Sparta Systems

Raising Quality Results on Supplier Audits Using EQMS for Pharmaceutical Companies

Whitepaper

Executive Summary

Supply chain integrity is necessary to a pharmaceutical company's success. Formal contracts, quality agreements, and product and chemical purchase specifications alone never guarantee supply chain integrity. Astute pharmaceutical companies implement audit processes as an integral component of supply chain management. Audits foster a culture of agreement adherence among partner suppliers. The benefits to both the pharmaceutical company and partner suppliers are mutual and strengthen the professional relationship. They include:

- Supply chain continuity and reliability
- Regulatory compliance, cost reductions
- Improved risk management
- Quality assurance
- SOP compliance
- Global visibility
- Enhanced customer satisfaction
- Positive public relations

The global nature of audits maximizes the advantages of risk management, regulatory compliance, cost reductions, and heightened visibility.

Agreement Does Not Guarantee Compliance

It is important to note that documentation of important legal, administrative and accounting matters plays a key role in providing a reference point to resolve specific issues, but it does not guarantee the integrity and purity of the supply chain. As this study presents, supply chain execution may or may not comply with industry best practices and supplier audits are vital to pharmaceutical companies, suppliers, and patients.

The Good and the Bad of Outsourcing

As in other industries, pharmaceutical companies strategically outsource some or all manufacturing of products or product precursors. Outside suppliers can offer a host of benefits. For example, a supplier may have a dedicated manufacturing plant for key products or components where the speed of production is quicker and product line changeovers can be virtually seamless. In this case, partnering with a supplier creates time and cost saving, which allows a company to remain focused on its core competencies. The decision to outsource frees up company resources and allocations to advertising, marketing, research, or other business needs.

Outsourcing also presents some challenges. Consider these crucial questions:

- What is the supplier's quality management process and how do you ensure it is being followed?
- What is the supply chain to the supplier and how complex is it? (Does the supplier have a supplier? If so, who is its supplier?)
- Is the supplier adhering to good manufacturing practices?

- Is the supplier adhering to all regulatory requirements?
- Who makes key decisions throughout the manufacturing process and on what basis are those decisions made?
- What Corrective/Preventive Action (CAPA) system is in place and how well does it operate?
- Will the supplier provide sufficient capacity, reliability, and product purity?
- Does the supplier have any kind of an internal or external audit process and if so, who is responsible for those audits?

When evaluating public relations, customer satisfaction, and regulatory compliance, the answers to these questions are increasingly important. For pharmaceutical companies, the consequences of recalls and poor supply chain integrity are serious. For example, FDA-initiated product recalls rose 69.5% from 2007 (5,585) to 2012 (9,469). As a result, supply chain processes have come under increased scrutiny and companies are liable for mistakes made by suppliers under this business arrangement.

Six Steps to the Audit Process

The audit process consists of six sequential steps:

1. Plan. Assigning auditors, defining audit scope and objectives, reviewing previous audit results, and building the audit template. Doing this initial step well will ensure a successful audit by anticipating adequate staffing and resources.

2. Schedule. Handling all calendar and workload aspects of the audit, and incorporating the strategic use of reminder and tracking systems. Scheduling guarantees that the right people and resources are in the right place at the right time.

3. Perform Audit. Documenting findings and objective evidence, addressing any discrepancies, and managing and communicating any needed changes. Recommendations and CAPAs often arise. The ultimate benefit to all parties comes from meticulous attention to detail and thorough execution of this step.

4. Report. Providing a formal audit report with appropriate trends and metrics analysis. Reports that are written and organized well allow all parties to understand and benefit from the audit process. Significant attention should be given to the quantity and type of data collected, report formatting, and diversity of readership. This can make the difference between an audit report that is inviting, clear, and helpful versus one that is unclear and cumbersome. Effective communication is key.

5. Action Tasks. Managing risk factors and an effective and efficient CAPA process. Any lack of follow-through creates major deficiency and liability. Action tasks must be ascribed top priority.

6. Close-Out. Ensuring all action items are addressed, responses are captured, and sign-offs are received. This final step assures nothing has been overlooked, guaranteeing audit integrity.

Audit Benefits for the Pharmaceutical Company

The audit process has many benefits for the pharmaceutical company. Audits verify whether the correct SOP is being followed. Audits check for quality agreement compliance and chemical purchase specification adherence. They elucidate key details that these documents do not routinely cover and can alert the pharmaceutical company to any supplier deficiencies at an early stage, and by implication, any supplier-to-supplier deficiencies.

When a pharmaceutical company builds an audit process, it has the opportunity to create a consistent format. When a pharmaceutical company sends in different auditing groups such as accounting, IT systems, HR, engineering, or materials, each

of those groups can access the shared supplier information. This streamlines all audits with multiple suppliers by eliminating duplication of effort. Audit steps and reporting formats acquire a uniform and consistent appearance, making everyone's job easier, faster, and more efficient.

Last, but certainly not least, every pharmaceutical company realizes its responsibility and liability. Pharmaceutical products are personal to the user. They are used within or in conjunction with a patient's body and failures here can have the gravest consequences. Audits help identify and correct minor issues before major issues develop. This can mean the difference between a simple internal process correction versus human injury, legal liability, financial loss, and the associated public relations disaster.

Audit Benefits for the Pharmaceutical Partner Supplier

Pharmaceutical companies and suppliers mutually benefit from the auditing process. On the one hand, audit data sharing and standardizations can reduce the staff time and expense associated with multiple audits from multiple pharmaceutical companies. On the other hand, supplier reputation can be strengthened via a history of audit cooperation and successful results.

Audits can help suppliers better understand strengths and areas of opportunity. Suppliers can incorporate those insights into processes and thereby become best in class. This strengthens the partner-supplier relationship and enhances the supplier's marketplace standing.

Global Audit Advantages

Implementing a global audit process is a daunting task and the advantages of performing a successful, effective audit are reflected in the reduced risk and cost faced by the company as production continues to move forward.

First, a global audit process enables companies to address risk areas effectively. Audits involve inspections of data, processes, metrics, and onsite equipment across the supply chain. Critical suppliers are better managed within this close working relationship. The audit process allows risk area deficiencies to be addressed as they are encountered.

Second, a global audit process ensures regulatory compliance. Format consistency congruent with regulatory requirements and internal standards can be built into the audit process. Simply knowing something is being measured or tracked focuses attention and encourages continuous improvement.

Third, a global audit process reduces costs. Identifying and addressing problems upstream is inexpensive. Cost reductions increase as audit areas expand. Time and materials wasted can never be regained. The global process enables for more streamlined audit and audit follow-up communications. Multiple or inconsistent sources of information can create confusion and lack of unity throughout the organization. A central voice saves time and money.

Fourth, a global audit process increases visibility. Audit data can be shared cross-functionally throughout the organization allowing for various departments to integrate data into systems quickly and consistently and informs executive leadership with facts and figures as crucial decisions are made.

Any audit process is better than no audit process. Effectively addressing risk areas, assuring regulatory compliance, reducing costs, and enhancing visibility are the four main reasons to establish a global audit process. The global audit process maximizes the benefit throughout the organization.

Conclusion

Pharmaceutical companies face the challenge of managing multiple suppliers. Constant supply chain challenges include efficiency, product purity, regulatory compliance, safety, cost containment, quality assurance, and public relations. Contracts, quality agreements, and purchase specifications have inherent limitations for creating supply chain integrity. An audit process mitigates the supply chain challenges and agreement limitations. The audit process is a win-win solution that enables the pharmaceutical company and its suppliers to raise performance levels and to strengthen relationships while improving patient-care quality.

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