ISPE®
Indonesia
Affiliate

SUPPORTING DOCUMENT FOR BATCH DISPOSITION

&

BATCH RECORD REVIEW

Jakarta 14 December 2017

Speaker:
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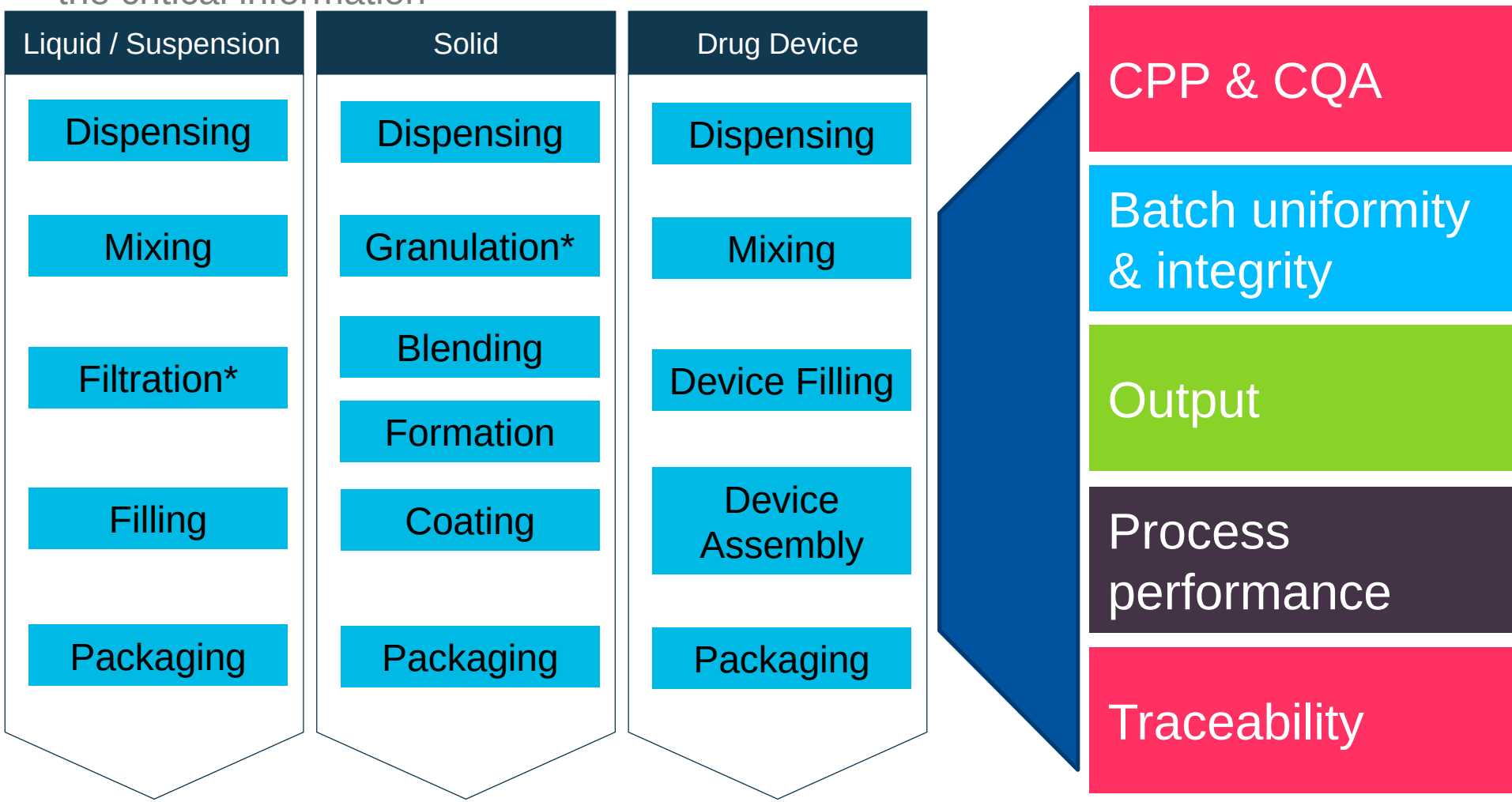
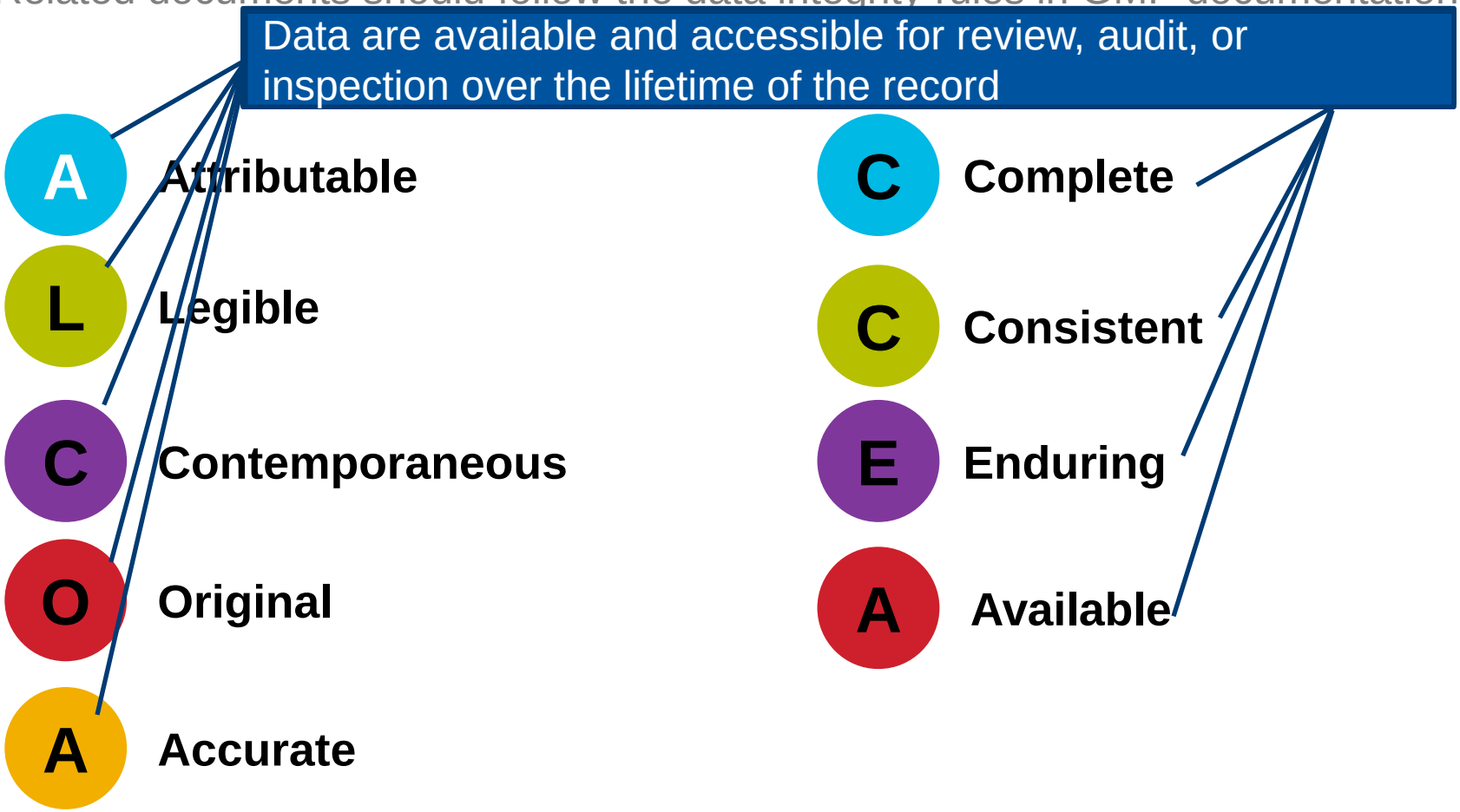
BATCH DISPOSITION DOCUMENTS

