Aztec Technologies Guides Biotech Leader's Digital Transformation

CHALLENGE

A biotechnology company's laborious manual data management processes were hindering efficiency and compliance, demanding a modernized approach for streamlined operations.

SOLUTION

Together with partners, Aztec Technologies designed and implemented manual data entry software (MDES), providing a digital solution that enabled real-time data entry, comprehensive audit trails, and compliance with life science industry standards.

RESULT

Aztec's MDES implementation and subsequent 24/7 system monitoring optimized efficiency, reduced turnaround times, and ensured transparent compliance, transforming the company's manufacturing operations.

Centered in the mid-Atlantic region, a prominent biotechnology company found itself at a crossroads. Struggling with disparate and outdated data management practices, employees had grappled with lengthy manual processes and intricate compliance complexities. Recognizing the urgent need for modernization, the company turned to Aztec Technologies, part of Trinity Consultants, to help move the organization toward digital transformation.

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CHALLENGE

For this innovative biotech company, the process of managing data in paper batch records in Microsoft Access databases, Excel spreadsheets, and multiple electronic data repositories was starting to feel archaic. Critical data—including process data, sample results, and material specifications—required meticulous manual compilation, analysis, and reporting. The cumbersome process, which was orchestrated by a single individual, involved navigating through equipment run files, offline calculations, and extensive documentation reviews before being archived. Transcription of the archived data then demanded 24 man-hours per lot—a full three days of work—further exacerbating operational inefficiencies. The dire need for a controlled data bank and compliant data entry method was clear, driving the company to seek a new option.

SOLUTION

Partnering with the systems integration experts at Aztec Technologies, the company embarked on a multi-year journey toward digital transformation. The Aztec team conducted a detailed assessment of the organization's data landscape and found that the existing software fell short of meeting compliance requirements for GXP data. This included the verification of data, electronic signatures, and audit logs. Collaborating with a trusted software development partner, Aztec leveraged its deep knowledge of the biotechnology and pharmaceutical industries to create a robust, bespoke Manual Data Entry Software (MDES). This system was specifically designed to incorporate web-based interfaces, streamline processes, and meet 21 CFR Part 11 Compliance standards while also maintaining batch context within the data.

The new system gave the company access to a controlled data lake, facilitating real-time entry and review of data, along with three user levels—operator, supervisor, and administrator—ensuring comprehensive oversight and control. Furthermore, it provided the capability to capture reasons for data changes, approvals, and rejections, ensuring data integrity and auditability. The system also included seamless, automated integration with JMP statistical software for secure data analysis, eliminating potential points of failure or data integrity loss.

RESULT

Aztec Technologies' implementation of the MDES revolutionized the company's data management paradigm, offering seamless data entry, review capabilities, and comprehensive audit trails. This transition heralded a new era of efficiency and compliance, significantly reducing data analysis turnaround times and minimizing the errors inherent in manual processes as well as eliminating multiple data repositories. Real-time data entry and review capabilities empowered operators to make informed decisions promptly, while comprehensive audit trails enabled transparency and accountability, facilitating consistent compliance with industry regulations. MDES has eliminated the need to enter critical product quality relevant data on paper, while providing a digital solution in compliance with regulatory requirements for computerized systems and GMP data integrity.

Today, Aztec employees around the world actively monitor the customer's data archival systems and MDES 24/7, ensuring continuous support and optimization. As the company continues its digital transformation journey, it is also poised to embrace automated equipment, leveraging the foundation laid by the MDES to streamline operations and enhance company-wide efficiency. MDES has continued to evolve, keeping current with the needs and demands of the biotech and pharma industries, as well as with the constant innovations occurring within the software applications.

"Drawing upon Aztec's extensive expertise and industry connections, we provide integrated solutions to empower every customer's unique goals," remarked Roop Kumar, Managing Director of Aztec Technologies. "This company's journey from the dark ages of data collection to the forefront of digital manufacturing showcases the transformative impact of innovative solutions in shaping the future of biotech manufacturing excellence."

ABOUT TRINITY CONSULTANTS

Trinity Consultants, a leading global environmental consulting firm, provides services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Founded in 1974, Trinity has the technical expertise, industry depth, and capabilities to help clients achieve their goals across the natural and built environments.

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