

# CQA and CPP

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July 2017



# Product & process focus exercise

- Product Critical Quality Attributes (CQAs)
- Critical Process Parameters (CPPs)

# What are these?

- Product - Critical Quality Attributes
  - The things that define the essential product quality
- CPPs (Critical Process Parameters)
  - The critical process parameter and ranges that ensure the CQA's are achieved (directly and indirectly)

# PQAs

Sterile

XX

XX

XX

XX

XX

Identity

XX

XX

XX

XX

XX

General Appearance



# PQAs examples

- Sterile
- Endotoxin free
- Particle free
- Volume
- Active concentration
- Purity
- Integrity container
- Shelf life stable
- Head space gas
- Batch i/d
- Label
- General Appearance



XXX

XXXX

Cleanroom  
(systems)

XXXX

## Potential CQAs

XXX

X

X

X

X

X

X



XXXXX

XXXX

XXXXX

XXXXX

XXXX

XXXX

XXXX

Cleanroom  
(systems)

Personnel  
controls

Water & steam  
systems

Business  
systems

Process Equipment  
(systems)

Facility Layout  
(system)

Maintenance

## Potential CQAs

Sterile

Endotoxin free

Particle free

Volume (Dose)

Active concentration (Assay)

Purity

Integrity of container

Shelf life stability

Head space gas (impurity  
control)



Quality  
System

Knowledge  
transfer

QC Testing

Monitoring Systems

Cleanroom (systems)  
Particle control  
Micro control  
Pressure Differences  
Recovery  
Air filters

Personnel  
controls  
Changing  
Garments  
Monitoring

Water & steam systems  
Pharmacopoeia specs  
Physical properties

Quality System  
SOPs  
Work procedures  
Interventions  
Training  
Process Validation

Process Equipment  
(systems)  
Manufacturing  
equipment  
Washing  
Filling  
Sterilising Filters

## Potential CQAs

Sterile  
Endotoxin free  
Particle free  
Volume (Dose)  
Active concentration (Assay)  
Purity  
Integrity of container  
Shelf life stability  
Head space gas (impurity  
control)



Business Systems  
Yield  
Efficiency  
improvements LEAN,  
Six sigma, CpK  
Work procedures  
Interventions  
Launch

Facility (system)  
Layout & flows  
Cleaning Disinfection  
Materials of construction

Knowledge transfer  
CQAs, CPPs., materials  
Manufacturing to  
development

Maintenance  
Preventative  
Equipment logs &  
manuals

QC Testing  
Physical, Chemical,  
Micro & Endotoxin

Monitoring Systems  
Airborne Particles  
Micro