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BATCH DISPOSITION

BATCH DISPOSITION REGULATION

Jakarta 14 DECEMBER 2017

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BATCH DISPOSITION
Definition

- Batch disposition = product disposition = lot disposition
- The documented control, status and/or usage for a Product. Examples include, without limitation, release, rejection, quarantine, hold, release for packaging, returns, destruction.

BATCH DISPOSITION
Definition

Applied to :

- ✓ **Drug Products including Validation and demonstration Batches.**
- ✓ **Active Pharmaceutical Ingredients (API) including validation and demonstration batches**
- ✓ **Raw Materials (RM);**
- ✓ **API Starting Materials;**
- ✓ **Intermediates;**
- ✓ **In-Process Materials;**
- ✓ **Medical Devices;**
- ✓ **Packaging Materials; and**
- ✓ **Other Materials.**

BATCH DISPOSITION
Responsibility

- WHO : Authorized Person

The person recognized by the national regulatory authority as having the responsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the laws and regulations in force in that country.

- EU : Quality Person

Responsible person for batch certification and release required at site is a basic concept of the European Pharmaceutical legislation, providing the competent national authorities a perfect recourse within a short timeframe in case of any issue with a batch certified and released by a particular QP

BATCH DISPOSITION
Responsibility

- US FDA : Quality Unit

A group organized within an organization to promote quality in general practice

- BPOM : Registered/Qualified Pharmacist

Personnel with adequate training and practical experiences which enable him/her to perform his/her function professionally. The head of Quality Management (Quality Assurance) should be given full authority and responsibility in all quality system /assurance duties, including:

BATCH DISPOSITION
Important Aspect

- Accordance to registered specification/parameter
- Consider following aspect :
  - Safety
  - Efficacy
  - Purity
  - Identity
  - Quality
- GMP/Compliance

BATCH DISPOSITION
Types

GMP Disposition

- Release from Manufacturing Site to Distribution (Technical Disposition)
- Toll manufacturing Marketing Authorization (MA) holds by other party)
- Country that required local people to do another step of release

Market Disposition

- Released product to market
- Performed by MA holder

Noted : GMP and Market Disposition can be done together

BATCH DISPOSITION Documents

GMP Disposition

- Batch Record
- Analytical Testing Record/CoA
- Related form/checklist
- Environmental Monitoring Result
- Certificate of Conformance
  - → Manufactured as per GMP
  - → Any occurrence/deviation has been investigated and assessed

Market Disposition

- Certificate of Conformance

BATCH DISPOSITION
Types of Disposition

The Product Disposition shall be documented, signed (written or electronic), and dated by the Quality Team representative making the disposition decision either :

- **Approved,**
- **Quarantine,**
- **Quarantine-Hold,**
- **Acceptable for Rework/Reclaim, and**
- **Rejected.**

Document the actual quantity of materials being assigned the disposition

BATCH DISPOSITION
Additional Aspect

Quarantined-Hold, Acceptable for Rework/Reclaim or Rejected)

→ **To be verified to have been segregated from the portion of the batch or lot that is to be approved prior to the approval of the rest of the batch or lot.**

For Prospective Validation,

→ **validation reports must be approved prior to product release and distribution of validation batches in accordance with the established site validation requirements.**

