ASEAN Guidelines on GMP for Traditional Medicines / Health Supplements (TM/HS)

CHAPTER 5 - DOCUMENTATION

Prepared by:

Brunei Darussalam and Lao PDR

Approved by:

ASEAN TMHS GMP Task Force

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Endorsed by:

ASEAN TMHS Product Working Group

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Muhammad Lukmani Ibrahim	Chair of ASEAN GMP TF	Mohd Nasrul Mohamad Noor	Malaysia
Quitevis, Ludivina Fama	Co-Chair of ASEAN GMP TF	Sharifah Mastura Ahmad Fuad	Malaysia
Mega Valentine	ASEAN Secretariat	Thiri Kyaw Soe	Myanmar
Hasmilawaty Mohammad Taib	Brunei Darussalam	Wah Wah Aung	Myanmar
Jamilah Metusin	Brunei Darussalam	Mary Angeline V. Francisco	Philippines
Hean Kimseat	Cambodia	Ms. Rochel Averion Francisco	Philippines
Som Samnang	Cambodia	Ong Hai Ann, Terrance	Singapore
Kristiana Haryati	Indonesia	Pinpong Intarapanich	Thailand
Widiastuti Adiputra	Indonesia	Thida Thaveerit	Thailand
Bounleuane Douangdeuane	Lao PDR	Lam Quoc Hung	Vietnam
Solivanh Sengchanh	Lao PDR	Luu Duc Du	Vietnam
Sivong Sengaloundeth	Lao PDR	Mak Sum Shing, Andrew	AAHSA
		Tamotsu Iwai	AAHSA
		Robles, Frances Evelyn	AATMI

OUTLINE

- Objective
- Purpose
- Principle
- General Guidelines
- Quality Control Documents
- Specifications
- Production Documents
- Packaging Instructions
- Batch Manufacturing Records:
  - Processing
  - Packaging
- Standard Operating Procedures and Records
- An example of Document Format

OBJECTIVE

- An essential element of quality assurance is good documentation practices.

- The system of documentation devised or adopted should have as its main objective to establish, monitor, and record “quality” for all aspects of the production, quality control and quality assurance.

- Record provides evidence of work done.

PURPOSE

- Clearly written documentation prevents errors that may arise in oral or casually written communication
- It provides assurance that quality related activities are carried out exactly the way they have been planned and approved
- The achievement of conformity and quality improvement
- Purpose of documentation :
  - To ensure that there are specifications for all materials and methods of manufacture and control
  - Employees know what to do
  - Responsibilities and authorities are identified
  - Ensure that authorized persons have all information necessary for release
  - Provide audit trail
  - Forms the basis for improvement.

PRINCIPLE

- Good documentation constitutes an essential part of the quality assurance system and should exist for all aspects of GMP.
- Clearly written documentation prevents errors from spoken communication and permits tracing of batch history of the product, from purchasing of starting materials to the distribution of finished products.
- It shall be able to record executed activities for maintenance, storage, quality control, distribution and other specific matters linked to GMP.
- For manufacturing activities, a documentation system must be prepared.
- The system consisting of manufacturing formulae and instructions, specifications, procedures and records must be free from errors and clearly established.

GOOD DOCUMENTATION PRACTICE GENERAL GUIDELINES

- The system of documentation shall be:
  - able to record the complete history of each batch.
  - adequate to permit investigation and tracing of any defective products.

- Documents shall contain all necessary information, to be kept up to date and any amendment shall be performed by following proper document change control procedure and authorised. It shall include provision for periodic review and revision as necessary.

- Product related records shall be retained for at least one year after the expiry date of the finished product.

GOOD DOCUMENTATION PRACTICE GENERAL GUIDELINES

Documents shall:

- be designed, prepared and laid out in an orderly fashion
- be written in detail and in simple language that can be easily understood by the user
- have unambiguous contents
- have title, nature and purpose shall be clearly stated
- not be hand-written
- be regularly reviewed and kept up to date
- prevent inadvertent use of superseded documents, when they have been revised
- be approved, signed and dated by an authorised person
- be distributed with care

GOOD DOCUMENTATION PRACTICE GENERAL GUIDELINES

Reproduced documents shall:

- be clear, legible and duly authorised.
- not allow any error during the reproduction of documents

Records shall:

- be made in clear, legible, and indelible handwriting. Sufficient space shall be provided for such entries.
- be signed and dated, and where appropriate the reason of the alteration to be recorded when any alteration made to the entry on a document. The alteration shall permit the reading of the original information.
- be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture the product are traceable.
- be readily available throughout the period of retention.

GOOD DOCUMENTATION PRACTICE GENERAL GUIDELINES

Electronic Data :

