Good Documentation Practices (GDocP)

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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

Good documentation practices (GDocP)

- **“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.**

Food and Drug Administration
Office of Criminal Investigations

U.S. Department of Justice Press Release

For Immediate Release
January 31, 2019

United States Department of Justice
District of Massachusetts

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

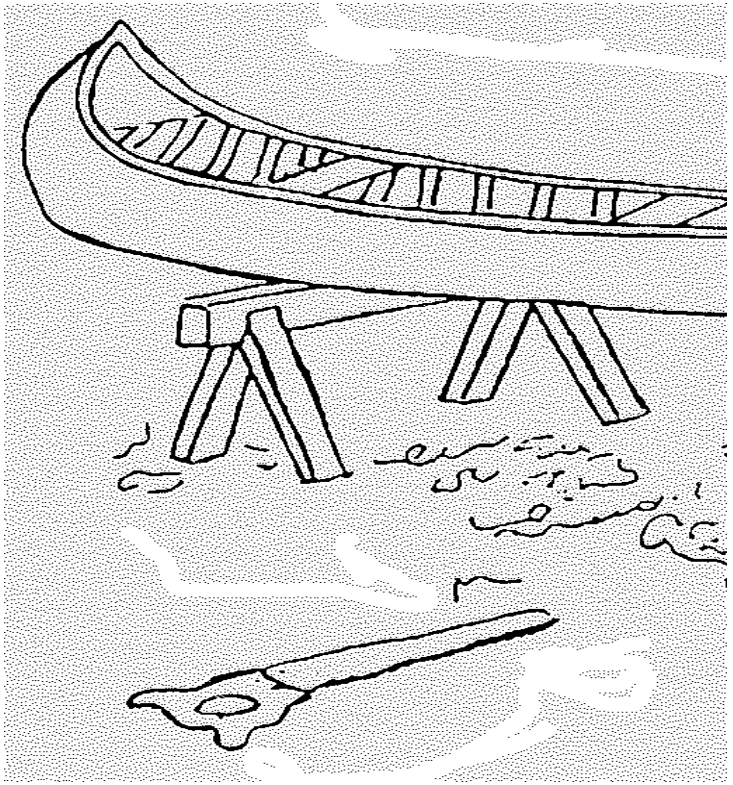
Legibility

Traceable

Documentation

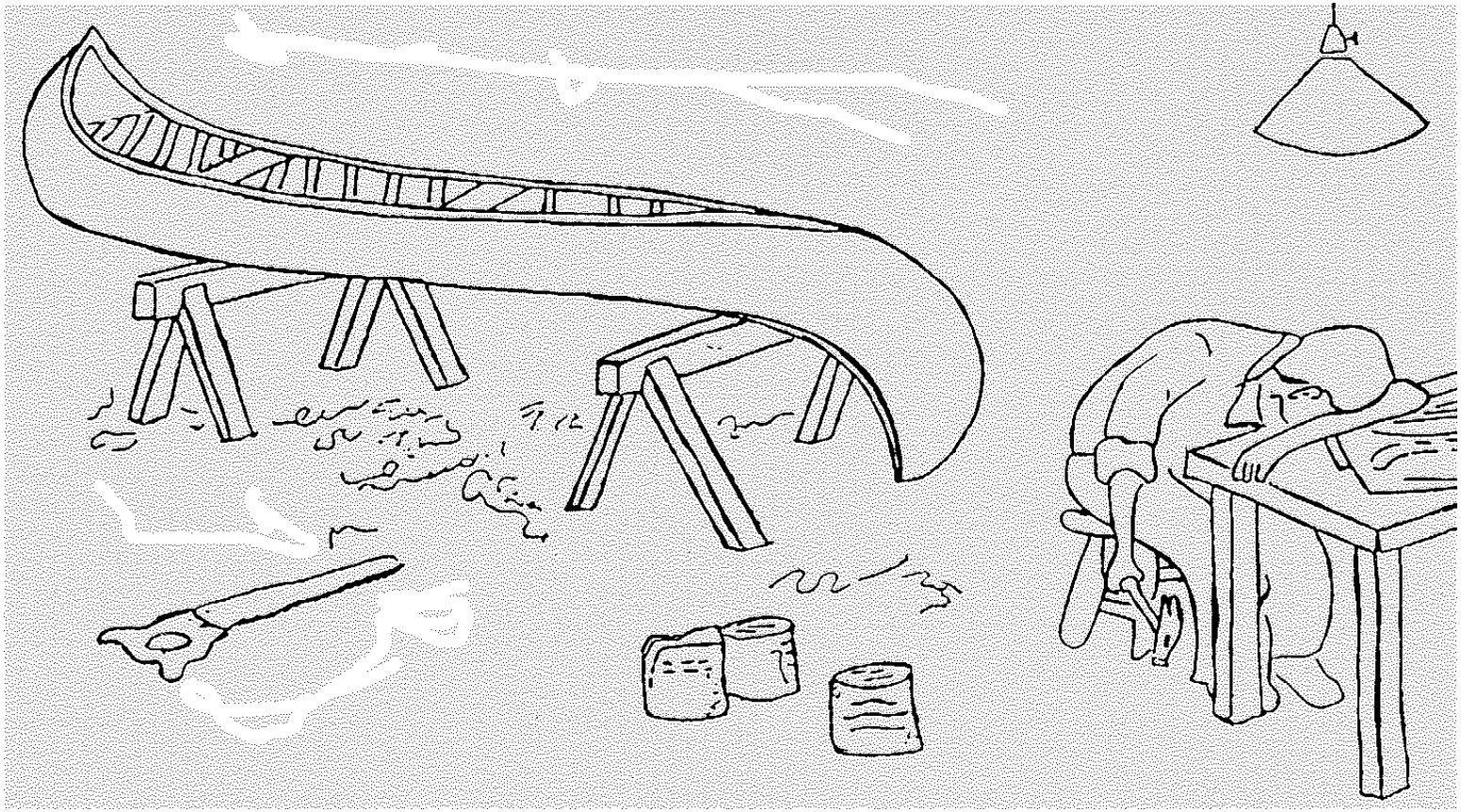
What is being made?

