

Commissioning and Qualification

Presented by Marc Fini
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Commissioning and Qualification

Performing qualification to avoid non compliance will lead you to failure.

Perform qualification to minimise the impact of risks on:

**Product
safety**

**Patient
safety**

Commissioning and Qualification

What is commissioning?



Engineering activity



Planned, documented and managed process



Start up and handover of 'systems'



Safety and functionality



DQ and stakeholder expectations



Find and fix problems

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What is qualification?



Science based




IQ, OQ, PQ



Documented verification that all aspects of a 'system' that can affect product quality, perform as intended



Confirm the critical functionality of direct impact systems



Targeted approach

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IQ

- Approved specifications, construction, materials and installation

OQ

- Operation as intended through all anticipated ranges

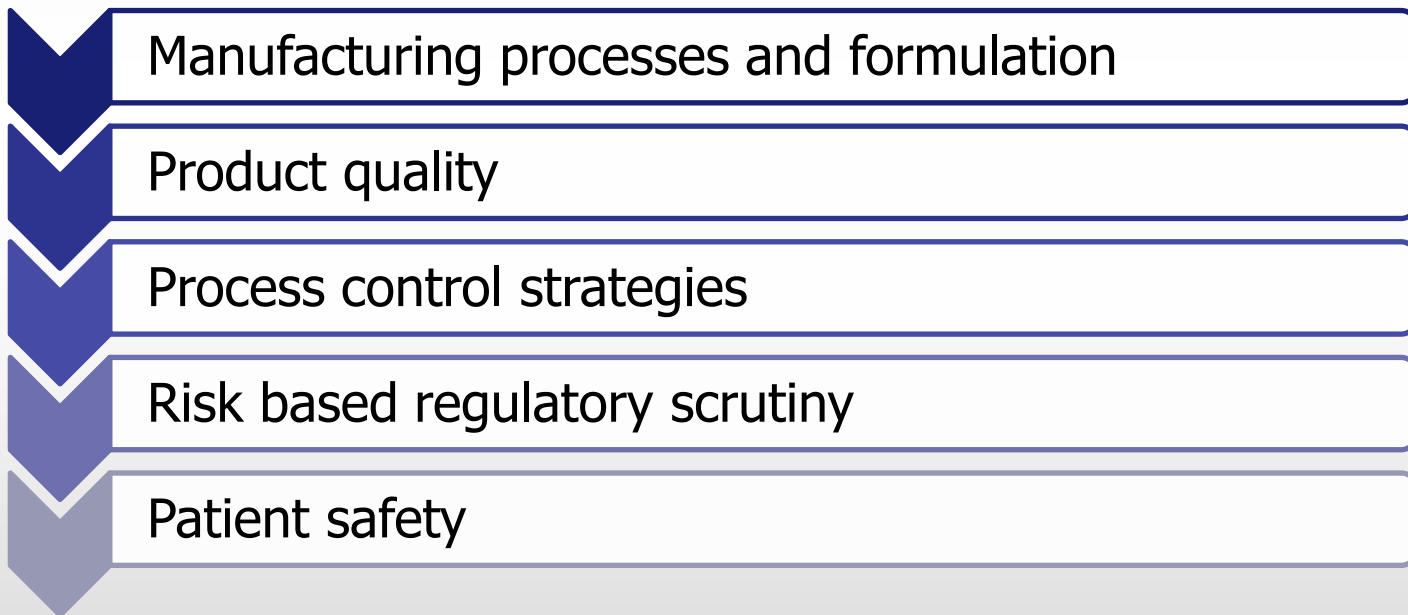
PQ

- Perform as intended, meeting pre-determines acceptance criteria

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Focus qualification on what's important.

