
PHARMACEUTICAL
CONSULTANCY
SERVICES
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)

© Pharmaceutical Consultancy Services, All rights reserved.

WHAT IS THAT; QUALITY ?

In our (pharmaceutical) world:

Product meets (assured), the requirements as described in the Regulatory Dossier

© Pharmaceutical Consultancy Services, All rights reserved.

RIGHT……

BUT NOW:

WHAT IS A

QUALITY*SYSTEM*?

© Pharmaceutical Consultancy Services, All rights reserved.

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

© Pharmaceutical Consultancy Services, All rights reserved.

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.

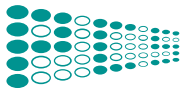
© Pharmaceutical Consultancy Services, All rights reserved.

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.

© Pharmaceutical Consultancy Services, All rights reserved.



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)

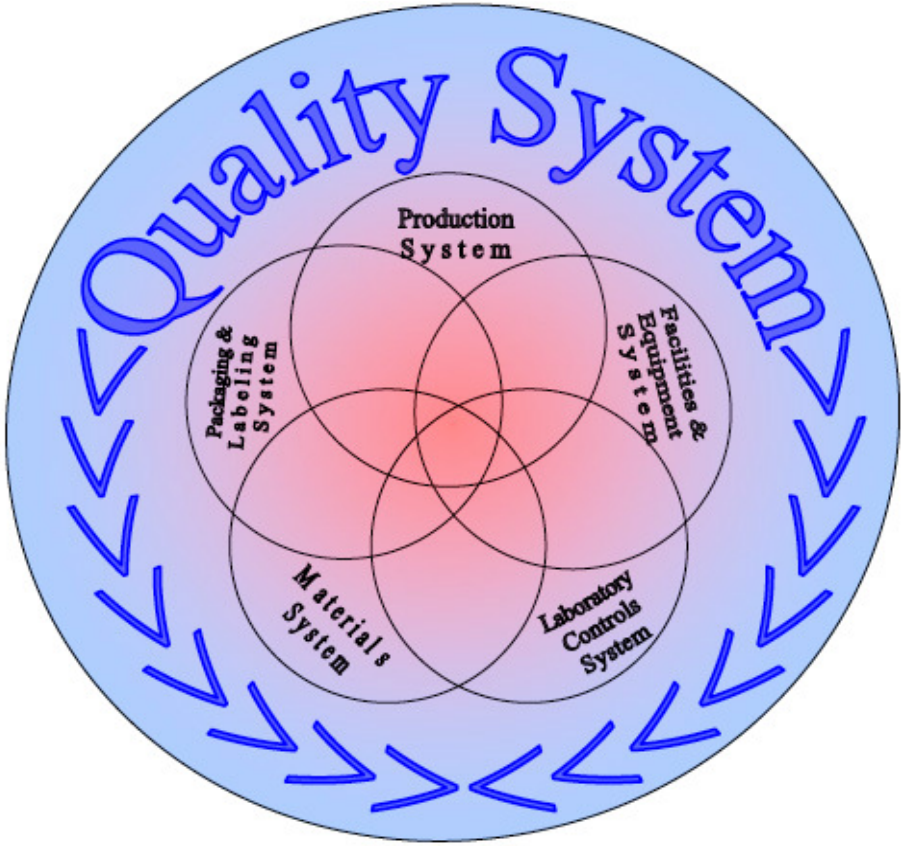
© Pharmaceutical Consultancy Services, All rights reserved.

A table with QMS-elements (not limited)

