Good Documentation Practices (GDocP)

Sreejesh PC
Assistant Professor
Department of Biotechnology
St Aloysius College, Mangaluru.

FDA Compliance
GDP & 21 CFR Part 11
Learning Objectives

1. To review the categories & general requirements for documents
2. To review specific requirements for each document
3. Do's and don'ts of data entry & recoding
• “If it isn’t documented, it didn’t happen”

• Documentation control is not optional; it is a legal requirement.

• Records and reports, along with procedures, “tell the story” of manufactured products and devices.

• “Good” documentation practices ensure the integrity and reliability of data.
Boston -- The former supervisory pharmacist of New England Compounding Center (NECC) was sentenced today in connection with the 2012 nationwide fungal meningitis outbreak that killed 64 and caused infections in 793 patients.

Glenn Chin, 49, of Canton, Mass., was sentenced by U.S. District Court Judge Richard G. Stearns to eight years in prison, two years of supervised release, and forfeiture and restitution in an amount to be determined later. In October 2017, Chin was convicted by a federal jury in Boston of 77 counts, including racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.
Definition

Documents:

- Approved instruction either in paper or electronic form which guides about how an activity shall be executed.

Records:

- It provide evidence that activities have been performed or results have been achieved.

- **Record** is often considered as document. They always document the past.
Aim and purpose of GDP

- GDP aim to ensure *globally-accepted standards* are met in record-keeping and reporting.
- GDP standards relate to:

  - Data accuracy
  - Data integrity / Validation
  - Reporting/record-keeping timeliness
  - Legibility
  - Traceable
What is being made?

Most of us when attempting a task need some sort of documentation.
And if the drawing is wrong!
• **Good data and record management practices (GDRP)** during inspections of GMP, GCP, GLP has been increasing.

• Paper records to **electronic** for pharmaceutical companies.
  – Electronic signatures and electronic records (ESER)
Paper to Electronic Notebook, Collection Form
Each document shall:
- Have a clear title.
- Identification number.
- Be approved by authorized person.
- Have the date of issue
- Have a due date of revision.
- List to whom it has been issued.
Types of Documentation

- Good documentation encompasses practically all the aspect of pharmaceutical production:
  1. **Building, Premises & Equipment**: installation, validation, cleaning and maintenance
  2. **Personnel**: Training, hygiene etc
  3. **Materials**: specification, testing, ware-housing, rejection/disposal.
  4. **Processing**: individual steps in the process of manufacturing
  5. **Finished goods**: specifications, testing, storage, distribution, and rejection/disposal.
  6. **Complaints & Recalls**: investigation, actions
Types of Documentation..

7. Quality manual:
8. Policies
9. Standard operating procedures (SOPs):
10. Batch Manufacturing records (BMR)
11. Specifications and testing procedures (QC Department)
12. Master formulae and instructions
13. Logbooks: operation, maintenance, and calibration
14. Records
15. Stock control and distribution records

"labels" as one set of documents.
PHARMACEUTICALS
STANDARD OPERATING PROCEDURE "Confidential and Proprietary"

SECTION
GENERAL OPERATING PROCEDURE

SUBJECT
PRODUCT COMPLAINTS.

1. PURPOSE
MAINTENANCE OF THE PRODUCTS COMPLAINTS REGISTER.

2. SCOPE
THIS PROCEDURE APPLIES TO ALL PRODUCT COMPLAINTS NO MATTER HOW TRIVIAL SOME MAY APPEAR.

2A ABBREVIATIONS
EG. FOR EXAMPLE
QM QUALITY MANAGER
SOP STANDARD OPERATING PROCEDURE

3. RESPONSIBILITY
THE QUALITY DEPARTMENT MANAGER (QM) IS RESPONSIBLE FOR THE INVESTIGATION OF ALL PRODUCT COMPLAINTS AND IS RESPONSIBLE FOR ENSURING THAT MARKETING, MEDICAL AND FRONT LINE PERSONNEL SUCH AS TELEPHONISTS AND RECEPTIONISTS ARE FAMILIAR WITH THE COMPLAINTS HANDLING PROCEDURE.

PRODUCT COMPLAINTS MAY NOT BE RECEIVED AT FIRST CONTACT BY A TECHNICAL PERSON. IT IS THEREFORE IMPORTANT THAT ALL FRONT LINE PERSONNEL ARE FAMILIAR WITH THESE PROCEDURES AND FOLLOW THEM EXACTLY. THE QM SHALL TRAIN ALL SALES PEOPLE, RECEPTIONISTS AND TELEPHONISTS IN THESE PROCEDURES.

