Quality System(s)
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?
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.
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).
## A table with QMS-elements (not limited)

<table>
<thead>
<tr>
<th>Change Control/Management</th>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deviation/NC</td>
<td>Distribution</td>
</tr>
<tr>
<td>CAPA</td>
<td>Artwork</td>
</tr>
<tr>
<td>Complaints/Incidents</td>
<td>Audit System (Internal/External)</td>
</tr>
<tr>
<td>PQR/APR</td>
<td>Documentation</td>
</tr>
<tr>
<td>Recall</td>
<td>CMC maintenance</td>
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<tr>
<td>Destruction</td>
<td>Technical Transfer</td>
</tr>
<tr>
<td>Vendor Management</td>
<td>Pharmacovigilance</td>
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<tr>
<td>Quality Control</td>
<td>Clinical Studies</td>
</tr>
<tr>
<td>On-going Stability</td>
<td>Marketing Material</td>
</tr>
<tr>
<td>Enquiries</td>
<td>Regulatory Affairs</td>
</tr>
<tr>
<td>Validation/Verification/Qualification</td>
<td>Data Management</td>
</tr>
<tr>
<td>External Inspections</td>
<td>Investigations</td>
</tr>
<tr>
<td>Facilities / Utilities / Equipment</td>
<td>Development Studies</td>
</tr>
</tbody>
</table>
Management Responsibilities

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

Enablers
- Knowledge Management
- Quality Risk Management
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
- ........

Control Systems

Organizational Systems
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 (!!)
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)
DEVIAN\(\text{IONS}\)
SYSTEM FAILURE INVESTIGATION

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

Industry Practice:
close deviations in
30 days
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
Other QMS-Elements

- Per individual QMS Element
  - Company Requirements
  - Regulatory Requirements
- Interactions between Requirements and/or Departments and/or Sites
Checklist per QMS-Element

An example assessment of a QMS, including progress per element
ICH-Q10 (PQS): QMS does function by managing its elements

OPTIONS:

1. TRUE
2. NOT-TRUE
3. DON’T KNOW
A QMS should be able to cope with ALL possible situations

OPTIONS:

1. TRUE
2. NOT-TRUE
3. DON’T KNOW
THANK YOU FOR YOUR ATTENTION