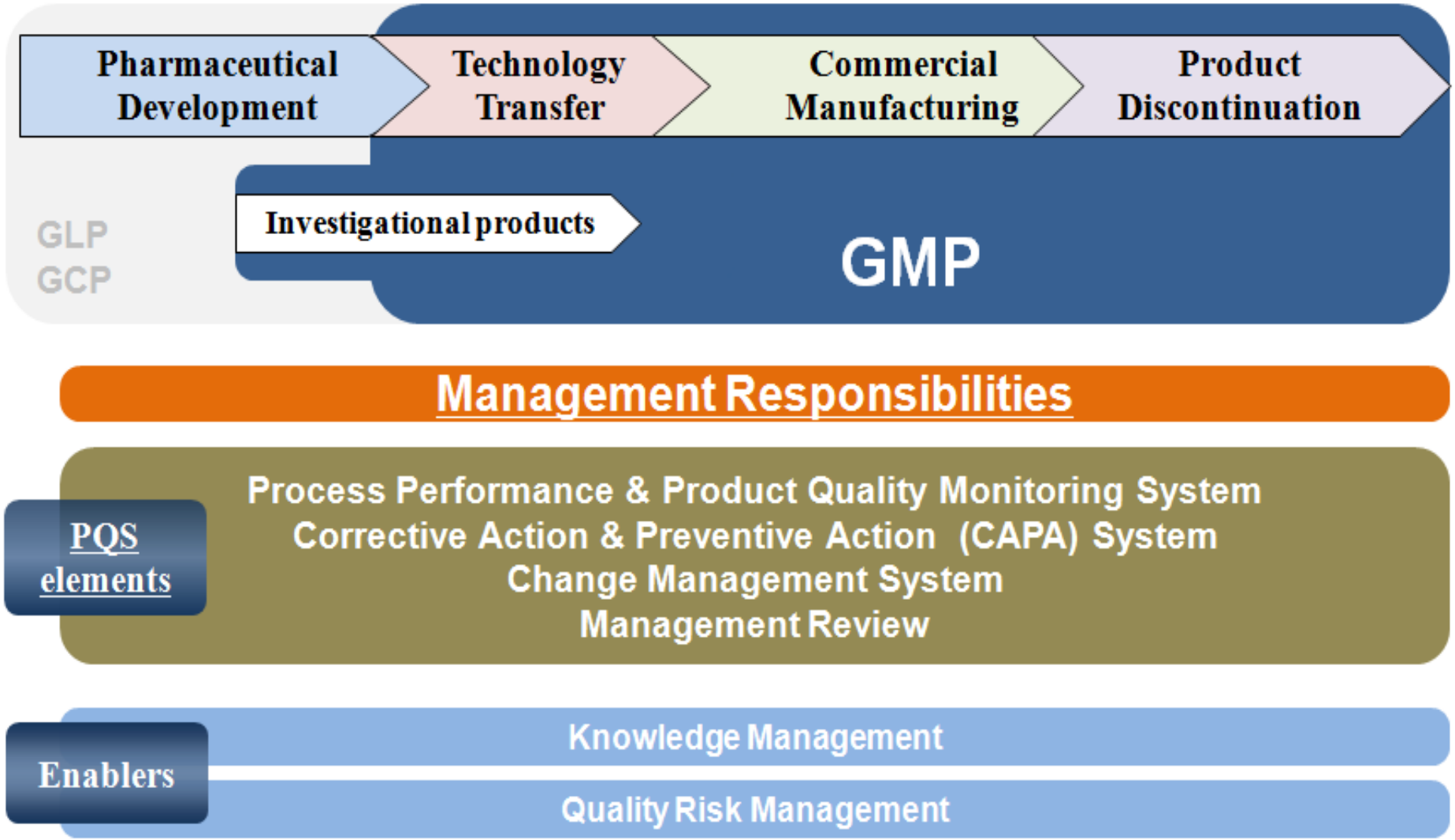
Change Control/Management	Training
Deviation/NC	Distribution
CAPA	Artwork
Complaints/Incidents	Audit System (Internal/External)
PQR/APR	Documentation
Recall	CMC maintenance
Destruction	Technical Transfer
Vendor Management	Pharmacovigilance
Quality Control	Clinical Studies
On-going Stability	Marketing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

© Pharmaceutical Consultancy Services, All rights reserved.