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



Documentation

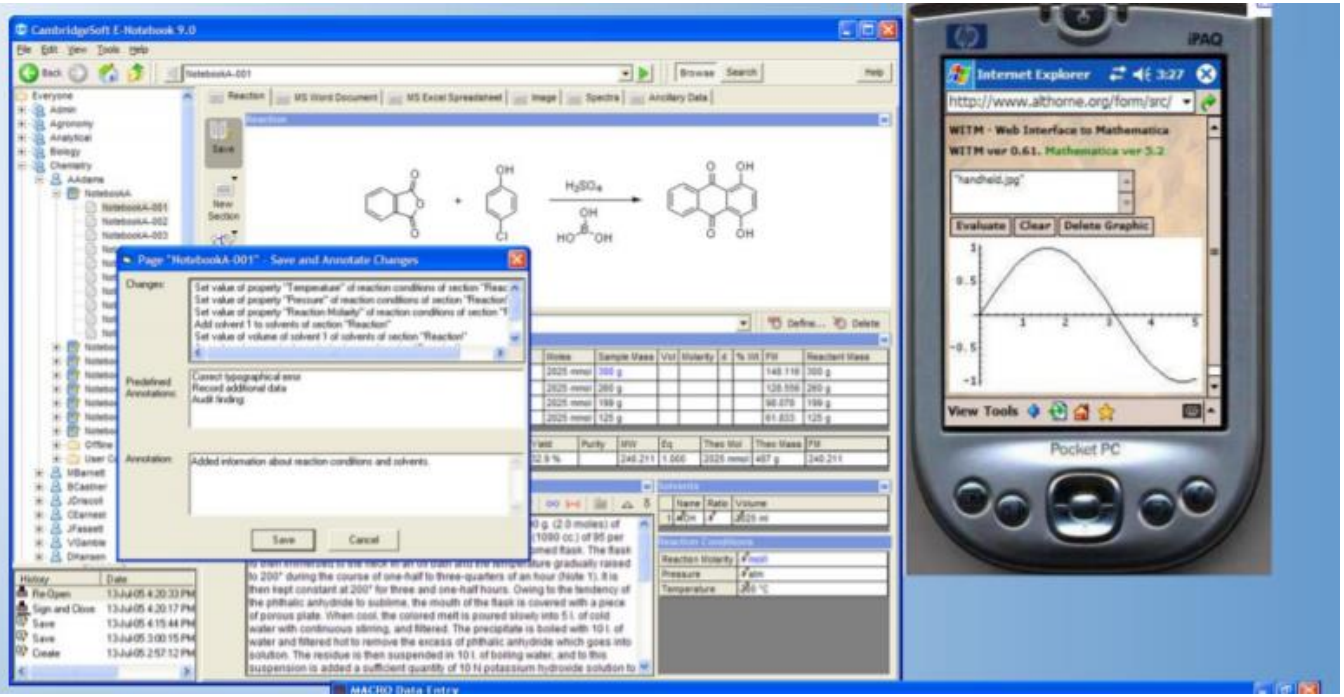
And if the drawing is wrong!



- **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)