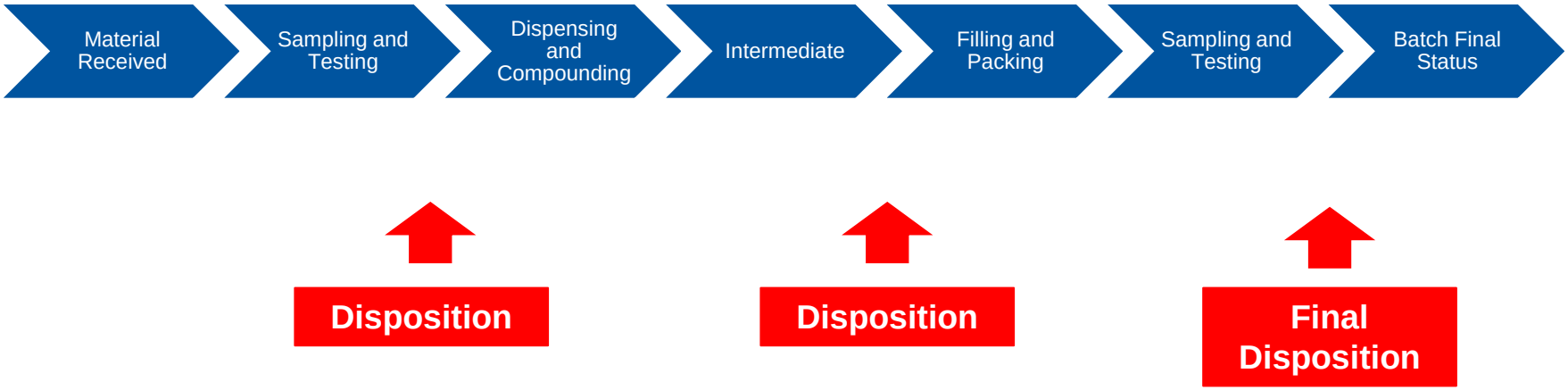
For Concurrent Validation,

→ **Preliminary validation report of each batch must be approved prior to product release and distribution of validation batch in accordance with the established site validation requirements.**

For Contract Manufacturing

Specify the requirements for approval of products produced by the contract vendor..

BATCH DISPOSITION
General Manufacturing Process



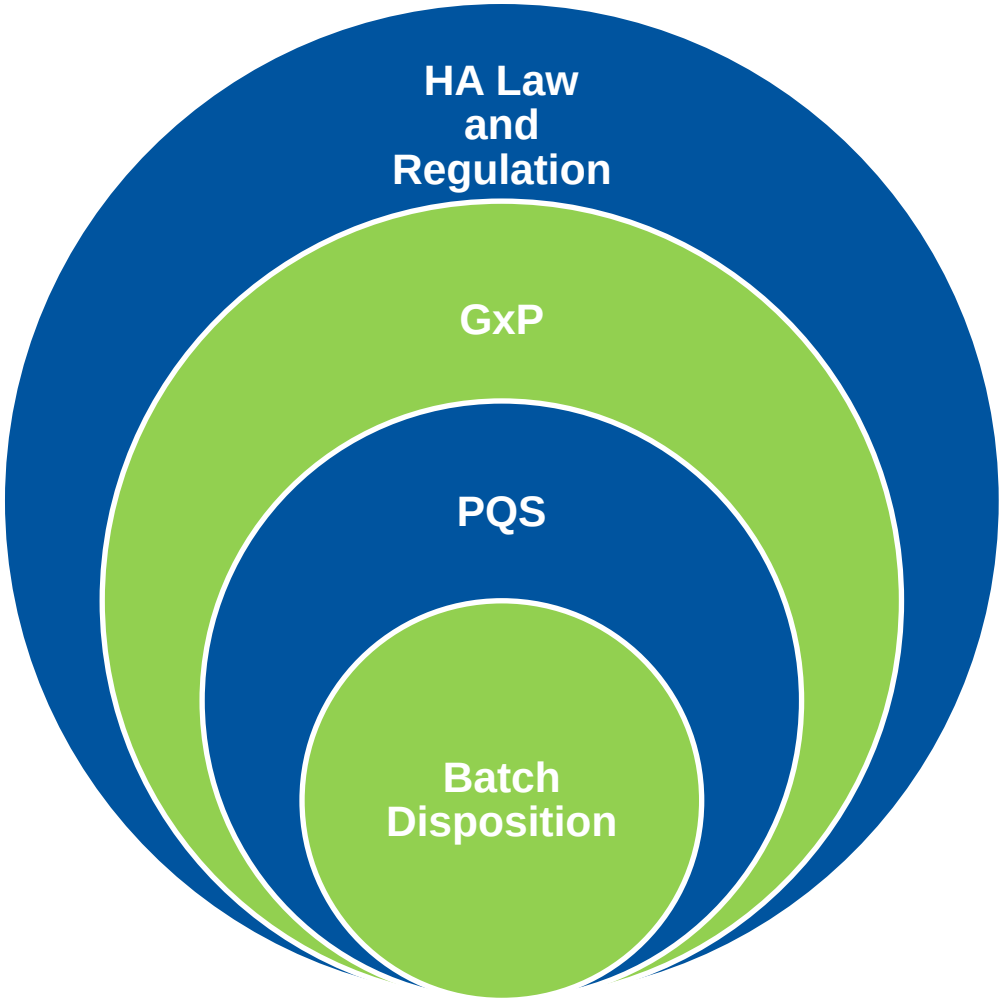
BATCH DISPOSITION
Pre-requisite System

System for assigning a disposition to materials in accordance to regulatory :

- Material/Process Control Documents
- Specifications,
- Certificate of Analysis (COA),
- Batch Records,
- Device History Record (DHR)
- Certificate of Compliance.
- Material status indication.