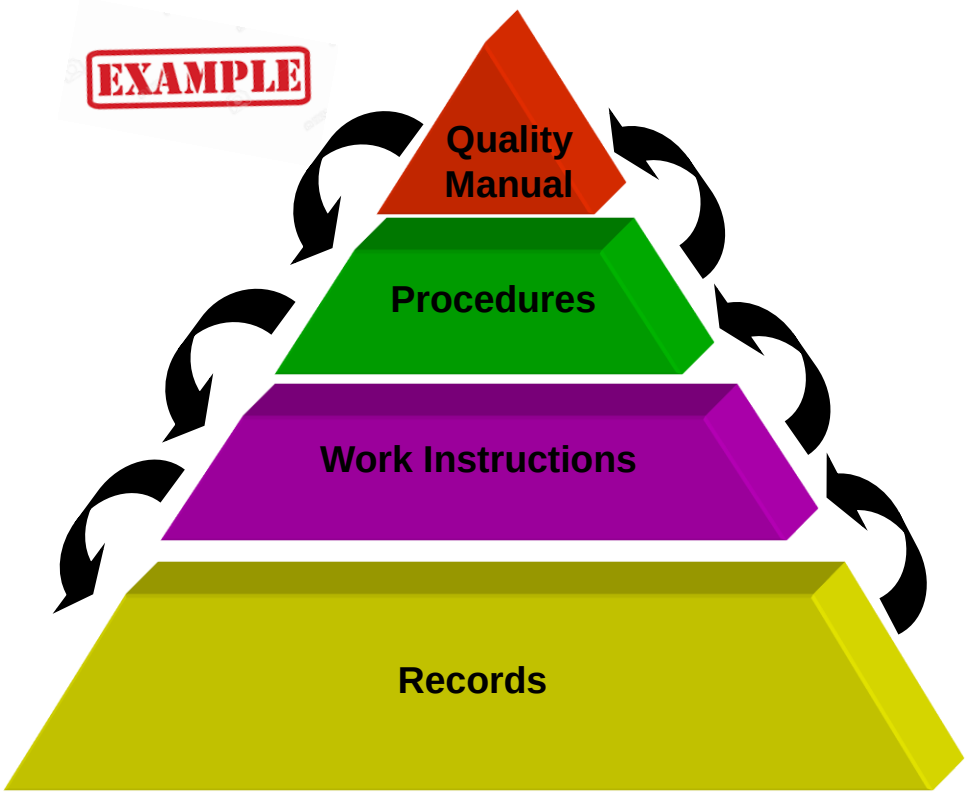
Data may be recorded by electronic systems, photographic or other reliable means, but there shall:

- be detailed procedure (e.g. SOP) relating to the system in use
- be checked and verified for accuracy of the records
- be authorised personnel to enter or modify data in the computer
- be a record of changes and deletions
- be traceability to all raw data
- be restricted by passwords or other means for access
- be independently checked and verified for the result of entry of critical data
- be protection and back-up for all batch records.

GOOD DOCUMENTATION PRACTICE GENERAL GUIDELINES

- The manufacturer shall practice what is documented in the written procedures.
- Under circumstances where there is a change in the practice, the written procedures shall be promptly updated.
- If a written procedure was revised, appropriate training shall be provided to ensure that the personnel carry out the work in accordance to the revised procedure.

TIERS OF DOCUMENTATION



Broadly, all documents relating to quality fall in to the following categories:

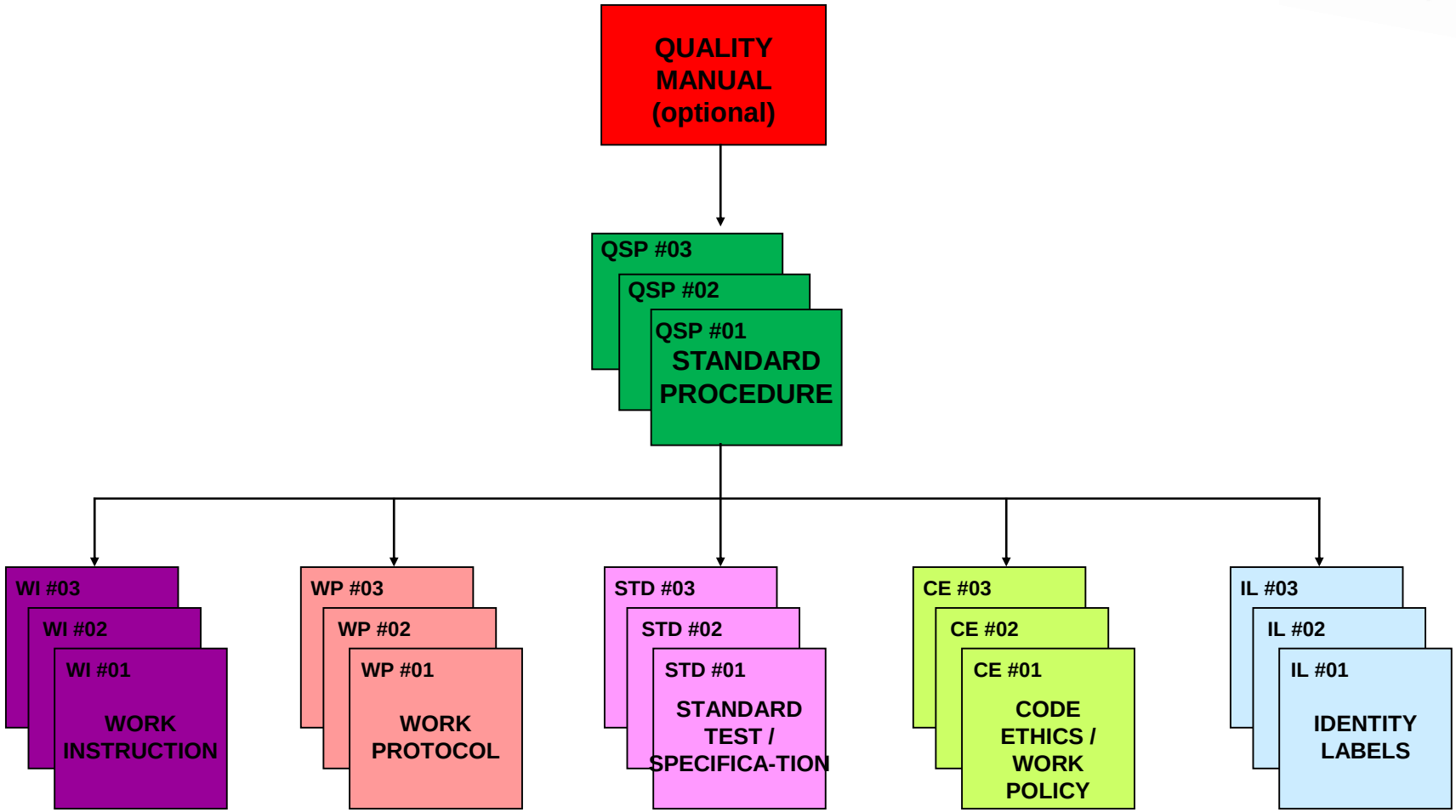
- Quality Manual (optional)
- Procedures (QSP and SOP)
- Work Instructions (can be merged with Procedures)
- Records

