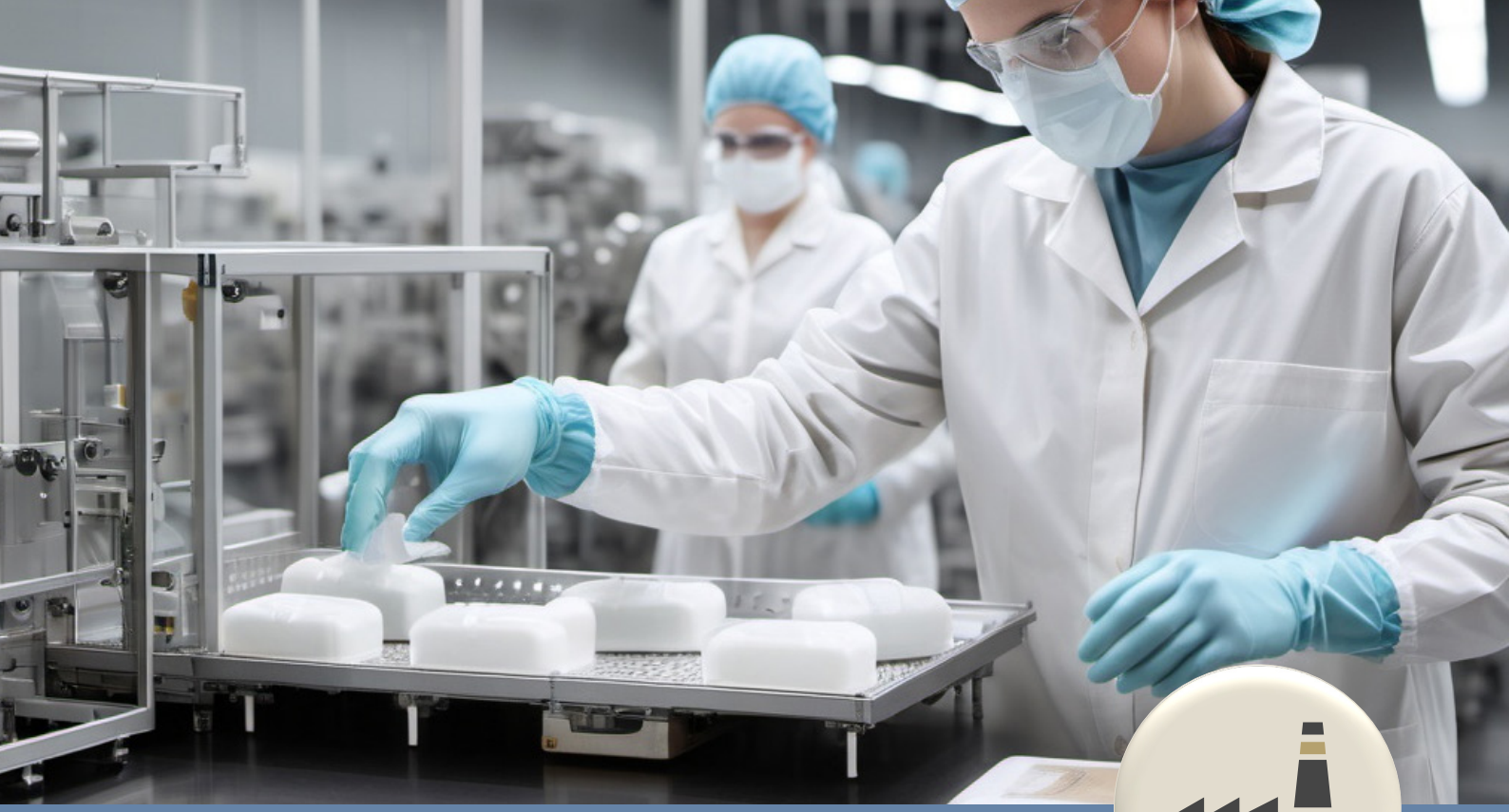
EFFECTUM
MEDICAL

SERVICE OVERVIEW

2024/25



OVERVIEW ALL SERVICES



OUTSOURCED LEGAL MANUFACTURER

Unlock Your Potential with Our Services

We offer a complete solution for companies to outsource the legal manufacturing, providing a dedicated support team throughout the entire product lifecycle. With products certified under MDD, MDR, and IVDD, partnering with us can help accelerate your time-to-market significantly.