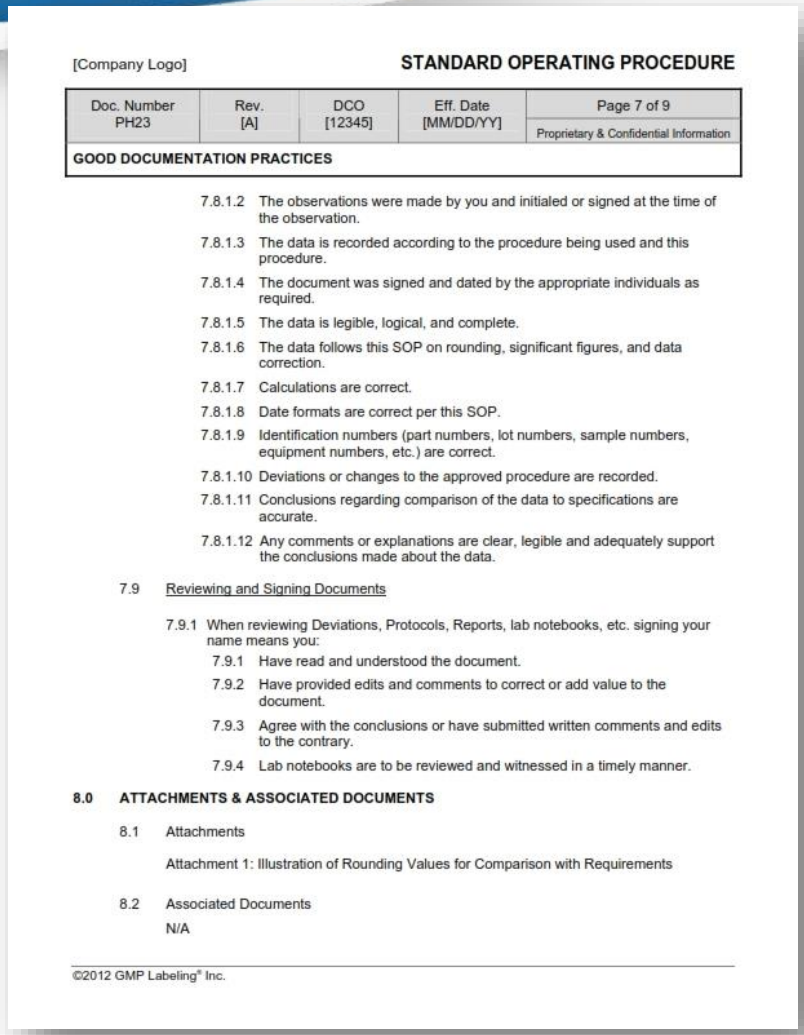


Paper to Electronic Notebook, Collection Form



Characteristic of Document

- 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.



[Company Logo] **STANDARD OPERATING PROCEDURE**

Doc. Number PH23	Rev. [A]	DCO [12345]	Eff. Date [MM/DD/YY]	Page 7 of 9
				Proprietary & Confidential Information

GOOD DOCUMENTATION PRACTICES

7.8.1.2 The observations were made by you and initialed or signed at the time of the observation.

7.8.1.3 The data is recorded according to the procedure being used and this procedure.

7.8.1.4 The document was signed and dated by the appropriate individuals as required.

7.8.1.5 The data is legible, logical, and complete.

7.8.1.6 The data follows this SOP on rounding, significant figures, and data correction.

7.8.1.7 Calculations are correct.

7.8.1.8 Date formats are correct per this SOP.

7.8.1.9 Identification numbers (part numbers, lot numbers, sample numbers, equipment numbers, etc.) are correct.

7.8.1.10 Deviations or changes to the approved procedure are recorded.

7.8.1.11 Conclusions regarding comparison of the data to specifications are accurate.

7.8.1.12 Any comments or explanations are clear, legible and adequately support the conclusions made about the data.

7.9 Reviewing and Signing Documents

7.9.1 When reviewing Deviations, Protocols, Reports, lab notebooks, etc. signing your name means you:

7.9.1 Have read and understood the document.

7.9.2 Have provided edits and comments to correct or add value to the document.

7.9.3 Agree with the conclusions or have submitted written comments and edits to the contrary.

7.9.4 Lab notebooks are to be reviewed and witnessed in a timely manner.

8.0 ATTACHMENTS & ASSOCIATED DOCUMENTS

8.1 Attachments

Attachment 1: Illustration of Rounding Values for Comparison with Requirements

8.2 Associated Documents

N/A

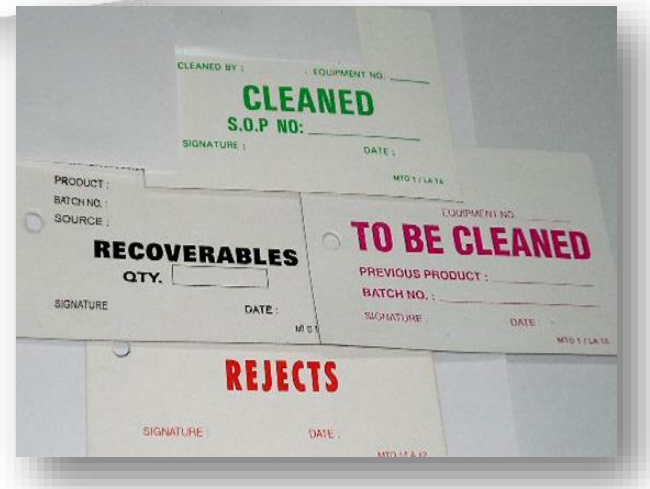
Types of Documentation

- Good documentation encompasses practically all the aspect of pharmaceutical production :

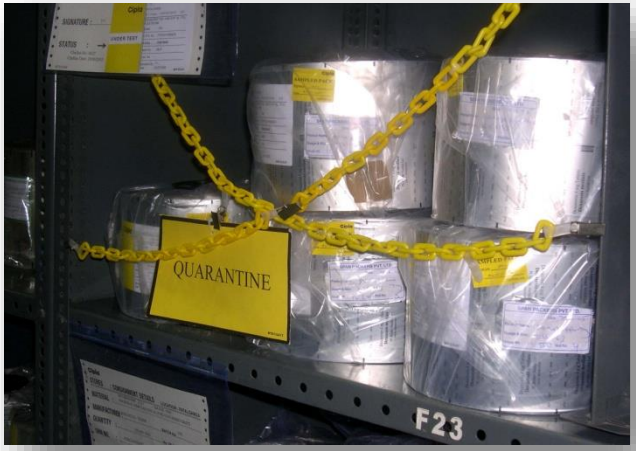
1. **Building, Premises & Equipment :** installation , validation , cleaning and maintenance
2. **Personnel :** Training, hygiene etc
3. **Materials**: specification, testing, ware-housing, rejection/disposal.
4. **Processing:** individual steps in the process of manufacturing
5. **Finished goods:** 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"

Procedure No:		Page No	1 of 7	Date Issued	
Revision No:		Supercedes:		Date effective:	

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	CATEGORIES
PRESUMPTIVE ADVERSE REACTION	1

Author:		Checked by:		Authorised by:	
Date:		Date:		Date	

Review date on or before 12 months from date of authorisation

[redacted] PTY. LTD.