Legend:
QSP - Quality Standard Procedure
SOP - Standard Operating Procedure

All levels are integrated to form a comprehensive and cohesive documentation network via a system of cross referencing

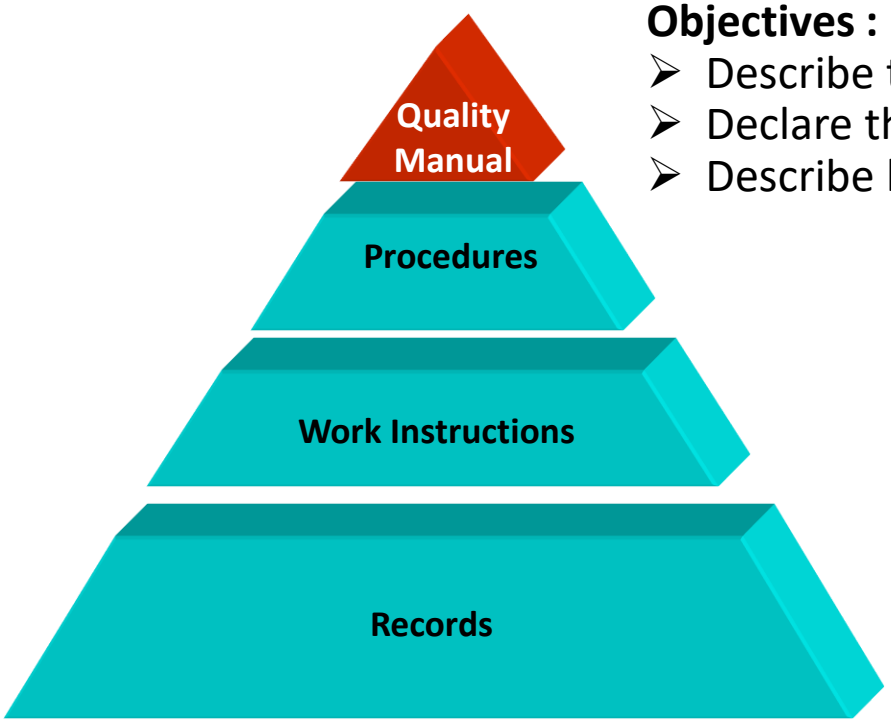
TIERS OF DOCUMENTATION

EXAMPLE



QUALITY MANUAL (OPTIONAL)

The strategic document that outlines the organization's system of providing quality assurance to achieve customer satisfaction.



Objectives :

- Describe the quality system structure
- Declare the quality policy and organization goal
- Describe how the organization meets the quality goal

Content of quality manual :

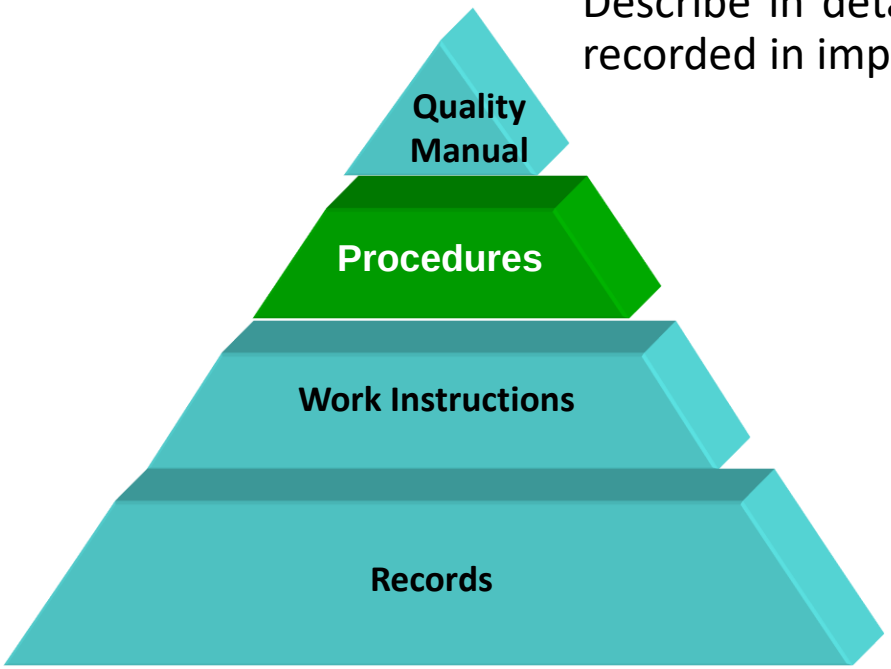
- The quality policy declaration
- The goal of quality;
- The organisational structure including responsibility and authority of each key personnel
- Procedures, instructions and resources for implementing the quality management.

User :

- All personnel in the organization
- Another parties, auditors, and customers

PROCEDURES

The tactical document that outlines the activities or operations of the organisation in implementing the stated quality policies.



