Documentation

"If it's not documented it's a rumour"

Jaap Koster

Purpose of Documentation

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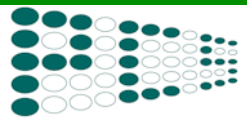
Purpose of documentation(1)

Two types of documents can be identified

- Documents which have to be revised
  - "Living" documents

- Documents which only contain recorded data
  - "Dead" documents
  - Validation documents are part of this, and will be seen quite a lot during inspections

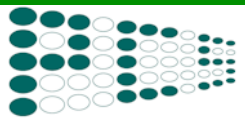


Purpose of documentation(2)

- Documents which have to be revised

  - **Noting down of knowledge**

  - Facilitates training of personnel
  - Facilitates reproducability of handling
  - Reduces the need of oral exchange of information
  - Enhances the quality and reliability of the work
  - Makes it possible to proof that Marketing Authorization dossier has been followed.
  - Rational of activities

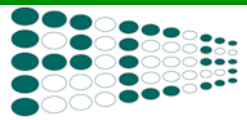


Purpose of documentation(3)

- Recorded data:
  - Describing of history
  - Evidence
  - Important aspect of Validation

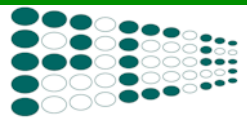
Required GMP documentation

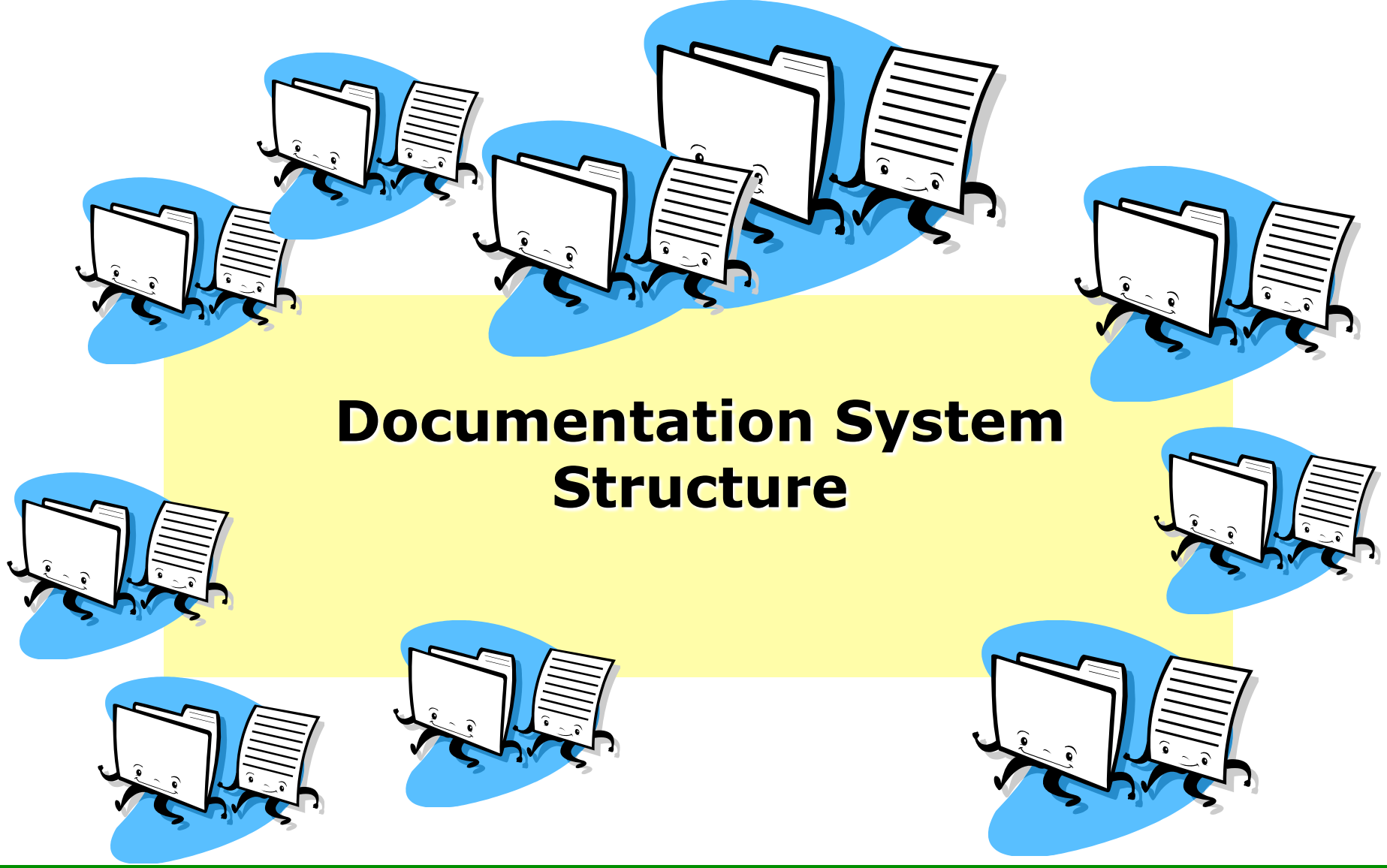
- **Validation**
  - Protocols, Reports and Records for validation purposes
  - Procedures
  - Validation Master Plan
  - Risk Assessment / Management procedures



