

 SOPHiA GENETICS®
Case Study

How RadBee helped SOPHiA
GENETICS digitise their quality
management system and pass their
certification audit in under five weeks

SOPHiA GENETICS is a global leader in data-driven medicine. They're responsible for the SOPHiA Artificial Intelligence which analyzes and learns from genomic testing around the world to deliver new insights and help clinicians diagnose and treat their patients.

HIGHLIGHTS

CHALLENGES

- Inefficient paper-based quality management system that made information retrieval challenging
- Tight deadline before impending recertification audit
- A massive growth phase, meant that the company outgrew its paper-based system.

SOLUTION

- Use Confluence, which was already used across the organization anyway, as the platform for controlled documents.
- Extend Confluence to comply with regulatory requirements and the specific controlled documents procedures of SOPHiA
- Created a staging environment which allowed the SOPHiA GENETICS team to provide feedback on new changes and prepare for the migration
- Perform system validation, required for regulatory processes
- Transitioned paper-based collection of documents to Confluence prior to audit
- Ensured new digitised quality management system met or exceeded compliance standards

RESULTS

- Successful recertification audit
- A new digitised quality management system
- 80% less paperwork
- An estimated 30% time saved on all future audits

CHALLENGES

Paper-based quality management system not keeping pace with company growth

For businesses in the pharmaceutical, biotech, and medtech industries, meeting strict regulatory and compliance requirements is non-negotiable. Failing to meet compliance standards might mean lost business or even a complete shutdown of operations.

These were risks that Jasmine Beukema, VP Quality at SOPHiA GENETICS, knew all too well.



“As a biotechnology company in the health industry, we need to prove that we’re handling data in the most secure way possible—which means passing our ISO 27001 certification audits,” **Jasmine says.**

“We’re constantly working to improve the quality of our products, processes, and the way we work together as a company, and it’s essential that we remain compliant with everything we need to be compliant to.”

Jasmine and her team have worked diligently to ensure that SOPHiA has always met the medical device industry’s strict standards over the years.



“Our company is a start-up company—we started six years ago and we’ve had a quality management system in place since the beginning,” **Jasmine reminisces.**

But while SOPHiA’s quality management system proved effective for its first few years of business, Jasmine quickly realised that it couldn’t keep pace with the rate at which SOPHiA was growing.

“At first, we used a paper-based system to ensure that all of our procedures met industry standards,” **she recalls**. “But our company has been growing very fast. Six years ago we were six people. Now, we’re over 150. Our paper-based quality management system just wasn’t working anymore.”

The problem with SOPHiA’s old paper-based quality management system was that it created excessive paperwork and unnecessary overhead—especially during critical times, such as audits.

“When you’re audited under a paper-based system you can find the right procedures, but it takes a lot of time. Whenever the auditor asks you a question, you need to go door-to-door and disturb people while they’re working to find the right binder and the correct documents,” **Jasmine grimaces**.

With a new audit only five weeks away, Jasmine knew that something had to change if SOPHiA was going to get recertified.

“We had an upcoming audit—which meant a very strict deadline. We only had five weeks to digitise our complete quality management system,” **Jasmine says**. “We needed an electronic solution, and we needed it fast.”

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SOLUTION

Extending Confluence to support controlled documents

With SOPHiA's tight deadline looming ever closer, Jasmine busied herself finding solutions that would help make SOPHiA's quality management system more user-friendly and less time-consuming.

“At first, we considered digitising everything ourselves,” **Jasmine says**. “We were already using Confluence and we knew that it could support what we wanted to do, but we didn't have the internal resources necessary for such a project.”

Fortunately, one of SOPHiA's quality consultants offered an alternative solution. They recommended RadBee, an Atlassian Solution Partner that specialised in helping pharmaceutical, biotechnology, and medical devices companies get the full benefit out of their Atlassian tools, such as Jira and Confluence.

Jasmine reached out to Rina Nir, CEO of RadBee, and instantly knew that she'd found her solution.