TABLETS

BATCH NUMBER:

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

a. Mettler PE24 electronic balance.
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 thermostatt.
g. Manesty Rotorgran oscillating granulator fitted with 20 mesh stainless steel screen.
h. Stainless steel 200 litre drum complete with lid and clamp.
i. Drum Tumbler.
j. Manesty Express Tabletting Machine complete with DCF/Vokes dust extracter.
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:

RAW MATERIAL	QUANTITY Decimal			ADDED BY
	7	500	kg	
	1	000	kg	

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

Operator: **Date:**

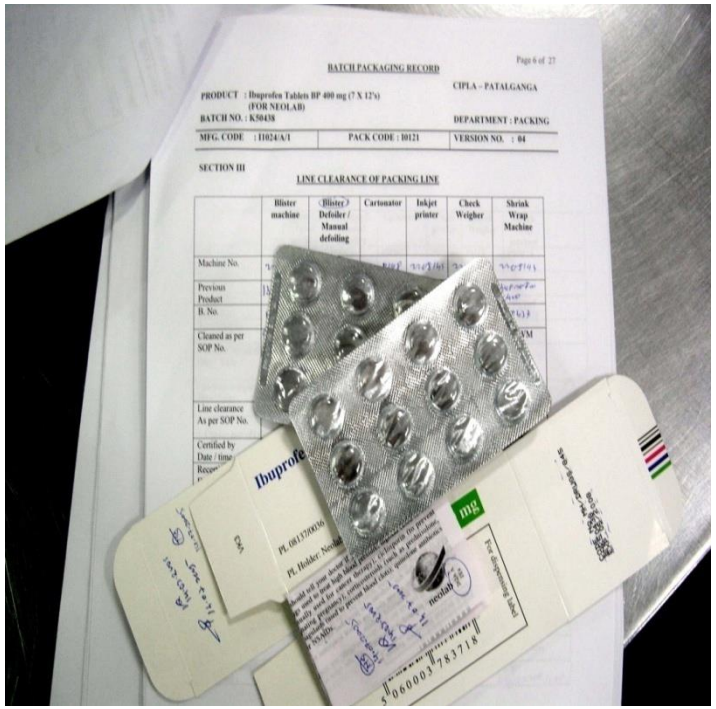
Documentation

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

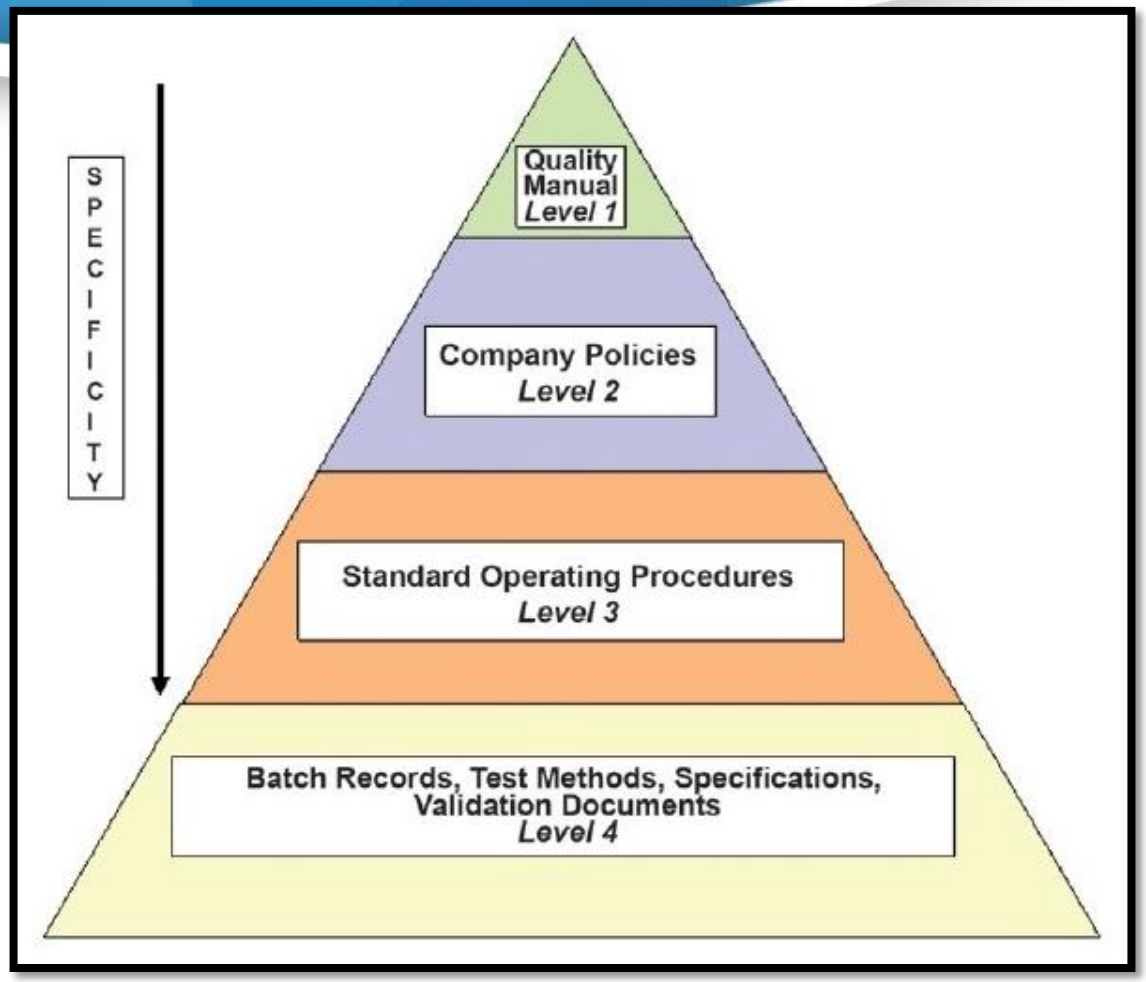
Record-Keeping Categories



- **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,)

