

Developing an Electronic Batch Record Solution

Meeting Pharmaceutical Manufacturers' Needs



How Lonza worked with pharmaceutical manufacturer Nephron Pharmaceuticals to develop and implement the MODA-ES® Platform in an accelerated timeframe

Executive summary

- Nephron needed an electronic batch record (EBR) solution to support rapid expansion of its 503B operations
- The company collaborated with Lonza to implement the MODA-ES® Platform in an accelerated 9-month timeframe
- With Lonza's MODA-ES® Platform in late-stage development, Nephron's requirements helped to further direct the software platform's functionality
- Nephron implemented and validated the software in parallel with Lonza's release testing
- The MODA-ES® Platform enabled significant growth in Nephron's product line and improved operational efficiency

Impact

MODA-ES® Platform helped enable Nephron to:

- Significantly improve the accuracy and quality of its batch record data
- Streamline processes and significantly improve operational efficiency
- Grow its product line by 250%
- Reduce its QA batch review time to a matter of hours

The challenge: Paper-based batch records limited Nephron's growth potential

The batch record process is an essential part of pharmaceutical manufacturing, providing evidence that a batch has been produced in accordance with regulatory requirements. Each batch record generates a wealth of information that is traditionally collected using paper-based workflows. However, these processes are typically time-consuming and resource-intensive, and can impact on the speed with which products can be released to the market, limiting commercial competitiveness.

This was the situation facing Nephron, a leading manufacturer of generic respiratory and 503B outsourced medications. With the opportunity to expand its 503B operations in reaction to increased demand and imminent drug shortages, Nephron found that exhaustive paper documentation workflows were contributing to restricted business growth.

Each of Nephron's paper batch records typically generated 100–300 pages. The physical resources required to archive these records were vast, and accessing stored records was both slow and labor-intensive. Because creating a single paper batch record takes up to 4 days, bottlenecks that arose with multiple batches caused critical workflow delays. Similarly, the review and approval of batch records were time-consuming, typically taking between 4 and 6 hours per paper batch record.

These delays and resourcing pressures limited Nephron's ability to quickly respond to market changes and expand its product line. Nephron recognized that to substantially improve the quality and efficiency of its manufacturing workflows and ensure compliance with regulatory requirements, the business needed to rapidly overhaul and optimize its batch creation, review, and approve processes.

The solution: Nephron partnered with Lonza to implement an EBR system

EBR systems are software-driven solutions for managing record-keeping and review workflows, which eliminate the time-intensive extraction, checking and analysis steps associated with paper-based batch record processes. These efficient and agile systems are not simply an electronic equivalent to outdated paper-based documentation (often referred to as 'paper on glass' solutions). Instead, they transform how pharmaceutical manufacturers operate by enabling real-time data collection and ensuring strict execution of batch processes, thereby improving the quality and consistency of data and supporting GMP compliance.

Looking to grow its product line, Nephron urgently required a solution. However, previous attempts at finding an affordable EBR that met its business needs had proven unsuccessful. Commercially available paperless systems were either pure 'paper on glass' equivalents or designed from an automation perspective without the possibility of user-mediated configuration. Maintaining such a system was complex and required extensive investment in IT resources, which was simply not cost-effective for a small-to-medium-sized company like Nephron. When Nephron discovered that its existing supplier, Lonza Informatics, was developing a new EBR system for pharmaceutical manufacturers – the MODA-ES® Platform – a collaboration evolved, based on the partners' mutual requirements.

Nephron's EBR requirements, fulfilled by Lonza's MODA-ES® Platform

- Offer excellent ROI
- Optimize batch record efficiency
- Improve record keeping accuracy
- Easy-to-use and user-configurable, allowing flexible process control
- Enable exception-based batch review, supporting real-time investigation and issue resolution

Working closely with Nephron, Lonza agreed to its aggressive timeline by reducing the implementation timeframe of the MODA-ES® Platform from its original and ambitious 14-18-month plan down to just 9 months. Geoffrey Swafford, Senior Implementation Manager at Lonza, said, "It was a demanding timeline, but Lonza had the experience and expertise to deliver against it."

Nephron agreed to validate and test the MODA-ES® Platform in parallel with Lonza's software release process. Early-stage implementation and validation enabled Nephron's requirements to drive improvements in functionality, and in particular, the system's user-friendly and configurable design. Bryan Beck, VP of Automation and Information Technology at Nephron, commented, "We needed a user-centric EBR platform that we could implement and grow rapidly to meet our expanding business needs."

The results: A collaborative approach enabled rapid success with the MODA-ES® Platform

Lonza developed and implemented the MODA-ES® Platform in just 9 months, an accelerated timeframe compared to the typical timespan of 2-4 years for the development and implementation of other EBR systems. The collaborative approach taken by Lonza and Nephron, with parallel implementation and robust testing of multiple beta versions of the software, enabled this expedited software roll-out.

Nephron was delighted to partner with Lonza and reports finding their MODA-ES® Platform to be an affordable solution that delivered excellent ROI. Reporting on how its performance exceeded Nephron's expectations, Bryan Beck noted, "The 6-hour review needed for paper batch records was reduced to an hour with the MODA-ES® Platform, so it increased our efficiency significantly.

The MODA-ES® Review and approve process allows for real-time review as the batch advances through the product lines from formulation through packaging." The improved efficiency afforded by the MODA-ES® Platform allowed Nephron to expand its product range from 25 to 58 products, in 200 different configurations, within an accelerated timeframe.

The flexible architecture of the MODA-ES® Platform enabled Nephron to configure the system to accommodate its range of products and any associated changes in manufacturing processes. This was possible without needing to re-engage with Lonza for updates or new software. Data was input in real-time and was only necessary when processes were modified, eliminating the need to create a full record every time, as was the case with paper-based records.

Nephron had strong support from its senior management team to drive this forward, including Lou Kennedy, the owner and CEO of Nephron. Bryan Beck highlighted, "Lou Kennedy set us the goal of electronically recording the entire Nephron product line. It's quite ambitious, as the product line continues to grow, but we're on track – we already have 70% of products in the EBR."

The MODA-ES® Platform: A new approach to electronic batch records designed around the needs of pharmaceutical manufacturing

Nephron's paper-based batch reporting systems were inefficient, impeding opportunities for expansion. Lonza's expertise in developing and implementing EBR systems helped Nephron rapidly transition from cumbersome paper-based batch reporting to an efficient solution – the MODA-ES® Platform – a flexible EBR system designed with the needs of Nephron and other small-to-medium-sized pharmaceutical manufacturing companies in mind.

The MODA-ES® Platform exceeded Nephron's expectations and helped the company achieve significant growth, ultimately enabling the delivery of its products to market faster than the competition. For Nephron, the next steps are to further expand the software platform's capabilities. Looking to the future, Bryan Beck concluded, "The recently released version of the MODA-ES® Platform will allow Nephron to automatically integrate various data from other systems into the EBR workflow. For example, environmental monitoring, levels in tanks, particles in rooms and data such as room temperature and cleanliness – this will be a game changer on our EBR platform."

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