Faster Market Access

- We partner with two leading Notified Bodies, eliminating your search effort
- Take advantage of our QMS certification (ISO 13485/ MDR/IVDR/ QSR)
- „Fast track certification“ provides significant time savings

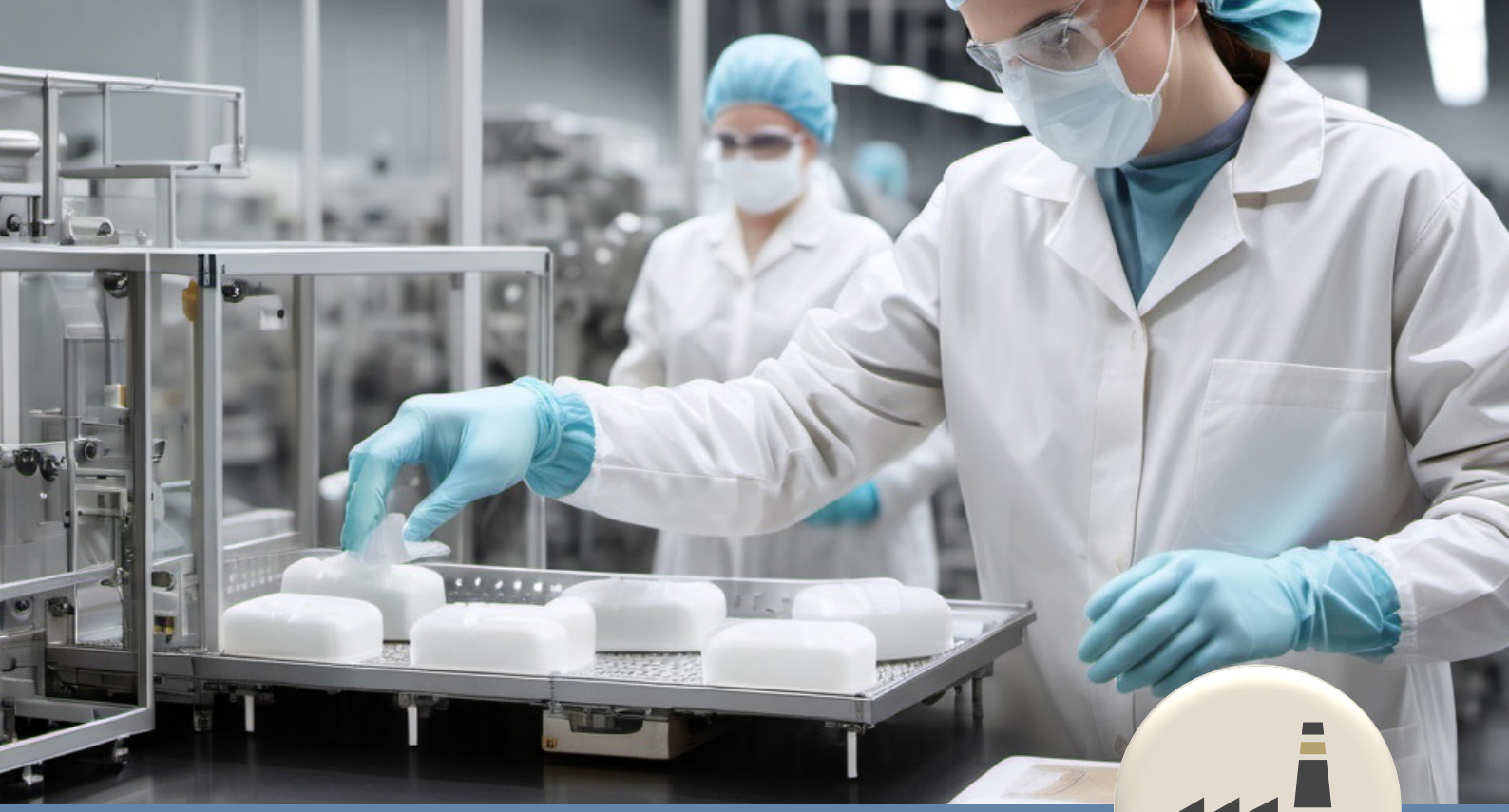
Mitigate Risks

- QMS audited annually since 2017
- Minimize risks with our approved and trusted supplier network
- Expand your team with experts in every domain of the medical device industry

Focus on your core activities

- Concentrate on new product development and lifecycle management
- Grow your business—we manage the regulatory and compliance challenges
- Maintain full control over your branding and design

Marius Wiederkehr
Head of Legal Manufacturing Services
marius.wiederkehr@effectummedical.com



OUTSOURCED LEGAL MANUFACTURER - FAST TRACK

Fast Track Certification:

With our Fast Track Certification, products within the same scope and similar or lower risk can be marketed immediately after completing Technical Documentation and issuing the Declaration of Conformity.

