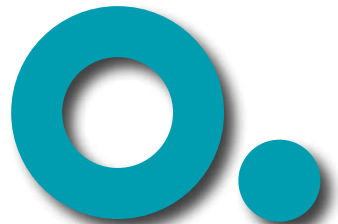


go.Med

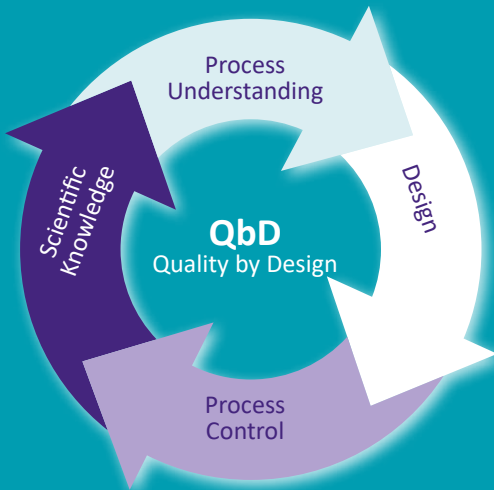
Accelerating High-Risk Medical
Device Development



What is the go.Med approach?

go.Med follows the systematic **Quality-by-Design (QbD)** approach. The innovative concept introduces quality assessment and risk management steps at the start of the product development process to address potential issues early on. This **prevents failures at an advanced development stage**, reducing costs and overall development time.


As a risk-based approach, it employs quality, efficacy and safety principles throughout the complete product lifecycle.



By uniting a set of entities, which work together, and by using the QbD approach, medical device developers achieve excellent results while minimising costs at the same time.

Medical device developers have many questions...

... go.Med provides the answers!



Will I have a market niche for my device?

Am I considering the right indication?

Is my pre-clinical and clinical data enough to prove safety and efficacy?

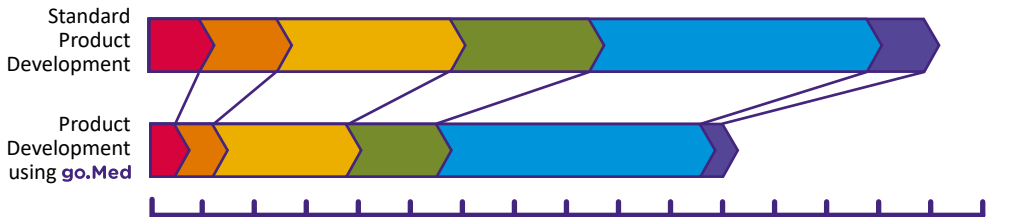
What is the class of my medical device?

What type of tests do I need to do?

Which entities could do these tests?

Is the device design according to the user needs?

go.Med is a connected network of entities committed to accelerating the arrival of technologically feasible, economically viable and high-quality devices, providing a smooth and swift transition from preclinical development to clinical testing.



■ Customer Requirements

■ Concept Design

■ Prototype and Manufacturing Process Optimization

■ In vitro & In vivo validation

■ Clinical Studies

■ Document Elaboration and Regulatory Submission

How can go.Med help?

go.Med's interdisciplinary team coupled with an innovative approach will help you minimize time to market by offering:

- Contact with health technology assessment (HTA), clinicians and end users at an early stage of development to identify possible design changes, indications of use and required tests
- Specialized facilities for characterization, prototyping and testing
- Financial & Business advice services
- A Key Account manager that will accompany you all the way to resolve any issues during the process

Services offered



Technology Development

Efficacy Testing
Safety Testing
Characterisation
Prototyping
Upscaling
Clinical Studies



Business Support

Strategic business advice
Market analysis
Market access strategy
Technologies scouting services



Financial services

Fund-raising support
Co-development options

Track record

go.Med has provided services to eight companies in different therapeutic areas. Some examples:

Dental



RTU scaffold combined with hydroxyapatite tailored for oral bone defect reconstruction

Ophthalmics



Synthetic cornea with long-term retention rates

Traumatology

CYBER SURGERY

High-precision robot for spinal surgery



Calcium phosphate cement for bone regeneration

- ✔ **One-stop-shop covering all development needs from pre-clinical development to clinical testing**
- ✔ **Reduced cost and faster time to market**
- ✔ **Innovative risk-based Quality-by-Design concept**
- ✔ **Tailored assessments and expert advice**
- ✔ **For high-risk medical devices in Class IIb and Class III**



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