

Smart consulting, enhanced medical solutions.

Together with our customers, we stimulate informed ideas, create lasting solutions, and inspire positive change.

Here at Congenius, we provide tailored expertise and leadership to global firms, established SMEs and aspiring start-ups in the medical device, in vitro diagnostics and pharmaceutical industry.

By reassuring our customers through knowledge & experience we form trusted partnerships that facilitate the successful registration & delivery of medical devices.

Our Services

We built our foundations in **Quality & Regulatory**, but our continued success within the MedTech industry has driven our expansion into **eHealth, Operations & Clinical**.

Quality

- ✓ Quality Management
- ✓ Quality Assurance (Design Control Activities & Quality Engineering)
- ✓ Auditing Internal & Suppliers
- ✓ Mock audit – MDSAP / FDA

Regulatory

- ✓ Regulatory Strategy
- ✓ Compiling of Technical Documentation (DHF/ DMR)
- ✓ Submission to Authorities
- ✓ Post Market Activities (PMS)
- ✓ Vigilance



eHealth

- ✓ Medical Software: SaMD / SiMD
- ✓ SW Requirements Management / SW Risk Management
- ✓ SW Project Management / SW Lifecycle Management
- ✓ Cybersecurity / Data Privacy / Data Security
- ✓ Artificial Intelligence / Machine Learning



Operations

- ✓ Process Engineering
- ✓ Equipment Qualification / Process Validation
- ✓ Test Method Validation
- ✓ Quality Control / Control Strategy
- ✓ Biocompatibility / Sterility & Product Cleanliness



Clinical

- ✓ Clinical Strategy
- ✓ Clinical Evaluation
- ✓ Clinical Investigations

Our Vision: Enable the smartest route to enhanced medical solutions

We have helped **over 105 valued customers to complete over 500 successful projects** by providing support as required. So, whether you are seeking assistance with a fundamental business need or looking for a skillset to complement your internal workforce, we can provide the necessary knowledge and experience to facilitate the successful delivery of your project.

Get in touch

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Our Partners

SWISS MEDTECH
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PLATFORM


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Startups

 Università
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