品質管理系統介紹

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Best Practice

與高手共事的必要性

Stay Hungry, Stay Foolish 。

--Steve Jobs--

What the customer care for?

- Purity
- Quality
- Strength
- Identity
- Integrity

GXP

Intended use (purpose)

GXP
GMP
GDP
GCP
GLP
GPvP
GAP
…..

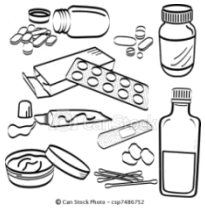
Quality of medicine

- Purity
- Quality
- Strength
- Identity
- Integrity

Pharmaceutical Supply Chain

Raw Material

Drug Product



Finished Product

Warehousing (Storage)

Distribution/ Transportation

Customer

GMP/GDP

Scope of GDP

Finished Product

Warehousing (Storage)

Distribution/ Transportation

Customer

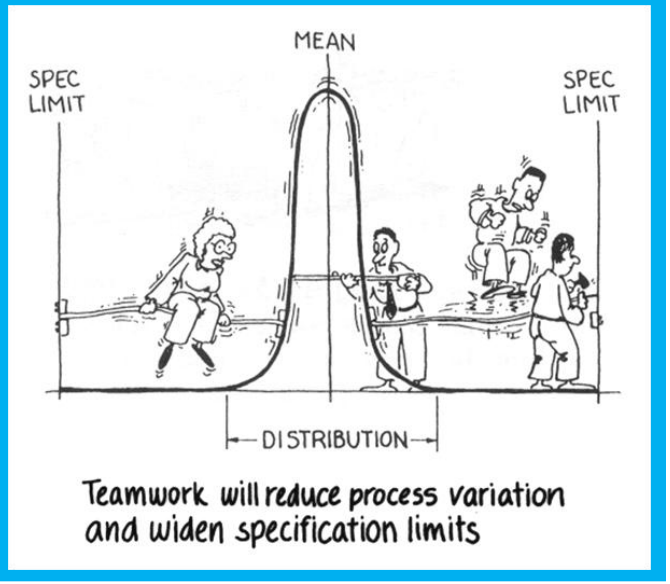
Quality System

The sum of all aspects of a system that implements quality policy and ensures that quality objectives are met.

(International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Q9)

Key factors with GDP implementation

1. Competent people
2. Appropriate facility/equipment
3. Defined procedure
4. Documentation system
5. Risk management
6. Continuous improvement



Personnel

Responsible person

- supervision of quality system

Competent person

- relate to all GDP activities

Organization chart

Job Description

Training

- Initial/On-going Training

Documentation

- documented records

Premise/Equipment/Vehicle

- Intended use
- Qualification /Validation
- Documentation

Premise/Equipment/Vehicle

Intended use

- Temperature / Humidity requirement
  - Storage area
    - ambient/cold chain (cool packs)/special care
  - Delivery vehicle
    - car/truck/insulator
  - Monitoring device
    - temp./humidity/alarm
  - Computerized system
    - validation

Premise/Equipment/Vehicle

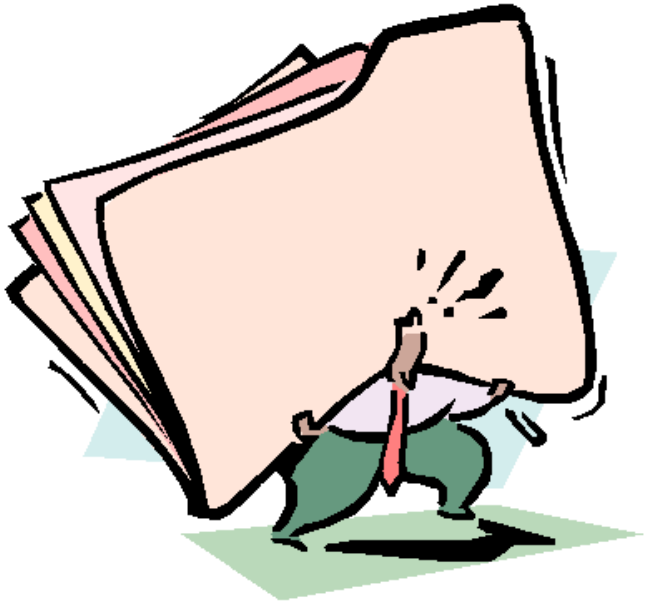
Qualification/Validation

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Performance Qualification (PQ)
- Re-qualification (RQ)
- Maintenance Qualification (MQ)
- Mapping

Premise/Equipment/Vehicle

Documentation

- Protocol
- Report
- SOPs



Procedures/Process Documents

- Written document to instruct details
- Describe purpose/application/responsibility/instruction
- Define scope of procedure
  - Flow chart
  - Process flow
- Periodical assessment

Medicinal Product Management (1)

- Receiving procedure: each operation in supply chain
  - Storage area
  - Hub(transient area)
  - Vehicle
- Storage consideration
  - Area- quarantine/qualified/reject/return
  - Special care-control substance
  - FEFO

