CASE STUDY

Natco Pharma looks to streamline development to enable faster regulatory approval

By Revvity Signals

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Introduction

Complex, manual R&D processes can delay the product development timeline and muddy the audit trail. To streamline processes and enhance compliance, Natco Pharma chose to transition to digital workflows, and selected Revvity Signals Notebook to help enhance development, strengthen control, and accelerate filings for regulatory approval.

- Digitizes report/request generation, saving staff time and effort
- Accelerates data transfer from lab to field
- Manages a robust audit trail for regulatory compliance

Natco Pharma is an industry leader in generic pharmaceuticals, with nine manufacturing facilities and research centers across India. Employing over 4,800 people, the company exports to over 50 countries worldwide. In the 2023-2024 financial year, the company achieved revenue of $499 million (4,195 crore). [1]

Rapid development that meets compliance needs

In a buoyant, growing sector, Natco Pharma seeks to gain market share, where being first-to-file and first-to-market offers significant commercial advantage. [2]

To support its business expansion strategy, the company looked for ways to streamline and accelerate its workflows while maintaining robust data audit trails for regulatory compliance. With complex ways of working established across multiple teams, managers knew that integrating disparate processes and systems offered the potential to save valuable time, cut costs, and improve productivity.

Naturally, Natco Pharma seeks to complete research and development (R&D), technology transfer, and lab and plant validation for each new product as quickly as possible, and file with regulatory agencies promptly and successfully. Always looking for efficiencies that will decrease the time and cost of experimentation, the company reviewed its workflows, which often relied on manual processes. For example, paper-based forms and templates such as sample forms, test requests, certificate of analysis (COA), working standard reconciliation forms and similar items took time to complete and validate, and often carried duplicate information. By re-architecting processes, Natco Pharma looked to reduce administrative tasks and improve data quality. In addition, improvements to data compliance would help to accelerate regulatory approvals, and the company reviewed opportunities to enhance data management.

P. Rama Seshagiri Rao, Manager of Data Quality Assurance at Natco Pharma, remarks, “Data authenticity is a major focus because regulatory agencies such as the FDA want to verify the compliance of each product. Providing a complete audit trail for the creation, modification, review, and approval of all records is essential for regulatory approval, and we wanted to find ways to streamline the process.”

Selecting Signals Notebook

To help fulfil the ambitious market objectives, Natco Pharma chose to transition to digital workflows, looking for end-to-end integration of its R&D processes and data management.

"Transitioning to an electronic system would open up new possibilities for data interconnectivity and dynamic field configurations, making it unnecessary to mimic the traditional formats with repetitive data entry. When it came to selecting the right solution for Natco Pharma, we based our selection criteria on five pillars: time, cost, innovation, compliance, and data archival retrievability," says P. Rama Seshagiri Rao. The result of our review was a clear choice for Revvity Signals Notebook."

For Natco Pharma, enhanced data integrity formed a key decision factor in favor of Signals Notebook. Robust compliance with the US Food and Drug Administration’s guidelines for data – Attributable, Legible, Contemporaneous, Original and Accurate (ALCOA) – would contribute directly to the company’s ambition to accelerate regulatory processes.

“Signals Notebook helps to ensure data authenticity, accuracy, relevancy and trustworthiness. Through discussions with Revvity and with a Proof-of-Concept evaluation, we understood that Signals Notebook can facilitate compliance effectively and securely. The system generates codes and unique tracking numbers for new projects without needing to complete documentation to request these from other departments. Where documents are required – such as experimental write-up, worksheets, internal requests, tabular records with embedded calculation formulae, and test request forms – templates are provided, where the completed documents are also stored. We can configure Signals Notebook to meet the user requirement, which is particularly useful for the chemist who is working on the bench, as it allows them to go ahead to the next step quickly.”

At the broader data management and administration scale, storing documents and experimental results in a single system, alongside inventories for raw materials, instrumentation, references and working standards will save Natco Pharma valuable time.

“We can get all the information to prepare the reports very quickly. If the inventory is available in the electronic notebook, then it is very useful for the chemist to go quickly to the next step, saying that, yes, I have the raw materials to start the reaction for the feasibility study. Similarly, automatic updates of reference and working standards include a dashboard update when a standard is about to expire, prompting product retests without delay,” adds P. Rama Seshagiri Rao.

“When tasks are assigned to chemists or group leaders, using Signals Notebook we can go to the next step very quickly, include the respective tests, and assign the task to the different R&D group leaders. Traceability and easy access of experimental results reduce the time needed to prepare the technology transfer documents.”

In addition, the Signals Notebook dashboard will allow team leaders to see the status of each project, allowing them to plan for the next experiment, closure, and feedback. As the company rolls out the solution, Natco Pharma will use Signals Notebook application programming interfaces (API) to integrate data with other systems. “Cost-effective configuration, connectivity, and collaboration with other instruments is very important”, explains P. Rama Seshagiri Rao.

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> ▪ **P. Rama Seshagiri Rao**
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> Manager of Data Quality Assurance at Natco Pharma

Accelerated productivity and a compliant audit trail

By deploying Signals Notebook, Natco Pharma is unifying its R&D processes and accelerating its journey to regulatory compliance, both key components of the company’s business strategy.

"As we digitalize previously manual processes and transition to Signals Notebook, it will help us to ensure data authenticity, accuracy, relevancy and trustworthiness. There is a definite time and cost reduction that is beneficial for process development. With all the dashboards available in Signals Notebook, it will be easy for us to go for the next stage of the process in a quick manner, complete our process flow successfully, and meet our filing objectives."

P. Rama Seshagiri Rao concludes, "We aim to complete R&D, technology transfer, lab validation, and plant validation processes as rapidly as possible, and then file the product with the different regulatory agencies quickly and without error. Signals Notebook will help Natco Pharma to enhance data management, streamline workflows and accelerate approvals, and drive our commercial strategy."

[1] https://www.natcopharma.co.in/wp-content/uploads/2024/09/Natco-Pharma-AR-2023-24-final-file.pdf
[2] https://www.grandviewresearch.com/industry-analysis/generic-pharmaceuticals-marketreport#:~: text=Report%20Overview,8.3%25%20from%202023%20to%202030.

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