



Zydus Lifesciences Limited is a fully integrated, global healthcare provider that primarily manufactures generic drugs. They develop and manufacture an extensive range of pharmaceuticals including skin care products, diagnostics, herbal products, and other OTC products. With a core competence in the field of healthcare, Zydus provides complete healthcare solutions ranging from active pharmaceutical ingredients, drug formulations, and wellness products to animal healthcare products. The company is a prominent player in the pharmaceutical formulations market with a strong foothold across multiple therapies.

Operations and Manufacturing facilities

Zydus has manufacturing capabilities across the value chain with more than 30 manufacturing plants worldwide. The group ranks 4th in the Indian pharmaceutical industry with research facilities and manufacturing sites spread across five states: Maharashtra, Gujarat, Goa, Himachal Pradesh, and Sikkim.

Stringent Regulations for Product Traceability Compliance

Being in the regulated industry and an active contributor to the field of research in the pharmaceutical domain, compliance is a stringent requirement at Zydus. In order to ensure the manufacturing of compliant products follow appropriate procedures that are well-documented, the manufacturing process has to be information-driven and cost-efficient.

In today's competitive and fast-moving manufacturing environment, Zydus has to facilitate regulatory compliance and data integrity. Quality adherence needs to be consistent, stringent, and cost-effective.

Challenges faced during Digitalization with Traditional Systems

To scale up digital technologies in operations, Zydus took a step forward to digitalize its manufacturing operations. The conventional manufacturing execution systems faced scalability and other compatibility issues. The need for a scalable framework that includes different standalone modules for phase-wise implementation was felt to reinforce a future-proof digitalization roadmap.

- 1. Firstly**, there was inconsistency in sample analysis as per schedules. At the Zydus oral solid dosages (OSD) production unit, as the in-process quality checks had to be done for every stage of multiple batches across several production lines, there were chances of missing sample analysis. With the increasing number of batches, it was difficult to monitor and perform regular analysis of the samples.
- 2. Secondly**, the IPQC instruments were not integrated due to which operators had to enter data manually into the BMRs. This manual data recording from port-based instruments led to data integrity issues such as inaccuracy and miscalculations. There was a high risk of transcriptional errors, inaccurate data inputs, and data inconsistencies. Moreover, it was a highly labor-intensive and costly process.
- 3. Thirdly**, trend analysis reports, yield calculations, etc. could not be easily generated. In the absence of an efficient, automated data integration system, getting insights into batch trends, yield calculations, and other decision-making metrics was a time-consuming process.

Inconsistency in Sample Analysis

Missing Instrument Integration

Document Integrity Related Issues



Revamping the System

Caliber's Phase-wise Solution Plan for Zydus

Caliber conducted a thorough study was conducted and proposed a phase-wise implementation of its robust, scalable solutions. CaliberIPQC was implemented to monitor and streamline the process of sample analysis schedules. CaliberIPQC is a standalone module of CaliberBRM that automates the in-process quality check process. CaliberIPQC enables a completely configurable sample withdrawal schedule as per the client's requirements. The system raises an alert for every scheduled sample analysis to ensure consistency. Without recording this data, the system doesn't allow further schedules to run.

With the implementation of the CaliberIPQC module, Zydus could establish test protocols predefined as per their requirements and SOPs. This reduces duplication of tasks. The In-Process Quality Control module generates and triggers calibration schedules automatically based on the set frequency. The system enables complete automation through instrument connectivity that eliminates manual intervention to reduce deviations.

By integrating port-based IPQC instruments using a standard RS232 port such as the balance, friability, hardness, thickness, moisture analyzer, and others, data automatically gets registered in the system, minimizing the scope for errors and discrepancies. It also promotes automatic data updates in real time. Moreover, the system allows end users to access the test results on any system, even tablets. CaliberIPQC allows users to generate trend analysis reports of the IPQC data at any time. This enhances decision-making capabilities for efficient business decisions.

Process positives with CaliberIPQC implementation

- 66 IPQC instruments integrated to ensure data integrity
- 776+ batches generated using IPQR
- Automated sample generation and analysis schedules eliminated the chances of missing sample analysis as per schedules
- Review by exception reduced review time by 30-40%
- Calibration schedule alerts triggered automatically
- Trends, yield calculation, IPQC dossier generated online with a single click for quick decision-making

Structured Training for Successful Implementation

Caliber extensively trained end-users and management personnel at Zydus for the successful implementation of its robust, optimized CaliberIPQC module. Comprehensive and administrative training was provided to shop floor and management personnel respectively to understand the thorough functioning of the system. The system can be accessed on different devices such as tablets and PCs to foster convenience of use.

Gaps and challenges during implementation

Since users were pre-equipped with knowledge about the traditional functioning of the systems, it was challenging to propose a new system. However, with a robust, user-friendly module such as the CaliberIPQC along with comprehensive training at ground level, implementation was a breeze. CaliberIPQC has already been successfully implemented at one of the manufacturing sites of Zydus. The management is extremely satisfied with the module as they haven't faced any data loss, connectivity problems, or interface/instrument-related issues.

Further investment in Caliber products

With a successful start of the journey with award-winning CaliberIPQC, Caliber further proposes Zydus for a complete digitalization roadmap for manufacturing. A phase-wise implementation plan suggests implementing CaliberLog that includes Punches and Dies management, online checklist preparation and issuance, eRegisters, and digitalization of logs. Going ahead, Caliber proposes to implement a robust Batch Record Management (BRM) solution. Implementation of BRM would prove to be a breakthrough in manufacturing and process automation at Zydus.

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Caliber offers the widest range of solutions for Process Automation, Quality Management, and Regulatory Compliance for highly regulated industries. Our key differentiator is our product suite which gives companies the unique opportunity to achieve Integrated Quality Management with a single suite of products.

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