Timeline: 1–6 months (Notified Body review).

We hold MDR certificates for several product groups (Class Is and IIa). Contact us to learn more about our current scope.

QMS setup and certification 9-15 Months	ISO/ MDR	**Technical File / Product Certification** 12-24 Months	ISO/MDR **CE**

Plug & Play (e)QMS (no Legal Manufacturer by Effectum Medical)

Effectum Medical acts as **Legal Manufacturer**

Fast Track Certification

The specified time frames are based on our experience and are non-binding. Liability is excluded.

Marius Wiederkehr
Head of Legal Manufacturing Services
marius.wiederkehr@effectummedical.com

THE PLUG & PLAY (e)QMS

Purchase and configure your own (electronic) Quality Management System

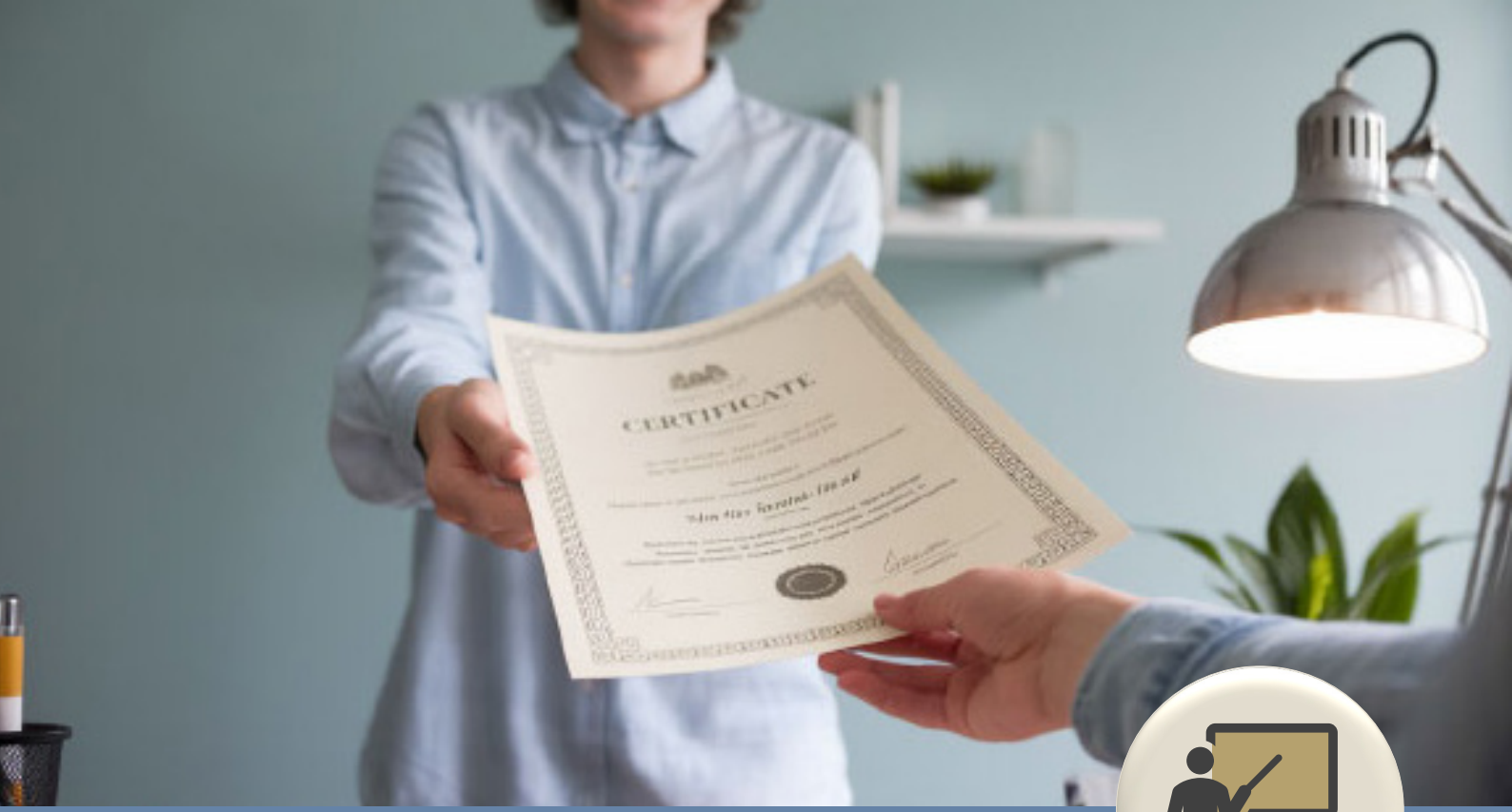
Our system is:

