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## **Quality Assurance (QA) Management Procedures**

In this episode you will find procedures and practical work instructions on every aspect of Quality Assurance and Technical areas to build up a highly effective Quality Management System for your pharmaceuticals business.

In this area you will find Standard Operating Procedures for establishing quality assurance practices, such as preparation, maintenance, definition, classification and change Control of Quality and Master file documentation necessary for your products; recording and reporting procedure for deviations management; quality concern investigation Process; customer complaint handling procedure; quality audit procedures; vendor assessment, evaluation and certification procedure; rework procedures for the defective manufactured products; procedures on training for your staffs and many other procedures according to your need.

All procedures have reference of prepared Forms and Templates for effective record keeping and reporting purposes. Forms are attached at the end of each procedure. Templates are listed separately.

### **SOP list**

#### **QMS-005 How to Write Standard Operating Procedure**

This SOP describes standard SOP format that you can use immediately for your quality procedures. This SOP has instructions on how to write a formal Operating Procedure for your systems which your people can follow everyday.

#### **QMS-010 All Documents - Classification, Definition and Approval Matrix**

In this SOP you will find all type of quality and Technical/Master file documents to build up a good quality management system for your manufacturing sites, definition of documents, their classification, approval requirements and retention requirements. This procedure has schematic diagrams for your understanding of how different types of documents are prepared and stored in a typical documentation database.

#### **QMS-015 Quality Documentation Management and Change Control**

This SOP describes how to generate new quality documents or change control of existing documents, review of quality documents, satellite file management, role of document author, approver, document control officer and satellite file administrator. In this SOP you will also find numbering systems of different quality documents like audit files, SOPs, forms, manuals, training files, QA agreements, project files etc and their effective archiving system.

#### **QMS-020 Documentation Rule for GMP Documents**

This SOP describes the principles to be followed in GMP documents, entry of data and information, signature requirements and correction technique of incorrectly entered data or information.

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#### **QMS-025 Quality Documentation - Control, Tracking and Distribution**

In this SOP you will find mainly the role of document control officer during the initiation, creation, circulation and approval of new quality related documents. It also describes the procedure of modification and review of existing document using a documentation database. Management of existing and superseded documents is also a part of this procedure. You will see all the forms referred during the instruction are attached at the end of the procedure.

#### **QMS-030 Preparation, Maintenance and Change Control of Master Documents**

This SOP particularly focused on the management of master file documents like specifications, control methods, raw materials, finished goods and packaging specification and test reports, formulation, stability files etc required to generate during the product registration in the market. This SOP gives instruction on their creation, change control, numbering system, approval requirements and maintenance in a simple master file database. You will see all the forms referred during the instruction are attached at the end of the procedure.

#### **QMS-035 Deviation Report System**

It is a regulatory requirement to capture all sorts of deviations evolves in your systems in order to maintain the continuous improvement of your processes and systems. This SOP describes how to categorize the deviations between production, audit, quality improvements, technical deviations, customer complaints and environmental, health and safety deviations. It describes the management responsibilities of initiating deviation, capture data, analysis, investigation, determination of assignable causes, generation of management report and initiatives to be taken on corrective and preventative actions.

#### **QMS-040 Shelf Life of Product**

This simple SOP describes the meaning of shelf life and provides direction on how to interpret shelf lives and storage conditions for your raw materials from the Certificate of Analysis, determining expiry date for your finished products by use of raw material date of manufacturing and their shelf lives.

#### **QMS-045 Vendor Selection and Evaluation**

This SOP describes the procedure to be followed during the vendor assessment and vendor evaluation for purchasing of raw materials, critical and non critical packaging components, laboratory supplies, engineering supplies and imported finished goods from the vendor. These instructions are essential for approving prospective vendor.

#### **QMS-050 Vendor Certification**

This procedure aims to describe the process by which a vendor may be certified to supply materials or services. This procedure applies to vendors that supply a material or service to be used at any stage of manufacture by operations. Here you will get the roles of each department in the process to certify an approved vendor.

