How 41textile built its digital QMS and validated five modules in 16 days

Scilife

41textile

See the Customer Story

Scilife + 41textile

About 41textile

41textile is a Swiss medical device company developing braided textile implants. Its solutions address challenges where soft and hard tissue meet, including reconnecting damaged tendons or ligaments to bone. Soft, flexible braided structures can pass through small surgical portals, offering potential applications across sports medicine, trauma, spinal procedures, and other areas of musculoskeletal care.

The Challenge

41textile began with three people working part-time and sharing around 13 to 15 roles. While establishing operations and preparing for ISO 13485 certification, the team needed a quality system that could grow with the business.

Inherited processes provided a foundation, but relied heavily on Word, Excel, and manual administration. Disconnected records made updates difficult to coordinate.

With limited personnel and colleagues working across locations, the company needed to connect its processes, reduce administrative work, and access records remotely.

The goal was to retain proven processes while avoiding the manual work of the past.



Industry

MEDICAL DEVICES

Regulations

ISO 13485 CERTIFICATION PREPARATION

Uses Scilife for

DOCUMENT CONTROL

CHANGE CONTROL

CAPA

EQUIPMENT

“Nothing was connected or linked.

The system worked, but it was very hard to keep alive.”



Philippe Gédet,
Chief Operating Officer

The Solution

“As we are a small team, we all have to take on several roles. That makes efficiency especially important.”

Michelle Stutz,
Chief Technology Officer

Building a connected, scalable QMS

41textile chose Scilife to keep its quality system lean, adapting supplier documentation to validate its own configurations and processes.

Scilife supplied evidence for core functionality, allowing the team to concentrate on its intended use and specific workflows.

Key reasons for selecting Scilife included:

- → **Connected quality processes**: documents, approvals, and quality records linked within one system.
- → **Reduced validation effort:** validation plans, configuration specifications, and testing protocols provided a foundation.environment
- → **Focused workflow testing:** the team checked approvals, audit trails, and links between records.
- → **Room to grow**: a modular approach supported immediate needs and future expansion.



Michelle Stutz,
Chief Technology Officer

“The documentation took a lot of the validation burden away from us. We were able to focus on validating whether the system worked the way we expected it to work. That meant checking our workflows, approvals, audit trails, and links between items.”

The Results

“The audit was quite straightforward. We were able to show almost everything in the system, and it did not take long for the auditor to trust it.”

***Niklas Frietsch**,*
Team Leader and Project Manager

- **Five modules validated in 16 days**: three colleagues completed initial validation in around 60 combined hours, covering Document Control, CAPA, Change Control, Audits, and Equipment.
- **Around 200 documents in progress**: SOPs, work instructions, templates, and controlled documents are managed together, without manually coordinating versions.
- **Confidence during internal auditing**: the team demonstrated processes directly in Scilife, helping an unfamiliar auditor understand and trust the system.
- **Controlled software updates**: release assessments identify changes requiring targeted revalidation. Updates without an impact on validated functionality receive a documented rationale.

The company continues building its QMS as it works toward achieving ISO 13485 certification.

Advice for other medical device startups



***Niklas Frietsch**,*
Team Leader and Project Manager

Prioritize the processes you need and validate early. Once the system is in use, your team can build evidence that procedures are actively followed, strengthening preparations for future audits.

“It is important to know what you need and prioritize it.”

Make quality your advantage with Scilife

Quality is full of opportunities. We're here to help you make the most of them.

Join life sciences companies like White Raven, Novartis, and Biocartis who trust Scilife to simplify their processes, support their teams, and stay ready for inspections.

With connected work˜lows and clearer oversight, you can spend less time managing compliance and more time moving your business forward. Give your team the tools to work con˜dently, keep quality at the heart of every decision, and focus on what matters most: helping bring safe, life-changing therapies to patients.

Now, over to you. What would better quality management look like for your team?

Get in touch

EMEA O˜i ce
Kantersteen 47
1000 Brussels
Belgium

US O˜ ice
Scilife Inc.
228 E 45th St. RM 9E
New York, NY 10017

scilife.io

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