Objectives :

Describe in detail how activities should be done, controlled and recorded in implementing the definite policy

Standard Operating Procedures explains:

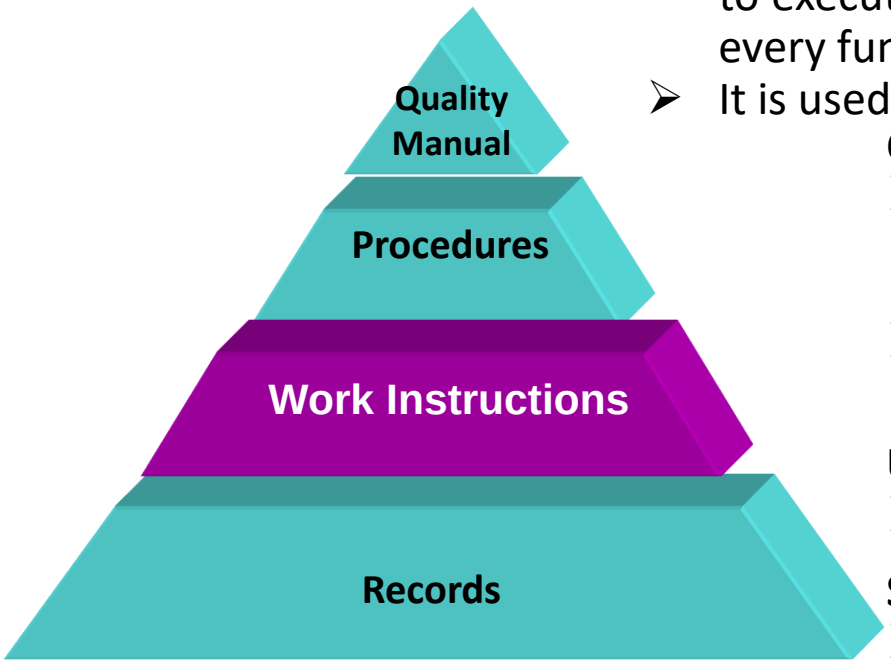
- What the process is and it's purpose
- Where activity is operating
- Who is responsible for every activity
- When activity is completed, sequential of the activities, frequency, etc.
- How activity can be finished follow the work instruction design or other reference documents
- Reference to the other relevant documents

User :

- All personnel who set up and run the processes

SUPPORTING DOCUMENTS OR WORK INSTRUCTIONS

The operational document containing instructions specifying how the activities are performed or products are accepted.



Objectives :

- It is an instruction document, step by step for guideline to execute the daily activity or operation for personnel in every function
- It is used departmentally, every task or every line.

Content of work instructions :

- Detailed explanation of instructions to finish the job, detailed handling of method, equipment and machine
- Related to the technical matters with stressing for operation, inspection & testing.

User :

- All personnel who operates the certain task

Supporting documents:

- Worksheet, checklist
- Visual (illustration, flow chart, layout plan, photo)

S.O.P. versus W.I.

QUALITY PROCEDURE/SOP

- Process oriented
- Describe step of procedure
- Supporting the Quality Manual
- Explain general description on certain process and give systematic action to ensure product quality
- Procedure guideline which involve several departments and/or sections
- During implementation need other supported documents
- Guideline at organization level

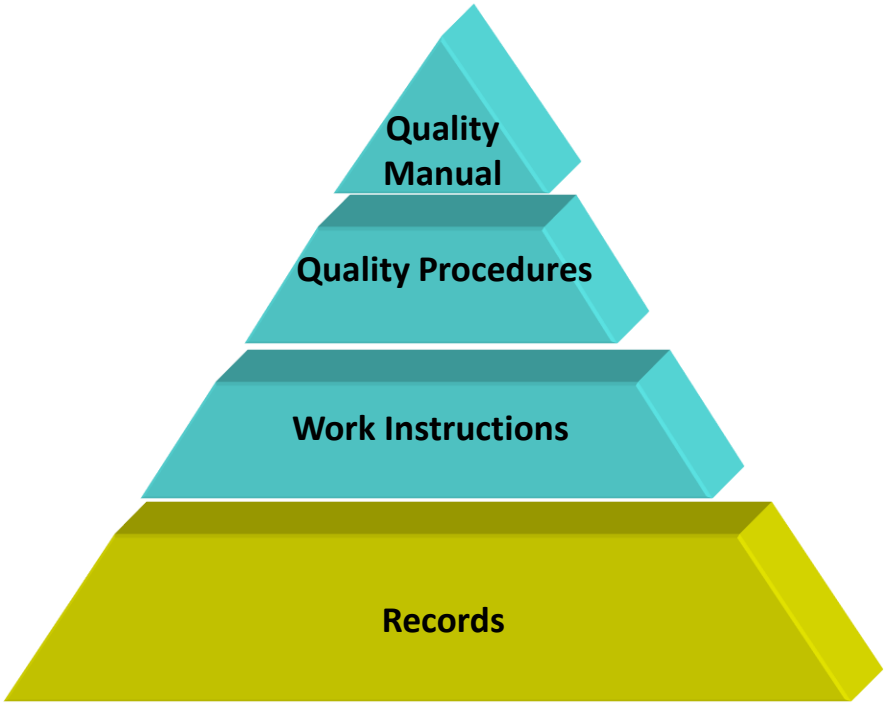
WORKING INSTRUCTION

- Task oriented
- Describe detail instruction
- Operation guidance
- Dedicated to explain special task, method, or technique which should be done to achieve target quality
- Instruction guidance which dedicated for certain department or section only
- During implementation can stand alone
- Guidance at operational level

SOP and WI can be merged depending on the documentation system adopted by the company

RECORDS

Records, including charts and data pertaining to design, inspection, testing, survey, audit, review or related results, should be maintained as important evidence to demonstrate:



- Quality System has been effectively implemented;
- that products and services have been developed and delivered appropriately with the requirements.