“I had a kick-off meeting with Rina via Skype. I noticed right away that Rina and her team had a lot of experience working with Confluence—the software we relied on. She was very confident and motivated to start the project with us,” **Jasmine recalls**.

RadBee quickly drew up a game plan that would solve SOPHiA's immediate needs and meet their tight deadline.

“RadBee understood the situation in regards to our short time frame. They were able to answer any questions we had about Confluence and about moving our quality management system. They'd done this before, and their expertise created a lot of confidence that they were the right solution.” **Jasmine smiles**.

Most importantly, RadBee demonstrated a fluent understanding of all the regulatory requirements SOPHiA needed to meet.

RadBee's first step after finalizing their initial plans with SOPHiA was to set up a staging environment where they could install prototype implementation. Jasmine and her team had full access to this staging area, which allowed them to monitor ongoing improvements and provide constant feedback.

“**Jasmine remembers**, *“The team at RadBee were very open to our suggestions, but they also came up with their own ideas on how to improve our quality management system.”*”

RadBee's main job in the weeks leading up to the audit was to extend Confluence to support SOPHiA's controlled documents—the official collection of documents kept for regulatory, operational, and quality processes. This would make finding procedures, linking procedures, and uploading supporting documents easy.

Once Jasmine and her team had approved their improvements in the staging set up, they were able to transfer these improvements to their production environment.

“*“In terms of efficiency, RadBee showed us how to optimize the use of a tool we were already using. They taught us a lot of tricks and shortcuts and links we could create,”* **Jasmine says**.”

RadBee also carried out the system validation—a formal, documented testing cycle to ensure that everything complies with requirements. And they still keep regular contact to ensure that everything's running smoothly with Jasmine and her team.

“*“Whenever we have a question, or a problem, or something that needs attending to quickly we can contact RadBee—even during evenings and on weekends,”* **Jasmine says**. *“They're always happy to help.”*”

And while normally a project like this takes much longer, RadBee pulled out all the stops. SOPHiA's controlled documents were ready within five weeks, just in time for their audit.

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RESULTS

An audit-ready, fully digitised system in under 5 weeks

A few days after SOPHiA's paper-based collection of documents were transitioned to Confluence, the company was audited for their ISO 27001 certification. They passed with flying colors.

“Passing the audit was a huge relief for the whole department,” Jasmine **sighs**.

She also noticed that this audit went more smoothly than previous audits, thanks to SOPHiA's new electronic system.

“This audit was much less stressful and less invasive on the company because we didn't need to disturb people while they were working to request specific documents,” **she says**.

As for the long-term benefits Jasmine is already seeing improved efficiency across the entire company.

“It's hard to put a number on exactly how much time RadBee's saved us, but I'd say that it will easily cut down on 30% of the preparation time before future audits,” **Jasmine says**.

“And it's streamlined so many other processes,” **she adds**. “For example, now we have an electronic approval system, so when we need to change a procedure, we can just assign someone to approve it using an add-on for Confluence (Comala workflow) . It's more effective, and it saves a lot of time.”

And by integrating SOPHiA's controlled documents with Confluence, a system that their team already used, they've cut down on the needless overhead that was squandering human resources.

“The process isn't completed yet—we had a mountain of documents that needed to be entered. But I'd say RadBee's already reduced our paperwork by about 80%,” **Jasmine marvels.**

In fact, Jasmine was so pleased by her results that she was happy to recommend RadBee to others—and she's confident that they'll always be happy to help whenever her team is in need of support.

“The best part of working with RadBee is their flexibility, their attitude, and their willingness to help. Overall, working with them was very good. They've easily paid for themselves.” **Jasmine smiles.**

Now, Jasmine and her team are confident that they're meeting compliance and regulatory requirements, and that their new quality management system will withstand future company changes and growth.

“Setting up our controlled documents on Confluence has definitely improved our compliance and made everything more efficient.”

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Regulatory compliance doesn't have to be a hassle.

Find out how we can help you improve your quality assurance processes and controlled documents in JIRA and Confluence.

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