Sorting out quality and compliance with a proactive cloud vendor

XCURES

Industry	Software as Medical Device (SaMD)
Regulations	• 21 CFR Part 11 • 21 CFR Part 820 (510(k)) • HIPPA • CCPA • GDPR
Uses Qualio for	• Documents • Training • Events

About xCures

xCures is a health and wellness start-up that provides an advanced algorithmic AI platform connecting cancer patients to targeted oncology treatment.

By transforming unstructured and complex medical information into actionable data, xCures' AI engine matches patients with the most suitable of the 9000 cancer treatment options currently available, including clinical trials – then liaises with clinical trial providers, predicts the outcome and secures treatment.

The challenge

xCures was struggling to meet its compliance requirements with a paper- and spreadsheet-based quality system underpinned by manual training processes.

A sponsor audit found an incomplete and improperly organized QMS. And as the company secured early funding and began to grow beyond start-up status, only *more* sponsor audits and FDA scrutiny could be expected.

Mike Trudnak, VP of IT and Information Security, knew that getting xCures' quality and compliance under control was 'Task #1', and began the search for a better way to manage quality.

100s of hours/year

Of admin work eliminated

1x FTE

Spend mitigated

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Manual, paper-based processes

"It was super-easy. Qualio did all the heavy lifting and we just grabbed the validation package.

We're in the business of precision oncology. Certainly we need a QMS, but let the experts be the experts. Cut that check and move on!"

— Mike Trudnak

VP of IT & Information Security, xCures



The solution

The xCures team is a mixture of IT, software, AI and medical oncological professionals – and so the need for an electronic quality management system was quickly accepted by Mike's colleagues. Mike identified multiple eQMS vendors, but homed in on Qualio because of several key factors:

1. The xCures team wanted to focus on their day-to-day work with minimal software upkeep demand, making a cloud-based system a must
2. Qualio's mature integrations offering with tools like Jira simplified testing and evidence collection processes for the xCures team, and was a must-have for VP of Engineering Bill Mahoney
3. Qualio's easy-to-use document management would allow the team to ditch unwieldy email chains and centralize information logically for their next audit

xCures became Qualio customers in July 2021. Qualio provided a rapid and straightforward onboarding process for Mike and the xCures team, allowing their new eQMS to be built and rolled out ready for the next phase of xCures' business plan.

> *"I'm wearing about sixteen hats here. So me getting back hundreds of hours in a year thanks to Qualio is the equivalent of about one FTE.*
>
> *Qualio has given us one more staff member in a company where we throw nickels around like manhole covers!"*
>
> **— Mike Trudnak**
> VP of IT & Information Security, xCures

The results

xCures relied on Qualio to upgrade their quality system for them, with minimal in-house effort

Paper out, cloud in

By replacing spreadsheets with an **intuitive and easy-to-use cloud-based platform**, the groundwork could be laid for business-wide engagement with quality – strengthening xCures' compliance for their FDA approval journey without the headache of on-premise upkeep.

Mike identifies his favorite Qualio feature as the new and improved document editing functionality, allowing electronic QMS documents to be built, manipulated and securely distributed on the fly from within Qualio.

Dramatic time savings

To build a business case for Qualio investment and the move from paper and spreadsheets to a dedicated software platform, operational efficiencies and time savings were presented as a key ROI factor. As expected, the xCures team noticed significant time savings after implementing their system, with Mike estimating **hundreds of hours of admin time** being sliced from the working year. As a result, around 1 FTE worth of time and operational cost was eliminated from the bottom line, freeing up xCures for targeted value-add activity.

A tool for the future

The disorganization of xCures' old quality system has been eliminated. The team anticipates Qualio as being **'front and center'** of their strategic goals for 2022, and can now look to tackle their upcoming FDA 510(k), SOC 2 and new sponsor audits with **confidence, compliance and control**.

Partnership

The xCures team were happy to lean on a **specialist cloud vendor** for the set-up of their new quality system, allowing them to focus on their life-saving work and go-to-market plans. Qualio performed the heavy lifting of **validation and implementation**, then committed to a long-term partnership to help Mike and the xCures team on their journey to continuous quality improvement. As Mike puts it:

"Some software companies sell you a system and completely take advantage of you. That's not what we got with Qualio. Everyone's walked away happy."