RECENT TRENDS OF BIOPHARMACEUTICAL PRODUCT, PACKAGING AND DEVELOPMENT

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FACTS ABOUT BIOPHARMACEUTICALS

Synthetic to biologics

Quality

Safety

Empirical to QbD

GDP

Regulation

Approval

Global

Combination product

Precise control

Cold chain

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BIOPHARMACEUTICAL PRODUCT

Vial	Prefilled syringe	Auto injector	Connected device
Supply Stability	Dose accuracy Convenience	Dose accuracy Convenience Patient compliance	Dose accuracy Convenience Enhanced patient compliance

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BIOPHARMACEUTICAL PACKAGING

Container Closure System

GMP requirements:

Safety, compatibility, protection and functionality

Combination product (Biologic + device)

GMP requirements +

Quality System requirements:

Design control

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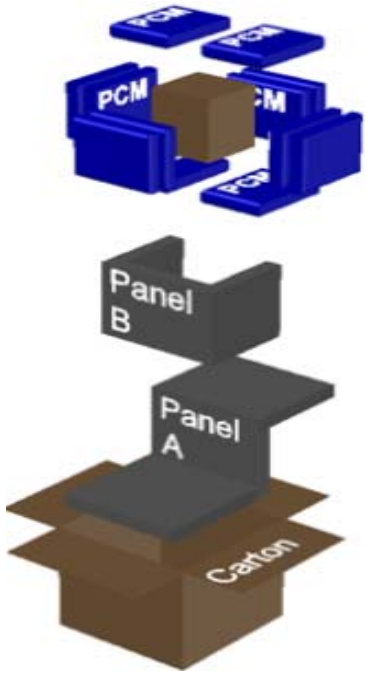
COLD CHAIN INSULATION SHIPPER



Polystyrene or Polyurethane insulation + water based PCM

Polystyrene insulation + Vacuum panel + water based PCM or gel

Example, Polystyrene insulation + water evaporation under vacuum

Lighter, smaller, improved thermal efficiency PCM

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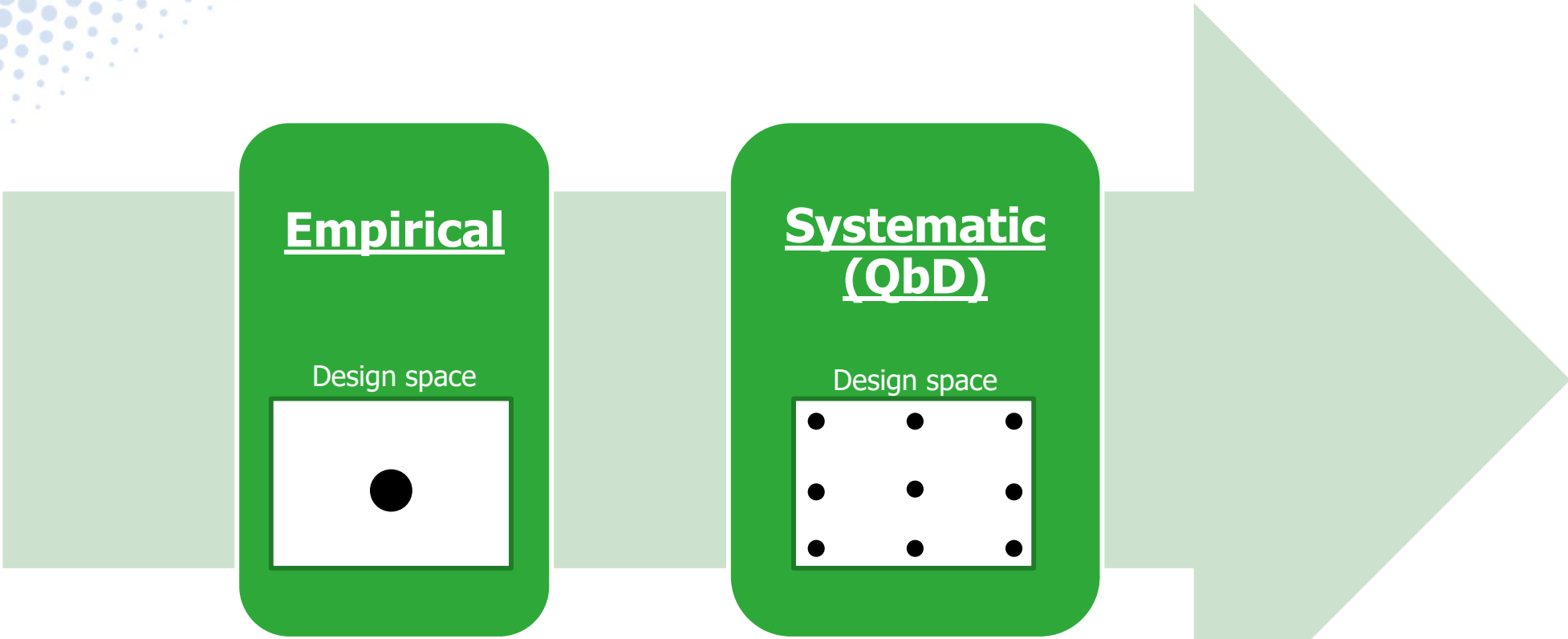
PHARMACEUTICAL DEVELOPMENT



e.g., 100 tests with target

e.g., 10 tests with extremes + 10 tests with target + 1st principles

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PHARMACEUTICAL DEVELOPMENT (CONTINUED)

Quality by Design (ICH Q8 Pharmaceutical Development)

- Knowledge, DOE, and risk management
- Better understand product development strategy
- Knowledge gained over the product lifecycle
- Regulatory expectation
- Examples: device design verification, predictive modeling using 1st principles

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