Case Study - Moving Closer to Pharma 4.0

Strides Pharma Science Limited is a global pharmaceutical company that engages in developing, manufacturing, and marketing pharma products for emerging and regulated markets. The company manufactures a wide range of technically complex and niche pharmaceutical products. Strides ranks among the world's top 5 soft gelatin capsule manufacturers. It has an edge in the production of oral solids, soft-gel capsules (SGC), topicals, modified releases, and liquids.

Adherence to Quality Standards & Regulatory Guidelines

Quality interventions at Strides are supported by a sophisticated IT-driven platform that has enabled the implementation of advanced quality standards across manufacturing facilities. With digitalization at the core of futuristic company goals, Strides is also progressively adapting to the automation of its manufacturing processes. Maintaining an electronic logbook is one of the most essential elements of effective quality management. It is a mandatory requirement as per FDA 21 CFR 211.182 equipment cleaning and use log requirements.

Challenges Faced due to Limited Functionality

Strides, one of the largest pharmaceutical manufacturing companies globally, must meet huge market demands within stringent timelines. Adhering to regulatory compliances is mandatory. While complying with the industry GMP guidelines and monitoring every stage of batch production, Strides faced certain pitfalls in its existing system. There were no cleaning controls for the area and equipment used in the manufacturing process. The businesses' manufacturing SOPs displayed inconsistencies. For example, a real-time business scenario such as mandatory recleaning for an area idle for 72 hours after cleaning was not covered.

The monitoring of the tooling life of punches and other cleaning controls were managed manually which was prone to discrepancies. Maintenance of punches and dies logs required manual intervention which was a cumbersome and labor-intensive process. It also posed risks of contamination and non-compliance with regulatory guidelines. With Strides manufacturing 380+ products, this manual management of quality controls accounted for 630+ logs.

Adding to the dependency on manual labor, the in-process quality checks had to be monitored manually due to the limitations in their traditional application. Further, at Strides, only the Production logs were digitalized. Other logs such as utility and engineering had to be managed manually. Moreover, the workflows and configurations were not user-friendly. They required the expertise of professionally trained personnel to execute.

Caliber's Scalable Offerings Establish Quality Processes

CalibereLog was implemented at the Pondicherry site. CalibereLog provides sophisticated, scalable, robust, and advanced technology to comprehensively automate logbooks. It does not limit to automating logbooks. CalibereLog also provides statistics and reports that facilitate informed business decisions. It is a complete solution that allows integration with enterprise apps and all laboratory equipment to let users completely control the data. One of the independent modules of the CaliberBRM, eLog gives users complete access to every movement in the manufacturing facility.

CalibereLog provides a complete checklist of rules that adhere to business SOPs and cleaning rules. This resolved the conflict of cleaning protocols of the area and equipment at the Strides manufacturing site. With elaborate punches and dies log in place, CalibereLog maintains detailed punches and dies issuance logs, defines inspection and discard rules, sets alerts for the restrictions on the number of punches, and provides several other controls over the punches and dies management, which is specifically a distinctive feature of CalibereLog.

Not restricted to the punches and dies management, the eLog also keeps a check on the entire equipment calibration and features a preventive maintenance calendar that ensures there is no business loss due to equipment breakdown. Moreover, the system also helps in maintaining audit trails inexpensively as the e-register automatically stores details of various processes and equipment at QC, QA, warehouse, and other departments. This way, Strides also maintained anytime audit-compliant documentation.

With CalibereLog offering such convenient, automated solutions, logs were accurately documented as well as configuration and workflows became user-friendly.

Quantitative Benefits to Enhance Strides' QC Processes

CalibereLog was implemented in December 2019 and within two months, we successfully implemented the module to provide these countable benefits:

- 176+ logs were digitalized (Production, Packing, Engineering, Warehouse)
- Implemented comprehensive Punches and Dies management
- Digitalized 515+ Punches and Dies logs with tooling life details and automated punch rotation rules
- Implemented e-registers feature to digitalize generic logs
- Generated 12 real-time configurable business rules
- Transport tool to export logs configured in QA instance to production instance which saved 30% of the time with zero errors
- Configured 85+ logs with a user-friendly report configuration tool in one week

Commitment to a Smooth Transition & Effective Implementation

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 CalibereLog 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.

Further Plans with Caliber Manufacturing Suite

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