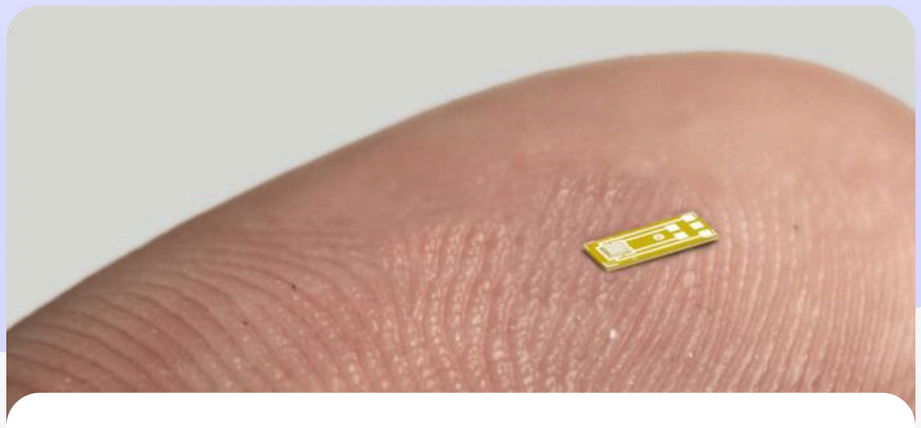
A right-first-time approach for the journey to market

InVivo Bionics



About InVivo Bionics

InVivo Bionics is a Norwegian company bringing a hybrid software/ hardware medical device to market.

Their innovative pressure microsensor, less than 1mm across, sits within the bladder and relays real-time information via the cloud to help treat patients with urinary dysfunction.

Industry	Medical device
Regulations	• EU MDR • ISO 13485
Uses Qualio for	• Documents • Training • Design Controls

The challenge

Founder and CEO Ingelin Clausen came from SINTEF, a contract research giant based in Trondheim, to set up InVivo Bionics in 2018. Ingelin's experience in a highly mature, successful life science organization meant she was keen to start her new project in the strongest, most quality-centric way possible.

The new InVivo Bionics team was keen to implement a system that would allow:

- Audit trailing and full traceability of quality data
- Centralization of the entire QMS in one tool
- Control of key quality areas like design controls, CAPAs and customer feedback as the company approaches marketization

