

## REPORTS AND DOCUMENTS

### REPORTS:

*Reports are oral or written exchange of information shared between nurses or a number of persons. Reporting is communication of information to another individual*

### DOCUMENTATION:

- Documentation is any communicable material that is used to describe, explain or instruct regarding some attributes of an object, system or procedure, such as its parts, assembly, installation, maintenance and use
- Documentation provides both,
  - I. Information on when, where, who, why & how to complete tasks
  - II. Evidence providing that the tasks have been completed

### INTRODUCTION:

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### Good Documentation Practice (GDP)

"GDP describes the standards by which documentation is created and maintained in the pharmaceutical industries"

- *DOCUMENTATION is the process of communicating in written form about essential facts for the maintenance of continuous history of events over a period of time.*
- *RECORD is the permanent written communication that documents information relevant to a client's health care management*
- GUIDELINES is a document that provides recommended practices and instructions
- POLICY is a plan or adopted course or principle of action intended to influence and determine the decisions or actions of an organization

### PRINCIPLE OF GDP:

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- A document bearing original sign should never be destroyed
- Never falsify information
- Never you a white-out and cover-over tapes
- Never obliterate information or record
- Never over-write a record
- Never use pencil – use permanent Black or Blue ink
- No spaces, lines or fields are left to be left blank
- Never use of symbols e.g., ditto marks or arrows to indicate repetitive and consecutive

### BENEFITS OF GDP:

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- Build confidence in the quality of product
- Reduce efforts to compliance with regulatory bodies
- Allows for achievement of required results
- Correct, complete, current, and consistent information effectively meets customers and stake holders requirements

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- Enable the production activities to be arranged into functional patterns for specific action
- Create structures so that staffs can systematically coordinate to conduct business
- Training of production staff
- Solve complicated problems
- Reduce or eliminate assumptions and second guessing
- Eliminate the needs to re-ask the same questions
- Specify clear instruction for staff

### **Good documentation needs,**

- Approve, review and update documents
- Change and current revision status of document identified
- Relevant versions of applicable documents available at point of use
- Document remain legible and readily identifiable
- Documents of external origin identified and their distribution controlled
- Prevent unintended use of obsolete documents, and archiving

### **ESSENTIAL OF GOOD DOCUMENTATION**

- In a GMP Environment, Documentation needs to meet certain requirements to ensure product quality & product safety
- If an instruction or record is poorly documented, then the manufacturer or quality assurance/control of a product can be negatively impacted, potentially reducing patient safety
- The standards of documentation within a company can directly impact the level of success in manufacturing quality products that are safe as well as success during audit situations
- Ensures documentation evidence, traceability, provide records and audit trails for investigation
- Ensure availability of data for validation, review and statistical analysis
- Control of Process – Ensure all staff to know what to do and when to do
- To improve performance
- Regulatory requirements

### **TYPES OF DOCUMENTATION**

#### 1. DOCUMENTS – procedural or instructional documentation

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- Reference for future use or a means to communicate information to others.
- Particularly important to ensure that knowledge is not lost when employee leaves.
- Ensure the quality & consistency of processed/activities/manufacturing.

#### **TYPES OF DOCUMENT USED:**

- I. SOPs
- II. MPs
- III. Training Schedule
- IV. Change control Documents

- V. Calibration form
- VI. Temperature & Humidity chart
- VII. CAPA
- VIII. Daily plans
- IX. DPRs
- X. Emergency repairs and maintenance form

2. RECORDS – evidence of compliance

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- Provide background history
- Protect intellectual property (Evidence of an idea or an finding including the date and the responsible person)
- Provide legally valid evidence

**TYPES OF RECORD USED**

- I. ERP (OPM)
- II. Humidity and temperature control records
- III. Calibration records
- IV. Emergency & maintenance records
- V. Training records
- VI. BMRs
- VII. Log books

