

Kadmon Pharmaceuticals Chooses TrackWise®



COMPANY OVERVIEW

NAME:

Kadmon Corporation LLC

INDUSTRY:

Global Biopharmaceutical

DISTRIBUTION:

Global

EMPLOYEES:

100+

SOLUTION:

TrackWise

Kadmon Corporation, LLC, is a global biopharmaceutical company offering products and services for the treatment and management of hepatitis C. Kadmon is also pioneering novel medicines in the areas of oncology, infectious diseases, immunology and neurodegenerative diseases. Headquartered in New York City, with operations in Boston and Pittsburgh, Kadmon is dedicated to challenging how treatments for serious diseases are developed today in an effort to develop the cures of tomorrow.

"TrackWise has transformed and improved our critical quality systems enabling efficient compliance, timely reporting and metrics."

*Christine Sheehy,
Senior Vice President of Operations*

THE OPPORTUNITY: Gaining Transparency and Moving from Paper to Digital

When Kadmon Corporation purchased Three Rivers Pharmaceuticals in October 2010, the organization doubled in size, growing in office space and employee numbers overnight. A conventional paper-based quality management system was sufficient for Three Rivers, but once the two companies merged into one, it was clear that multiple office locations and an increased number of employees would heighten the complexity of record keeping. Physical folders with important insights into product changes and updates could be easily lost or misfiled, resulting in an internal concern regarding a potential compliance risk.

Given the lack of transparency and scalability of the paper-based system, there was a need for a better solution to control the quality of relevant data using a closed loop change control process that was automated, centralized, and easily visible by all levels of management. The ideal solution was an enterprise quality management software (EQMS) system that was configurable, could support company growth, and document any clinical and commercial deviations and the resulting investigations, corrective and preventive actions (CAPAs), change controls, and effectiveness checks.

THE SOLUTION: An Electronic, User-Friendly Solution to Streamline Reporting

After evaluating another well-known software solution, Kadmon selected Sparta Systems' TrackWise EQMS to streamline its reporting and data presentation needs. Several Kadmon employees were familiar with TrackWise and considered it a top-rated quality management solution, making the choice to implement the software an easy one. Working closely with Sparta Systems to implement TrackWise SelectStart, the Company's purpose-built solution featuring preconfigured industry best practice quality processes, Kadmon was up and running with the software in less than four months, with minimal roadblocks.

Kadmon relied on SelectStart's out-of-the-box capabilities to quickly meet specific quality requirements, and to better monitor open issues and to track product updates. Prior to TrackWise, Kadmon relied on Excel spreadsheets to compile and share information with senior management. Using the web-based software, management can now easily run targeted reports and gain access to critical decision-making information. The ability to create personalized quality dashboards encouraged a cross-collaborative environment at Kadmon, eliminating errors and wasted time. Switching to an electronic system came with initial skepticism; however, the Kadmon staff found the implementation and transition to be quite smooth. Working with Sparta Systems' training team, concerns were addressed quickly, and employees soon became very comfortable with the user-friendly system.

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THE RESULTS: An Improved Quality Metrics Reporting Process

More than 45 Kadmon employees, nearly 20% of the company, are now using the technology to track and manage deviations, investigations, CAPA, change controls and effectiveness checks, resulting in improved management of the organization's overall quality metrics reporting process. The Company now has access to accurate data in a timely manner which increases the level of information sharing in a much clearer, precise format.

All manufacturing, packaging and testing at Kadmon is outsourced, and the Company is ultimately responsible for the tracking of vendor changes and deviations. Kadmon works with close to 60 GxP vendors and the volume of vendor activity is high, making TrackWise even more important when it comes to maintaining a streamlined supplier quality management process. Access to realtime, more precise supplier quality information helps Kadmon identify trends and issues earlier and ensures reporting is accurate and credible.

TrackWise allows greater visibility of critical information to employees of all levels, automatically generating reports to management and improving effective decision making, transparency of operational information, and collaboration throughout the organization. TrackWise also implements a high level of accountability within the Kadmon organization enabling action items to be assigned to individual people and groups and tracked through to completion. Widely considered one of the top quality management solutions available, TrackWise SelectStart enables Kadmon to leverage industry best practices, add processes as needed, and get up and running quickly, while providing the organization with a sense of comfort knowing its quality management system is centralized and streamlined for improved business efficiency.

Get in Touch

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REV1:210709



Sparta Systems, a Honeywell Company, is the world's premier provider of cloud and on-premises quality management software. For nearly three decades, companies in the life sciences have relied on Sparta for the innovative tools, analytics and expertise that speed up quality and compliance.

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