Importance of audits in a QA system

Audits in a QA system are known as quality audits. They are a systematic examination of a quality system which is carried out by an external quality auditor or an audit team. The main purpose of which is ensuring that procedures correctly mirror documented standards. Audits are an important part of a QA system and are a key part in the ISO quality system standard ISO 9001.

Quality audits are becoming more regular in todays, pharmaceutical industry due to increasing complex regulations and expanding globalization. Companies in the pharmaceutical industry often undergo developments and new research cycles for manufactured products and as a result these companies must establish quality assurance departments ensuring process quality is efficiently maintained. Regular quality audits of the QA procedures provides' an effective way for management to evaluate the efficiency of these procedures.

Quality audits consist of

- system
- audits Process
- audits Product
- audits compliance

System audits

A quality system audit is defined by ISO10011-1 (1990) as a "systematic and independent examination used to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. It is "a documented activity performed to verify, by examination and evaluation of objective evidence, that applicable evidence of the quality system are suitable and have been developed, documented and effectively implemented in accordance with specific requirements."

It is the role of quality system audits to ask such questions as; How is the system defined? Who is the responsible party for producing the product? What is the extent of involvement of the managerial department in the daily running of a quality system? Who is the responsible party for ensuring that the quality of the produced products is up to customer standards? What kind of direct and indirect processes are used in the production of the product/s. What are the

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procedures put in place to help the organisation production efforts. How are these procedures maintained and updated, and by whom? Where can the procedures be found?

Quality system audits tend to focus on the macro nature of a quality management system i.e. the general and broad range rather than a small limited scope.

Process audits

Process audits are analytical in nature, unlike the more general system audits they are much more readily defined and narrowed down. The central focus of these audits is that of; people, material and machines. It must verify how these factors are brought together in order to produce a reliable product. It must compare and contrast the active processes in which the products are produced to that of the written procedures. It is essentially a guide for the manufacturing process.

It is also focused on the process itself. It must ask whether or not the process is valid and reliable. Is the process producing expected results on a consistent basis? Do the processes need to be changed or updated in order to fit the current and/or future needs of the customer.

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