Hierarchical document system

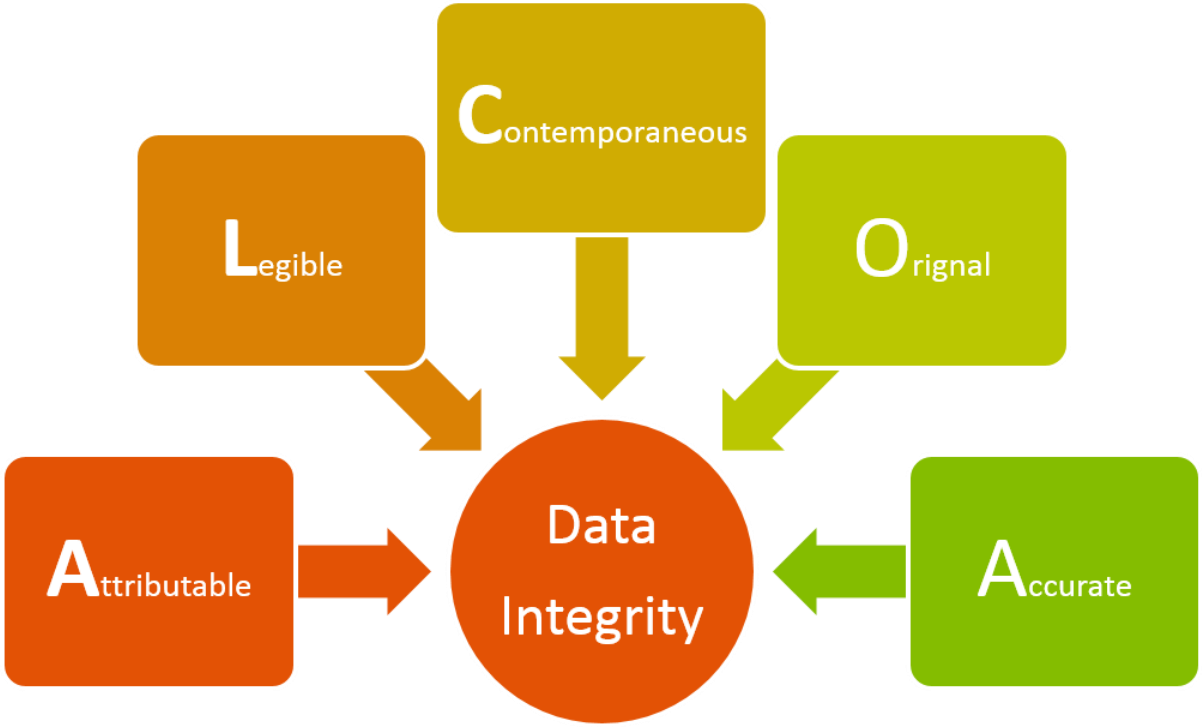
The organization should establish a hierarchical document system



Security / Data Integrity

The protection of data from unauthorized & unaccountable changes.

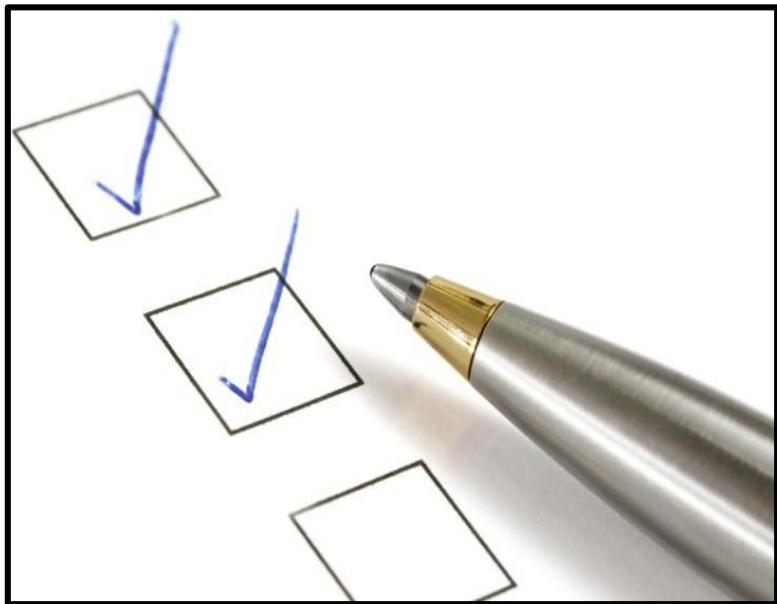
ALCOA: FDA's Data Integrity Focus



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

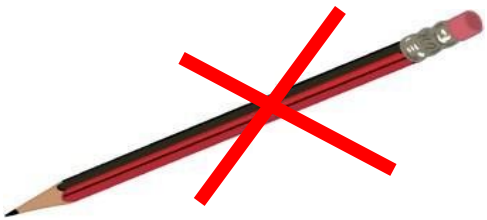
- Data must not be able to be altered or erased once entered or recorded
- Data may be recorded by
  - Electronic data processing systems or
  - By photographic or
  - Other reliable means.
- Only authorized persons shall be able to enter or modify data in the computer.

