

TG Therapeutics Safeguards Security and Boosts Availability with TrackWise Digital[®]



TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases.

THE OPPORTUNITY: Kicking Security Fears with the Cloud QMS

When Phay Lee, Senior Manager of Quality Systems, arrived at TG Therapeutics Inc., she was already well experienced with on-premises quality management system (QMS) software. But to meet the demands of the company's virtual workforce, Lee needed a product with both the intuitive functionality to enable simultaneous access for multiple users and the ability to minimize downtime.

A cloud solution was the obvious answer. But between its valuable intellectual property (IP) and patients' highly sensitive personally identifiable information (PII), TG Therapeutics also needed confidence that a cloud QMS could provide the robust security of traditional enterprise on-premises solutions.

In 2018, TG Therapeutics began their search for a new QMS. But first, Lee had to address stakeholders' ongoing reservations around security.

"There was some apprehension around potential security risks," explains Lee. "We had reservations about security issues and regular backups, not to mention how to encourage widespread adoption with staff who were used to on-premises software."

"Security was our biggest concern ... we needed a QMS solution that our remote staff could access safely and securely."

*Phay Lee, Senior Manager,
Quality Systems, TG Therapeutics*

THE SOLUTION: TrackWise Digital Provides Secure Self-Service for Remote Teams

Lee had long been a convert of Sparta Systems' TrackWise QMS, having used the enterprise solution at previous companies. After plenty of research and recommendations, Lee's team decided on TrackWise Digital, which not only builds on the heritage of the on-premises offering but provides new benefits in the form of a robust, digitally mature cloud solution.

TrackWise Digital's security controls include use of a Privacy Shield framework. Plus, this digital, GDPR-ready QMS has achieved both SOC II attestation and ISO 9001:2015 certification. And thanks to Sparta's Privacy by Design approach, TrackWise Digital complies with Title 21 CFR Part 11 and all the associated rules of data integrity and security.

In addition, TrackWise Digital's secure cloud software provides a self-service system that has slashed TG Therapeutics' reliance on external IT support and expensive outsourcing to IT consultants. With its virtual

teams relying on cloud servers instead of physical servers, TG Therapeutics is also less at risk of compromised server rooms.

The enterprise cloud QMS has also helped TG Therapeutics improve business continuity.

"With TrackWise Digital, there's no need for administrators to take the system down to do any configurations or system admin work, which was a huge advantage," says Lee. "In the two years TG has used TrackWise Digital, we've not shut down the system to any user yet."

"TrackWise Digital worked just as effectively as the enterprise version and with greater usability."

*Phay Lee, Senior Manager,
Quality Systems, TG Therapeutics*



THE RESULTS: Security and Streamlined Processes that Improve Productivity

The self-service system has provided a significant boost to productivity, helping to reduce downtime and costs. Lee's team can access remote servers without the need for costly external IT support.

Lee also notes that TG Therapeutics experienced an increase in efficiency almost immediately. "As a lean virtual business dependent on the cloud, TrackWise Digital helps us to be much more agile and faster, so we can better manage the business. We saw processes becoming more streamlined and remote staff across multiple locations found it easier to access the cloud QMS," Lee says.

TrackWise Digital also streamlined the company's previously paper-based change control process. Now, digital signatures are obtained quickly, real-time reporting is achieved, and many time-consuming manual tasks have been eliminated.

Best of all, TrackWise Digital has proven to be a secure, reliable tool that has encouraged widespread adoption across the company's previously reluctant user base. "We've even found that other teams outside of the quality assurance department are using TrackWise Digital," says Lee. "There's wider usage and collaboration across multiple teams."

"TrackWise Digital has enabled us to save time and money and work in a more agile way mainly because the software is so user-friendly it encourages widespread adoption,"

*Phay Lee, Senior Manager,
Quality Systems, TG Therapeutics*

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