General principles for documentation

- In compliance with regulatory dossier and the manufacturing licence
  - Validation to be in line with dossier
- Clear and without errors
- Available where needed
- Approved (authorized) by assigned persons
- The reproduction process shouldn’t allow errors





Documentation System Structure

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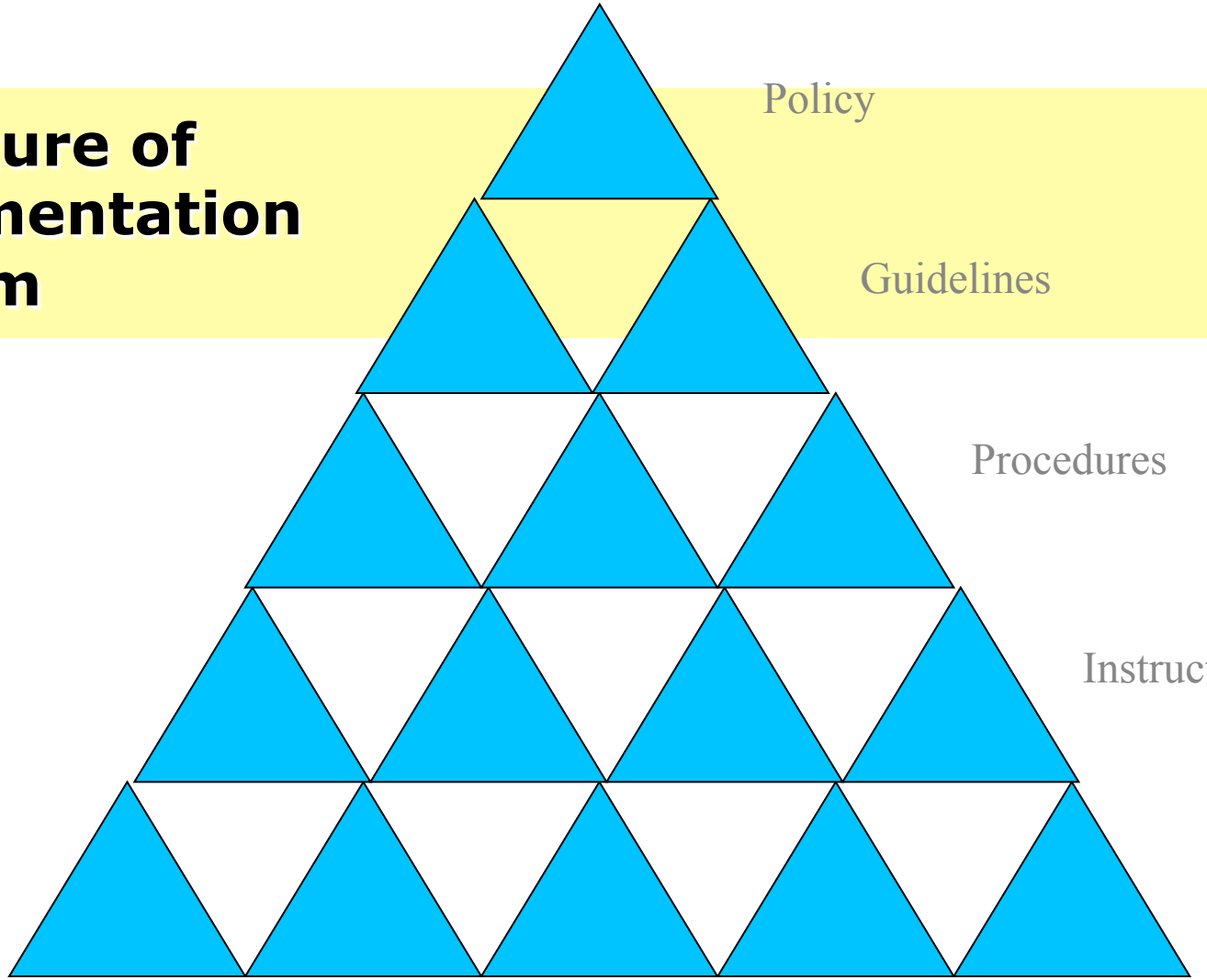
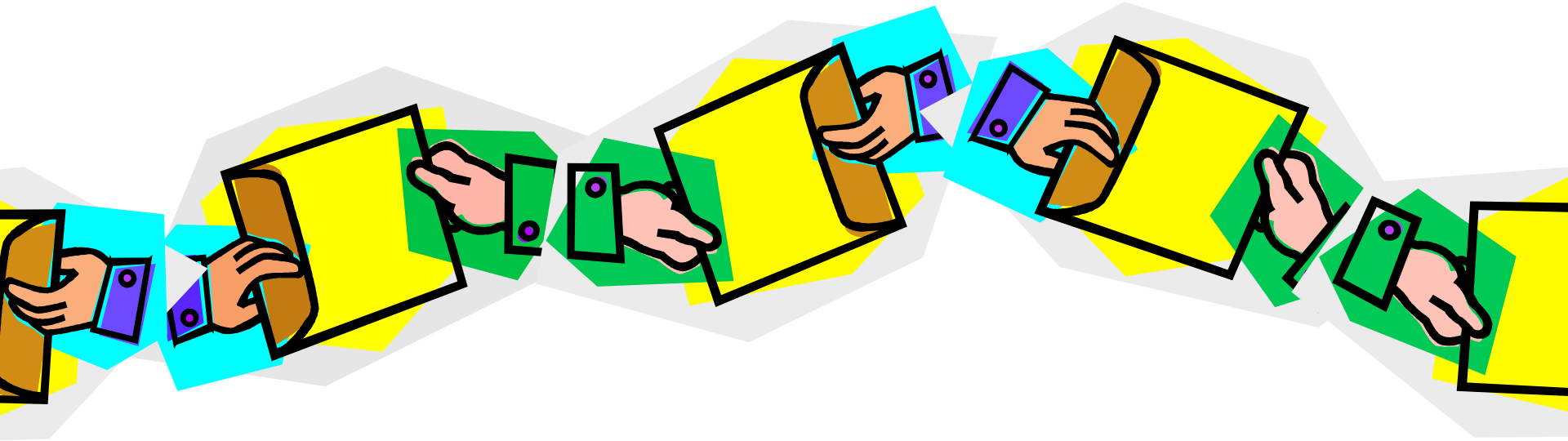
Structure of Documentation System



