

SUPPLIER AUDITS ENSURE FULLY COMPLIANT PROGRAM

BACKGROUND

Actively managing audits plays a significant role in helping to ensure a robust supply chain and the safety of patients. The FDA estimates that up to 40 percent of finished drugs used by U.S. patients are manufactured abroad, and 80 percent of the Active Pharmaceutical Ingredients (APIs) and other bulk chemicals used in U.S. drugs come from foreign companies. Globalization and economic pressures continue to drive manufacturers to seek more cost effective outsourcing strategies with suppliers. These strategies will further tax the already strained resources of regulatory agencies. It is therefore imperative that audit programs are thoroughly evaluated, risk based and robust to ensure an unadulterated drug product.

SCOPE AND OBJECTIVE

Compliance Implementation (CIS) was retained by a Global Pharmaceutical Company to review its internal and external audit plan and to audit key external suppliers. Using a risk-based methodology, CIS evaluated potential patient implications in addition to collective and compliance risk as it related to Good Manufacturing Practices (GMP). Once the risks were identified, they were assessed, analyzed and evaluated. A GAP analysis was then developed evaluating financial resources, manpower, timing and the expectable level of organizational risk acceptable to remediate the deviations that were uncovered during the inspections. CIS along with the sponsor then entered the risk control phase. Once the acceptable level of risk was determined and the gaps remediated for a particular manufacturing component the frequency and types of audits could be incorporated into the overall supplier management/audit program moving forward.

- Risk based review of current systems and components
- GAP analysis developed
- Remediation executed
- Updated audit plan implemented



PROVEN EXPERTISE

Compliance Implementation Services (CIS) is a global consulting firm specializing in compliance strategies for pharmaceutical companies. Our auditors identify, assess and prioritize your organizations exposure to risks, subsequently developing and implementation risk evaluation and mitigation techniques to ensure adherence to Good Manufacturing Practices (GMP).

CIS' experts have a deep understanding of the following areas:

- Global auditing experience US, EU, Asia
- Risk-based approach to auditing
- Risk mitigation analysis and plans
- Vendor compliance
- Employee training
- Supplemental resourcing
- Audit plan development

METHODOLOGY

CIS provided the client with the following deliverables to ensure a robust and fully compliant audit program based on risk:

- API suppliers, packaging suppliers
- Contracted services
- Packaging suppliers
- Documentation
- Communication
- Training
- Harmonization of systems in an effort to gain efficiencies

DELIVERABLES

CIS provided the client with the following deliverables to ensure a robust and fully compliant audit program based on risk:

- Risk Analysis Report
- GAP Analysis Report
- On site audits in the US & EU
- Remediation Action Plans
- Supplemental Resourcing
- Training
- A comprehensive compliant Global Audit Plan

BENEFITS

The pharmaceutical industry has embraced an ever-evolving and more complex outsourcing model as it relates to development, testing and manufacturing. We are seeing the same model evolve in quality and compliance outsourcing. Pharmaceutical companies will seek expertise on compliance strategies abroad, advice on overcoming regional challenges, and the implementation of robust quality and supply chain auditing systems.

- An objective review of current audit plans
- An audit plan that is risk based
- Increased confidence in suppliers
- A global perspective
- A robust and fully compliant audit program in line with the most current regulations and industry best practices



AUDIT FREQUENCY

Upon completion of the audit barring any imminent concerns, the quality unit should evaluate its findings and ensure that the facility is in compliance given the predetermined level of risk associated with its position and criticality within the supply chain. Depending on that criticality, the frequency of inspections will be between 1-5 years. Some general guidelines are listed below.

Frequency/ Years	Supplier
1-2	API Supplier, Sterile Facilities, CMO, CRO
2-3	Critical Raw materials, Primary Packaging, Repackages
3-4	Disposal Contractors, Other Raw Materials
5	Repackaging Distribution Centers