Pharmaceutical Container-Closure Qualification

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Suitable for its intended use?

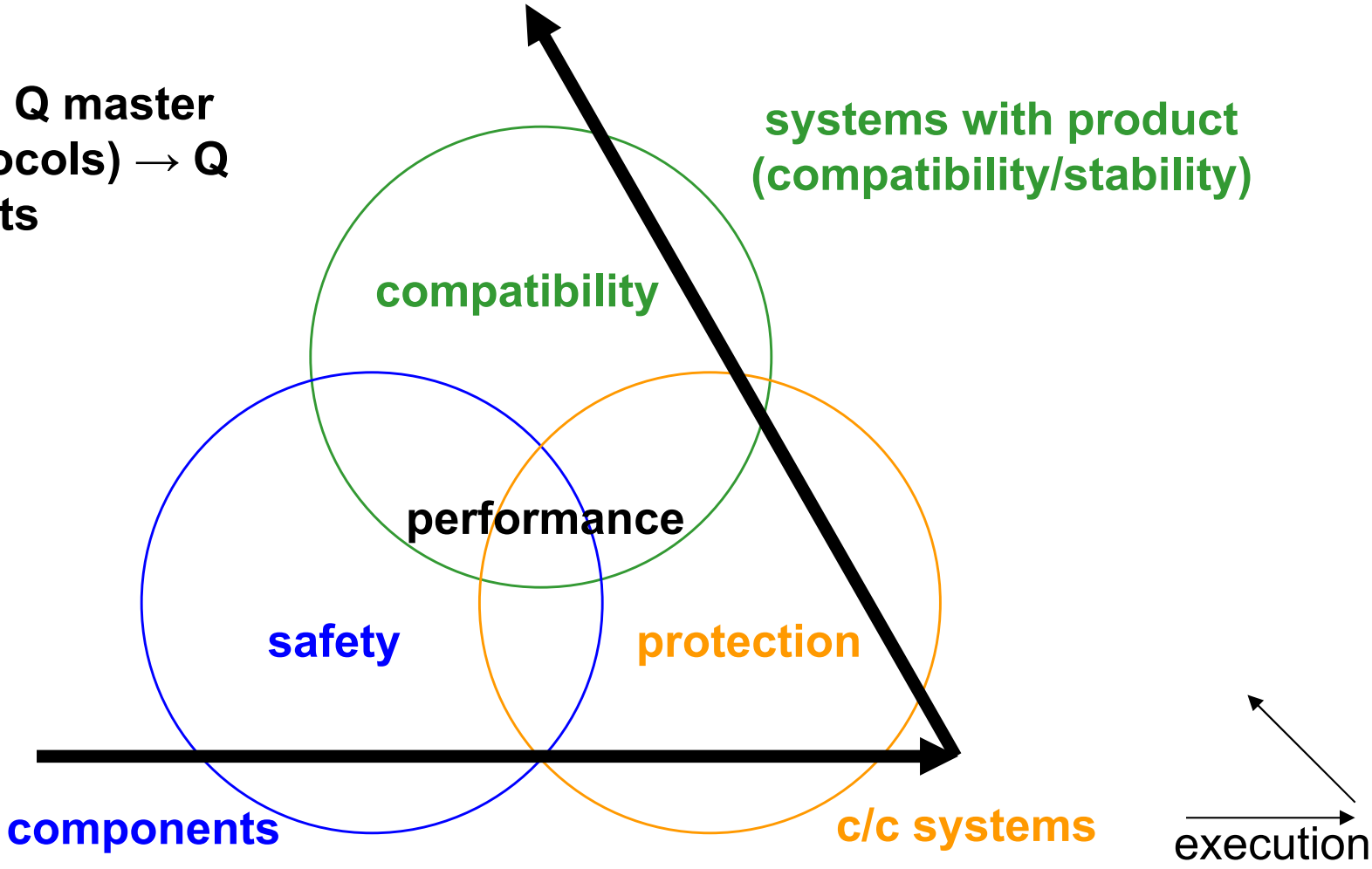
Safety

(Protection, Compatibility, Performance)

Show the evidence using scientific and engineering data!!

Container-Closure (C/C) Qualification Model

Deliverables: Q master plan → (protocols) → Q history reports



Resources

- Compendial testing: USP, EP, JP and other methods
- Guidance: FDA, EMEA and others
- Legal requirements: US, EU and others
- Supplier's certificate of assurance, drawings, etc,
- Drug product knowledge
- Technical experiences
- Other

Qualification Consideration for Components

Components: rubber stoppers, glass vials, aluminum seals, rubber plungers, plastic bottles, plastic CR closures, blister films, scavenging canisters, etc.

- USP/EP/JP: physicochemical test for elastomeric closures for injections, chemical resistance for glass containers (for injections), biological reactivity, etc
- Functionality and Machinability
- Regulations: heavy metals, animal sourcing
- Inspection suppliers & incoming QC strategy
- Other

Qualification Consideration for C/C Systems

C/C systems: glass vial/rubber stopper/aluminum seal, glass cartridge/disc seal/rubber plunger, glass syringe/rubber plunger, plastic bottle/IHS closure, blisters, bags, etc.

- WVTR
- Dimensional stacked tolerance
- OxTR
- Sealing/Integrity
- Machinability
- Functionality

Qualification Consideration for Systems w/ Product

- Prediction modeling (drug stability, moisture, oxygen)
- Package screening study
- Product stability
  - Leachables
  - Compatibility

Conclusions

Suitable for its intended use?

Scientifically Proven
Qualification Report

Medicines can be delivered to patients safely!!

Q&A