Documentation Process



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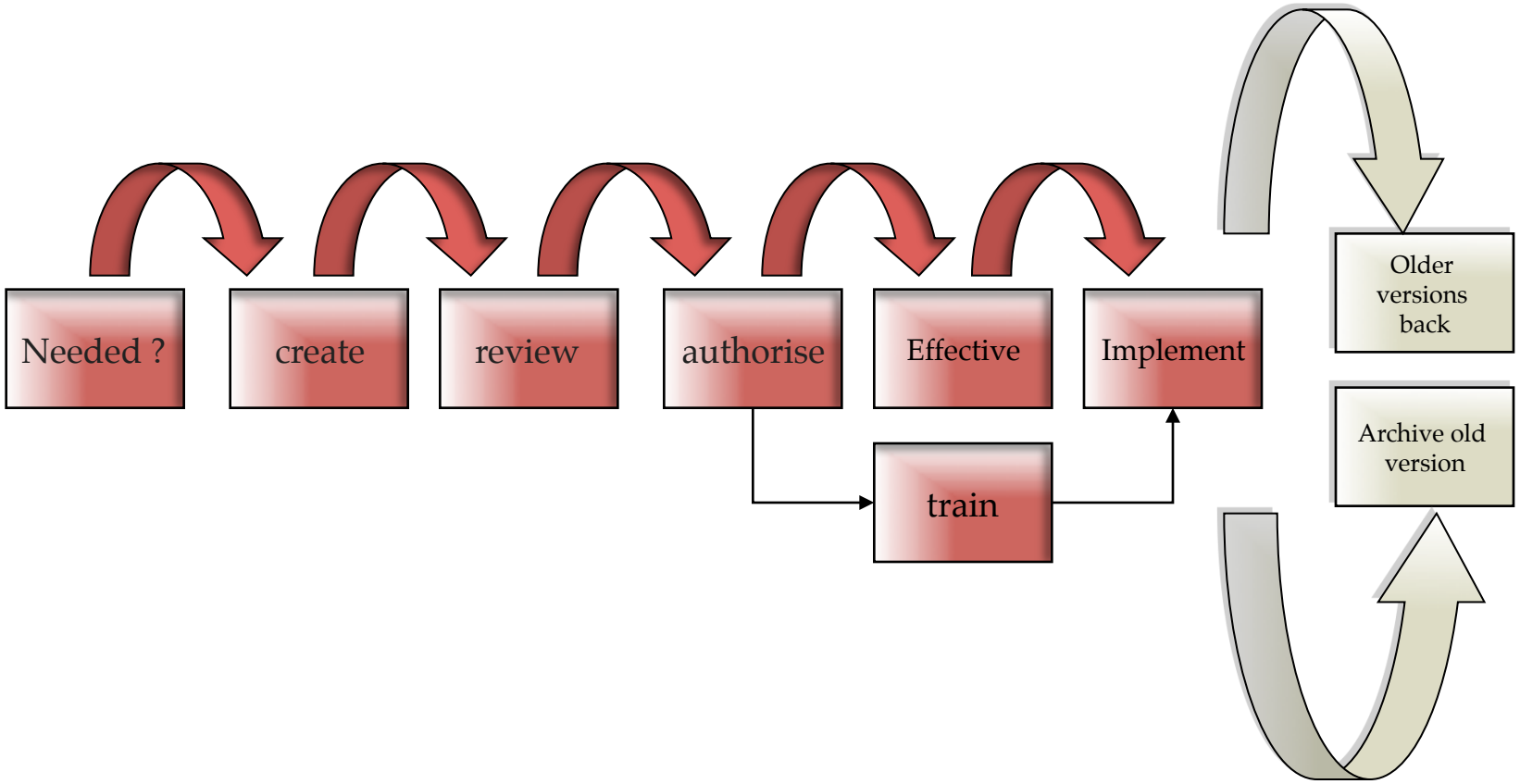
NEW DOCUMENT