4. PROCESS DESCRIPTION
4.1 PRODUCT COMPLAINT CODES EXAMPLES
CRITICAL COMPLAINT

PRESUMPTIVE ADVERSE REACTION

<table>
<thead>
<tr>
<th>Author</th>
<th>Checked by</th>
<th>Authorised by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Date</td>
<td>Date</td>
</tr>
</tbody>
</table>

Review date on or before 12 months from date of authorisation.
SAFETY PRECAUTIONS:

a. Wear proper protective clothing at all times.
b. Wear gloves, disposable hat and face mask when weighing out and handling powders.
c. At all times keep hands and clothing clear of rotating machinery.
d. If the operator has long hair then ensure it is tied up adequately.
e. Avoid materials coming into contact with the skin. Wash thoroughly.

Safety Instructions read and understood

Operators: ______________________ Date: ______________________

EQUIPMENT REQUIRED

b. Stainless steel scoop.
c. 20 mesh stainless steel hand screen.
d. 20 litre stainless steel bucket.
e. Stainless steel Bonser Anderson rotating mixer fitted with dust extraction.
f. 40 tray Weesburg Martin granule drying oven fitted with time clock and thermostat.
g. Manesty Rotor Gran oscillating granulator fitted with 20 mesh stainless steel screen.
h. Stainless steel 200 litre drum complete with lid arid clamp.
i. Drum Tumbler.
j. Manesty Express Tableting Machine complete with DCF/Vokes dust extractor.
k. 6 x 20 litre plastic pails lined with clean plastic bags and ties

All equipment clean and in working order.

Operator: ______________________ Date: ______________________
Supervisor: ______________________ Date: ______________________

1 Granulating Solution

Date Commenced: ______________________

Weigh into a 20 litre stainless steel bucket the following:

<table>
<thead>
<tr>
<th>RAW MATERIAL</th>
<th>QUANTITY</th>
<th>ADDED BY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7 500 kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 000 kg</td>
<td></td>
</tr>
</tbody>
</table>

Stir until Povidone is completely dissolved and there are no lumps remaining.

Operator: ______________________ Date: ______________________
Finished Product Label

National legislation, but includes:

• Name
• Active ingredients and amounts
• Batch number
• Expiry date
• Storage conditions, precautions if necessary
• Directions for use
• Name and address of manufacturer
Record-Keeping Categories

- **Primary Records** (production formulas, supply source, contracts, packaging)
- **Procedures or supporting procedures** (instructions and guidebooks, SOPs)
- **Subsidiary records** (help to meet GMP e.g. calibration reports, print outs,...)
- **Quality Control records** (testing results, testing methods, recall procedures, investigations, self-inspection reports, CAPA, )
The organization should establish a hierarchical document system.
The protection of data from unauthorized & unaccountable changes.
Security / Data Integrity

How do maintain the record

• Bound notebook pre-numbered
• loose sheets (Pre-numbered, the printing have to be controlled and also the storage as control records)
• Every register Forms shall have
  ▪ Format / control number / header
  ▪ Date of opening
  ▪ Date of closing
  ▪ Table of content where applicable
Record writing / Data Entry

- Data must not be able to be altered or erased once entered or recorded.
- Data may be recorded by:
  - Electronic data processing systems or
  - By photographic or
  - Other reliable means.
- Only authorized persons shall be able to enter or modify data in the computer.
• Enter complete and accurate information at the time work is performed.
• Enter signature or initials (according to procedure)
• When one or more person complete the task, all person must sign.
• Never sign your name for performance of a job for work actually performed by someone else.
• Limit the use of abbreviations and acronyms.
Record writing / Data Entry

- **Use** **blue** or **black** Ball point pens
- **Don’t use** gel pens, ink pens or pencils
- **Don’t use** red/ green colour ink.
• Spaces and cells *cannot* be left blank!
• Never use ditto
• Corrections to *written records* must be made properly
  – NEVER USE “correction” liquid, tape or material.
  – DO NOT USE “write-overs” (Don’t turn a “6” or “9” into 8)
How are mistakes corrected?

• Draw a single line through the error
• Make the correction next to the error
• Write an explanation for the error
• Sign and date the correction
Over writing

Wrong
574672

Correct
574672

 Corrections should be counter signed

100mg 100.23 mg

Signature with date

[Signature]
30/05/2004
Some Interesting Digit Overwrites

Don’t Do that…. You are employee not a Labor
How to use Error Code?

✓ For correcting any error in raw data, draw a single line (horizontal line) through the wrong entry without obscuring the original entry.

Eg.

