Delivering Quality Management and Computer System Validation Services for a Leading Indian Pharmaceuticals Enterprise

Business Situation
Our client is a leading Indian pharmaceuticals manufacturer focusing on nonsteroidal anti-inflammatory drugs, bacterial infections and cardiovascular disease. It has USFDA, EMEA, WHO and UKMCA-approved plants in India and Japan. The company’s IT landscape comprises SAP ECC 6.0 as well as non-SAP systems across India. Currently, all its systems are validated and in production (support and maintenance mode).

Challenge
The IT systems interfacing with the company’s core business processes need to be GxP compliant to avoid warnings and penalties from local regulatory agencies in the countries where it operates. This requires that the company’s IT systems meet all quality expectations with zero noncompliance. Also, all members of the IT team have to be trained on the latest company QMS and the latest GxP regulations.

The company has to meet these quality and compliance requirements while maintaining competitiveness in its industry peer group. Hence, it needs to have its IT systems production-ready ahead of its industry peers.

Solution
As the first step, we conducted workshops with the client. These workshops yielded the following areas of focus:

- End-to-end validation of SAP and non-SAP systems.
- Change management support.
- Establishing a quality management system (QMS) to define the processes for validation of the computerized systems.

The QMS was further defined and comprised the following key components:

- Change control, deviation, CAPA, incident and risk management, audit and training.
- Standard operating procedures (SOP).
- Templates.
- Quality instructions (QIs).

Based on the focus areas determined, we developed distinct approaches for the project mode and the support mode of operation of the client’s SAP and non-SAP systems.

Our approach for the project mode was driven by our proven validation approach. This approach comprised the following stages:
- **Due diligence and planning:** project planning through a validation master plan.
- **QMS creation:** creation of QIs, templates, SOPs and documents to ensure quality.
- **Realization:** testing of functionalities and ATR preparation.
- **Closure:** sign-off on documents and creation of a validation summary report.

The approach for the support mode comprised the following activities:

- Maintenance of the validated system through quality elements such as change control, deviation, CAPA and training.
- Risk management/GAMP 5 compliance.
- Providing support during internal and external audits.
- Review of support deliverables (URS, FRS, DS, OQ-Test script, OQ-actual test result, OQ-Test cycle log, traceability matrix, system release certificate and transport log).

Our validation approach ensured that during the FDA audit, no warning letter (483) was issued to the client by either the FDA or the MHRA or WHO.

For implementation details, see the accompanying graphic.

**Benefits**

The benefits of the solution include the following:

- An end-to-end validation process with defined and documented procedures and instructions for each validation activity has allowed the client to stay competitive, with zero noncompliance. Over the past three years, the client has not received a single warning letter during audits by the FDA, MHRA or WHO for CSV-related activities.

- Standard validation templates, processes, quality instructions (QI), SOPs and a clearly defined validation methodology allowed the client to achieve validation within tight timelines, enabling faster time to market for its core manufacturing processes.

Additionally, the following activities enabled continuous improvement and ongoing compliance:

- Risk-based validation approach and regulatory/functional risk analyses.
- Supporting the client in internal and external GxP compliance audits.
- Ensuring 21 CFR part 11, EMEA annex 11 and GAMP-5 compliance.
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