US QUALITY SYSTEM APPROACH



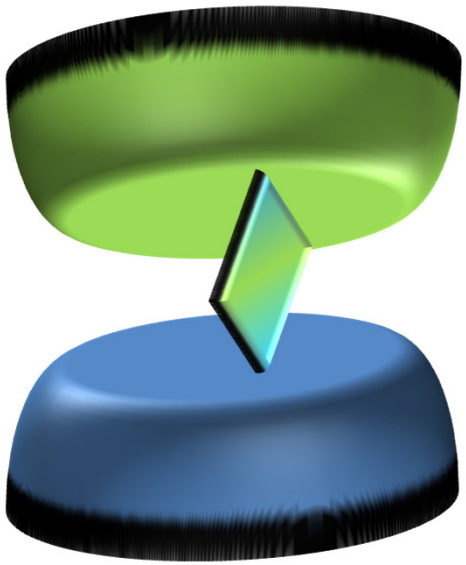
© Pharmaceutical Consultancy Services, All rights reserved.



© Pharmaceutical Consultancy Services, All rights reserved.

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
- ……



Control Systems

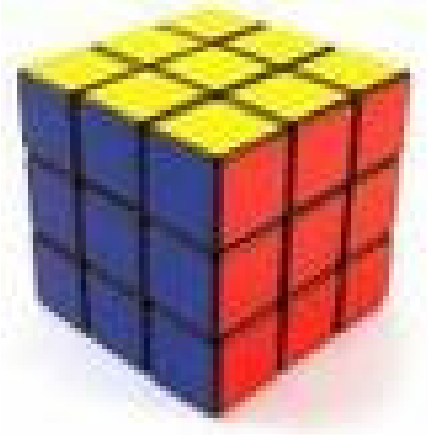
Organizational Systems

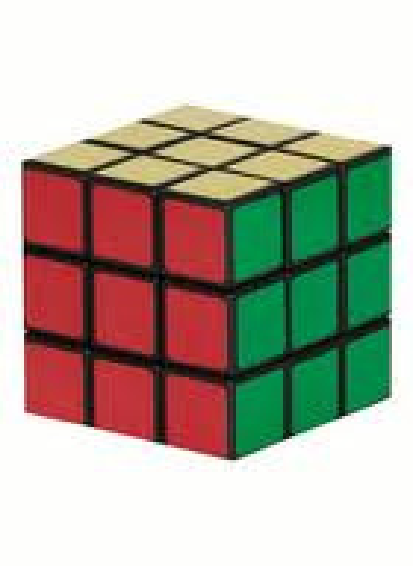
- Responsibilities
- Management Review
- Continuous Compliance
- ……

© Pharmaceutical Consultancy Services, All rights reserved.

DEPENDING FROM WHICH ANGLE YOU WATCH

We are talking about the same system.
Depending on where you stand, you might see something else, however it's still one system.





© Pharmaceutical Consultancy Services, All rights reserved.

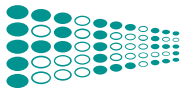
Performance or Quality ?

- 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 (!)

© Pharmaceutical Consultancy Services, All rights reserved.

CHANGE CONTROL & DEVIATIONS

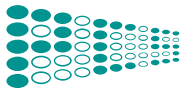
© Pharmaceutical Consultancy Services, All rights reserved.



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.....

© Pharmaceutical Consultancy Services, All rights reserved.



