Veeva MedTech

CUSTOMER STORY

SOPHiA GENETICS™

SOPHiA GENETICS Transforms Quality Management to Ensure Compliance and Scalability

SOPHiA GENETICS, a software company dedicated to establishing the practice of data-driven medicine as the standard of care and for life sciences research. But significant growth presented SOPHiA GENETICS with the challenge of establishing a quality management system that could help it optimize efficiency and ensure regulatory compliance as it scaled.

By planning from "as-is" to "to-be," SOPHiA GENETICS increased the number of approved documents by more than five-fold in just a few months, leveraging Veeva Vault Quality Suite and adapting business processes. Melissa Finocchio, Chief Regulatory Officer, and Tom Petty, Director, Quality Systems & Knowledge Management, share their company's story.

HEADQUARTERS
Switzerland

FOUNDED
2011

NUMBER OF EMPLOYEES
500+

SOLUTIONS
- Vault Quality
- Vault PromoMats

Growing Medtech Launches Digital Transformation

In just over a decade, SOPHiA GENETICS has grown more than 500 employees and has a platform and sales presence in 72 countries. In July 2021, SOPHiA GENETICS went public on the NASDAQ. One year later, the company reached the milestone of one million genomic profile analyses.

"We've had a significant growth," said Finocchio. "And now, with more than one million profiles available for community diagnostics, we have a wealth of information that's helping drive data decisions and break down silos. That's why we decided to start our digital transformation journey. We needed to be ready to scale and remain compliant as we move forward."

The first step for SOPHiA GENETICS was to prepare for resistance. Even at a relatively new company, Finocchio knew she would encounter push-back on changing the way they performed their daily duties. So she and her team decided from the outset to keep in mind the difference between standardizing—where everyone must perform tasks in exactly the same way—and harmonizing.

"I like to put it in musical terms," Finocchio explained. "If we're singing a song and somebody's off in their own key, we're going to have problems. But if everyone is singing their own part in harmony, we can work together."

With that mindset, SOPHiA GENETICS set out to identify and prioritize processes for standardization and harmonization. Critical processes that were highly visible around the world were often the best candidates for standardization. But Finocchio and her team had to consider the current, or "as is," state of these processes, including how automated they were, what pain points they were causing, how many other processes they touched, and the balance of cost versus impact in standardizing each process.

"Oftentimes we're really tempted to tackle the big, complex processes that everyone uses," said Finocchio. "Although standardizing these processes may eventually yield the biggest return, it won't deliver the quickest win. Meanwhile, you'll probably lose people along the way, especially as executives notice the cost of what you're implementing and realize they haven't seen any results yet. That's why your biggest pain point isn't always the right place to start."

> *With more than one million profiles available for community diagnostics, we have a wealth of information. We needed to be ready to scale and remain compliant…that's why we started our digital transformation.*
>
> — Melissa Finocchio, Chief Regulatory Officer, SOPHiA GENETICS

Choosing the Right Things to Automate

After identifying and prioritizing the processes to address, Finocchio and her team took the time to understand these processes in depth so that they could choose between standardization and harmonization. They read existing documentation and used the "Five Whys" to interview stakeholders about why these processes were running the way they did. From there, they determined the minimum viable process in each case and made that their goal.

As part of this step, the team identified processes to automate. Contrary to conventional wisdom, they found that not all automation is worth the effort. “If a process isn’t performed very frequently, it may not benefit from automation,” explained Finocchio. “Tasks that are repetitive or involve data used across your organization are good candidates for automation.”

Team members then adapted their planned or “to be” state, based on what they had learned about the “as is” state and the best practices built into Veeva Vault Quality. Next, they planned for their implementation by measuring the gaps between “as is” and “to be”, planned their scope, and carefully documented a transition plan.

Supporting Global Expansion with Scalable QMS

“We wanted a tool that could scale with the company,” explained Petty. “And at the time, we were having a lot of challenges using the tools that we used to establish our initial QMS when the company was small. We had about 100 employees and it was working at the time. But now that we’re multinational and moving towards a business process-based quality system, we needed a tool that could perform and scale with us. That’s why we chose Veeva MedTech.”

SOPHiA GENETICS chose its quality management solution by carefully evaluating its user requirements and then assessing different solutions. The Veeva Vault Platform was the only solution that could meet 100 percent of SOPHiA GENETICS’ user requirements in 15 key areas, including regulatory, document control, audit management, supplier management, nonconformance handling, global quality management, and information security. The next question was, which specific Veeva products should SOPHiA GENETICS implement?

“Our Executive Team was highly convinced that Veeva Vault Platform was the way forward for us,” recalled Finocchio. “But we now distribute to a global market and need to make sure all of our customer-facing documentation is reviewed and approved by our legal, regulatory affairs, and quality departments, and that our sales and commercial teams have access to the latest information. Developing our own tools for this would have been far too expensive. Fortunately, Veeva’s Quality Management solution met all our needs.”

> *This happened while we were still straddling our old system and our new Veeva platform. In two days with multiple auditors, we pulled 300 documents out of Veeva Vault Quality to show them, and with no major non-conformities. In a very dynamic landscape in a medical device company, that's not easy.*
>
> — Tom Petty, Director, Quality Systems & Knowledge Management, SOPHiA GENETICS

Data Availability and Audit Readiness

As SOPHiA GENETICS' rollout of Veeva Vault Quality approached, anticipation built throughout the company — especially in the executive offices. "Our CEO was so excited," recalled Petty. "He asked me to put a countdown clock on our website with a pink box that told everyone how many days we were from the launch."

Once SOPHiA GENETICS went live on the new system, that anticipation translated into rapid adoption. In January 2022, the company submitted 22 documents to the system, of which 18 were approved. By March, those numbers had swelled to 364 and 287 respectively.

"One of our main goals is to make data available through the community and break down silos," Finocchio confirmed. "The more customers we have putting data into the system, the better our data becomes."

SOPHiA GENETICS recently put Veeva Vault Quality to the test as part of an audit. The company shared 300 documents with auditors in just two days—without a hitch.

"This happened while we were still straddling our old system and our new Veeva platform," said Petty. "In two days with multiple auditors, we pulled 300 documents out of Veeva Vault Quality to show them, and with no major non-conformities. In a very dynamic landscape in a medical device company, that's not easy."

For more information, watch the full playback of SOPHiA GENETICS' session, visit the Veeva MedTech website, or contact us.

Watch the playback now