**CONSTITUTES GOOD DOCUMENTATION:**

1. Clearly Written documentation:
  - All documents must be accurate & written in manner that prevents error and ensure consistency
2. Using indelible ink:
  - All records must be filled out in indelible ink for long term legibility. Don't use pencil or ink that can be erased
3. Legible hand written entries
4. Reviewing & approving
5. Staff signatures:
  - Hand written signature must be unique to the individual and listed within the site signature register to ensure that signature is traceable to a member of staff. Staff are not permitted to sign for another member of staff unless delegated
6. Page Numbering:
7. Concise:
  - The document must provide clear information that is understood by all customers
8. Traceable:
  - Who recorded it, where and why
9. Contemporaneous:
  - The information should be documented at the correct time frame along with flow of events
10. Enduring:
  - Long lasting and durable
11. Accessible:
  - Easily available for review

**CHANGES OR AMENDMENTS ARE MADE IN A COMPLAINT MANNER**

**A. MAKING A LEGIBLE CORRECTION:**

If correction needs to be made, the original record must be still legible

1. Make a single line through the error-never use correction fluid, multiple cross-marker pen to obscure the original record
2. Provide a brief comment why the change is required
3. Initial the change so that it is clear that the correction is deliberated
4. Record the date of the correction next to the initials so that there is a record of when the change was made

**EXAMPLE:**

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**WEIGHT OF INGREDIENT ~~14.5 Kg~~ 14.75 kg Ams 2212.04.2020**

Here's how a corrected entry might look:  
 Don't Deface the Original Entry!!!  
 NO OVER WRITTINGS

**B. HANDLING OMITTED DATA:**

If an entry was omitted and must be made at a time later than the activity was performed

1. Clearly indicate the date the activity was performed and the date the activity is recorded on the documentation
  2. Document an explanation to substantiate the entry & reason for the delay in recording
  3. Sign & date the change
- Back dating of entries is not permitted

**COMMON DOCUMENTATION ERRORS:**

- Missing signature and dates at the time of activity performed
- The write-over
- Non-uniform date and signature entry
- Writing a note that activity was performed on one day and signed for another day
- Blank spaces'
- Illegible writing
- Too many corrections

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**DISTRIBUTION RECORDS**

**INTRODUCTION:**

Distribution records are written data related to distribution of drugs from manufacturer to distributors. They are one of the most important records required by GMP regulators. These records should be maintained in such a way that a batch related distribution record is easily available

**OBJECTIVES:**

- The objective of this guidelines is that if there is some adverse drug reaction or some quality defects, the manufacturer should be able to recall the batch of the

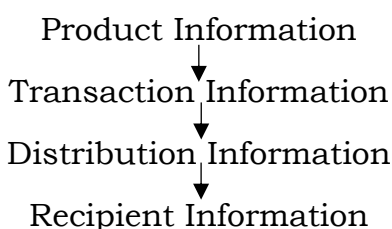
drug promptly. The information containing in these records is a key for notification of customers in the event of a product recall.

- Every distributor is also obliged to maintain a complete and accurate record of further distribution
- A distribution register may be maintained for detailed information of each batch of drug product.

**CONTENT OF THE RECORD:**

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- Name
- Strength of the product
- Name and address of consignee
- Date and quantity shipped
- Control number of drug product



**Product Information:** Describe the product being transfer to a new owner (e.g. drug name, manufacturer, lot number, strength, dosage form)

**Transaction Information:** Describe the sale, transfer, return or other disposition of the product (e.g. quality, invoice number, invoice date)

**Distribution Information:** Describe the party selling or transferring owner ship of the product (e.g. business name, name and signature of person)

**Recipient Information:** Describe the party receiving the product (e.g. business name and address, date received, name and signature of the person)

**DOCUMENTATION**

Distribution records include a wide range of documentation such as invoices, bills of lading, customer’s receipts and internal warehouse storage and inventory records

**EXAMPLE:**

Lot #132A Product 500mg. Aspirin tablets

Quantity Produced: 500 cases of 12 bottles of 100 tablets

QUANTITY SHIPPED	CUSTOMERS	DATE SHIPPED	INITIALS
30 CASES	THULASI PHARMACY, Erode	01/12/2019	ML
40 CASES	Walgreens. Brentwood, TN	14/02/2020	JS
150 CASES	CVS PHARMACY, TN	05/04/2020	CK

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