CHANGE MANAGEMENT: WHY

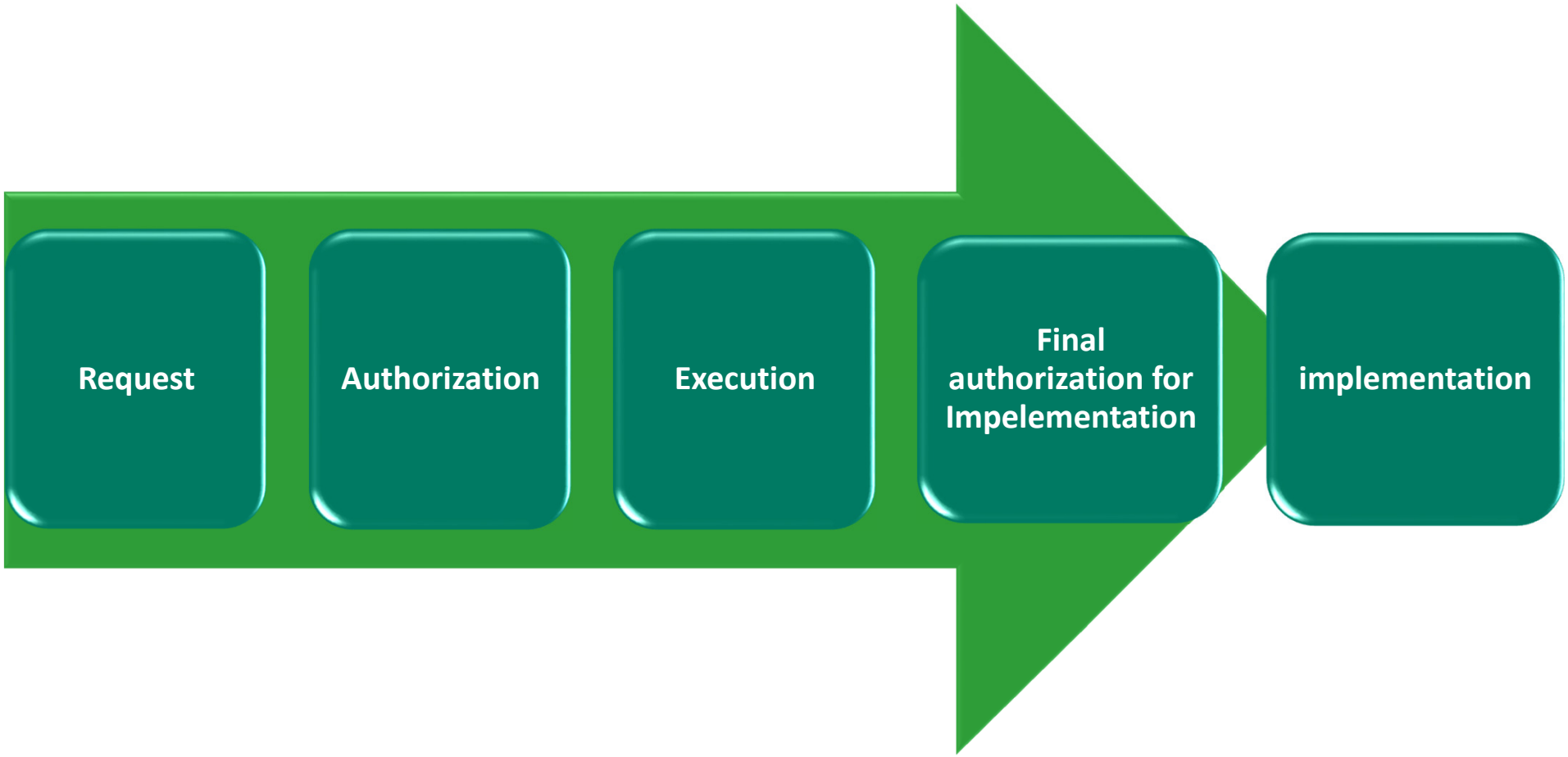
- Preventing undesired changes
- Careful considerations
- Planning of associated actions (SOP's/Validation)
- Communication of change
- Correct Documented Change.

CONTROLLED PROCESS FOR CHANGE

- Many ways to manage, e.g. Documentation (wherein the document itself the changes are managed)

© Pharmaceutical Consultancy Services, All rights reserved.

