

Basic Principles of GMP

Documentation

Part 1

15



Documentation

Objectives

1. To review general requirements for documents
2. To review specific requirements for each document
3. To consider current issues applicable to your countries



Documentation

General Principles – I

- Good documentation is an essential part of the QA system
- Should exist for all aspects of GMP
- Purpose of documentation
 - *Defines specifications and procedures for all materials and methods of manufacture and control*
 - *Ensures all personnel know what to do and when to do it*
 - *Ensure that authorized persons have all information necessary for release of product*

15.1



Documentation

General Principles – I

- Purpose of documentation (cont.)
 - *Ensures documented evidence, traceability, provide records and audit trail for investigation*
 - *Ensures availability of data for validation, review and statistical analysis*
- Design and use
 - *Depends upon manufacturer*
 - *Some documents combined into one, sometimes separate*

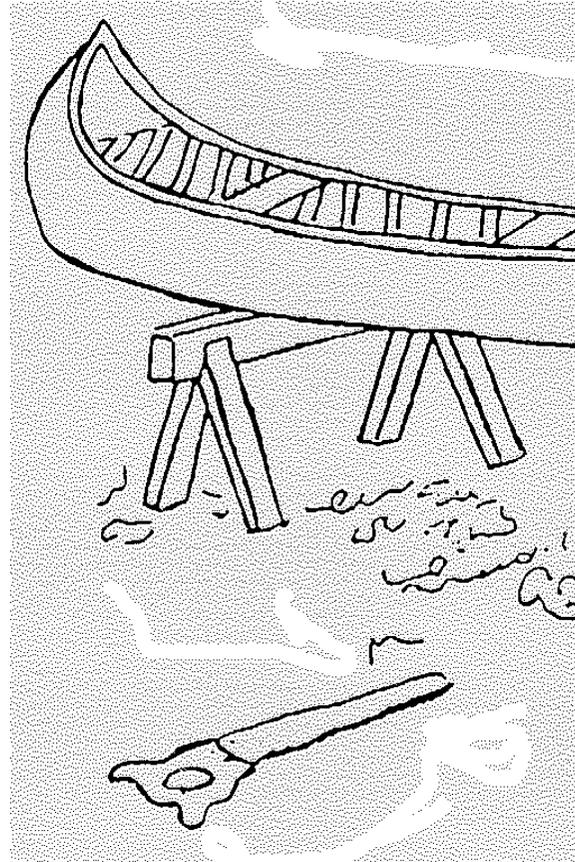
15.1



Documentation

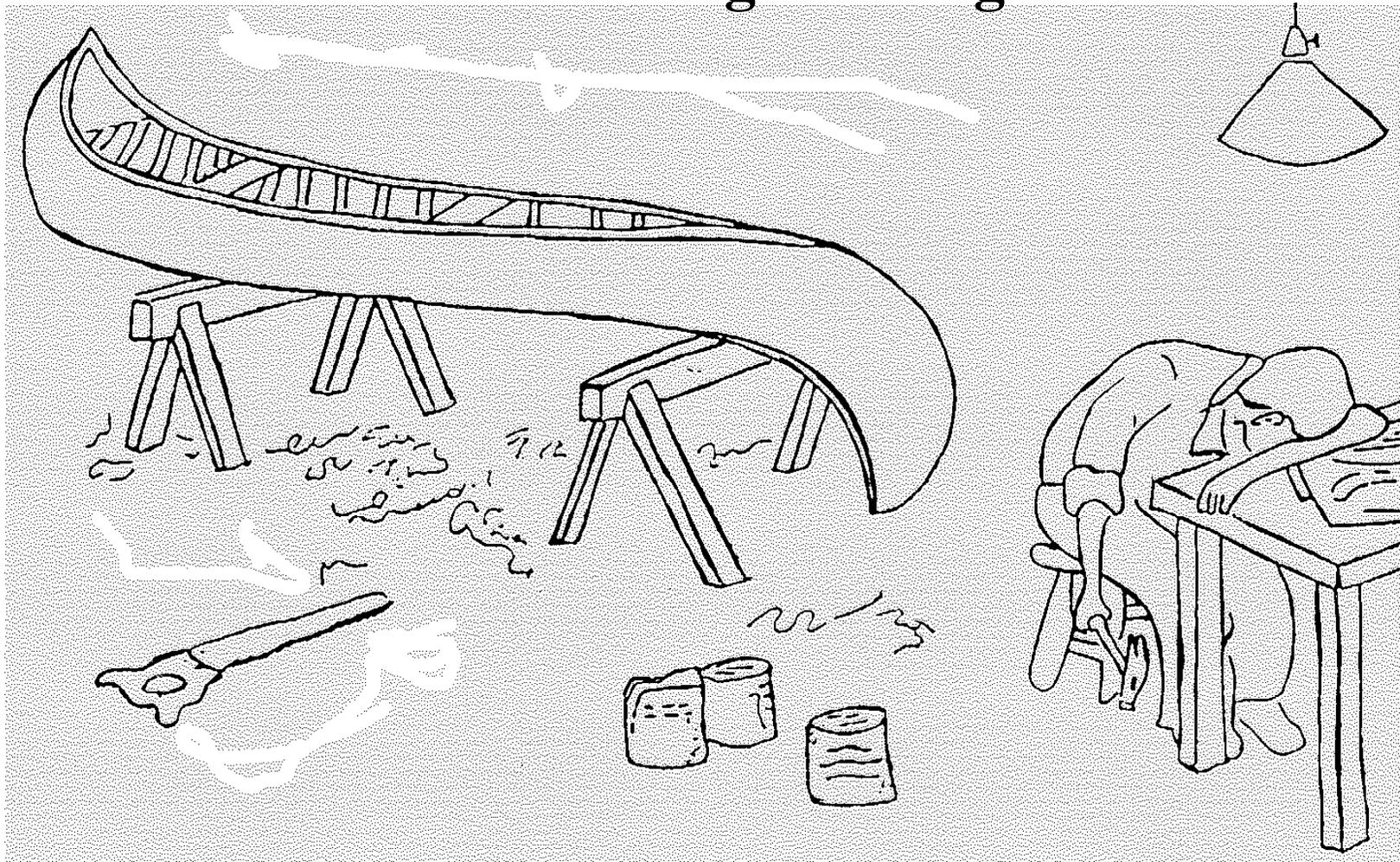
What is being made?

