

Mini Review on vendor audit.

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Abstract

Audit is a systematic examination and evaluation of an organization for obtaining evidence and evaluating it to determine the extent to which requirements criteria re fulfilled. There is a proper process of audit which includes preliminary planning, presurvey, survey, data collection and analysis and report of the audit. The audit is of three types- Internal audit, External audit, Third party audit. External audit is a non-regulatory audit in which company are carry out the audits on its vendors to check out the compliance of the vendors towards the regulatory bodies. It ensures that vendor show compliance towards the standards. Vendors are the sellers of raw materials to the finished product manufacturing company. Vendor audit, rating, selection, evaluation, qualification is important to finalize the vendor from which the raw material will be purchased. It gives about the knowledge that which vendor is suitable for the purchasing of material. This review article focuses on the procedure for vendor selection, evaluation, and auditing process. Vendor audit is questionnaire based which includes the points which will be checked during the audit. The final report of vendor audit have all the data and form the basis of vendor certification and decertification.

Keywords: Vendor, Audit, Regulations, Compliance, Qualification.

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Introduction

An audit as a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which agreed criteria are fulfilled. Audits are required for the verification and monitoring. It gives information about that how efficiently and effectively company or industry control their quality of their process procedure and products. Food and Drug Administration and Good Manufacturing Practices audits are required for the pharmaceutical industries for products that ensures the compliance towards the regulatory bodies and to determine the effectiveness of their quality systems [1].

Various process in Audits

First party audit or self inspection

In this the auditing team belongs to the same organisation and inspect its own organization. Internal auditor performs the audit to check the effectiveness of the organization's internal quality system. The main purpose is to identify minor problems and errors before it becomes a major problem to prevent quality defect or quality problems [2].

External audit

It is a non-regulatory audit. These audits are carried by industry or company to its supplier or vendors or sub-contractors to check the quality system and management. It ensures that its vendors or subcontractors or suppliers shows compliance (Quality management standards) (Quality management system for medical devices organization) standards [3]. It reduces the risk of failure of the Pharmaceutical product hence the assurance is already done.

Third party audit

It is an audit that is carried out by the inspectors or regulators. This type of audit is required for any company's accreditation for the quality system. This type of audits may be unannounced.

Audit process



Vendor or supplier: A vendor or supplier is a person or company that sells its goods and services to others. It is the authorized person or company who provide the active pharmaceutical ingredients, other raw material, equipments or machines to the pharmaceutical industries for the manufacturing of good quality product [4].

Vendor audit: Supplier selection is defined as the, process of finding the suppliers being able to provide the buyer with the right quality products and/or services at the right price, at the

right quantities and at the right time. A vendor audit is an objective assessment of all processes of vendor or contractors to provide evidence that it shows the compliance towards the customer need, specification, standards, procedures, law, rules and regulations [5].

Vendor evaluation is a system for ranking the performance of the supplier and in terms of various issues. It is essential for effective and quality purchasing. Supplier evaluation and selection has become a very important area of consideration for purchasing managers in today's highly competitive environment.

As the cost of raw materials purchased for production usually constitute a higher percentage of the total cost of finished products, it has become increasingly necessary for organizations to get the best value for money from suppliers.

Vendor selection is important because the material which we are purchasing is directly uses in the manufacturing of final product so if the raw material is of inferior quality it directly affect the quality if the finished product so, the vendor should be certified [6].

Q.U.E.S.T. Approach

Q=Question phase

What type of excipient is required for the drug manufacturing to fulfill the drug product characteristics, safety, purity and efficacy of the drug product. The defined specification raw material should be prepared or sell by the vendor.

U=Understanding phase

The requirement related to particle size, particle structure, special features and functionality. Based on the pre trials perform at laboratory scale and outcome of compatibility, stability and development activity, the requirement of excipient can be finalized. Document should be kept.

E=Evaluation phase

Best potential vendor is identified based on the requirements.

S=Site audit phase: verifications

Based on the specificity of excipient, the on site audit shall be carried out for the verification.

T=Track phase

Monitor and review. The vendor's performance must be monitored on regular intervals. The monitoring process involves a review of problems associated with the goods or services supplied by the vendor. Requalification is carried on periodic basis [7].

Vendors are rated on these factors



- Vendor is new to the company or not
- Evaluate the vendor's reputation
- Checking the FDA, GMP inspection documents and reports
- Relations with other companies
- Vendor's failure and recall history
- Checking the vendor's capacity
- Checking the location of the vendor
- Checking the seller price of the API
- Evaluation parameters for the API

Vendor certification

It is the system that assure the company that supplier's product is produced under controlled conditions, resulting in consistent quality conformance to the specifications. It is a customer-supplier partnership.

Selection of vendor to be certified: The selection of vendor to be certified should be jointly made by the head of Production and Purchasing and Quality assurance manager [8].

Review of historical data and test result: Analyze the quality data of different batches delivered during the last 3 years and prepare trend analysis. Analyze report deviations with regard to [9] out of specification situations, normal failure levels, and corrective and preventive action.

Site audit: The quality assurance manager or any other authorized person may perform an on site audit should specifically.

- To determine: Accuracy, precision, reliability of test, inspection data of vendor
- To review: Process productivity and reproducibility, perform GMP compliance audit, review the potential risk for contamination and mix-ups, ensure that vendor in-process controls include the use of statistical process control, ensures the absence of any significant online problems.

Recommendation: It is not necessary to perform on site inspection always as an alternative evaluation of historical data [10], by questionnaires review of all quality data and reports by the review of their performances over the last three years.

Decision on certification: The data that is obtained by these steps are reviewed by the quality assurance manager and sent

for approval to quality control production and purchasing final release must be authorised by quality control [11].

Step after certification: After vendor approval quality control or quality assurance will reduce the number of quality tests and inspection of incoming goods that are agreed in certification report [12].

Conclusion

Certification gives out the information that the vendor is reliable. It results in reducing the number of incoming inspections and higher output. Any failure by the supplier or vendor for matching the customer requirement and specification leads to the decertification of the vendor for that material. Depending upon the nature of the failure it may be possible for the recertification.

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