Record writing / Data Entry

- 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.

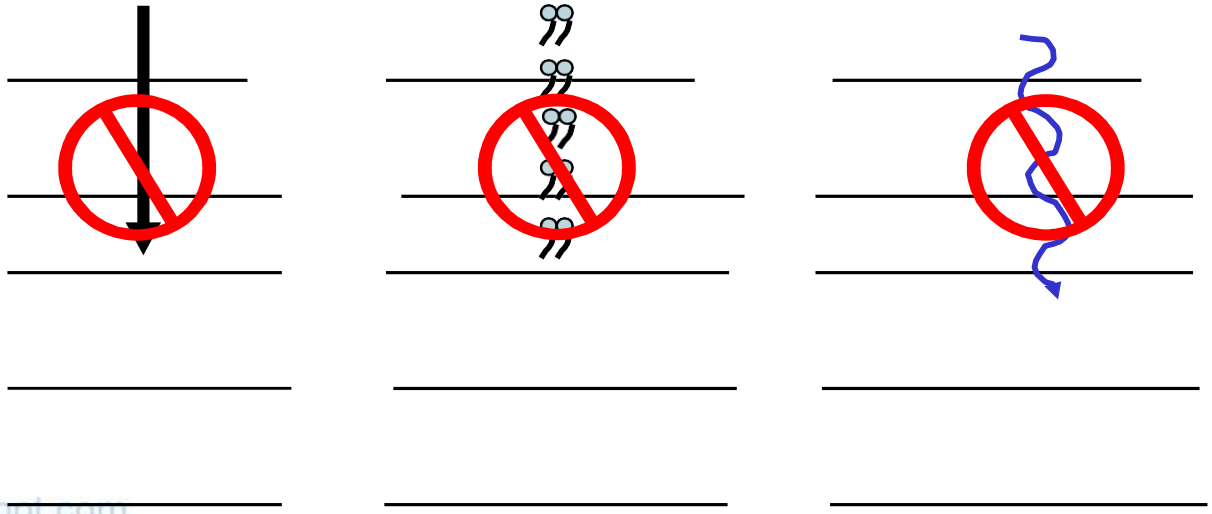
Record writing / Data Entry

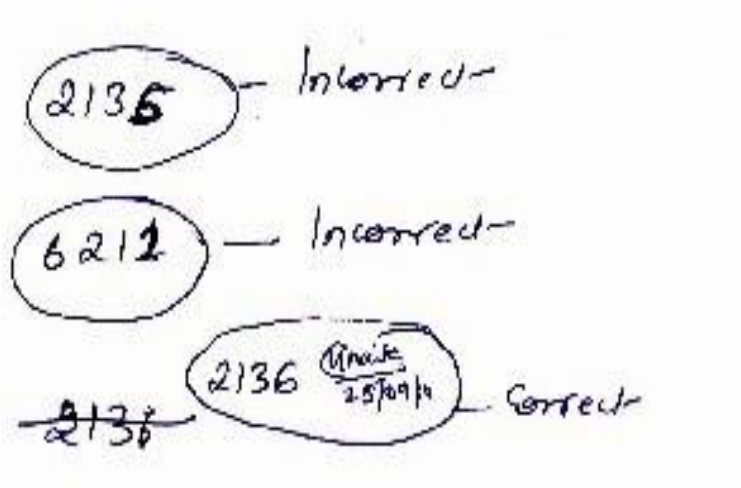
- **Use blue** or **black** Ball point pens
- Don't use gel pens, ink pens or pencils
- Don't use red/ green colour ink.



Record writing / Data Entry

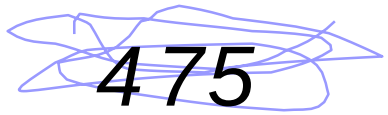
- Spaces and cells *cannot* be left blank!
- Never use ditto
- Corrections to *written records* must be made properly
  - NEVER USE "correction" liquid, tape or material.
  - DO NOT USE "write-overs" (Don't turn a "6" or "9" into 8)