<table>
<thead>
<tr>
<th>Recording Time</th>
<th>Recording Date</th>
<th>Recorded By</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:03</td>
<td>15:13</td>
<td>*</td>
</tr>
<tr>
<td>15:05</td>
<td>15:25</td>
<td>#</td>
</tr>
<tr>
<td>15(^\text{th}) Aug 18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15(^\text{th}) Aug 18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>XYZ</td>
<td>15(^\text{th}) Aug 18</td>
<td></td>
</tr>
<tr>
<td>ABC</td>
<td>15(^\text{th}) Aug 18</td>
<td></td>
</tr>
<tr>
<td>*R ABC</td>
<td>15(^\text{th}) Aug 18</td>
<td></td>
</tr>
<tr>
<td>*R XYZ</td>
<td>15(^\text{th}) Aug 18</td>
<td></td>
</tr>
<tr>
<td>Test N°</td>
<td>Temp.</td>
<td>pH</td>
</tr>
<tr>
<td>---------</td>
<td>--------</td>
<td>---------</td>
</tr>
<tr>
<td>1</td>
<td>20.5°C</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>7.5</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>6.4/2</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test N°</th>
<th>Temp.</th>
<th>pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NVT</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>NVT</td>
<td>NA</td>
</tr>
<tr>
<td>3</td>
<td>NVT</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NVT</td>
<td></td>
</tr>
</tbody>
</table>
What’s that number?

27 ?
29 ?
24 ?
2 %

Hmmmm, What do we do now?
• **Maintenance of Documents:**
• Documents, as required under local rules, shall be
  • meticulously maintained
  • regularly reviewed
  • kept up-to-date (i.e. Document Control System).

*Good documentation is the cornerstone of GMP compliance*
Further Readings:


• Part 11, Electronic Records; Electronic Signatures - Scope and Application

Q : 1

<table>
<thead>
<tr>
<th>Antibiotiques (ROSCO)</th>
<th>Diamètre (en mm)</th>
<th>Résultats (S, I ou R)</th>
<th>Antibiotiques (ROSCO)</th>
<th>Diamètre (en mm)</th>
<th>Résultats (S, I ou R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ampicilline</td>
<td>12 mm</td>
<td>R</td>
<td>Doxycycline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicilline</td>
<td></td>
<td></td>
<td>Acide nalidixique</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Augmentin</td>
<td></td>
<td></td>
<td>Lévofoxacine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cefotaxime</td>
<td>15 mm</td>
<td>R</td>
<td>Ciprofloxacine</td>
<td>2.0 mm</td>
<td>S I</td>
</tr>
<tr>
<td>Erythromycine</td>
<td></td>
<td></td>
<td>Norfloxacine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentamicine</td>
<td>26 mm</td>
<td>S</td>
<td>Alinecé</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amikacine</td>
<td></td>
<td></td>
<td>Alinecé</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>12 mm</td>
<td>R</td>
<td>Alinecé</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chloramphénicol</td>
<td>21 mm</td>
<td>R</td>
<td>Alinecé</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MISE EN COLLECTION (3 tubes)  

Date d'envoi de la collection (souches et papier filtrés): 27/19
<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>19:44</td>
<td>010771</td>
<td>UMK</td>
<td>Yes</td>
</tr>
<tr>
<td>14</td>
<td>19:44</td>
<td>008342</td>
<td>SAS</td>
<td>Yes</td>
</tr>
</tbody>
</table>

[Handwritten note: 18th Jul 18]
### Time Point (Hr) | Scheduled | Actual time | TDV (+/- in min) | Comments
---|---|---|---|---
0.00 | 19 Jul 18 | 08:28 | NA | NA
0.50 | 19 Jul 18 | 09:52 | NA | NA
1.00 | 19 Jul 18 | 10:22 | NA | NA
1.50 | 19 Jul 18 | 10:52 | NA | NA
2.00 | 19 Jul 18 | 11:22 | NA | NA
2.50 | 19 Jul 18 | 11:52 | NA | NA
3.00 | 19 Jul 18 | 12:22 | NA | NA
3.50 | 19 Jul 18 | 12:52 | NA | NA
4.00 | 19 Jul 18 | 13:22 | NA | NA
4.50 | 19 Jul 18 | 13:52 | NA | NA
5.00 | 19 Jul 18 | 14:22 | NA | NA
5.60 | 19 Jul 18 | 14:52 | NA | NA
6.00 | 19 Jul 18 | 15:22 | NA | NA
7.00 | 19 Jul 18 | 16:22 | NA | NA
8.00 | 19 Jul 18 | 17:22 | NA | NA
10.00 | 19 Jul 18 | 19:22 | NA | NA
12.00 | 19 Jul 18 | 21:22 | NA | NA
16.00 | 20 Jul 18 | 01:22 | NA | NA
24.00 | 20 Jul 18 | 09:22 | NA | NA
I swear, honey, I only cooked it for three hours.

I'm going to need to see all ESI from the oven, including metadata.
Thank you for your attention

pc.sreejesh@gmail.com
Whatsapp:9946546888
Quality Assurance & Quality Control