4C ACCELERATOR

TO **ENABLE** YOUR MEDTECH STARTUP

WHAT IS IT ABOUT?

C1 | Commercialization: How do I generate revenue in the healthcare industry?

C2 | Certification: How do I get my product and company certified?

C3 | Clinical Studies: How can I provide the necessary evidence by collecting clinical data?

C4 | Copyright: How can I leverage data and intellectual property rights to my advantage?

Regulatory Thinking®: How do I integrate these 4Cs into a regulatory plausible business model?

WHAT IS THE GOAL?

- You will have identified corresponding barriers to **shorten the time-to-market** and addressed them in an individual project plan.
- You will be familiar with the **reimbursement options** in the German healthcare market (e.g., selective contracts).
- You will understand how **quality management systems** (e.g., ISO 13485) and regulatory processes become a strategic concept and how they effectively lead to the **approval of your product** (e.g., Medical Device Regulation, In-Vitro-Diagnostic Regulation).
- You will be able to assess whether and what kind of **clinical studies** you need and how to best implement them (e.g., ISO 14155, ISO 13612).
- You will know how to deal with **data protection** requirements (GDPR) and how to **strategically protect** and exploit intellectual property rights (e.g., patents).

HOW IS THE APPLICATION & SELECTION PROCEDURE?

GOT QUESTIONS? CONTACT US!

Lea Renz
Email: renz@mi-incubator.com
Phone: +49 152 52998535

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