Process Control described in the batch documents should described & guarantee the critical information



BATCH DISPOSITION DOCUMENTS

Related documents should follow the data integrity rules in GMP documentation



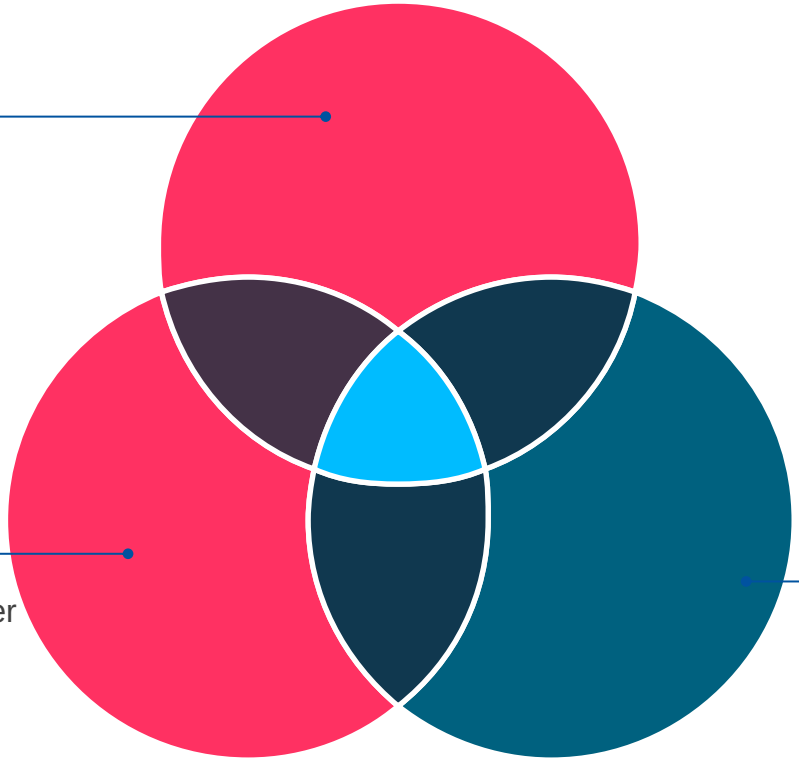
BATCH DISPOSITION DOCUMENTS

Documents reviewed and referenced during disposition should fulfill the compliance status of requirements

GXP Compliance

i.e. :

- GMP during process
- GLP during analysis
- GDP during shipment
- etc



Regulatory Compliance

i.e. :

