Quality System(s)

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WHAT IS THAT; QUALITY?

There are multiple understandings, depending from which angle you are answering the question:

- Logistically right time, place and amounts
- Financially right price
- Technically right product!

General definition:

FITNESS FOR INTENDED USE

The client returns (and not the product)
WHAT IS THAT; QUALITY?

In our (pharmaceutical) world:

Product meets (assured), the requirements as described in the Regulatory Dossier
BUT NOW: WHAT IS A QUALITY SYSTEM?
1st What does system mean?

(GOOGLED)

• A group of interacting, interrelated, or interdependent elements forming a complex whole.
• A condition of harmonious, orderly interaction complex.
• An organized and coordinated method; a procedure
• A naturally occurring group of objects or phenomena
Ok, so what is a Quality-System?

- A Quality **System** (for us) is an holistic approach:
  There is no exception (it’s all)
- Systems
- People
- Equipment
- Buildings/Premises
- Utilities
- Products
- Processes
- ................

**Your** companies system should assure that the above assets delivers a product consistent according specification, fit for purpose.
Finally, we can define 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 or QMS Elements

Depending on how you like to call it:

• The individual items (deviation, training, etc) are called elements of the overall Quality Management System
• OR the individual item is called a Quality System and the overall is Quality Management Systems
• OR maybe other views
• Either way: it should do the job.
• For now: I use the term Quality System and the individual items elements of the QMS (completely arbitrary)
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US QUALITY SYSTEM APPROACH
QMS should be supported by the organizational systems

- 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
- ............
Pharmaceutical Development → Technology Transfer → Commercial Manufacturing → Product Discontinuation

GLP
GCP

Investigational products → GMP

Management Responsibilities

- Process Performance & Product Quality Monitoring System
- Corrective Action & Preventive Action (CAPA) System
- Change Management System
- Management Review

PQS elements

Enablers

- Knowledge Management
- Quality Risk Management
We are talking about the same system. Depending on where you stand, you might see something else, however it’s still one system.
Performance or Quality?

- Quality is **not** a specific Pharmaceutical topic
- Basic principle: good performance on the QMS-elements delivers a well functioning QMS and as a result: Right Quality
- Well performing QMS supports short- and long term business objectives.
- One of the key/mandatory objectives for short- and long term business objective MUST be (in pharma/vaccine world): safety/efficacy/quality for the recipients.
- GMP requirements MUST be built in, in yours’ QMS.
- A QMS cannot create miracles (!)
CHANGE CONTROL & DEVIATIONS
CHANGES VS. DEVIATIONS

• "CHANGES"
  – Normally: planned
  – Starts: before execution

• "DEVIATIONS”
  – Normally: unexpected (unplanned)
  – Starts during regular work

• PLANNED DEVIATION vs. TEMPORARILY CHANGE
  – In English Planned Deviation might be a contradiction, however in other languages completely normal
  – My personal opinion: it doesn’t much matter how you call it, as long as you arrange it (decently)
  – Batch Records......
CHANGE MANAGEMENT: WHY

• Preventing undesired changes

• Careful considerations

• Planning of associated actions (SOP’s/Validation)

• Communication of change

• Correct Documented Change.

CONTROLLED PROCESS FOR CHANGE

• Many ways to manage, e.g. Documentation (wherein the document itself the changes are managed)
CHANGE CONTROL SOP

Request  
Authorization  
Execution  
Final authorization for Implementation  
Implementation
DEVIATIONS

1. Details

2. Corrective Action (CA)

3. Root Cause Analysis

4. Impact Assessment

5. Preventive Action (PA)
The process:
1. Documented Deviation
   – Timely: notification at least within 24 hours
2. Correction
3. Investigation into the root cause
4. Corrective Action(s) (CA), prevent recurrence
5. Scale and seriousness (Impact Assessment)
6. Preventive Action(s) (PA)
   – Root Root Cause Analysis
   – Risk Assessments

• CAPA systeem
TRAINING REQUIREMENTS

Or better: knowledge management (?)

- Per employee
  - Plan (e.g. per year and during induction)
  - CV (Resume)
  - Each training
  - Job Description
- Traceable
- Overview for management
CONCLUSION
Other QMS-Elements

- Per individual QMS Element
  - Company Requirements
  - Regulatory Requirements
- Interactions between Requirements and/or Departments and/or Sites
An example assessment of a QMS, including progress per element
THANK YOU FOR YOUR ATTENTION