- **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**.
- Can be **combined with our Bootcamp and support packages**, to receive guidance and assistance in configuring your own QMS, and any other topic you wish to receive support

Combine our Plug & Play (e)QMS with Bootcamp and support packages for extra guidance. We assist with **QMS configuration & setup, suppplier audits, PRRC services, and technical documentation.**

Contact us to learn more!

Camilla Messerli
Head Quality Management & Regulatory Affairs
camilla.messerli@effectummedical.com



PLUG & PLAY (E)QMS BOOTCAMP – ON-SITE, HYBRID, OR SELF-STUDY

Plug and Play (e)QMS Bootcamp

Enhance your (e)QMS management and technical documentation skills with our Plug & Play (e)QMS Bootcamp. Choose between our hybrid Spring 2025 Bootcamp or the self-study option for flexible learning at your own pace. Our Bootcamp is ideal for companies using or planning to purchase our Plug & Play (eQMS) SOP Packages.

Self-Study Bootcamp Includes:

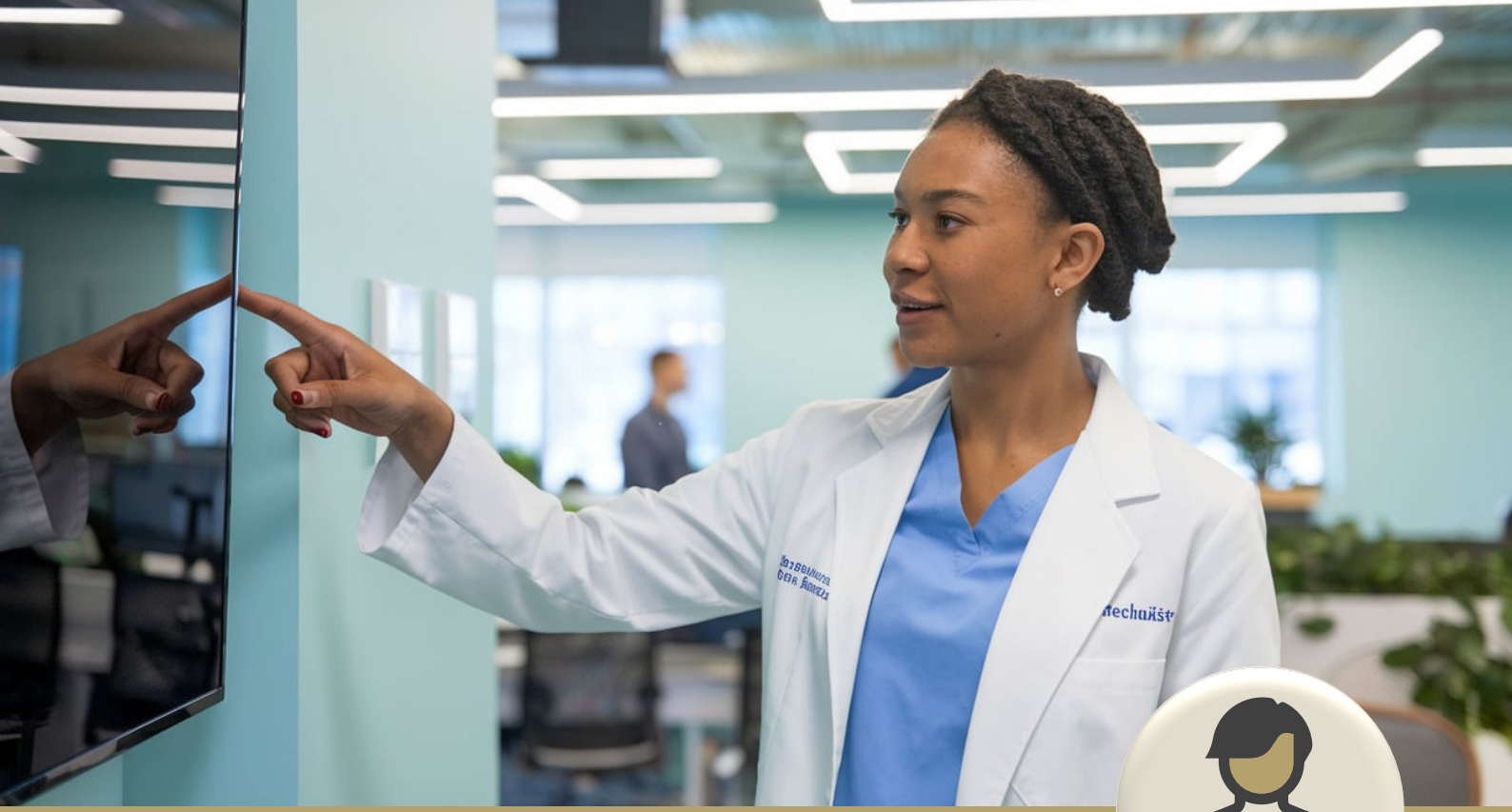
- **Self-Study Modules:** Five detailed modules to build your QMS expertise.
- **1-on-1 Q&A Sessions:** Schedule an hour with an expert after each module.
- **12 Months Free Access:** Revisit content anytime with access to Effectum's e-Learning platform and additional training videos.