All Records should be :

- legible and clear;
- Dated;
- readily identifiable and retrievable;
- carry authorisation status;
- retained for a designated period;
- protected from damage and deterioration while storage.
- All calculations should be duly recorded

FORMAT OF DOCUMENT

- ✓ No “best format” in documentation system.
- ✓ Each document should be suitable for all users
- ✓ In general, all quality documents can be written in the following format :
  - ☛ narrative
  - ☛ flowchart
  - ☛ combination narrative and flowchart
  - ☛ electronic / computerized system

DOCUMENT NUMBERING SYSTEM

Every document shall have a unique number

- to facilitate traceability
- Yet simple to facilitate saving and controlling of the document

CONTENT OF DOCUMENT

What should be written in the document:

- Name of document
- Name of company, department or division of the maker
- Document number
- Revision number
- Page and number of pages of document
- Date of approved
- Effective date
- Name and signature of the person who prepared the document
- Names and signatures of the person who reviewed and person approved the document
- Content of procedure/instruction

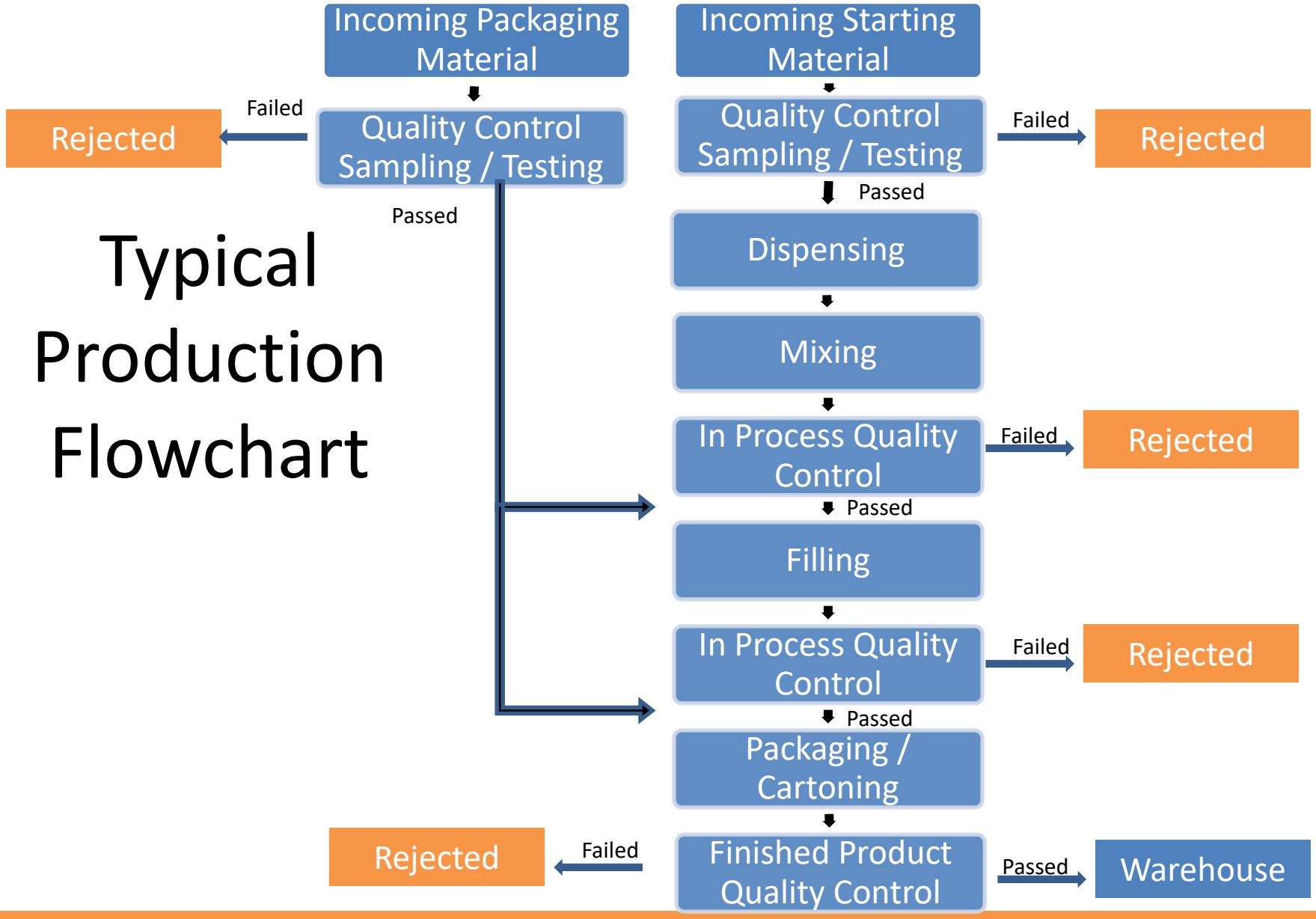
NARRATIVES DOCUMENT

- The most common format being used
- The narrative document can be described as the following:
  - Policy reference
  - Objective : why and for what
  - Coverage area
  - Document reference
  - Responsible person
  - Detail procedure
  - Record if needed