Quality by Design (QbD)



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Risk based approach

- Design strategy
- Commissioning and Qualification strategy
- Automation and Maintenance strategies

Tools

- Commissioning and Qualification strategy
- Impact assessments
- Technology transfer

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Maintaining the validated state requires:

Operational
analyses

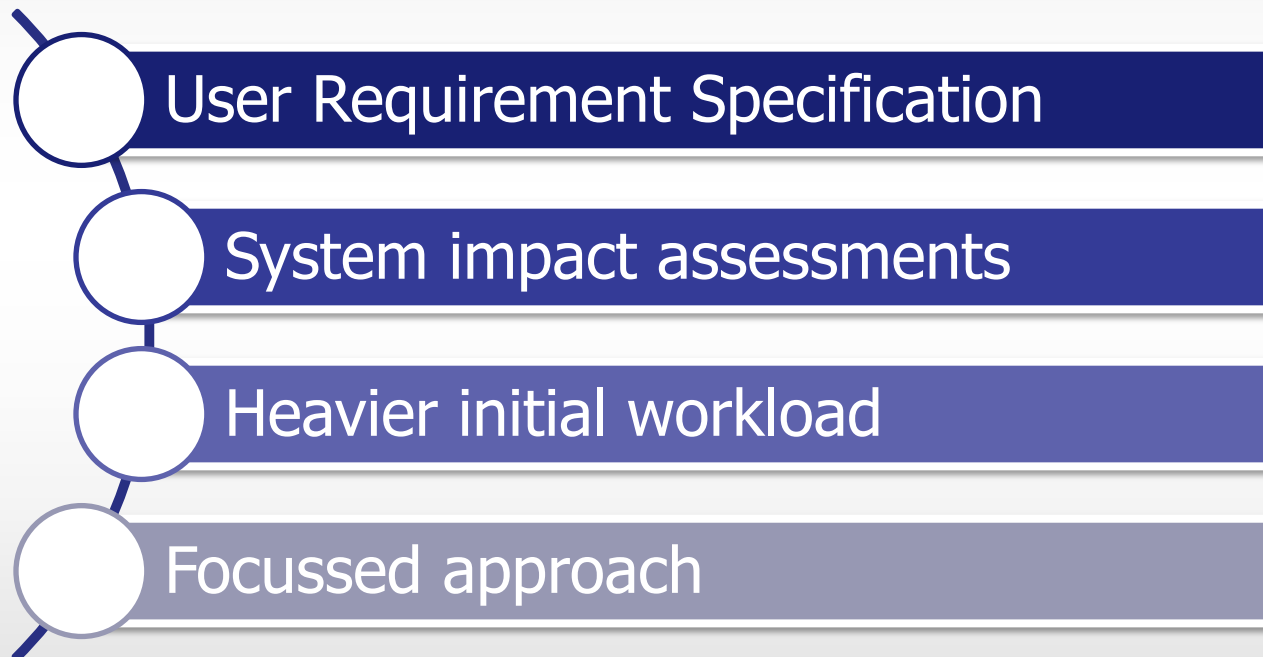
Change
management

Feedback
loop

Process
performance
reviews

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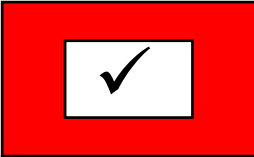

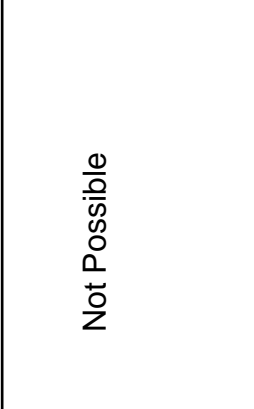

The basis for qualification:




Impact Assessment

Components

Systems

	Critical	Non-Critical
Direct Impact		
Indirect / No Impact		

 Commissioning only

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Costs

- Technology transfer
- URS
- Risk assessments
- Impact assessments
- DQ

Benefits

- Better engineered system
- Streamlined qualification
- Priorities
- Targeted approach
- Compliance

Commissioning and Qualification

There are components of commissioning and qualification that require careful management.

The methodology for change and deviation management needs to be determined before validation begins.

The commissioning and qualification effort needs:

- Engineering evaluation
- QA evaluation
- Project structure and strategies
- Tracking of implementation

