Congenius | MArS Market Access & Pricing Strategy

Building the foundation for MedTech start-ups

Formulate a sustainable strategy from day one with Congenius and MArS.

Read on to find out how our MedTech experts can help you successfully take your idea to market – and keep it there.

MedTech start-ups face varied and complex challenges:

Regulatory pathways, reimbursement requirements, clinical evidence, and quality systems must be considered at a very early stage of development.

We support MedTech innovators with building the right foundation from the start, using a structured approach focusing on four critical pillars for successful medical device development and market access.

1 **Reimbursement strategy**

2 **Regulatory strategy (EU & US)**

3 **Clinical strategy**

4 **Quality management**

1 Reimbursement strategy

Ensure your product is not only approved but also paid for.

Early understanding of reimbursement pathways is fundamental for commercial success.

We can support you with:

- Early pricing and reimbursement landscape analysis
- Identification of relevant payer processes (EU/US)
- Alignment of clinical evidence generation with reimbursement needs
- Strategic positioning of your product in the healthcare system
- Price assessment for investors or internal go-decisions

2 Regulatory strategy (EU & US)

Identify a clear regulatory pathway and reduce approval risks.

Choosing the right regulatory pathway early on saves time and cost, and mitigates development risks.

We can help you define:

- Regulatory classification and pathway
- EU MDR strategy
- FDA pathway (510(k), De Novo, PMA)
- Technical documentation structure, essential requirements, and applicable standards
- Regulatory submission planning

3 Clinical strategy

Generate the right evidence at the right time.

Clinical evidence is essential for regulatory approval, reimbursement, and market adoption.

Our support includes development and preparation of:

- Clinical evidence strategy
- Clinical evaluation documentation
- Clinical study design strategy aligned with regulatory and reimbursement requirements
- All necessary study documents including submission to competent authorities, ethics committees, and IRB as required
- Literature search and reviews for subject-device and state of the art

4 Quality management

Build a scalable QMS foundation that grows with your company.

Successful MedTech development requires a structured process framework according to ISO 13485.

QMgeniuS is our tailored QMS solution developed specifically for start-ups. During your development activities, we can provide initial support with the two core processes:

Product development process

- Setup of a structured development process
- Integration of an electronic Requirements Engineering and Traceability tool to ease Design Control management
- Creating documentation aligned with ISO 13485 expectations and electronic workflows

Risk Management according to ISO 14971

- Hazard identification and risk analysis
- FMEAs for design, software, usability, and manufacturing process
- Integration of Risk Management activities in the electronic Requirements Engineering and Traceability tool to ease risk control management
- Creating documentation aligned with ISO 14971 expectations and electronic workflows
- If applicable, cybersecurity assessment according to ANSI/AAMI SW96 and IEC 81001-5-1

Let's build your MedTech foundation together.

Congenius and MArS specialise in supporting MedTech start-ups and early stage companies – enabling innovation from strategy to market access.

Our approach:

- Strategic guidance from concept to market
- Integrated view across regulatory, clinical, and reimbursement
- Pragmatic introduction of QMS-processes
- Practical implementation tailored for early stage companies
- Building systems that scale with your growth

Get in touch with our experts to find out how we could help with your MedTech journey.

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