FLOWCHART DOCUMENT

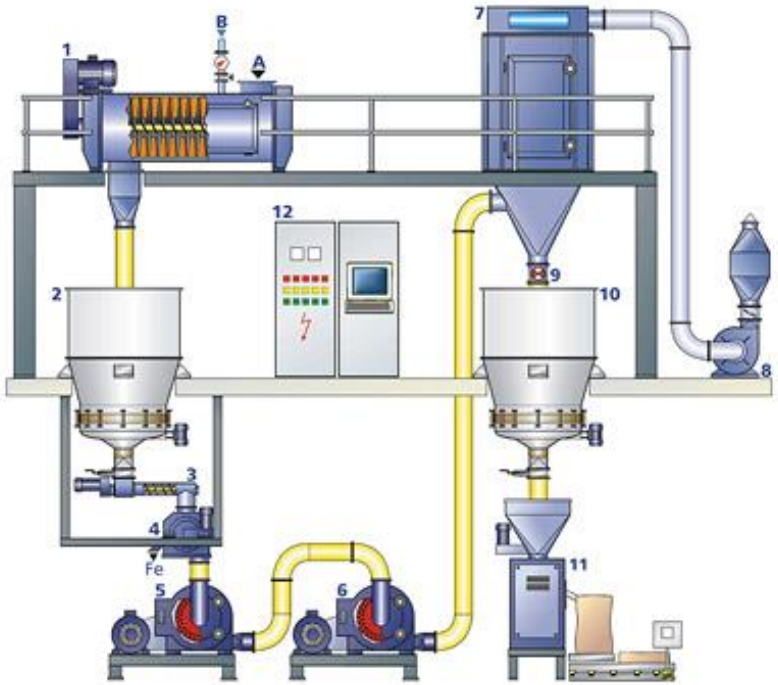
- Schematic representation which describe the flow of processes in certain target activity
- Very clear and easy to understand
- Sample of the flowchart document can be written as beside schema
- For complicated process, sometimes flowchart alone might not be able to capture detailed information therefore it should be combined with a narrative

Typical Production Flowchart



COMBINED DOCUMENTS

Sometimes narrative document and flowchart are also supported by design/lay out



Legend

1 = Mixer
2 = Intermediate bin with activated discharge
3 = Feed metering unit
4 = Metal separator
5 = UPZ fine impact mill with pin discs
6 = UPZ fine impact mill with pin discs
7 = Automatic reverse-jet filter
8 = Fan
9 = Rotary valve
10 = End-product bin with activated discharge
11 = Bagging unit
12 = Control cabinet

A = Feed product
B = Perfume addition
C = End product

DOCUMENT CONTROL

As mentioned in the previous slides, documents shall:

- Be approved, signed and dated by appropriate authorised persons
- Be properly authorized before making any change
- Records shall be made or completed each time action is taken in such a way that all significant activities concerning the manufacture of the product are traceable

- There shall also be a way to differentiate master hard copy document from all duplicated copies (e.g. stamp “MASTER WHEN RED” on master copy and stamp “CONTROLLED COPY” on distributed copies)
- Distributed documents should be recorded (e.g. using distribution list)

DOCUMENT CONTROL

- Obsolete documents:
  - Control copies shall be retrieved from users based on distribution list and properly destroyed to prevent inadvertent use
  - Obsolete master documents shall be marked "obsolete" and archived
- Create a list/index of all documents established

DISTRIBUTION OF DOCUMENTS

- Only up-to-date documents shall be distributed
- Copy of documents should be distributed to relevant parties and available at point of use e.g. Processing and Packaging Instructions should be available in Production Areas whereas Test Methods shall be available in QC labs
- Only document Controller or QC/QA are authorised to distribute the document in accordance to written procedure

REVIEW AND REVISION OF DOCUMENTS

- Documents shall be reviewed periodically to confirm that they are up to date.
- Changes to the procedures/steps on the document shall go through the proper change control and approved by an authorised person

- The newly revised documents shall state:
  - The date of revision
  - Reason for the revision
  - The new effective date

RECORD KEEPING RULES
"Do Not" Rules

- DO NOT leave any blanks in forms (shall indicate "nil" or "N/A" when there is no legitimate entry)
- DO NOT leave mistakes uncorrected (check your entries)
- DO NOT scribble out mistakes (shall not obscure original entries)
- DO NOT write correct entries over incorrect entries (writing over shall not obscure original entries)
- DO NOT forget to initial and date entry
- DO NOT use pencil (all entries should be made using permanent ink)

LIST OF DOCUMENTS REQUIRED

1. Quality Control Documents

2. Production Documents

3. Standard Operating Procedures (SOPs) and Records

QUALITY CONTROL DOCUMENTS

- Must be readily available from Quality Control Dept.:
  - Specifications:
    - Natural materials
    - Starting and packaging materials
    - Intermediate and bulk products
    - Finished products (FP)
  - Sampling Procedures
  - Testing Procedures and records (incl. analytical worksheets and/or laboratory notebooks)
  - Analytical reports and/or certificates
  - Data from environmental monitoring, if appropriate
  - Procedures for and records of calibration of instruments and maintenance of equipment
- Any QC documentation (e.g. test records, data, reports, etc) relating to batch record – retained at least one year after expiry date of Finished products

QUALITY CONTROL DOCUMENTS

Specifications:

- Describe the required characteristics or composition of a product or material or test, while test procedure is required to evaluate the specific quality attributes

- Provide the specific details defining the quality of:
  - Natural materials
  - Starting material
  - Packaging materials,
  - Intermediate and bulk products
  - Finished products

- All specifications should be approved by authorised personnel (QC/QA manager)

SPECIFICATIONS – NATURAL MATERIALS

Where appropriate the content shall include for :

- Scientific name and if possible with reference to the authors.
- Details to the source of the natural material (country or region of origin, cultivation, time of harvesting, collection procedures, possible pesticides used, etc.).
- Whole plant/animal or only a part material is used.
- When dried plant/animal, drying system shall be specified.
- Pictorial demonstration macroscopical and/or microscopical examination
- Storage condition and shelf life where applicable

Annex 1 – Specification for Foeniculi vulgare

Assurance for materials from animal parts origin should be free from undesirable disease (e.g. Transmissible Spongiform Encephalopathy).

SPECIFICATIONS – NATURAL MATERIALS

Testing procedures shall be available if the following tests are conducted (where appropriate):

- Identifications tests (incl. active constituents, known markers)
- Assay (known therapeutic activity or markers where possible)
- Limit tests e.g. Ash value, presence of essential oils, loss on drying
- Test for heavy metals and likely contaminants, foreign materials and adulterants
- Tests for radioactivity, mycotoxin, fungal and microbial contamination
- Tests for residual solvents in extracts or Finished Products (if applicable)
- Other tests, as required.