- Alignment with submitted dossier
- Registered shelf life
- etc

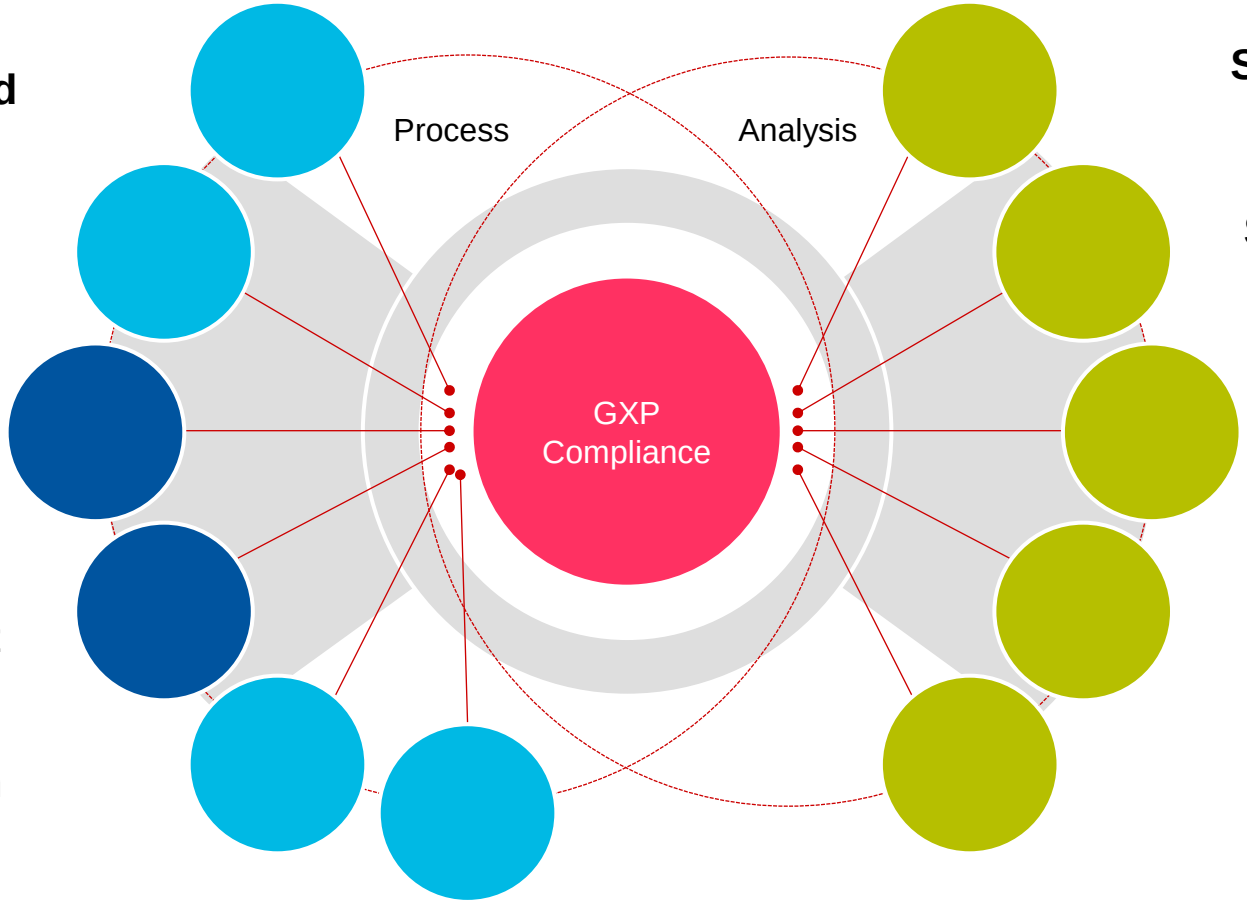
Country Specific Requirements

i.e. :

- Variable Data Format (dd/mm/yy or mm/yyyy)
- Security Label requirement
- etc

BATCH DISPOSITION DOCUMENTS for INTERMEDIATE or FINAL RELEASE

Batch disposition is not only related to analysis results & batch record



BATCH RECORD :
These documents are typically used and completed by the manufacturing department. Batch records provide step-by-step instructions for production-related tasks and activities, besides including areas on the batch record itself for documenting such tasks.

BATCH RECORD

DEFINITION :

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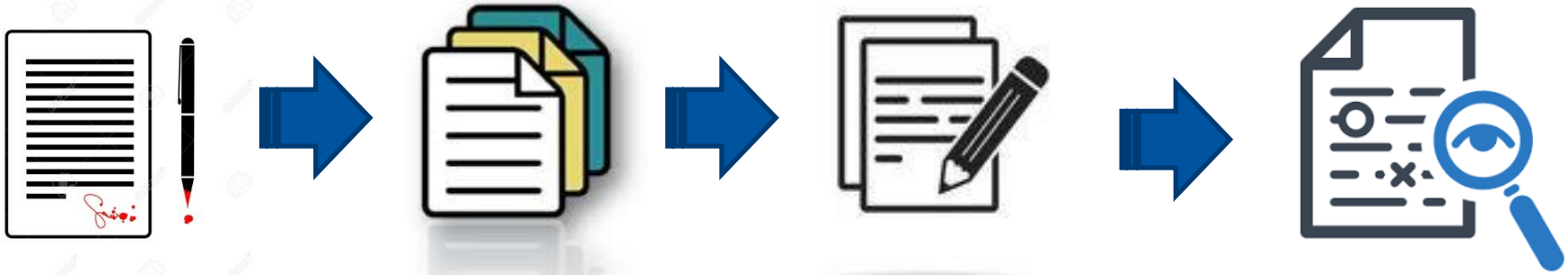


PROCESS CONTROL in BATCH RECORD

Definition & General Term

Tools & Equipment

- Personnel
- Premises & Environment
- Equipment
- Test on production machines
- Microbiological provisions
- Metal check

