Driving the Pharmaceutical, Biotech and Medical Device Industries towards Excellence

GMP COMPLIANCE

CASE STUDY- IMPLEMENTATION OF A RISK BASED GLOBAL AUDIT PROGRAM

ISSUE:

A multinational pharmaceutical company auditing process was being executed on three levels, with the central QA function focusing on strategic audits.

Organization roles and responsibilities of the audit groups were not transparent and difficult to understand. Audits were not planned based on formalized risk assessment and there was no overarching governance body for audit oversight.

OBJECTIVE:

To implement a risk based global audit program for the multinational pharmaceutical manufacturer enabling focused and consistent evaluation of their compliance risks.

The new program allows for the allocation of the audit resources commensurate with the level of risk. Audit activities contribute to the overall risk management, knowledge management and continuous improvement activities in the organization.

DELIVERABLE:

An audit governance body was established to provide oversight of the audit activities via implementation of a consolidated audit program, risk based audit planning, defined KPI's, active participation in the agency inspections, and management of the auditor selection and training programs. The audit governance body ensured critical issues were escalated to the audit steering committee, providing timely management information and facilitating the decision making process.

Audits of the key strategic sites (CMO's, suppliers and own sites) were be performed by the central group, whilst audits of smaller local suppliers are assigned to the local sites. The roles and responsibilities of the central audit group and the site QA were clearly defined by the audit governance body and cascaded across the organization.

The risk based audit planning tool utilizing the risk criteria, allowed the company audits to focus on high risk products, processes and sites. The resource planning tool developed provided accurate calculation of the auditor time for each audit and the overall annual audit resource requirements.

The inspection management process utilizing risk assessment enabled proactive assessment of the company sites' need for support in preparation for agency inspections. The audit governance body ensured adequate resources are allocated to each site (based on risk assessment) prior to, during and post agency inspections. All responses to the agency inspection were reviewed by the audit governance body to ensure impact on the network sites had been assessed prior to submission.

Implementation of the total disclosure approach to the internal audits further improved the transparency of compliance issues, enabling speedy response and resolution of non-compliance issues.

The central audit database provided up to date information on the current suppliers and their audit status, minimizing risk of duplicate audits. Audit findings, the action plans and the current status of each action were available to authorized personnel.

BENEFITS:

Implementation of the improved audit program has allowed for transparency of the roles and responsibilities, brought consistency to the audit program, focused the attention to the high risk areas and provided accurate and timely compliance information to the senior management.

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