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GMP | Manufacturing Procedures

In this episode you will find procedures and practical work instructions on many areas of manufacturing division. Some procedures can be commonly used in any manufacturing site. Some procedures are set up to provide a common guideline for all types of manufacturing activities by using an example of a tablet packaging plant.

In this area you will find exciting procedures on Clothing Requirements Inside the Factory Area, Cleaning Responsibilities and Methods for Employees, Factory Cleaning Procedure, Manufacturing Pest Control, Tours of Factory, Requirements of Production Logbook, Packaging Configuration for Production Line, Checking of Components Prior to Use, Tag Out Procedure, Procedures for Line Clearance, Line Opening and Line Cleaning, Reconciliation of Component and Product, Operation of Barcode Reader as an example, Intermediate Bulk Container (IBC) Operation and Cleaning, Tablet Packing Machine and Cartoner-construction, operation and cleaning as an example, Manufacturing Instruction for Tablet Packing as an example, Mop Cleaning Procedure, Scheduling Production Lines, Vacuum Leak Testing Procedure, Weighing Equipment - Checking and Calibration, Operation of Checkweigher as an example, Tablet Packing-Start up and In-process Testing as an example, Packed Tablet Sampling by Production Personnel for Testing as an example

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

SOP list

MAN-005 Clothing Requirements Inside the Factory Area

This SOP covers the clothing requirements needed in all Factory areas for your manufacturing site. The different levels of cleanliness must be maintained to minimize microbial and particle contamination. This procedure contains general rules and restriction to be followed by your manufacturing employees, defining different environmentally graded areas and entry requirements for those areas.

MAN-010 Cleaning Responsibilities and Methods for Employees

This SOP describes the cleaning procedures to be followed by all employees working in the manufacturing area in order to prevent contamination of product by foreign materials from another batch, or by dirty parts, which may contain bacteria. This SOP contains instruction on responsibility of cleaning, degree of cleaning to be done, popular cleaning aids and solutions permitted to use for cleaning, rubbish removal and outline of cleaning methods for different environmentally graded areas.

MAN-015 Factory Cleaning Procedure

This SOP defines the methods, frequency and the intensity of Factory Cleaning. The purpose of cleaning is to remove debris from within the plant in a sanitary and effective manner and to avoid contamination from dust or foreign materials. This procedure describes which popular cleaning aids and solutions are to be used to clean the floors, walls, sinks and windows in the Production areas, office areas, change rooms, workshops, laboratories, stores, canteens, plus the toilet facilities. This procedure also describes the scope and responsibility of contract cleaners.

MAN-020 Manufacturing Pest Control

This SOP describes the responsibilities of all employees and pest control services, classification of pests, frequency of the pest control service and effective treatments against all types of pest.

MAN-025 Tours of Factory

This simple procedure describes the management of visitor's entry, their safety and security inside the manufacturing site.

MAN-030 Production Logbook

This procedure outlines the generation, maintenance and filing of Production logbooks. Production logbooks form part of the documentation system required by the Code of GMP to provide complete and up-to-date histories of all batches of product. The logbook provides a key link in the process of traceability.

MAN-035 Packaging Configuration for Production Line

This SOP provides an alphabetically indexed diagram of shipper packing and pallet packing configurations for any packaging process. This procedure contains schematic diagrams of different packaging configurations and calculations of total unit to be packed per container which can be useable into your packing lines.

MAN-045 Checking of Components Prior to Use

This SOP sets out a procedure to ensure that only components of correct code and batch number are issued for a batch and only issued components will be used in a finished product batch. This SOP also describes the procedure to be followed during returning of components to warehouse from the production lines.

MAN-050 Tag Out Procedure

This SOP describes how to prevent the risk of personal injury or damage to equipment likely to be caused by operating or attempting to operate machinery or equipment diagnosed as being unsafe, in need of repair or maintenance or formally removed from service. The SOP covers all isolation, condemning, repair or maintenance work that necessitates a device or machine to be taken out of service. This SOP applies to any situation where energy (either supplied to equipment, or stored within it) needs to be isolated to ensure the safety of any person working on or near equipment, processes or services - for any reason whatsoever.

MAN-055 Procedures for Line Clearance, Line Opening and Line Cleaning

This SOP describes the procedure and order to be followed when performing a Line clearance, Line opening and Line cleaning for a batch production. The procedure has been established to prevent mix-ups of products, containers, components, labels and mistakes in documentations. Mix-ups and mistakes can occur when correct procedure and GMP are not followed. Particular care should be taken when starting a new operation, at the change of shift and when additional components are needed. In this procedure you will find example of line clearance, opening and cleaning checklist based on an example of tablet packing line.

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MAN-060 Reconciliation of Component and Product

This simple SOP describes the concept of reconciliation, how to reconcile finished goods and determine the allowable discrepancies of components and products when reconciled.

MAN-065 Example-Operation of Barcode Reader

This SOP describes the set up and operation of a standard barcode reader for carton components used in the packing lines.

MAN-070 Example-IBC Operation and Cleaning

This SOP describes the operation and cleaning procedures that relate to the use of the Intermediate Bulk Containers (IBC's) used to store and transfer of raw material on the process lines. The procedure instruction covers how to receive the bins from warehouse dispensary, movement towards the process lines, lifting and emptying the contents from the bin, cleaning and returning the bins back to warehouse dispensary.

MAN-075 Example-Tablet Packing Machine and Cartoner-construction, operation and cleaning

This procedure describes the machine construction and operation, machine start up and cleaning of a typical tablet Blistering machine and the Cartoner for tablet packing. You will be able to create a new procedure for your packing line based on the format of this SOP.

MAN-080 Example-Manufacturing Instruction for Tablet Packing

This procedure describes how to create a complete manufacturing instruction for your process line to be followed by your manufacturing employees. To make the instruction more practical and easy to understand, a sample instruction is added in the form of a protocol for a typical tablet packing process. All the related blank forms are attached at the end of the procedure for a better understanding.

MAN-085 Mop Cleaning Procedure

This simple procedure outlines the operation of the factory laundry in a safe and hazard-free manner. This procedure can be used in any manufacturing site for the purpose of mop cleaning.

MAN-090 Scheduling Production Lines

This procedure describes how to produce a monthly manufacturing schedule following an agreed 12 months plan, to provide a sequence of work that will enable the scheduling of support groups (i.e. Quality, Technical and Warehousing), incorporate any planned engineering down time (i.e. project work, calibration and preventative maintenance), create and release batches according to the agreed weekly schedule, provide key dates for product supply to support Customer Service.

MAN-095 Vacuum Leak Testing Procedure

This SOP describes the set up and operation of a standard vacuum Leak Tester for the very popular vacuum leak testing used in a typical packing line.

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MAN-100 Weighing Equipment - Checking and Calibration

This SOP outlines the procedures required for the checking/calibration and repair of balances, scales, checkweighers and load cells typically used in the standard packing lines.

MAN-110 Example-Operation of Checkweigher

This SOP describes the set up and operation of a standard checkweigher used in a typical packing line for weight checks of each packed unit.

MAN-115 Example-Tablet Packing-Start up and In-process Testing

This procedure contains instructions that enable the production operators working in a typical packing line to carry out Start-Up and In-Process Tests required in order to produce quality products and to ensure in-process controls. A typical tablet packing process is used here as an example.

MAN-120 Example-Packed Tablet Sampling by Production Personnel for Testing

This procedure describes the process of sampling manufactured finished good required to be taken by production personnel for the laboratory testing. A typical tablet packing process is used here as an example.