

The Right Partner for Startups and Small Businesses

Case Study RetroBrain R&D GmbH

The Company

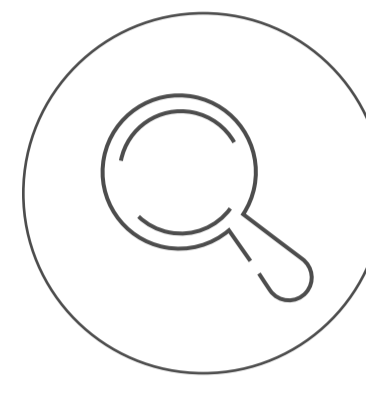
RetroBrain R&D GmbH is a startup in the field of software development.

RetroBrain researches and develops video games designed to address challenges in everyday medical care and therapy. The focus is on older adults living in nursing homes.

- ✓ Successful EU certification as a medical device
- ✓ Full compliance with legal requirements
- ✓ Building internal expertise in regulatory affairs

“Especially as a startup, it’s important to have someone in the background who really understands the market [...]”

- JASMIN MÜLLER
RetroBrain R&D GmbH



Overview

Retrobrain sought external support from the Johner Institute for its regulatory approval project.

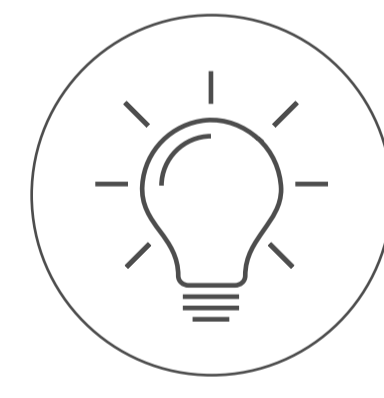
With the help of tailored consulting and services, as well as participation in various seminars, the company not only successfully obtained certification but also built up internal regulatory expertise. Since the project’s completion, the Johner Institute has continued to serve as a reliable partner for regulatory matters.



Challenge

Retrobrain has developed a product that has been classified as a medical device.

However, as a small startup consisting of software developers, project managers, and physical therapists, the company lacked the in-house expertise needed to determine exactly what steps to take to bring the product to market as a medical device in Europe. This lack of regulatory expertise had to be sourced externally.



Solution

A team of consultants from the Johner Institute supported Retrobrain in the initial setup of its quality management system and the preparation of all technical documentation, successfully guiding the company through the certification process.

Since the project’s completion, the Johner Institute has continued to serve as the company’s regulatory partner, providing ad hoc support – for example, with updates to software documentation or the optimization of business processes.

AN OVERVIEW OF THE SOLUTION

- ✓ Direct consulting support in setting up a quality management system
- ✓ Preparation of all technical documentation
- ✓ Following successful certification, the Johner Institute remains regulatory partner



Result

“The Johner Institute brings together such a wealth of expertise. And as a medical device startup, that’s exactly what you need most during this phase.”

- JASMIN MÜLLER
RetroBrain R&D GmbH

Retrobrain has successfully obtained approval for its medical device on the European market and is very satisfied with the collaboration. The following aspects are particularly appreciated:

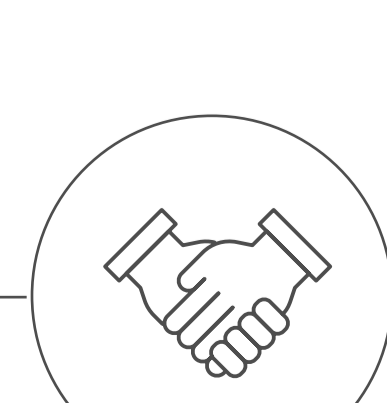
- Expertise and foresight in the regulatory field
- Professional and competent project management
- A relaxed and straightforward relationship as equals
- Clear and accessible knowledge sharing
- Effective internal communication and collaboration within the consulting team
- Efficiency, flexibility, and consistent reliability

Conclusion



JASMIN MÜLLER
(Head of Science),
RetroBrain R&D GmbH

“As a startup, it’s especially important to have someone in the background who truly understands the market, knows the regulatory landscape, and is familiar with the pitfalls of certification thanks to years of experience. The Johner Institute brings together so much expertise. And as a medical device startup, that’s exactly what you need most during this phase.”



Would you like to work with us?

CONTACT