#### **QMS-055 Product Complaint Procedure**

This procedure covers the receipt, logging, evaluation, investigation and reporting system of all complaints received from customers for the marketed products. This SOP contains step by step instruction to be followed in the customer complaint management like numbering of complaint, registration, evaluation of complaints, determination of assignable cause for the complaint deviation, implementation of corrective and preventative actions, trending of complaints and handling of counterfeit products.

#### **QMS-060 Annual Product Review**

This procedure provides a guideline to annual product review which is required to be performed for each product produced for the commercial market to evaluate data, trends and to identify any preventative or corrective action that would lead to product quality improvements and report them to management.

#### **QMS-065 Rework Procedure**

This SOP contains the step by step instruction to be followed when the rework of an in-process or completed finished good is required. This SOP covers the reworks of in-process manufactured goods where new batch number is introduced for the reworked part and rework of manufactured finished good keeping the same batch number. This sop also describes how to create rework protocols for each individual case.

#### **QMS-070 Authorized Person**

This simple procedure describes the accreditation, accountabilities and responsibilities of an Authorized Person, responsible for release of finished goods for sale.

#### **QMS-075 Product Identification and Traceability**

The purpose of this SOP is to define the method used for the identification of all contributing materials that could affect product quality and to ensure their full traceability. Here you will find instruction on all the records and documents used for the identification and traceability of incoming raw materials and out going finished goods.

#### **QMS-080 Audits**

This SOP describes the process of planning, performing, reporting and follow-up of different audits for your systems like Internal Quality audit, Vendor audit, Environmental Health and Safety (EHS) audit, EHS workplace inspection, Housekeeping audit. This SOP also describes the process to be followed by manufacturing personnel during an audit from a Regulatory authority.

#### **QMS-085 Example-Checklist for Batch Documentation**

This SOP describes the identification of all documentation relevant to a production process in the form of "Batch Documentation Checklists" and to ensure their collection by completion of the checklists by Authorized Persons. This procedure is based on an example of tablet packaging process described in the 'Manufacturing' category.

### **QMS-090 Evaluation of Batch Documentation and Release for Sale**

This procedure describes the process of collection, evaluation and record of batch related document generated during the production of a batch before an authorized person can release the batch for sale. This procedure is based on an example of tablet packaging process described in the 'Manufacturing' category.

### **QMS-095 GMP Training**

This SOP describes how to design and deliver GMP related trainings for your manufacturing staffs, training assessment design, recording of assessment and preparation of training reports.

### **QMS-100 How to Write Training Materials**

This simple SOP contains instructions on how to write training materials, identification of training requirements, available resources, preparation of training aid checklists for your manufacturing staffs.

### **QMS-105 House Keeping Audit Procedure**

This SOP describes the requirements, checklists and reporting procedure on housekeeping audits. Individual checklist forms are attached at end of the procedure for different areas like process, laboratory, engineering stores, warehouses. This procedure also describes the handling of non-compliance found during the housekeeping audits.

### **QMS-110 Management and Control of Contract Work**

The procedure describes the management and control of contract work provided by the contractors for packaging and finished products for your company as well as control of contract works done by your company on behalf of others.

### **QMS-115 Criteria for Sourcing of RM, Critical Packaging Components and Imported Finished Goods**

The purpose of this SOP is to describe the process for approval of an external vendor/manufacturer supplying products to your company. It covers raw materials (including bulk products for subsidiaries and contract manufacturers), critical packaging components in contact with product and imported finished goods. The SOP also references affiliated documentation detailing the scope of active materials used and the approved manufacturers of these materials.

### **QMS-120 Quality Concern Investigation Process**

This procedure contains instruction to be followed when conducting Investigations and to raise and assess Deviation Report when an Investigation or Incident Investigation occurs. This procedure is to be used in conjunction with SOP QMS-035, which covers the approval and follow-up activities associated with a Deviation Report. Here you will find collection of information for an incident or a deviation, steps to be followed for a cross functional investigation, reporting and implementing of the outcomes of investigation.

### **QMS-125 Change Management System** **QMS-130 Cross functional investigation**