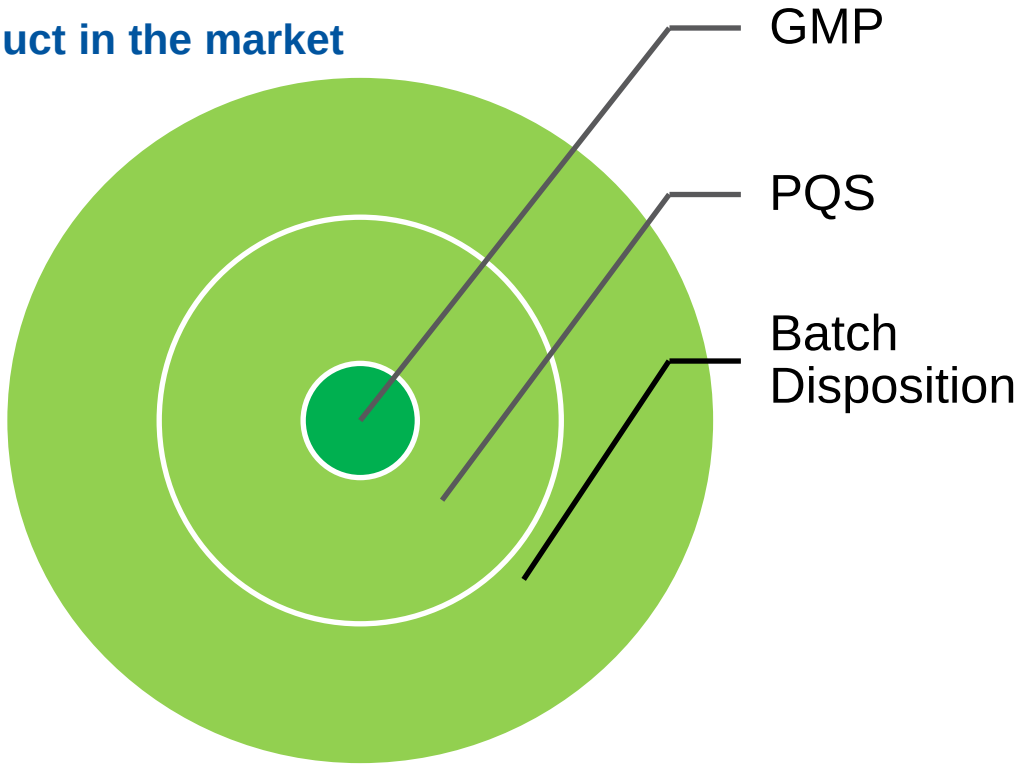
- Standard Operating Procedures (SOP)
  - Process Validation
  - Out of Specification and Deviation Management
  - Complaint and Market Action
  - Stability Management
  - Reprocess and Reworking
  - Line Clearance
  - IPC
  - Retained Sample
  - Supplier Management
  - Change Management
  - Packaging Development