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



~~475~~

SPC

14-05-2020 485

Over writing

Over Writing

Wrong	Correct
574673	574673 28/05

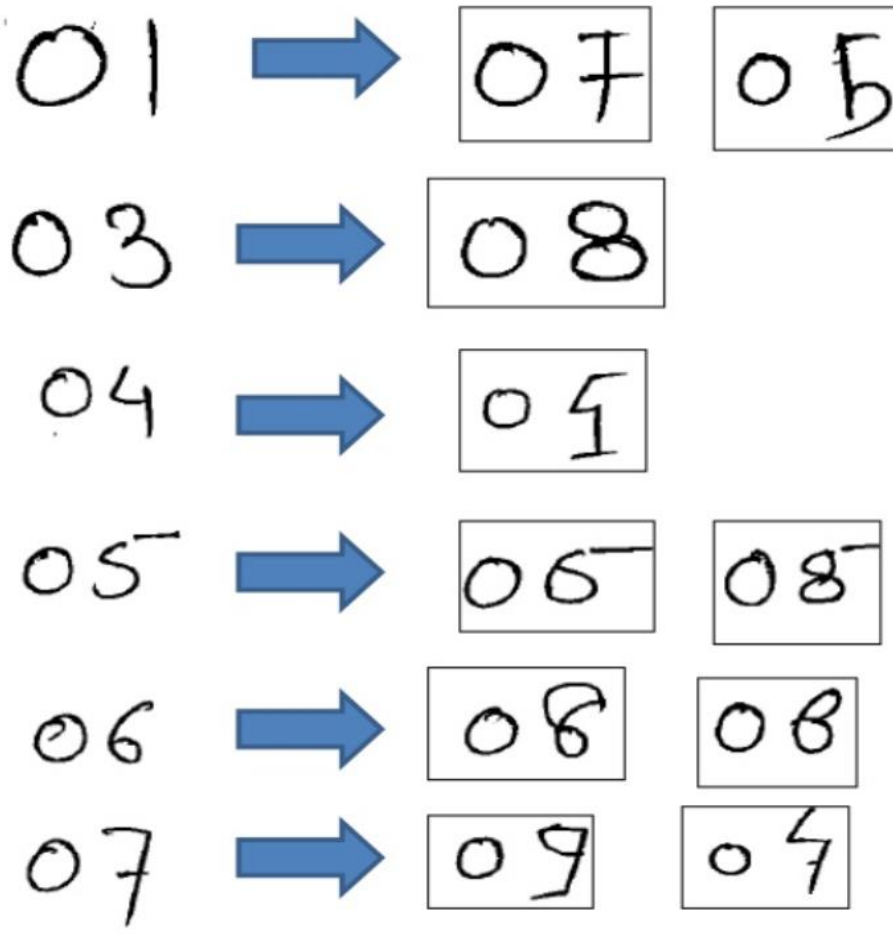
Corrections should be counter signed

~~100mg~~ 28/5/2004 100.23 mg

Signature with date

~~28/05/2004~~ 28/05/2004

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.

Recording Time	Recording Date	Recorded By
~~15:03~~ * 15:13	15th Aug 18	*XYZ* *15th Aug 18*
~~15:05~~ # 15:25	15th Aug 18	*ABC* *15th Aug 18*

(R) *ABC* *15th Aug 18*

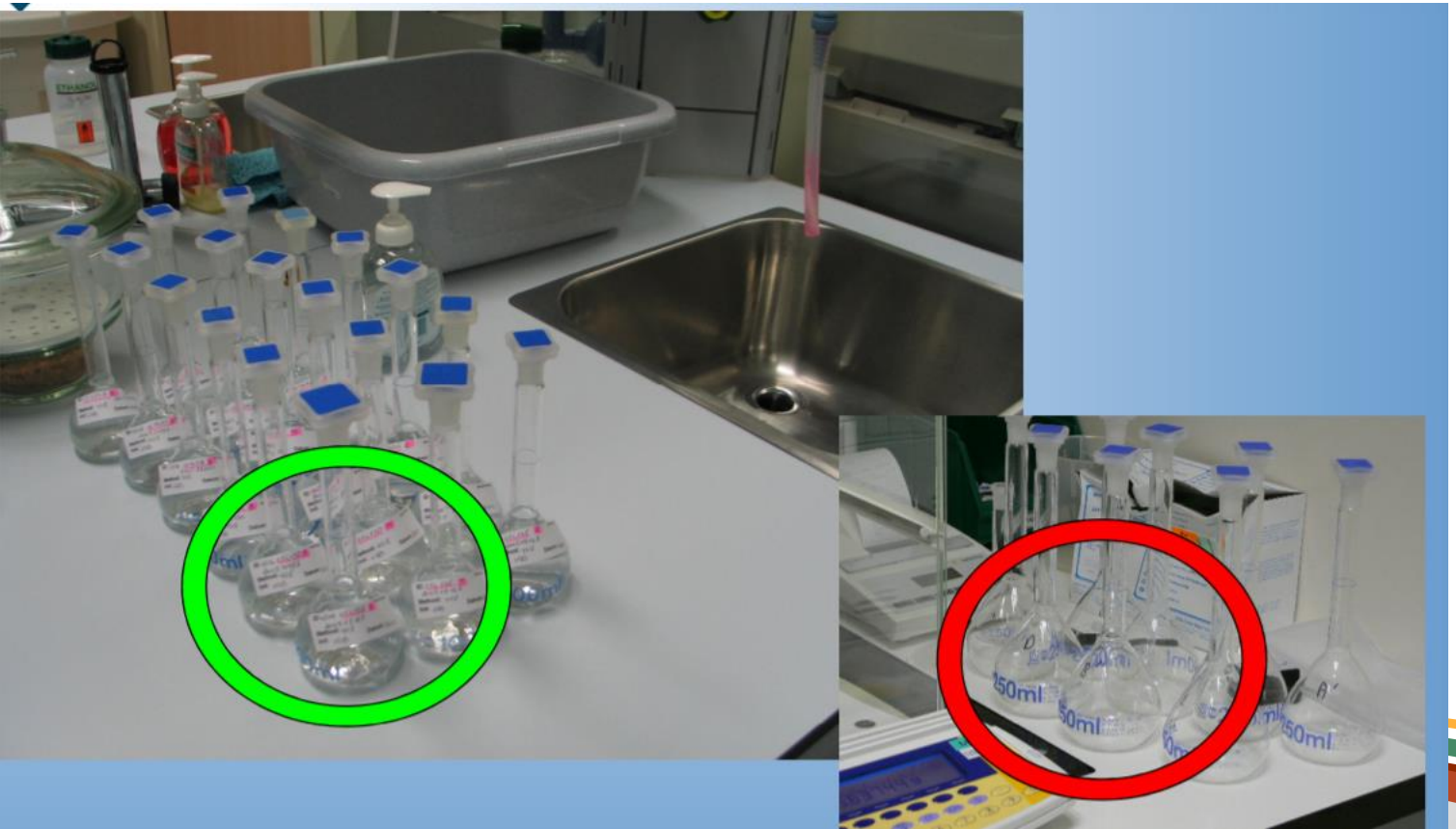
* (R) *XYZ* *15th Aug 18*

Test N°	Temp.	pH
1	20.5°C	
2	"	7.5
3	"	
4	"	

16/07/2008

Test N°	Temp.	pH
1	NVT	
2	NVT	NA
3	NVT	
4	NVT	

16/07/2008



What's that number?