Spring 2025 Hybrid Bootcamp Includes:

- **Expert-Led Modules:** Six workshops (2-4 hours each) over three weeks.
- **Flexible Participation:** Join workshops on-site or remotely and network with other companies.
- **Six Months Free Access** to additional training materials.

Earn a certificate upon completion. Connect, learn, and grow with Effectum's Plug & Play (e)QMS Bootcamp!

Camilla Messerli
Head Quality Management & Regulatory Affairs
camilla.messerli@effectummedical.com



RENT AN EXPERT

Rent an Expert for Your Project

Need specialized support for your medical device project? Are you prepared to integrate AI technologies into your medical device? Do you need assistance in conducting a comprehensive audit?
We offer experienced professionals on a flexible basis to help you succeed.

Quality/Regulatory Affairs Manager:

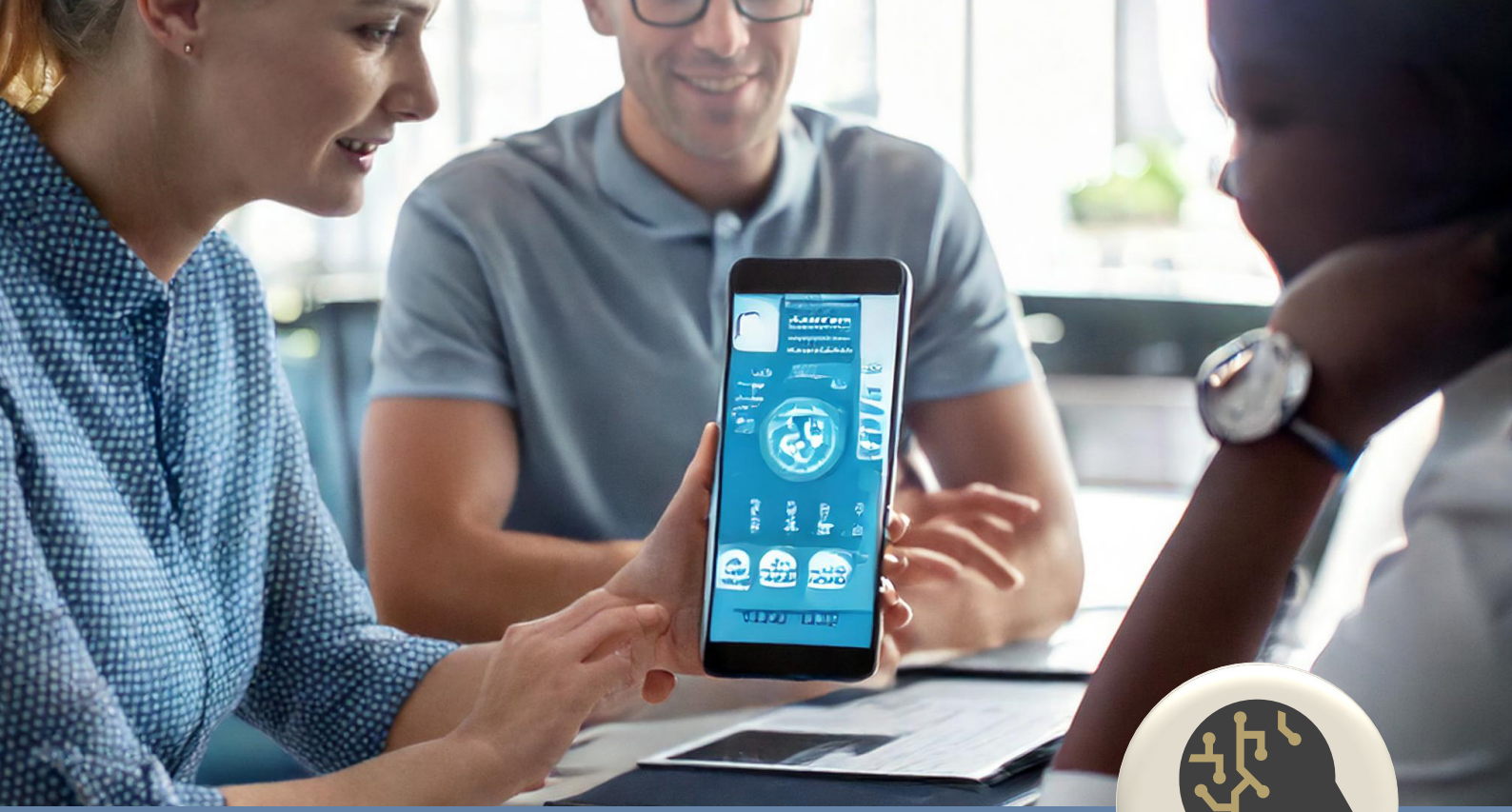
- Auditing / Supporting audits
- (e)QMS Management
- Regulatory monitoring
- Training
- PRRC
- Submission support
- and much more...

Medical Device Expert:

- Technical writing/document reviews
- Software in medical devices
- Biocompatibility
- Clinical Evaluations
- Supply Chain planning
- Independent reviews
- and much more..

Gain the expertise you need, when you need it.

Judith Oriwal
Senior Project Manager & Medical Device Expert MD/IVD
judith.oriwal@effectummedical.com