BATCH DISPOSITION
GxP – Pharmaceutical Quality System – Batch Disposition



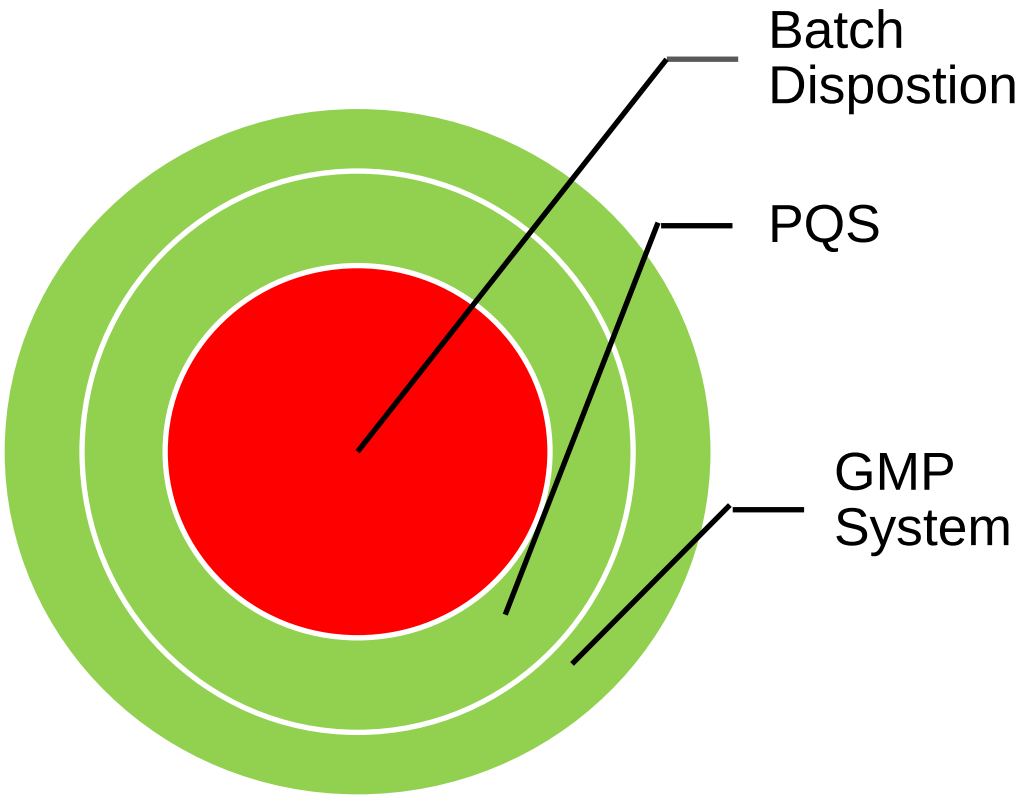
BATCH DISPOSITION
GxP – Pharmaceutical Quality System – Batch Disposition

- Batch disposition = confirmation activities not quality testing activities
- Quality must be built from beginning, not testing at the end
- More robust GMP and PQS System = More robust in Batch Disposition Process = less chance of having bad product in the market

