Procedure: Manufacture of Product

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| Quality representative signs to confirm document complies with quality management system | | | |
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# Purpose

To define the requirements for manufacture of products at [Company] that meet Good Manufacturing Practice (GMP) standards.

# Scope

The scope of this procedure includes any product manufactured which is required by a customer to meet GMP standards.

# Responsibilities

Amend to reflect your organisational structure.

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| --- | --- |
| Role | Responsibility |
| Production Manager | * Supervises production operators and supervisors. * Ensures only trained and experienced personnel manufacture products. * Complies with the quality management system. |
| Production operators and supervisors | * Follows this procedure and all OHS&E requirements. * Completes all documents, checklists, labels required by this procedure. |

# Procedure

## General

Each batch of product must be manufactured to an approved batch processing instruction (BPI). The BPI is filled out as the batch is manufactured, in real time. If a deviation to the BPI occurs, this must be fully documented at the time.

All work carried out to manufacture products must be recorded in indelible blue or black ink on documents that will when completed form the batch manufacturing record.

Only suitably trained and experienced production operators and supervisors are to work on the manufacture of GMP product.

## Equipment, facilities

Use specified and validated cleaning regimes only to ensure no batch to batch variation.

Equipment and facilities are to be appropriate for the product to be manufactured and clean according to the cleaning regimes listed in Form FP709-2: Cleaning Regimes for Product Manufacture Checklist.

## Preparation of manufacturing area

The facility (or facilities) where the batch is to be manufactured is to be clean and clear before proceeding. This is to ensure there is no contamination of the batch from materials or product manufactured previously in the facility. A preparation checklist, Form FP709-1 Pre-manufacture Checklist is available to ensure this is carried out. A checklist is to be completed for each facility, room or area where the product is to be made. The checklist must be completed and approved by the Production Manager before proceeding.

## Preparation of documents

The following documents must be available for batch manufacture and checked by the Production Manager before use:

* an approved copy of the BPI for the product, refer to Procedure QP708: Batch Processing Instruction and Recording.
* a completed copy of Form FP709-1: Pre-manufacture Checklist for each manufacturing facility to be used during product manufacture
* a copy of Form FP709-2: Cleaning Regimes for Product Manufacture Checklist
* current MSDSs for the materials to be used
* any additional OHS&E instructions for containment of starting materials, intermediates, solvents, catalysts or product not detailed in the BPI or MSDSs
* details of the previous batch manufactured in the facilities to be used
* a reference copy of the equipment cleaning procedures.

## Dispensing of raw materials

Raw materials must be:

* checked for identity by checking the label against the BPI
* be approved for use
* be within retest or expiry date
* be taken from a container or containers that are all clearly labelled, sealed, clean on the outside, in good condition and show no signs of damage by pests or moisture
* if dispensed by weight, weighted using the correct scales or balance for the appropriate accuracy and which are within the re-calibration period
* if dispensed by volume, measured using the correct volumetric containers for the appropriate accuracy and volume of liquid dispensed
* if not dispensed directly into equipment for manufacture, dispensed into suitable clean containers and labelled with a dispensing label.

## Filling out documents

All information is to be recorded on the documents according to Good Documentation Practice (GDP):

* completed at the time the action being undertaken
* using indelible blue or black ink
* errors must be crossed out, with a single line so it is clear where the error is and its wording is still readable
* any changes must be initialled and dated
* the correction should be written as close as possible to the error.

## Deviations

All deviations from the BPIs are to be fully explained and documented, signed and dated.

## Sampling and in-process testing

All samples are to be taken at the prescribed time, in the appropriately labelled containers and tested as detailed in the BPI. Samples and sample quantity are to be noted on the BPI for reconciliation.

## Data recording

Data logging is to be confirmed as detailed in the BPI. On the completion of the batch this data is to form part of the manufacturing record.

## Disposal of production by-products

At appropriate stages as indicated by the BPI, the liquid phase of washes and other by-products of production are collected into the appropriate containers and transferred to the by-product storage area. The logs for each container are updated as necessary.

## Completion of batch

At the completion of batch manufacture ensure that:

* all services and utilities are turned off
* equipment is cleaned
* facility is cleared of wastes, by-products and labels
* all containers of raw material are returned to appropriate stores in a clean condition
* all surfaces are cleaned
* batch specific signage is removed
* all documents required for batch review are present, complete and correctly reflect batch manufacture; including all deviations according to Procedure QP708: Batch Processing Instruction and Recording.
* batch records are managed as controlled documents according to Procedure QP403: Control of Records.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
| BPI | Batch Processing Instruction |
| GDP | Good Documentation Practice |
| MSDS | Material Safety Data Sheet |
| OHS&E | Occupational Health, Safety & Environment |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP403 | Control of Records. |
| QP708 | Batch Processing Instruction and Recording. |
| FP709-1 | Pre-manufacture Checklist |
| FP709-2 | Cleaning Regimes for Product Manufacture Checklist |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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