ARTIFICIAL INTELLIGENCE (AI) MACHINE LEARNING (ML) DEVICE CERTIFICATION

Do You Use Machine Learning or Artificial Intelligence in Your Device?

Our services help you integrate ML and AI into medical devices while ensuring regulatory compliance:

- **Gap Analyses & AI Readiness Checks:** Review existing documentation and ensure AI Act compliance.
- **CE Certification Support:** Expert guidance for obtaining CE certification for ML/AI software.
- **Customizable Templates:** Access to templates that simplify technical file preparation.
- **AI Act Compliance:** Established processes to meet new AI Act requirements efficiently.

Let us guide you through the complexities of Artificial Intelligence (AI) / Machine Learning (ML) integration with ease!

Marius Wiederkehr
Head of Legal Manufacturing Services
marius.wiederkehr@effectummedical.com

REGULATORY OPINION

Expert Regulatory Insights for Your Success

Navigating regulatory affairs can be complex, but our expert guidance keeps you ahead. We provide tailored regulatory opinions, backed by years of experience, to help you meet global compliance standards while optimizing your market access.

Why Choose Us?

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

Whether you‘re launching a new product or ensuring ongoing compliance, our Regulatory Opinions provide the clarity and strategy you need to succeed.

Partner with us for regulatory success!