Most of us when attempting a task need some sort of documentation

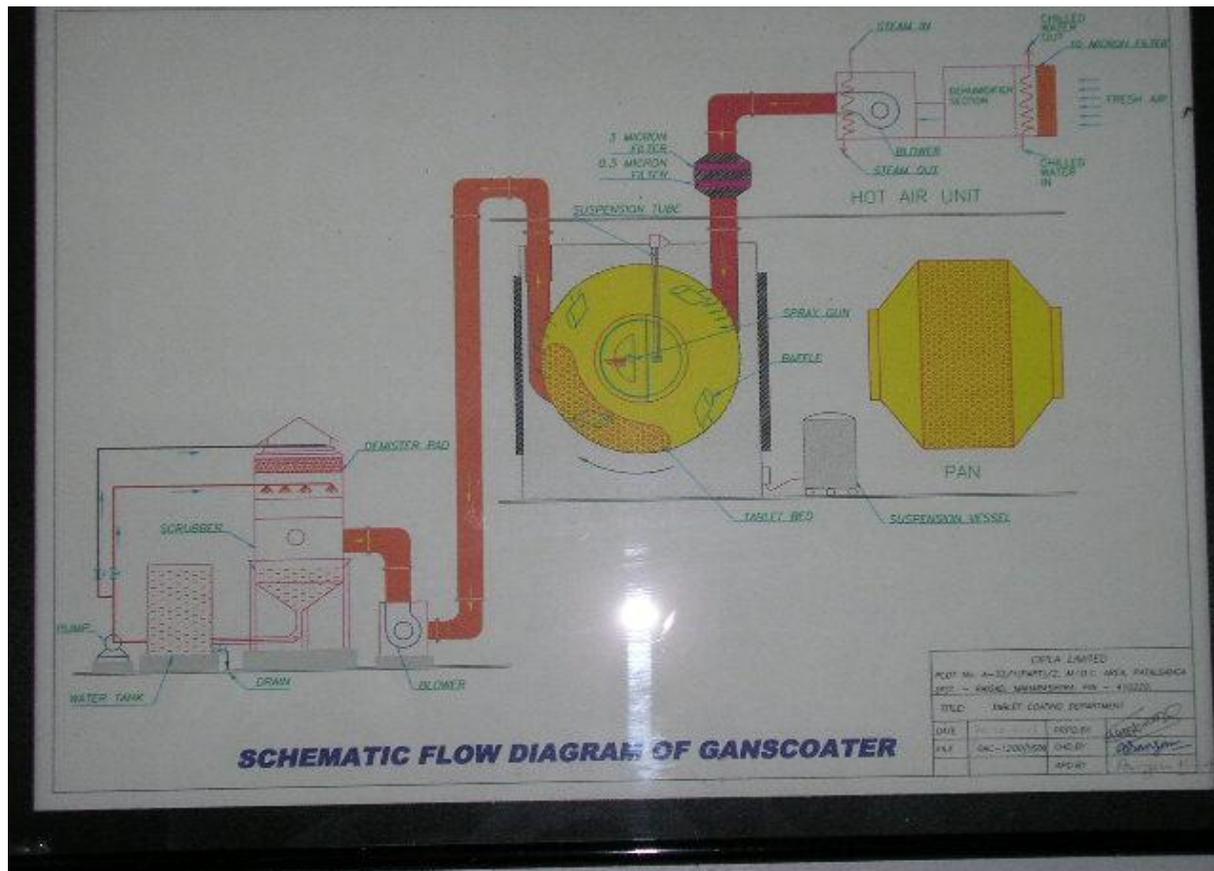


Documentation

And if the drawing is wrong!



Documentation



Documentation

Why are documents so important?

- Communication
- Cost
- Audit trail



Documentation

General Principles – I

- Documents should be
 - designed
 - prepared
 - reviewed
 - distributed *with care*
- Comply with marketing authorization
- Design of documentation important

15.2



Documentation

General Principles – II

- Look at the “Style” of the document
 - *Instructions in the imperative*
 - *Short sentences preferred to long sentences*
- Approval of documentation
 - *Approved, signed and dated by appropriate responsible persons*
 - *No document should be changed without authorization and approval – change control*

15.3



Documentation

General Principles – III

- Contents of documents should be clear (easy to understand) and include, e.g.
 - *Title, nature, objective or purpose*
- Layout in orderly fashion
- Easy to be filled in and checked
- Clear and readable – (also copies if these are made)
- No errors if master documents are copied for working documents

15.4



Documentation

General Principles – IV

Documentation control

- Regular review of documents
- Kept up to date (current) – amended – through change control
- Superseded documents removed and not used
 - *Distribution and retrieval of documentation*
- Retention time for superseded documents

15.5



Documentation

General Principles – V

Data entry

- Clear, readable and indelible
- Design to allow for sufficient space for entries
- Changes to entries:
 - *signed, dated and reason given*
 - *original entry still readable*
- Entries at the time of action
- All significant actions recorded – traceable

15.6 – 15.8



Documentation

General Principles – VI

Data entry (cont.)

- Electronic data processing systems, photographic systems or other reliable means
- Systems require SOPs and records
- Accuracy of records checked
- Authorized persons - access and changes
- Password controlled
- Entries checked

15.9



Documentation

General Principles – VII

Data entry (cont.)

- Batch records stored electronically:
 - *Protected*
 - *Back-up transfer, e.g. magnetic tape, microfilm, paper print-outs*
- Records kept 1 year after expiry date of product
- Data readily available during retention period