27 ?

29 ?

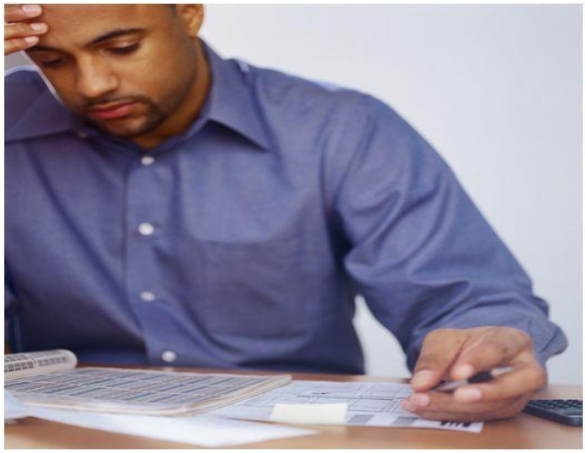
24 ?

2 %

Hmmmm, What do we do now?

DOCUMENTATION

- **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 corner stone of GMP compliance

Further Readings:

- Good Documentation Practice (GDP) Guideline. Indian Pharmaceutical Alliance, Spenta Multimedia Pvt Ltd,.2018.
- Part 11, Electronic Records; Electronic Signatures - Scope and Application
- ISO/IEC 17799:2000 (BS 7799:2000) Information technology - Code of practice for information security management (ISO/IEC, 2000)

Q : 1

LABORATOIRE

Numéro de laboratoire : 56

Date d'entrée dans l'incubateur : 4/8/18

Bouteille pédiatrique ☐ Bouteille adulte ☒ Poids : 716 g

VIRAGE ☐ NON si non, date de sortie de l'incubateur : .....
si non, résultat contrôle de stérilité : .....
☒ OUI si oui date de virage : 6/8/07

Examen à frais : Coloration de Gram :

Culture (résultats intermédiaires) :

GS +
7/8 Mc + (L+) → galerie Kl gl+ L+ H2S+ gaz+ Cp : Indol ⊖ Cit ⊕ ONPG ⊕ nit ⊖ URE ⊖

Culture (résultat final - espèce) : Citrobacter freundii

Observations :

Date : 13/8/07 PARAPHE investigatrice principale

MISE EN PAPIER FILTRE (2 tubes) ☒ OUI ☐ NON si OUI date de réalisation : 6/8/07

Antibiotiques (ROSCO)	Diamètre (en mm)	Résultats (S, I ou R)	Antibiotiques (ROSCO)	Diamètre (en mm)	Résultats (S, I ou R)
Ampicilline	12 mm	R	Doxycyline		
Amoxicilline			Acide nalidixique		
Augmentin			Lévofloxacine		
Céfotaxime	15 mm	R	Ciprofloxacine	20 mm	S I
Erythromycine			Norfloxacine		
Gentamicine	26 mm	S	AUTRE :		
Amikacine			AUTRE :		
Cotrimoxazole	12 mm	R	AUTRE :		
Chloramphénicol	12 mm	S R	AUTRE :		

MISE EN COLLECTION (3 tubes) ☒ OUI ☐ NON si OUI date de réalisation : 7/8

Date d'envoi de la collection (souches et papier filtres) : 17/9

Q:2 ?

13	19:44	010771	UMK	Yes
14	19:49	008342 ~~004342~~	SAS	Yes

18th Jul 18

Q: 3?

Time Point (Hr)	Scheduled		Actual time	TDV (+/-in min)	Comments
	Date	Time			
0.00	19th Jul18	Pre-Dose	08:26	NA	NA
0.50	19th Jul18	09:52	09:52	NA	NA
1.00	19th Jul18	10:22	10:22	NA	NA
1.50	19th Jul18	10:52	10:52	NA	NA
2.00	19th Jul18	11:22	11:22	NA	NA
2.50	19th Jul18	11:52	11:52	NA	NA
3.00	19th Jul18	12:22	12:22	NA	NA
3.50	19th Jul18	12:52	12:52	NA	NA
4.00	19th Jul18	13:22	13:22	NA	NA
4.50	19th Jul18	13:52	13:52	NA	NA
5.00	19th Jul18	14:22	14:22	NA	NA
5.50	19th Jul18	14:52	14:52	NA	NA
6.00	19th Jul18	15:22	15:22	NA	NA
7.00	19th Jul18	16:22	16:22	NA	NA
8.00	19th Jul18	17:22	17:22	NA	NA
10.00	19th Jul18	19:22	19:22	NA	NA
12.00	19th Jul18	21:22	21:22	NA	NA
16.00	20th Jul18	01:22	01:22	NA	NA
24.00	20th Jul18	09:22	09:22	NA	NA


CASE IN POINT
by Tom Fishburne
I SWEAR, HONEY, I ONLY COOKED IT FOR THREE HOURS
I'M GOING TO NEED TO SEE ALL ESI FROM THE OVEN, INCLUDING METADATA
CaseCentral

Thank you for your attention

pc.sreejesh@gmail.com
Whatsapp:9946546888

Quality Assurance & Quality Control