Method & Process

- Manufacturing & Expiry date
- Materials Handling & Processing
- Calculation of yield
- Time limits and holding times
- In-Process controls

Starting Materials

- **Specification Compliance**
- **Releasing Status**
- **Retesting Date**
- **Expiry Date**

IN PROCESS CONTROL in BATCH RECORD

Liquid / Suspension	Solid Oral	Drug Device (i.e. nasal spray)	IPC parameter (but not limited to)
Dispensing	Dispensing	Dispensing	4 eyes principle
Mixing	Granulation	Mixing	Torque agitator, mixing time, inlet t°, product t°, air flow, LOD
Filtration*	Blending		Filter, clarity, pH, mixing time, PSD, Bioburden testing
	Formation	Device Filling	uniformity of mass, DT, friability, dimension, hardness
Filling	Coating*	Device Assembly	uniformity of mass, DT, friability, dimension, hardness
Packaging	Packaging	Packaging	Appearance, leak test, batch coding

RECONCILIATION

- At the end of each specific process, the printed component and product will be tallied by operator, e.g labels, cartons, leaflets, tablets, etc
- These components will be reconciled, comparing the number at the start with number at the end of the process including all waste that occuring during the process.

$$\% \text{ Reconciliation} = \frac{\text{Qty. Used} + \text{Qty. Returned} + \text{Samples} + \text{Others x 100}}{\text{Qty. Issued}}$$

- All component and products should reconcile 100%, however allowance/tolerance is made to allow for counting error and/or minor inconsistencies. ANY UNSUAL situation and out of tolerance tally must be investigated immediately on checking the reconciliation.

Example-Allowable Tolerances for Printed Components

Batch Size (Packs)	0 – 50,000 Packs	Over 50,000 Packs
Cartons used on packs	99 -101%	99.5 - 100.5%
Leaflets used on units	99 -101%	99.5 - 100.5%
Labels used on units	99 - 101%	99.5 - 100.5%