Medicinal Product Management (2)

- Authenticity assurance
  - Avoid falsified/ counterfeit medicines
  - System in place
- Procedure for customer complaints

Supplier/Supporting Chain Management

- Responsibility of contract giver
  - Medicine holder
  - Wholesale distributor
- Responsibility of contract receiver(acceptor)
  - Wholesale distributor
  - Subcontractor
- Responsibility of subcontractor
- Evaluation program
  - Assessment/ audit
  - Agreement

Non-Comformity Management

Non compliance with procedure/process

- Document facts
- Evaluate impacts
- Corrective action
- Preventive action
- Follow-up

Written Document

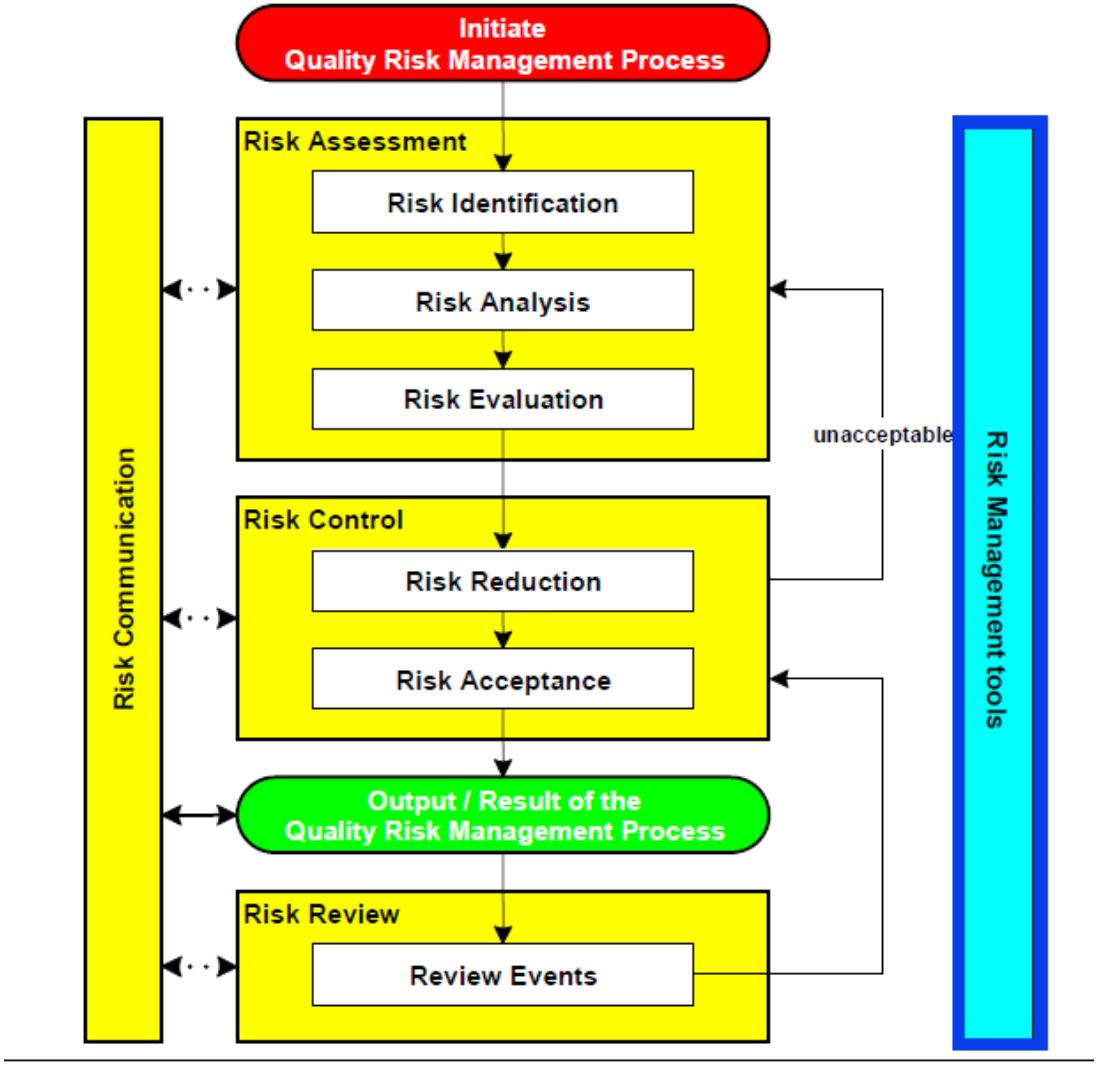
Quality Related Issues

- Handle of complaints
  - Procedure in place
  - Responsible personnel
  - Investigation
  - CAPA
  - Source of improving program

Self-Improvement Program

- Self inspection program
  - Monitor the compliance with GDP
  - Propose corrective measures
- Planned schedule/procedure
  - Competent personnel
- Self-inspection report
  - Observation
  - CAPA
  - Provide to the senior management

Risk Management Implementation



Overview of ICH Q9 Quality Risk Management process.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