CHANGE CONTROL SOP

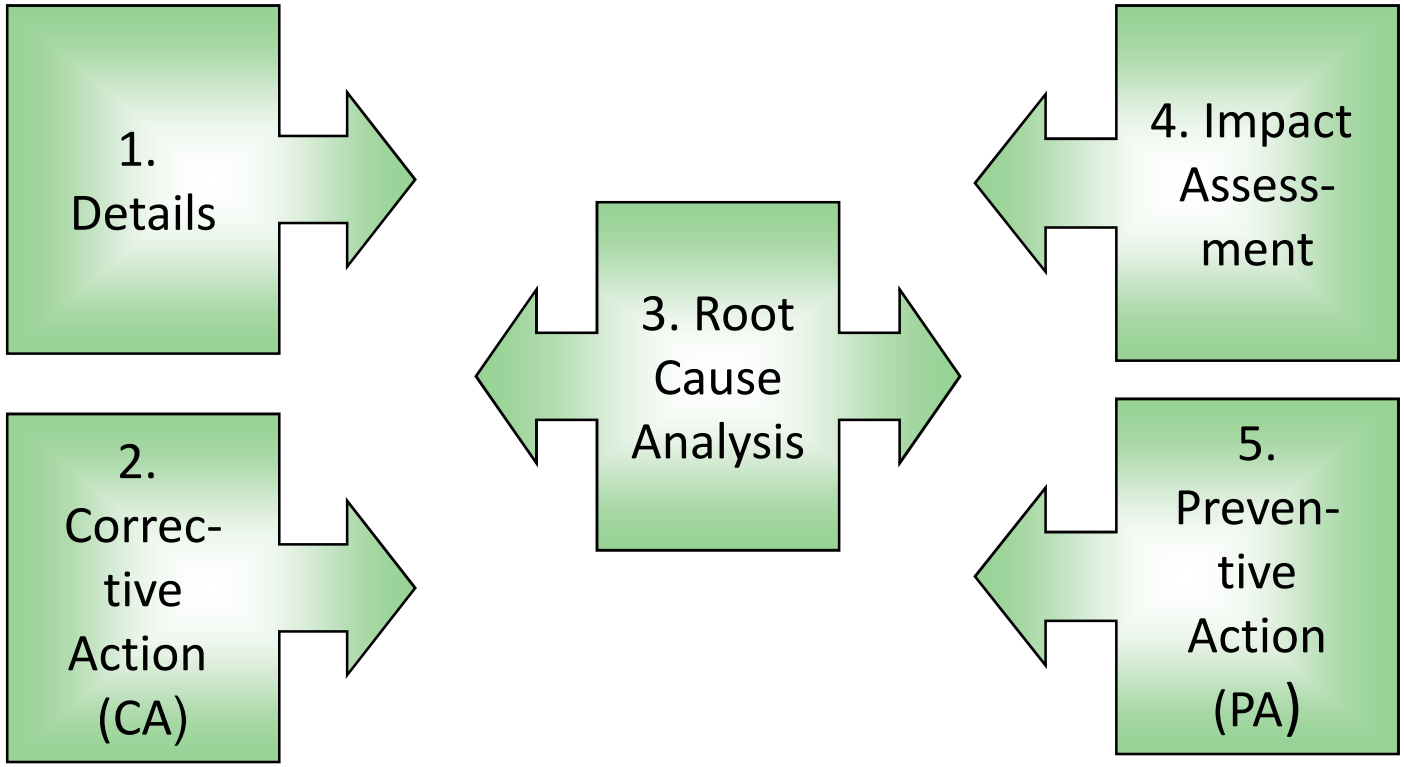


© Pharmaceutical Consultancy Services, All rights reserved.

DEVIATIONS

© Pharmaceutical Consultancy Services, All rights reserved.

DEVIATIONS



© Pharmaceutical Consultancy Services, All rights reserved.

SYSTEM FAILURE INVESTIGATION

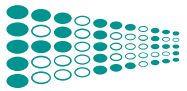
The process:

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 Anal
   - Risk Assessments

Industry Practice: close deviations in 30 days

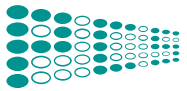
- CAPA systeem

© Pharmaceutical Consultancy Services, All rights reserved.



TRAINING

© Pharmaceutical Consultancy Services, All rights reserved.



TRAINING REQUIREMENTS

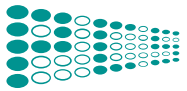
Or better: knowledge management (?)

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

© Pharmaceutical Consultancy Services, All rights reserved.

CONCLUSION

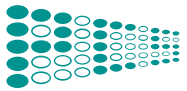
© Pharmaceutical Consultancy Services, All rights reserved.