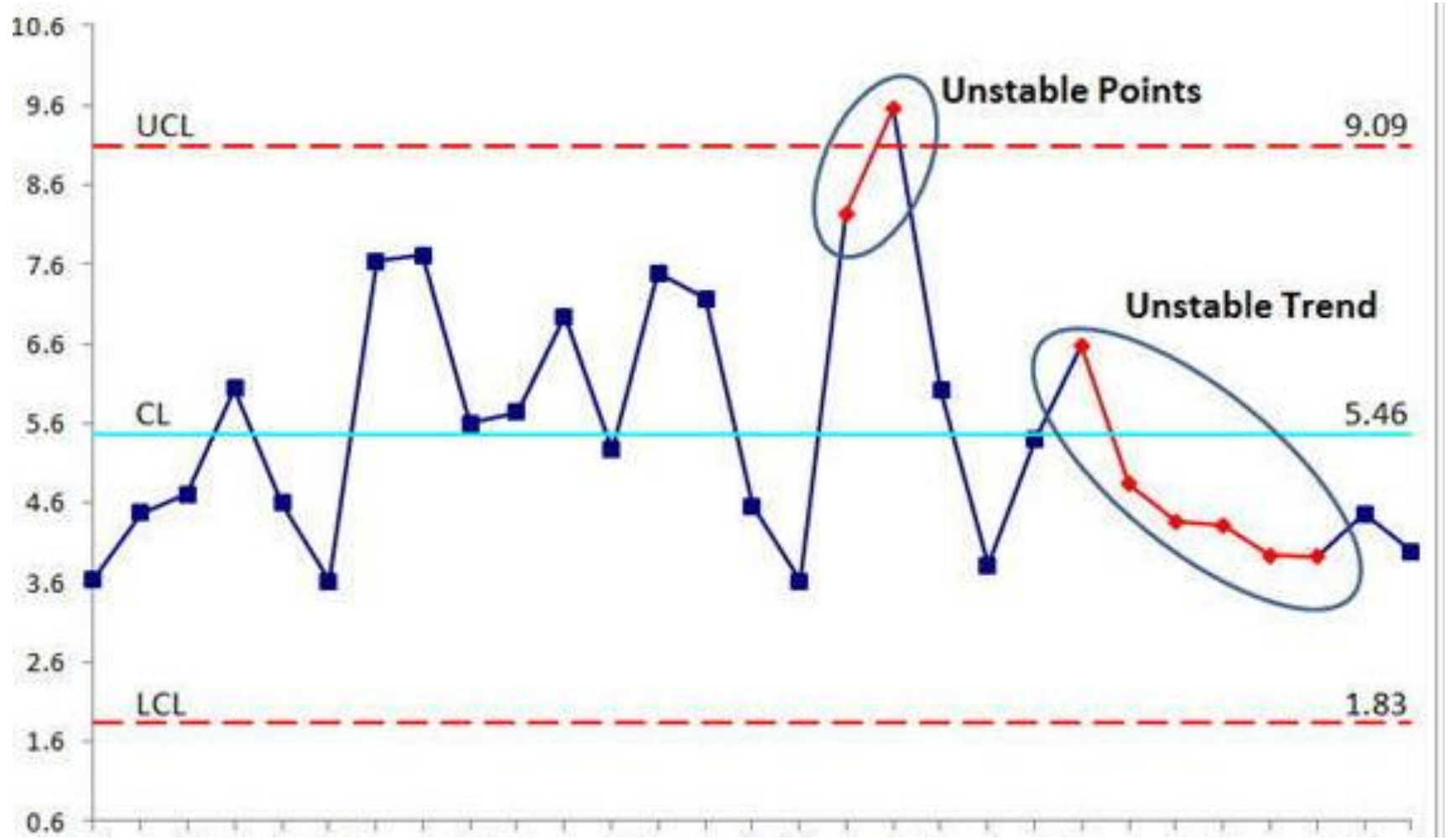
LABORATORY CONTROL RECORD

Laboratory control records should include complete data derived from all tests conducted to ensure compliance with established specifications and standards, including examinations and assays.

Sample Identity	Reference/Method	Traceability of the Sample	Record of Raw Data
Record of Calculation	Statement of Test Results	Signature of Test Performer	Signature of Reviewer
Any modification of AM	Calibration status	OOS investigations	Standard & instrument