2x

Speed to market

100%

Company engagement with Qualio

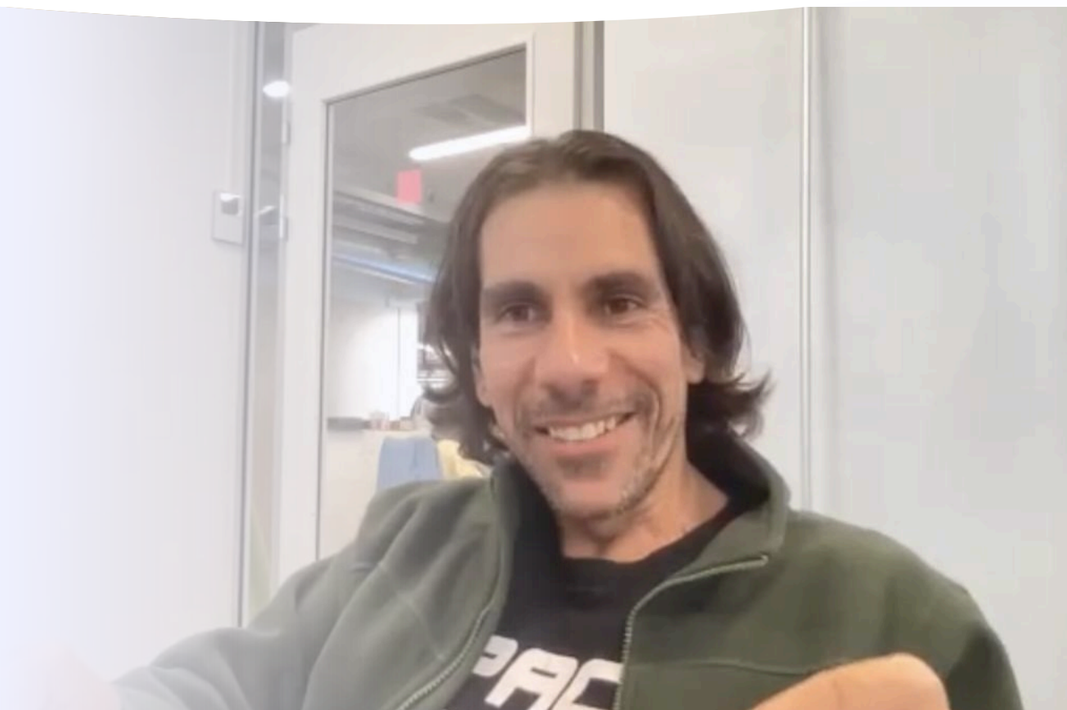
1x FTE

Spend mitigated by Qualio

We've taken the stance that our QMS isn't just for regulatory purposes. It is the company. So everything we do is in Qualio. We're embedding as much as we possibly can."

— Daniel Aragao

Chief Technology Officer, InVivo Bionics



The solution

As a holistic eQMS platform housing all quality activity in an easy-to-use interface, Qualio was selected as the best eQMS for InVivo Bionics' plans.

After a white glove onboarding and validation set-up, Qualio now provides a central quality platform accessible across the InVivo operation.

Staff, consultants and suppliers all log into Qualio to access and act on accurate, up-to-date quality information – and drive a high-quality pathway to the European market.

Qualio provides a single place where multiple quality functions can operate in a single platform. If I want to track training, I can do that. If I want to see feedback and CAPAs, I can see them. If I want to view my user requirements, I can. Qualio lets us do a better job and gives us a higher-quality quality system."

— Daniel Aragao
Chief Technology Officer, InVivo Bionics

The results

The InVivo Bionics team has clustered around a single source of quality truth for their journey to market

Strong design control management

Chief Technology Officer Daniel Aragao works closely with InVivo's product engineering team and with medical subject matter experts within Qualio's Design Controls area.

Engineers assess risk probabilities, while clinicians and nurses assess risk severity and advise on patient requirements. **Requirements** are then categorized, device **risks and controls** added, and **verification and validation** tests recorded.

Time-stamped design control changes then form tasks for Daniel and the team to strengthen and **evolve their product with complete confidence**.

Collaborative quality

Qualio knits together the InVivo operation to strengthen and accelerate the route to market. Documents are written, reviewed and circulated by the **quality team** to produce a core of relevant, appropriate information. **Staff** log in to complete training on those documents.

Quality **consultants** supporting InVivo's route to market log in to audit InVivo's quality landscape and make data-driven recommendations. And **suppliers** are provided with content from Qualio to align their activity and provide a higher-quality service.

Culture of quality

Daniel uses Qualio to ensure quality is embedded into each and every process in the company, instead of being relegated to a tickbox regulatory exercise.

"We didn't want to just get a tick and say, 'regulatory done'. If we'd wanted to do that, we'd have purchased templates from some random company and created some documents. But that wouldn't reflect our way of operating. We're building a quality product. So we bought a tool that gives us a quality culture. Instead of pushing quality to one department, Qualio breaks down that barrier."

Daniel plans to introduce Qualio's Events functionality in the near future, using CAPA workflows to capture and act on internal feedback. In this way, the entire business drives the quality of InVivo's medical device, even pre-production.

Faster, higher-quality route to market

Without the daily hurdles of email chains, paper and cluttered data, Daniel estimated the company's speed to market with Qualio was **'maybe 100% or 200% faster'** than it would've been.

That prediction has come true. Since going live with Qualio, the InVivo team has stormed their quality objectives, going through **design verification in 2024**, securing **ISO 13485 certification using Qualio in 2025**, and now chasing **CE mark accreditation in 2026**.