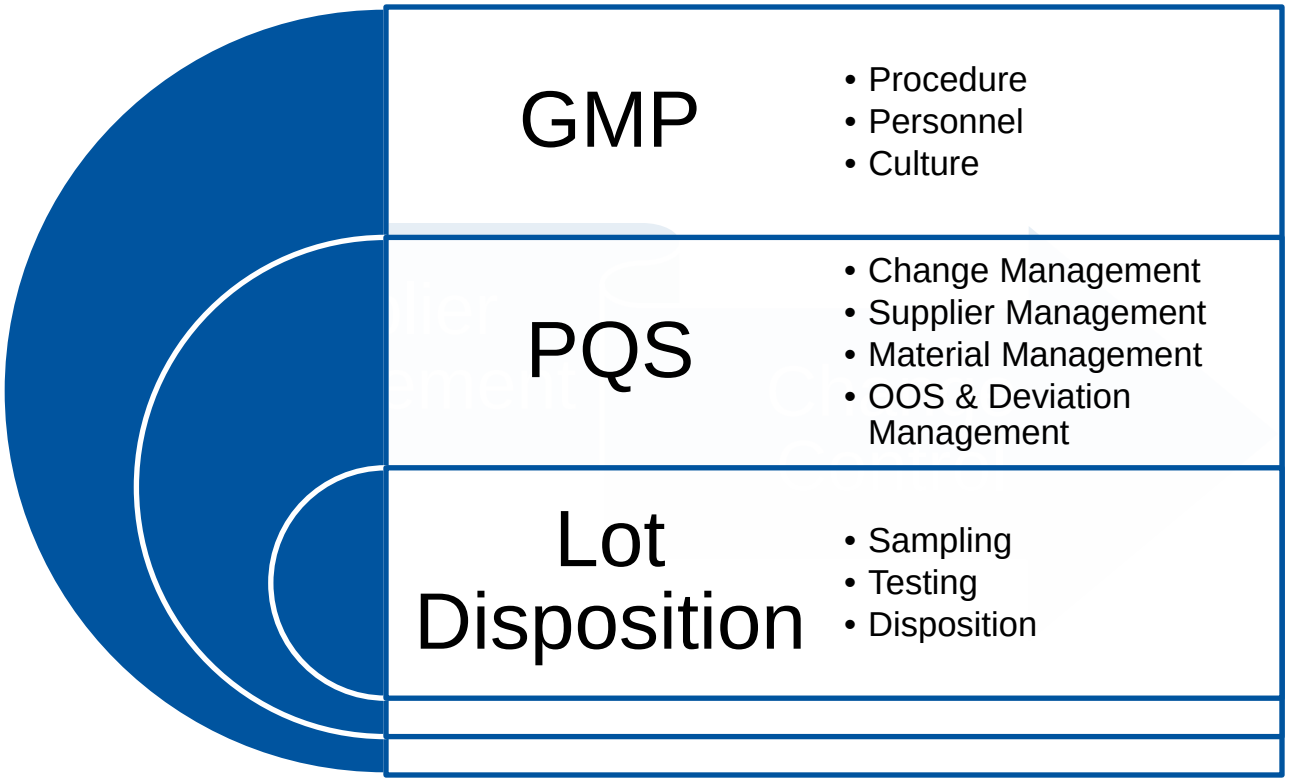


BATCH DISPOSITION
GxP – Pharmaceutical Quality System – Batch Disposition

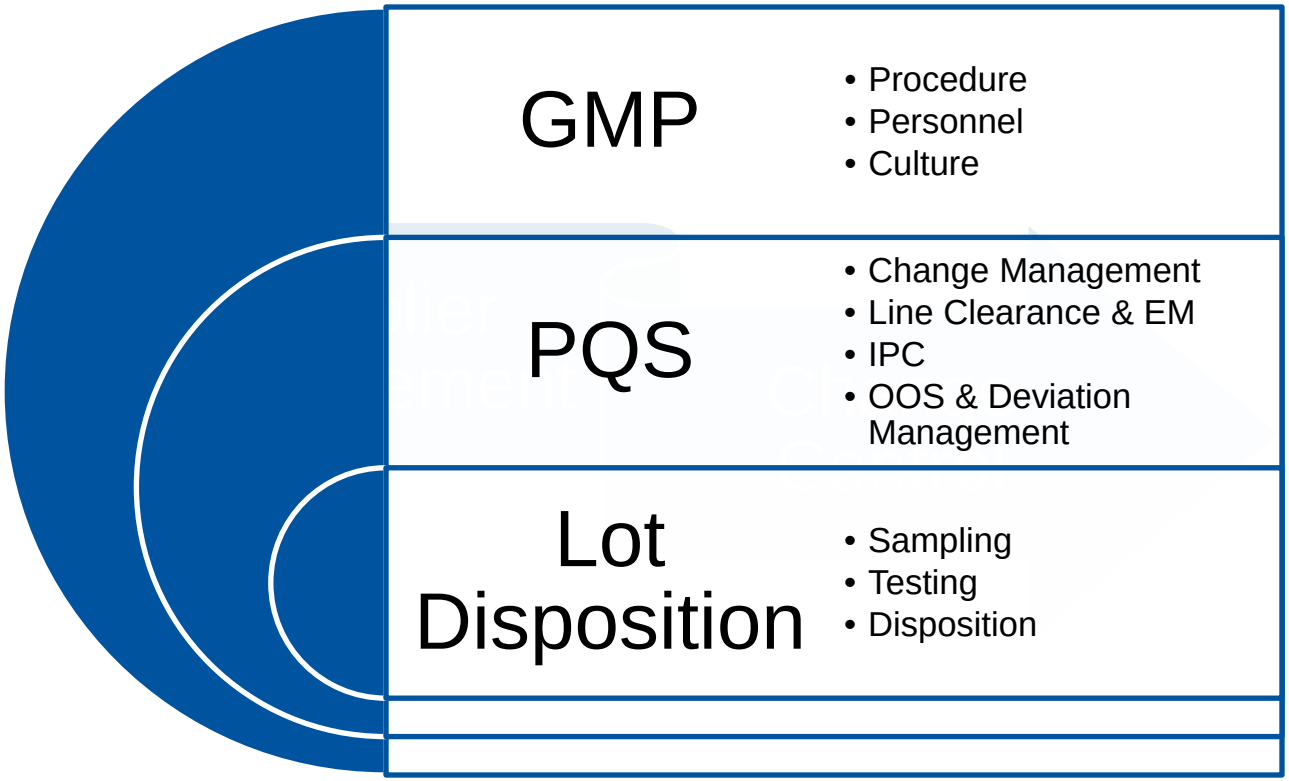
- **Less robust GMP and PQS System = Vunerable in Batch Disposition Process = Micro Manage = High chance of having bad product in the market**



