Documentation

Documentation allows visualization and communication of work assignments. In practice, the documentation of a quality program is arranged into four levels ranging from general policies and procedures to records of performance. These four levels cover:

i. Why the organization has a quality program
ii. The what, when, where, and who aspects of quality-related tasks
iii. How these tasks are to be performed
iv. Records of what actually was done

"What" describes what to do and what was done. This hierarchy of documentation gives increasing detail about the organization, its operations, its methods, and its accomplishments. Specifically, the levels of documentation include the following.

1. **Quality Manual**
2. **SOP (Manufacturing and Quality) Documents**

This family of documents includes: product specific manufacturing (PSM) documents, general manufacturing operation (GMO) documents, quality control analytical methods (QCA) documents, good manufacturing practices/sanitation (GMP) documents, equipment specific sanitation documents, and pre-operation sanitation documents.

i. PSM Documents
ii. GMO Documents
iii. QCA Methods Documents

3. **SSOP (Standard Sanitary Operation Procedure) Documents**
   i. GMP Documents
   ii. Equipment-Specific Sanitation Documents
   iii. Pre-Operation Sanitation Documents

Quality Manual

The company's quality policy and the descriptions of its processes must be contained in a corporate quality manual. It should express the organization's total commitment to quality, how it is organized to fulfill that commitment, and its approach to fulfilling it. The purpose of the manual is to outline the quality program, including procedures and detailed instructions, and to serve as a reference.

The composition of the manual varies from organization to organization, but usually includes:

- The quality policy of the organization
- Documented organizational processes, procedures, instructions, and Standards

- Controls, such as inspection equipment, checkpoints, measurements required, and reviews
- Identification of required measurements
- Identification and preparation of quality records

All documents included in the quality manual and describing the company's quality program must be properly controlled. Prior to use, documents should be reviewed and approved by authorized personnel; changes to documents should be made following an established document control procedure. Appropriate documents should be available at all work locations where required; obsolete documents should be removed to prevent their inadvertent use.

In general, the term *document* is used for items that describe a quality program; *record* is used for evidence to demonstrate effective operation of the program. Thus, description of a process is a document; a test report is a record.

Quality Audits

Quality audits are programs designed to verify or examine a product or manufacturing process over time. These can be classified as manufacturing quality audits, sanitation/GMPs audits, HACCP audits, product quality audits, and other special types of audits. A quality audit is a fundamental part of a quality assurance (QA) program. It allows for quality verification of a product during manufacture, in the warehouse, in the distribution system, and in the market to assess performance over time or for comparison to competitor brands.

Each person with responsibility for a portion of the program should conduct regular assessments or reviews of the effectiveness of the quality program and its operation. Such assessments are a normal part of good process management. In addition, there should be a systematic review of the quality program by an authority that is not directly responsible for the process or its operations; such a review is a quality audit.

A quality audit is a planned, systematic examination of a manufacturing program and its implementation to determine its adequacy and the degree of conformance to it. It concentrates on quality-related aspects of production. A quality audit consists in examining a representative portion of the manufacturing program and drawing an inference about the total system based on this sample

There are two types of quality audits: internal audits and third-party audits. An internal quality audit is a review conducted by employees of the organization. A third-party audit is conducted by an outside organization.

An internal quality audit usually is referred to simply as a quality audit, or an audit. Internal audits focus on quality and are the eyes and ears of top management; their task is to make an independent assessment of compliance to standards and procedures and evaluate whether those standards and procedures are adequate, effective, and efficient. This helps

management to obtain factual information about the status of the quality program and identify opportunities for improvement. Internal audits also help to improve communications and can be used as tools for training personnel who participate as observers.

An organization should plan and schedule internal audits periodically for every element of the quality program. For a mature system, it might be sufficient to audit each element once a year, but newly implemented elements should be audited more often.

The members of an audit team are trained and qualified employees in the QA department. They are independent of the process being audited, but at the same time, they are familiar with the process. One way to gain familiarity is to study the process documentation. This study should include the trainee in an audit team as an observer, giving the trainee an opportunity to learn about both the process being audited and the auditing process. Being an auditor is an excellent way for a person to understand the requirements for a quality program and the objective evidence that must be collected to demonstrate the effectiveness of the system.