What is a Quality-System?

A Quality **System** is holistic, there is no exception (it’s all)

- Systems
- People
- Equipment
- Buildings/Premises
- Utilities
- Products
- Processes
- ..................

Your Pharmaceutical QMS should assure that the above assets delivers a product consistent according specification, fit for purpose.
QUALITY SYSTEM ELEMENTS

- Documentation
- Training
- Deviations
- Change Management
- Equipment Management
- Vendor management
- Sample management
- Out of Specification
- Stability
- Etc.

The above mentioned Quality System Elements should assure that the principle stated in former slide manages the assets properly.
QMS (ANOTHER VIEW)

• Material Control System
• Production and Process Control System
• Records and Document Control System
• Facility and Equipment Control System
• Laboratory Control System
• Divergences Control System
• Validation

• Responsibilities
• Management Review
• Continuous Compliance

Control Systems
Organizational Systems
Quality Risk Management

Essentials

Validation

PROCESS

Facilities control  OJT/HR

UNDERSTANDING

CQP/CQA, Batch Records

Deviations/OOS Trending  Investigations

Incoming Material-controls  Batch Release

Vendor qualification

Personnel Qualification
Facilities control
OJT/HR

Process

Understanding
CQP/CQA, Batch Records

Incoming Material-controls Batch Release

Complaints Recalls External-audits

Change-control PQR Self-Inspection

Deviation/OOS Trending Investigations

Vendor qualification

Personnel Qualification

Etc

RM

Documentation control
Holding & Distribution

FP

Management review

Commons Risk Management

Validation

Essentials
Facilities control   OJT/HR
PROCESS
UNDERSTANDING
CQP/CQA, Batch Records

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Etc

Vendor qualification

RM

Documentation control Holding & Distribution

Etc

FP

Management review

Personnel Qualification

Quality Risk Management

Essentials

Validation
BSL & GMP REQUIREMENTS IN QMS

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BSL & GMP REQUIREMENTS IN QMS
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“URS”

Closed process
- e.g. no centrifuge
Early inactivation
Etc.
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