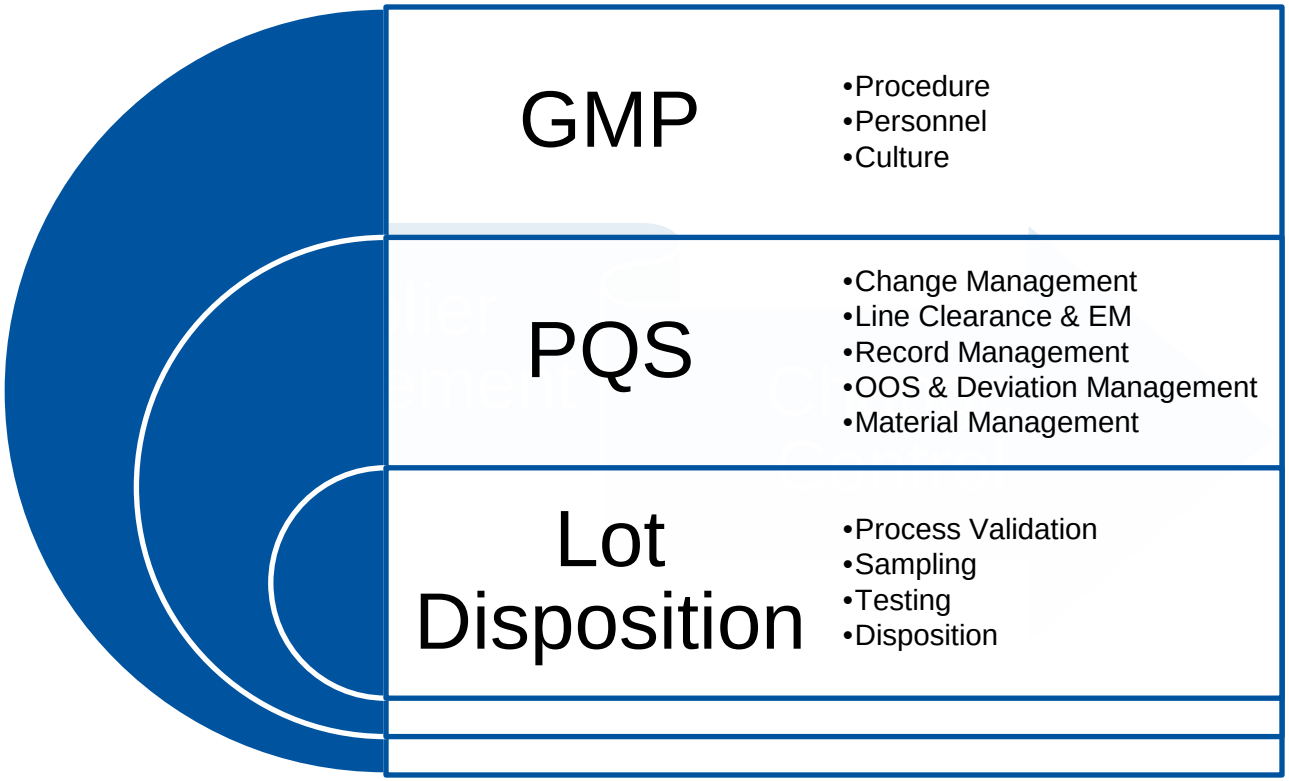
RAW/PACKAGING MATERIAL DISPOSITION
Prerequisite System (not limited to)



INTERMEDIATE DISPOSITION
Prerequisite System (not limited to)



FINISH PRODUCT DISPOSITION
Prerequisite System (not limited to)



BATCH DISPOSITION
Key Principles

- **Confirmation activities**
- **Sampling and testing based on sampling approach with destructive testing**
  - IPC
  - Process Validation
- **Holistic approach more sustainable than micro manage**
- **Keep adding checking and sorting step at the end of process are not always best solution**


GRACIAS
THANK
YOU
ARIGATO
SHUKURIA
BOLZÍN
MERCI
BIYAN


TIME FOR QUESTIONS
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