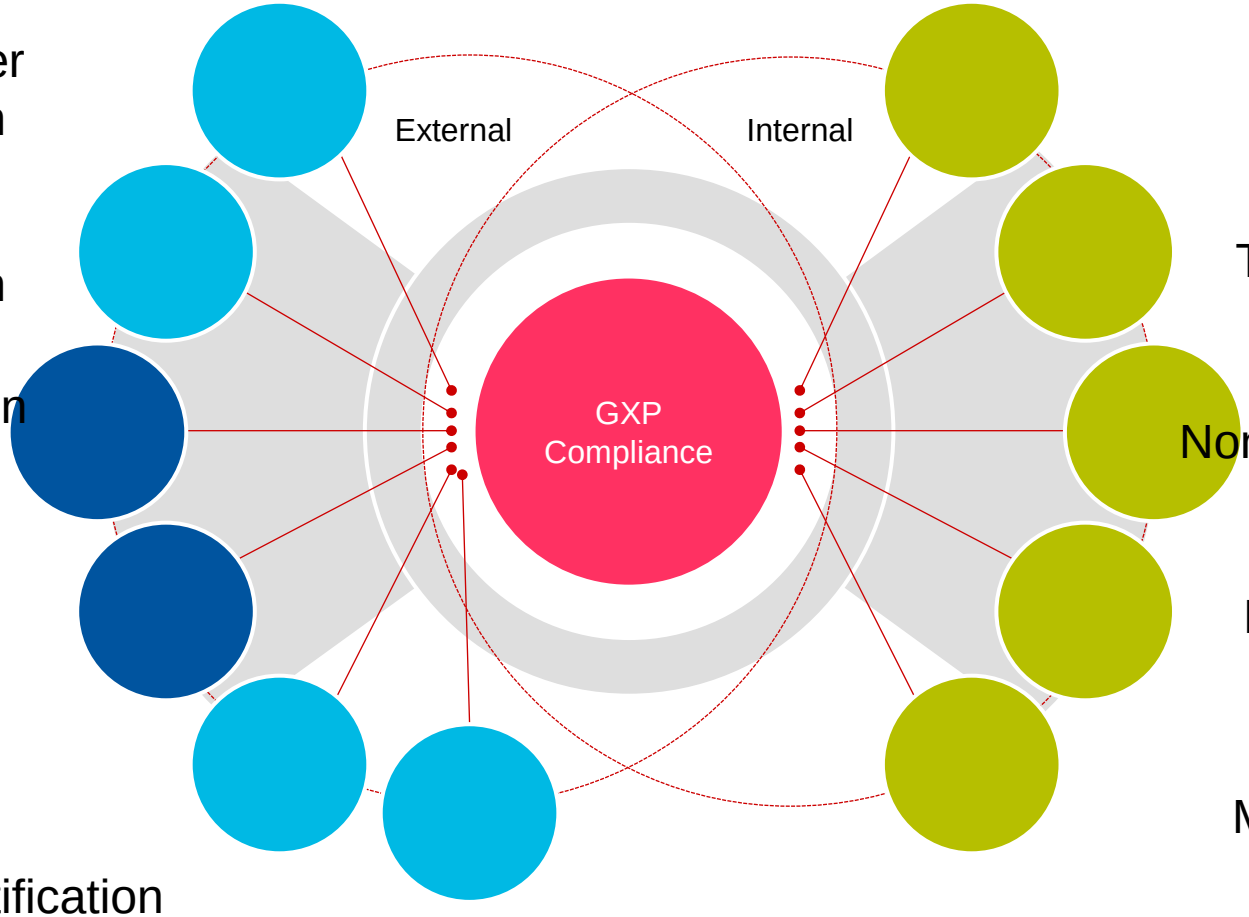
LABORATORY CONTROL RECORD

Out of Trend



BATCH DISPOSITION DOCUMENTS for STARTING MATERIALS

Batch disposition is not only related to analysis results & batch record



Manufacturer Qualification

Supplier Qualification

Supply Chain Route

Audit Status

CoA & CoC

Further Certification (Halal, TSE/BSE, etc)

Sampling Report

Test Analysis

Non Conformity

Investigation

Change Management

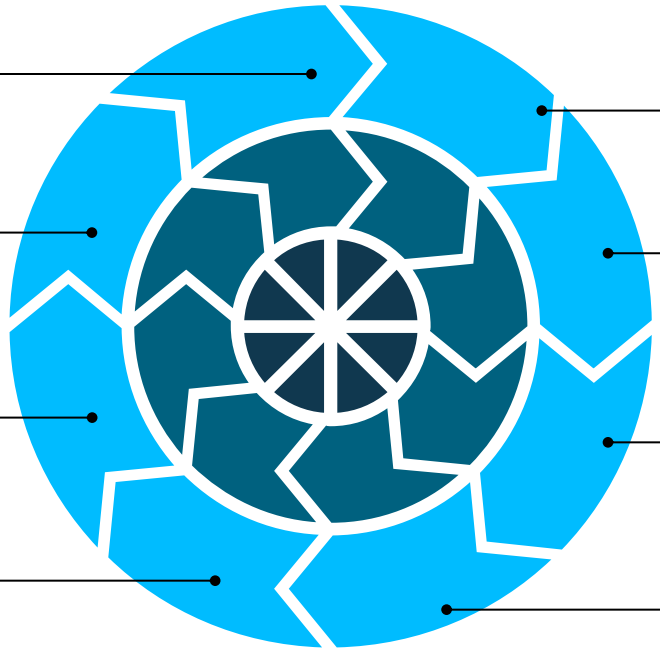
GENERAL RULES
Remember !!

Record immediately

No loose pieces of paper

Proper Correction

No “on behalf”



Legibly in ink

Signing records

Record Deviation

No assumption

Minimum Content of CoA

Manufacturer Letter Head	Name of Product	Marketed country	MA number	Strength/potency
Dosage form	Package Size	Lot/Batch number	Manufacturing date	Expiry date
Analysis results & Specification	Any Remarks	Certification Statements	Name & Position authorized person	Signature & date

Example of Certification Statement :

”I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country / product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP”.


Thank You