Camilla Messerli
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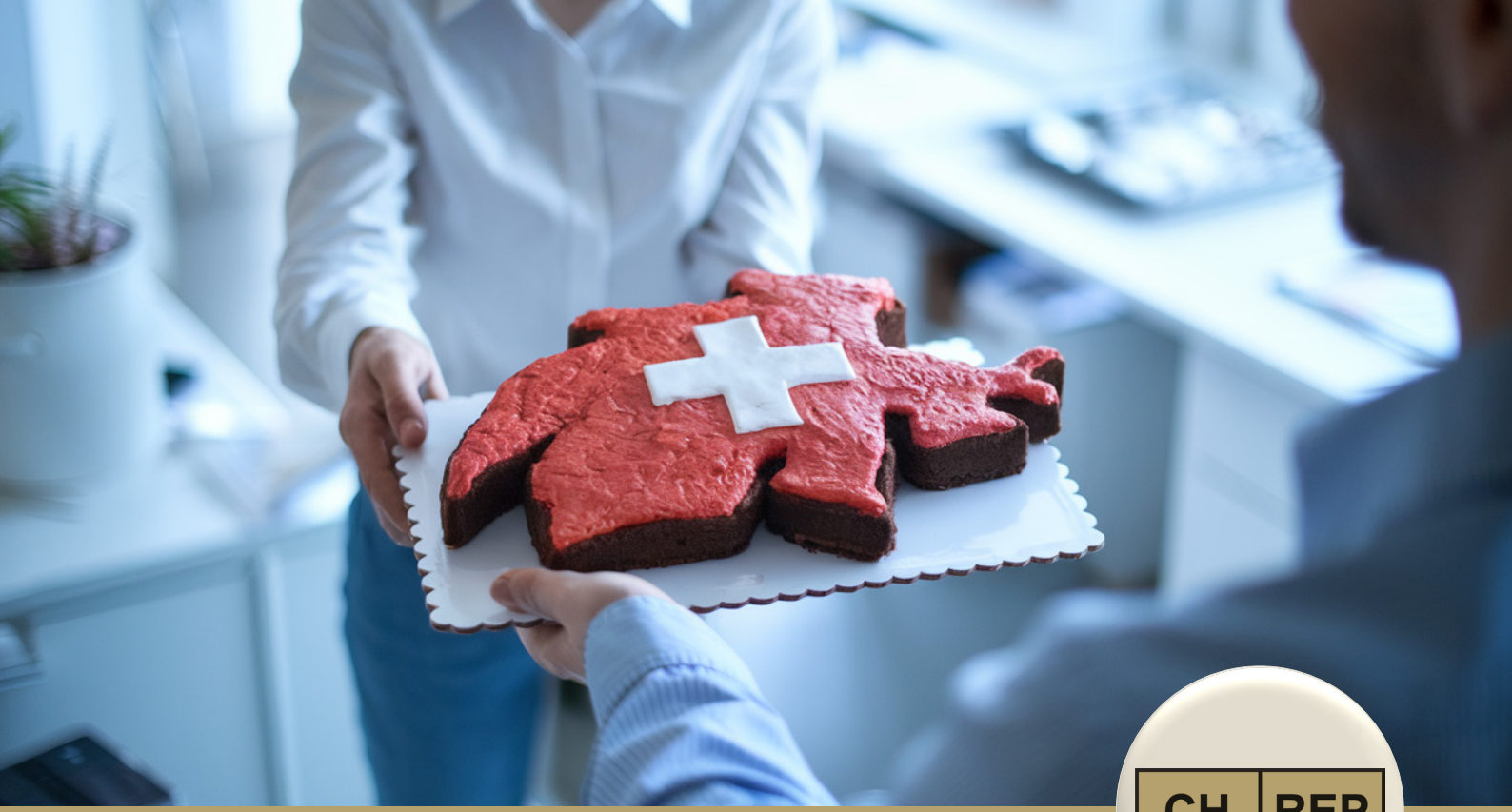

SWISS AUTHORIZED REPRESENTATIVE (CH-REP)

Your Trusted Swiss Authorized Representative

As your Swiss Authorized Representative (CH-REP), we ensure your compliance with the Swiss medical device regulations. Our expert team takes on the responsibility of representing your company, ensuring your products meet all necessary requirements for smooth market access in Switzerland.

Why Choose Us?

- **Regulatory Expertise:** We navigate every step with our knowledge of Swiss regulations.
- **Local Presence:** As your Swiss representative, we ensure quick and reliable communication with authorities.
- **Simple & Efficient:** Request your personalized offer online—fast, transparent, and hassle-free. Visit our website today for your online quote! www.effectum-chrep.com

Effectum CH-REP AG is proud to serve as **a Swiss representative for foreign clinical trial sponsors**, in compliance with the Swiss Ordinance on Clinical Trials with Medical Devices (ClinO-MD) effective July 1, 2020.

Contact us today to learn more about our services as a Swiss Clinical Study Representative for international sponsors.

Camilla Messerli
Head Quality Management & Regulatory Affairs
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MEDICAL

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