Annex 2 – Text Method for Foeniculi vulgare

SPECIFICATIONS – STARTING MATERIALS & PACKAGING MATERIALS

- All Starting and Packaging Materials specifications should consist of the following data, where applicable:
  - Description of the material
    - Designated name of material & internal code reference
    - Reference, if any, to pharmacopoeia monograph
    - Name of approved suppliers, and if possible, original producer of the products
    - Specimen of printed materials, including colour
    - Microbiological standards, if any;

SPECIFICATIONS – STARTING MATERIALS & PACKAGING MATERIALS

Where appropriate the content shall include for :

- directions for sampling and testing or reference to procedures;
- qualitative and quantitative requirements with acceptance limits;
- storage conditions and precautions; and
- the maximum period of storage before re-examination
- Assurance for materials from animal parts origin should be free from undesirable disease (e.g. Transmissible Spongiform Encephalopathy).

Annex 3 – Specification for Ascorbic Acid

Annex 4 – Test Method for Ascorbic Acid

SPECIFICATIONS – INTERMEDIATE AND BULK PRODUCTS

- Specifications for intermediate and bulk products,
  - shall be available if purchased or transferred,
  - or if data obtained from intermediate products are used for the evaluation of the finished product
  - the specifications shall be similar to specifications for starting materials or for finished products

SPECIFICATIONS – FINISHED PRODUCTS

All specifications of finished products should describe the following:

- Designated name of product (and internal code reference where applicable);
- Formula or a reference to;
- Description of dosage form and package details;
- Directions for sampling and testing or reference to procedure where applicable;
- Qualitative and quantitative requirements with acceptable limits where applicable;
- Storage condition and any special handling precautions, where applicable;
- Shelf-life or expiry date.

SPECIFICATIONS – FINISHED PRODUCTS

Specifications for finished products (contd.):

- Qualitative and quantitative requirements, with the acceptance limits, where applicable:
  - Physical appearance such as colour, taste, texture, size, etc;
  - Uniformity of weight (for tablets and capsules), disintegration (for tablets, capsules and pills), hardness and friability (for tablets), and viscosity (for internal and external liquids);
  - Heavy metals limits;
  - Microbial limits;
  - Other tests, as required, such as preservatives

OTHER QUALITY CONTROL DOCUMENTS

For other Quality Control Documents *(e.g. Sampling Procedures, Testing Procedures and records, Analytical reports and/or certificates)* please refer to the details Chapter 7 – Quality Control

PRODUCTION DOCUMENTS

- Manufacturing Formula and Processing Instructions
- Packaging Instructions
- Batch Processing Records
- Batch Packaging Records

PRODUCTION DOCUMENTS – MANUFACTURING FORMULA

Formally authorised Manufacturing Formula and Processing Instructions should be available for each product and batch size to be manufactured and often they are combined in one document

Shall include:

- Product name with reference code relating to its specification
- Description of product dosage form and strength, and batch size
- List of all starting materials
  - Amount of each
  - Designated name and reference which is unique to the material
  - Substance that may disappear during processing
- Statement of expected final yield with acceptance limits.

PRODUCTION DOCUMENTS – PROCESSING INSTRUCTIONS (1)

Shall include:

- Statement of processing location and equipment used
- Method/SOP (or reference to methods) for setting up equipment e.g cleaning, assembling, calibrating
- Detailed stepwise processing instruction (e.g. Checks on materials, pre-treatments, sequence for adding materials etc)
- Instructions for any in-process controls with limits
- Requirements for bulk storage of products; include container, labelling, special storage conditions if applicable
- Any special precautions.

PRODUCTION DOCUMENTS – PROCESSING INSTRUCTIONS (2)

- Shall describe the different operations carried out upon crude material such as:
  - Sorting
  - Cleaning
  - Drying
  - Crushing, and
  - Sifting
- Shall include drying time, temperatures, and methods used to control fragment or particle size
- Shall also describe sieving process/other methods of removing foreign materials.

PRODUCTION DOCUMENTS – PROCESSING INSTRUCTIONS (3)

- In particular, written instructions and records, shall be available to ensure that each container of the product is carefully examined to detect any adulteration/substitution or presence of foreign matter, such as:
  - metal, glass pieces, animal parts or excrement, stones, sand or rot and signs of decay.
- For product preparation, instructions shall include:
  - details of base or solvent
  - time and temperatures of extraction,
  - details of any concentration stages and
  - methods used.

PACKAGING INSTRUCTIONS

- Formally authorised Packaging Instructions should be available for each product pack size and type.
- Shall include:
  - Product name
  - Description of product dosage form, strength (if applicable)
  - Pack size (expressed in terms of number, weight or volume of product in final container)
  - Complete list of all packaging materials required for standard batch size including quantities, sizes and types with the code or reference number relating o the specifications of each packaging material
  - An example/ copy of relevant printed packaging materials and specimens indicating where to apply batch number references, and shelf life of the product

PACKAGING INSTRUCTIONS

- Special precautions to be observed
- Description of packaging operation
- Details of in-process controls with instructions for sampling and acceptance limits

BATCH PROCESSING RECORDS

- Batch Processing Record is that part of Batch Manufacturing Record
- Should be kept for each batch processed
- Should be based on the relevant parts of the currently approved Manufacturing Formula and Processing Instructions.
- Method of preparation of such records shall be designed to avoid transcription errors.
- Record should carry the batch number of the product being manufactured.