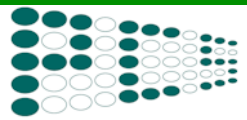
CHANGE



Making Effective

- Authorised documents can only be made effective if users have been trained

- Effective master document will be archived in a place with restricted access.



Distribution

- Only effective documents should be distributed either as hard copy or electronically
  - Distribution of hard copies
    - Exchange of old and new version
  - Electronical distribution
    - Managing of printed documents.

Data

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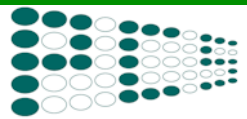
Data (1)

- Data
- Data can be recorded :
  - On Paper (forms, print-outs,hasty notes, etc.)
  - Electronically (files, bits en bytes)



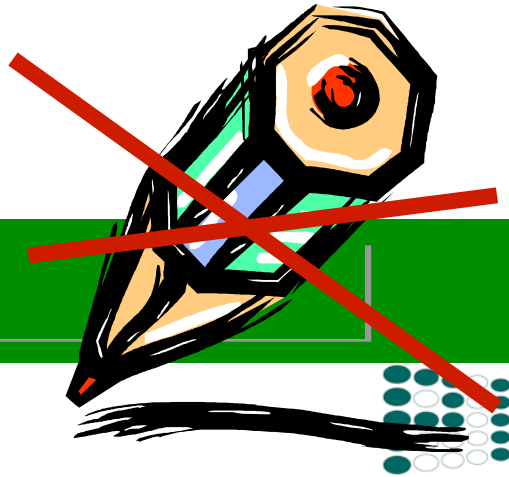
Data (2)

- Kinds of data:
  - **Raw data**, the original data (print-souts, but also h
    notes!)
  - **Meta data** are data about data (name of operator, da
    of work)
  - **Master data** are authorised data which can be used to fill an automated system.

Good Documentation Practices (1)

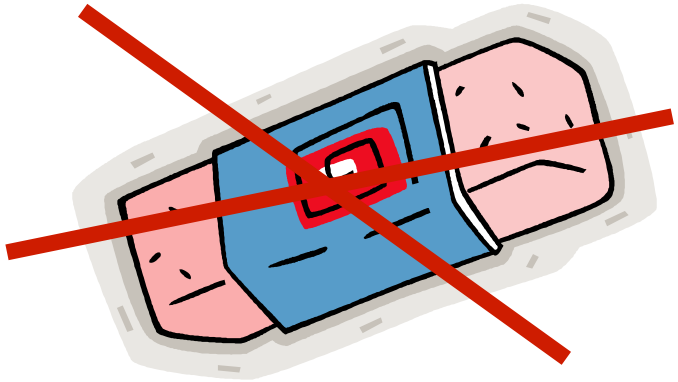
- Handwritten entries should be made in clear, legible, indelible way.