Other QMS-Elements

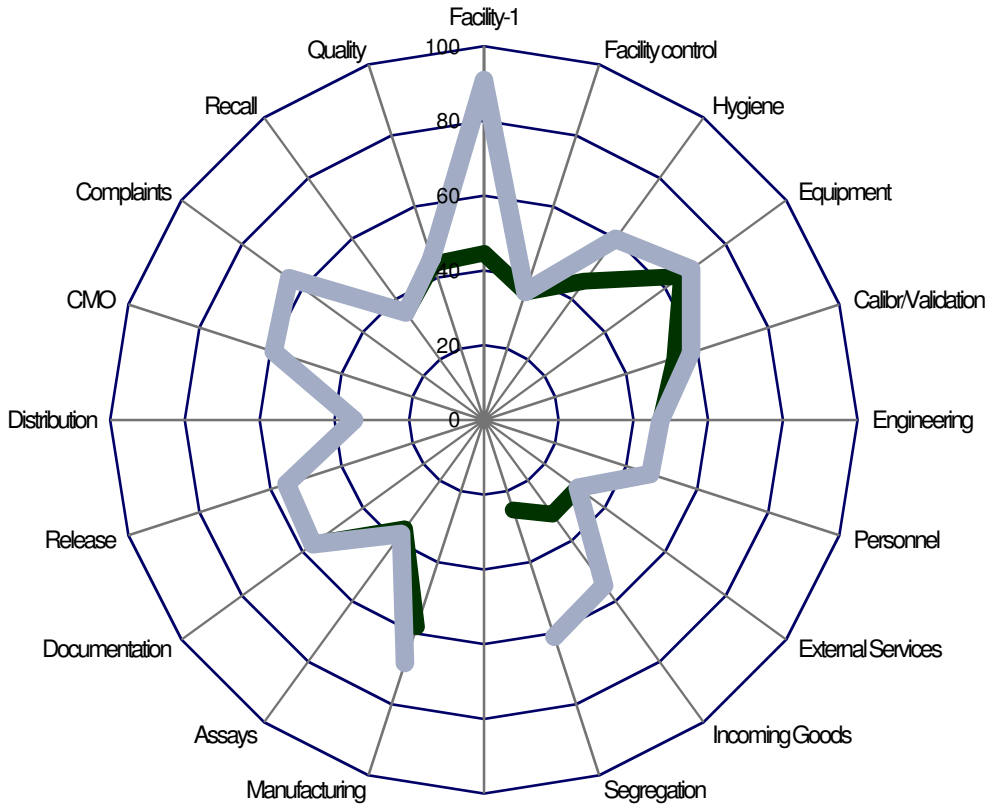
- Per individual QMS Element
  - Company Requirements
  - Regulatory Requirements
- Interactions between Requirements and/or Departments and/or Sites

© Pharmaceutical Consultancy Services, All rights reserved.



Checklist per QMS-Element

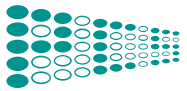
An example assessment of a QMS, including progress per element



© Pharmaceutical Consultancy Services, All rights reserved.

TESTING

© Pharmaceutical Consultancy Services, All rights reserved.



BY HAND RAISING

ICH-Q10 (PQS): QMS does function by managing its elements

OPTIONS:

1. TRUE
2. NOT-TRUE
3. DON’T KNOW

© Pharmaceutical Consultancy Services, All rights reserved.

BY HAND RAISING

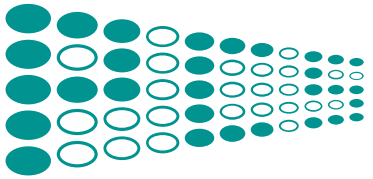
A QMS should be able to coop with ALL possible situations

OPTIONS:

1. TRUE
2. NOT-TRUE
3. DON’T KNOW

© Pharmaceutical Consultancy Services, All rights reserved.

THANK YOU FOR YOUR ATTENTION



PHARMACEUTICAL
CONSULTANCY
SERVICES

Veluwemeer 112
3446 JD Woerden
T +31 (0)182 – 503 280
M +31 (0)6 – 23 047 982
F +31 (0) 182 – 502 589
info@pcs-nl.com
www.pcs-nl.com