BATCH PROCESSING RECORDS

Before any processing begins line clearance should be done and documented:

- Recorded verification that equipment and work station clear of previous products, documents or materials not required for planned process

- Equipment clean and suitable for use

BATCH PROCESSING RECORDS

During processing, the following should be recorded at time action is taken, and after completion, and the record shall be dated and signed by person responsible for processing operations:

- Product name
- Dates and times of
  - Initiation
  - significant intermediate stages and
  - Completion of production
- Name of person responsible for each stage of production
- Date and signature of operator of different significant steps of production and where appropriate, of the person who checked each of these operations (e.g. weighing, adding active material)

BATCH PROCESSING RECORDS

- Batch number and/or analytical control number include quantities of each starting material actually weighed
- Any relevant processing operation or event and major equipment used
- A record of in-process controls, date and signature of person carrying them out and results obtained
- Product yield obtained at different and pertinent stages of manufacture
- Notes on special problems including details, with signed authorisation for any deviation from the manufacturing formula and processing instructions

BATCH PACKAGING RECORDS

- Is part of Manufacturing Record and should be kept for each batch or part of batch processed.
- Shall be based on relevant parts of Packaging Instructions
- Method of preparation of such records should be designed to avoid transcription errors
- Record shall carry Batch Number (BN) and quantity of bulk product to be packed, as well as BN and planned quantity of Finished Products (FP) that will be obtained

BATCH PACKAGING RECORDS

Before any packaging operation begins:

- Recorded checks that equipment and work station clear of previous products, documents or materials not required for planned packaging operations

- Equipment clean and suitable for use

BATCH PACKAGING RECORDS

Information should be entered at time each action is taken, and after completion, and the record shall be dated and signed by person(s) responsible for packaging operations:

i. Product name

ii. Dates and times of packaging operation

When there is risk of contamination, packaging activity should be done within the day itself

iii. Name of responsible persons carrying out packaging operation

iv. Date and signature of operators of different significant steps

BATCH PACKAGING RECORDS

v. Records of verification for identity and conformity with Packaging Instructions including the results of in-process controls

vi. Details of packaging operations carried out, including references to equipment and the packaging lines used

vii. Samples of printed packaging materials used, which include the batch/lot number, expiry date and any additional overprinting

viii. Notes on any special problems or unusual events

ix. Quantities and reference no. or identification of all printed packaging materials and bulk product issued, used, destroyed or returned to stock and quantities of obtained product – for adequate reconciliation

Annex 5 - Sample Batch Manufacturing Record

STANDARD OPERATING PROCEDURES (SOPS) & RECORDS

- Written procedures and records must be available for receipt of each delivery of each starting materials and packaging material.

- Records of receipt should include the following:
  - Name of material on delivery note and containers
  - In-house name and/or code of material
  - Date of receipt, date and signature of receiving staff
  - Name of supplier and manufacturer
  - Manufacturer's batch/reference no.
  - Total quantity and no. of containers obtained
  - Batch Number assigned after receipt
  - Any relevant comment (e.g State of containers)

STANDARD OPERATING PROCEDURES (SOPS) & RECORDS

- SOPs should be available for the following:
  - Internal labelling, quarantine and storage of starting materials, packaging materials and other materials as appropriate
  - Operation of each equipment and placed in close proximity to instrument or equipment
  - Sampling (which specify person authorised to take samples, sampling tools, and sampling instructions)

STANDARD OPERATING PROCEDURES (SOPS) & RECORDS

Describe details of batch/lot numbering system

- Objective – ensuring each batch of intermediate, bulk, or Finish Products is identified with a specific Batch Number
- Batch numbering procedures shall assure that same Batch Number will not be repeatedly used; this applies also to reprocessing.
- Batch Number allocation should be immediately recorded e.g. in logbook.
- Record should include date of allocation, product identity and size of batch.
- SOP for batch numbering that are applied to processing stage and to respective packaging stage should be related to each other.

STANDARD OPERATING PROCEDURES (SOPS) & RECORDS

- Quarantine, release and rejection of materials and products, in particular release for sale of Finish Products by authorised person.

- Records shall be maintained of distribution of each batch of product in order to facilitate recall of batch if necessary.

STANDARD OPERATING PROCEDURES (SOPS) & RECORDS

- SOPs and associated records should be available for the following:
  - equipment assembly;
  - operation of analytical apparatus and calibration;
  - maintenance, cleaning, and sanitisation of equipment and premises;
  - personnel matters including qualification, GMP training, clothing, and hygiene;
  - environmental monitoring;
  - pest control;

STANDARD OPERATING PROCEDURES (SOPS) & RECORDS

SOPs and associated records should be available for the following:

- adverse product reactions, complaints and product recalls
- returns and recovered products, rejected products/materials;
- disposal and destruction of the rejected products/materials;
- self-inspection / quality audit
- change control , handling deviation, Corrective Action Preventive Action (CAPA)
- product quality review

STANDARD OPERATING PROCEDURES (SOPS) & RECORDS

- Logbooks
  - Should be kept for major or critical equipment
  - Shall record the usage (name of products and batch number) and as appropriate, any calibrations, maintenance, cleaning, or repair operations, including dates and the identity of the people who carried out the operations
  - Should be recorded in chronological order (for use of equipment and areas where product been processed).

- Several of the mentioned procedures, specifications and/or records may be combined together in one specific document, e.g.:

  a) Batch Processing Instruction and Batch Packaging Instruction; and

  b) Processing Records and Batch Packaging Records can be merged into a single document.

REFERENCES

1. ASEAN Guidelines on Good Manufacturing Practice for Traditional Medicines.
2. ASEAN Guidelines on Good Manufacturing Practice for Health Supplements.
3. ASEAN Training Module on Guideline for Cosmetic GMP(2003) – Chapter on Documentation (2005).

THANK YOU!

ONE VISION, ONE IDENTITY, ONE COMMUNITY