- Records should be made or **completed at the time each action** is taken and in such a way that all significant activities concerning the manufacture of medicinal products are **traceable**.



Good Documentation Practices (2)

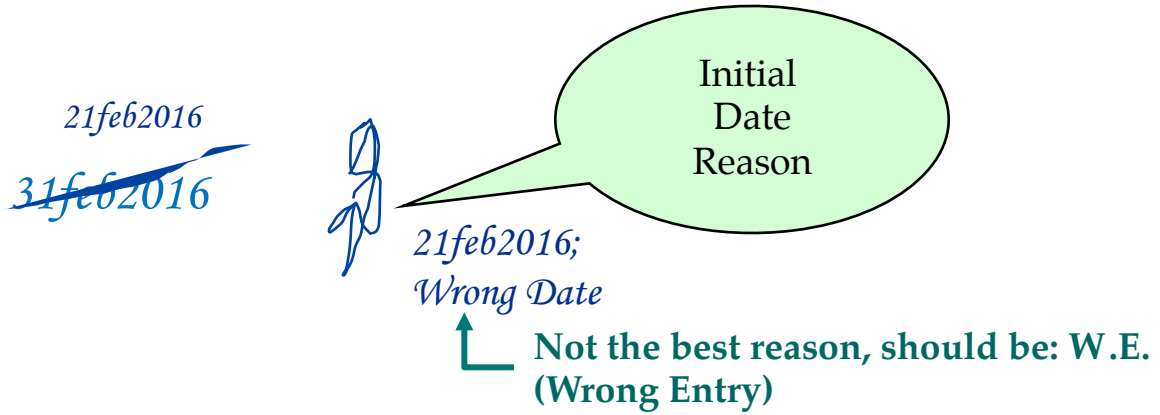
- Any alteration made to the entry on a document should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.



Possible ways of noting down handwritten data

Recording Rules

- Initial and date
- Pens: waterproof; only blue blue ?
- No pencils
- Cross references between documents
- Not allowed:
  - Handwritten changes in official documents (Masters).
  - Loose (abbreviated) notes for SOPs.
  - Post-IT, and the more



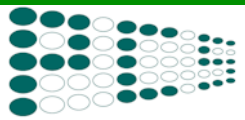
Noting down of data(2)

- If alteration is not self explaining add an explanation.

pH ~~7.5~~ 5.7 (requirement 5.3 – 5.8)

Noting down of data(3)

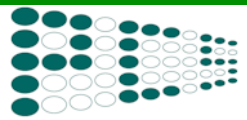
- Use only indelible inkt
  No pencil, fountain pen or fineliner
- Write as legible as possible.
- Define the way of noting down the date (mm/dd/yyyy or dd/mm/yyyyy)



Noting down of data(4)

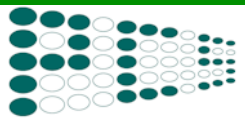
- Define how to note decimals :
  with aid of:comma (,) or point (.)

- Define the way to round off.



Noting down of data(5)

- Iniatials are used to identify the person who performed a task
- Signatures are used after taking a decision, e.g. Authorisation of a report or relase of a batch

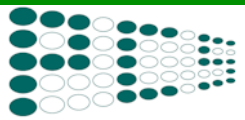


Noting down of data (6)

- The design of a document should support teh entry of data such as in process control data, observations and remarks
- Parts of pages which will not be used should be crossed out
- EOD (End of Data) sign in last used line

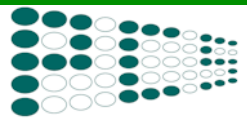
Noting down Data (7)

- An index might be very useful for complex documents like batch production records and validation reports
- Laboratory journals and logbooks should not consist of loose pages



MHRA new guideline on Raw Data

- Computer Systems Access to be validated and considered seriously
- Validation to be considered for intended purpose
- When complex System: print outs not accepted.
  - Reconstruction
- Data during validation studies: trust worthy
- Take into consideration: data must be retreivable (sometimes 30 years)
- WHO issued a draft on this topic as well.



Archiving

Retention of Documents (1)

- It should be clearly defined which record is related to each manufacturing activity and where this record is located.

Secure controls must be in place to ensure the integrity of the record throughout the retention period and validated where appropriate.

Retention of Documents (2)

- Retention time: should be defined for each type of document
  - Including for investigational medicinal products which might kept longer than commercial products
- Document supporting dossiers: life cycle approach
- Easy to find
- Remark: validation documents should not contain instructions