15.9



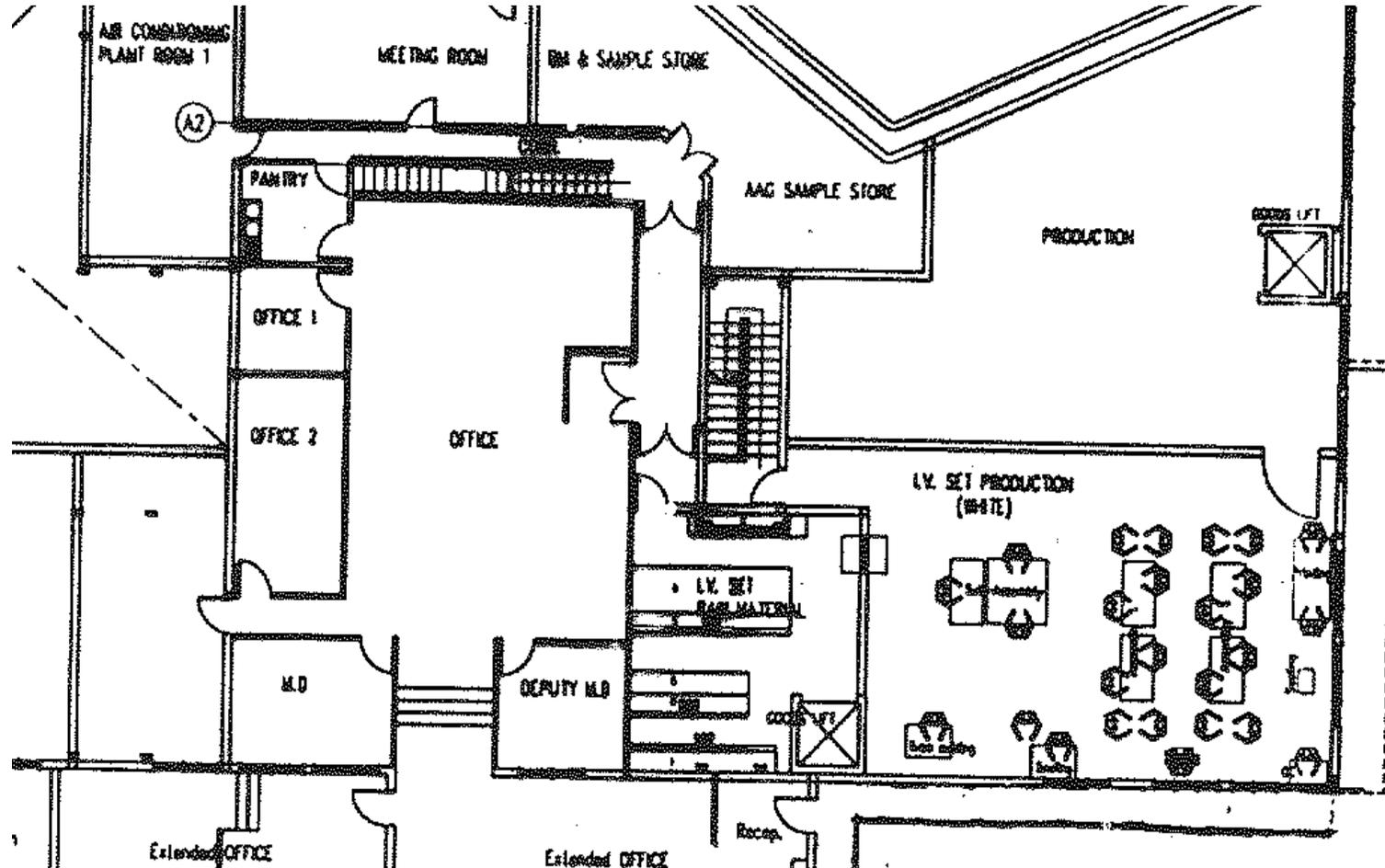
Documentation

Types of Documentation

- Labels
- Specifications and testing procedures
- Master formulae and instructions
- Batch processing and batch packaging records
- Standard Operating Procedures (SOPs)
- Records
 - *Stock control and distribution records*
- Other documents ...



Documentation



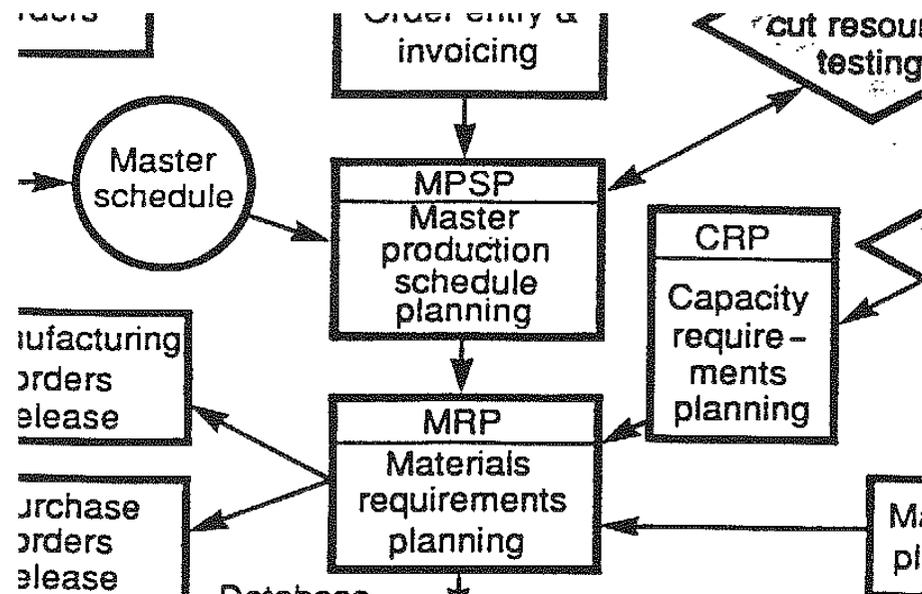
Documentation

- Photographs can be documents and part of a herbal identification, provided they are properly authorized and controlled



Documentation

- Flow charts provide substantial information at a glance



Documentation

Types of Documentation

- The different types of documents will be discussed in detail in Documentation: Part 2

