Implementing Custom Single-Use Solutions for Cellular Therapy

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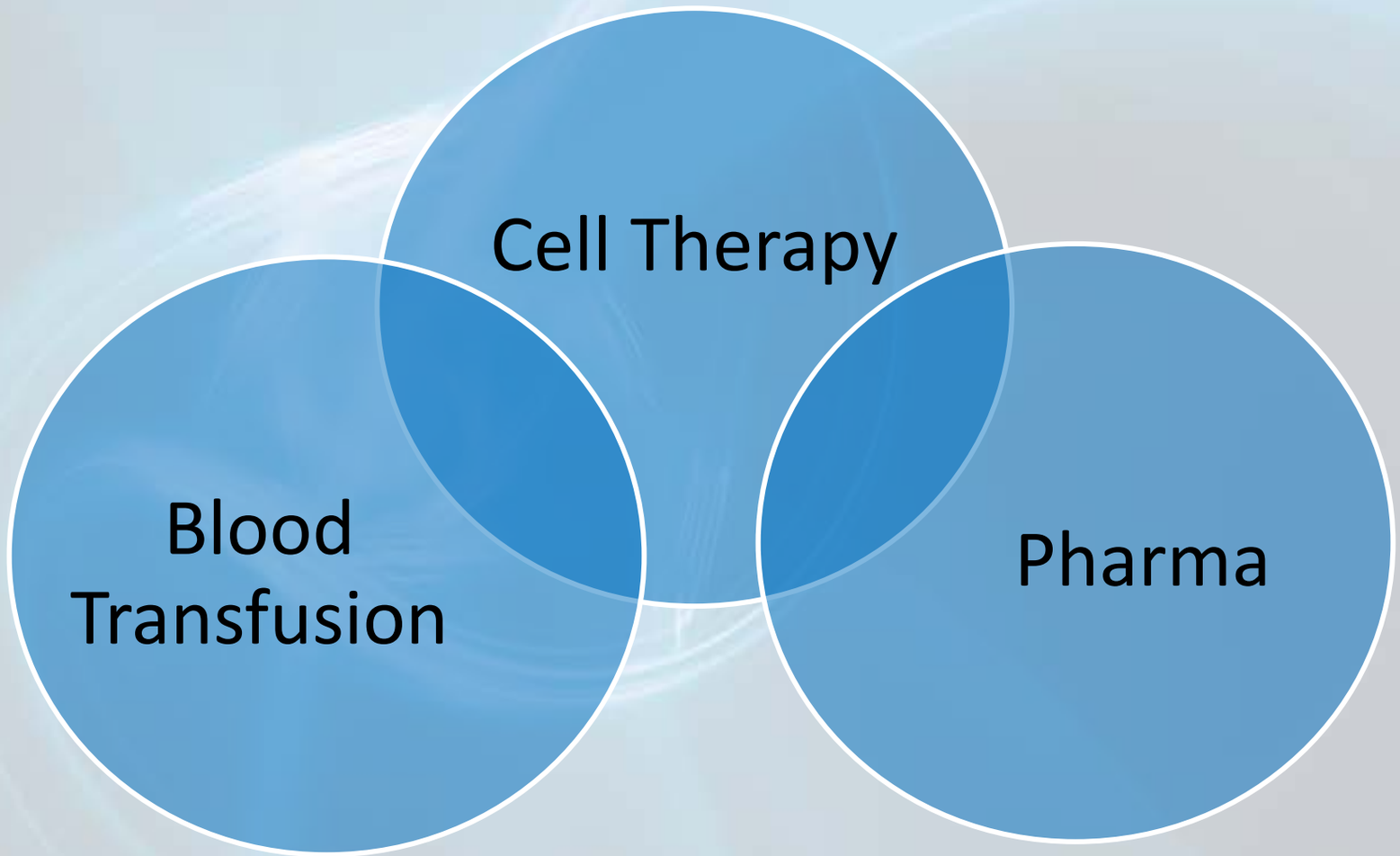
Industry Overlap and Process Development



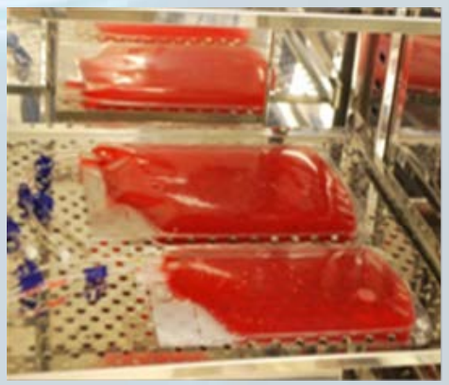
Consider the entire process to understand the different requirements

Single-Use Solutions for Cell Therapy

Items to consider during process development

- Challenges to closing the system at early stages
- When is the right time to close the processing steps
- Benefits to implementing custom closed-system processing designs
- Steps to consider when trying to optimize production scale
- Assembling and implementing custom closed-system solutions

“Open”



“Closed”

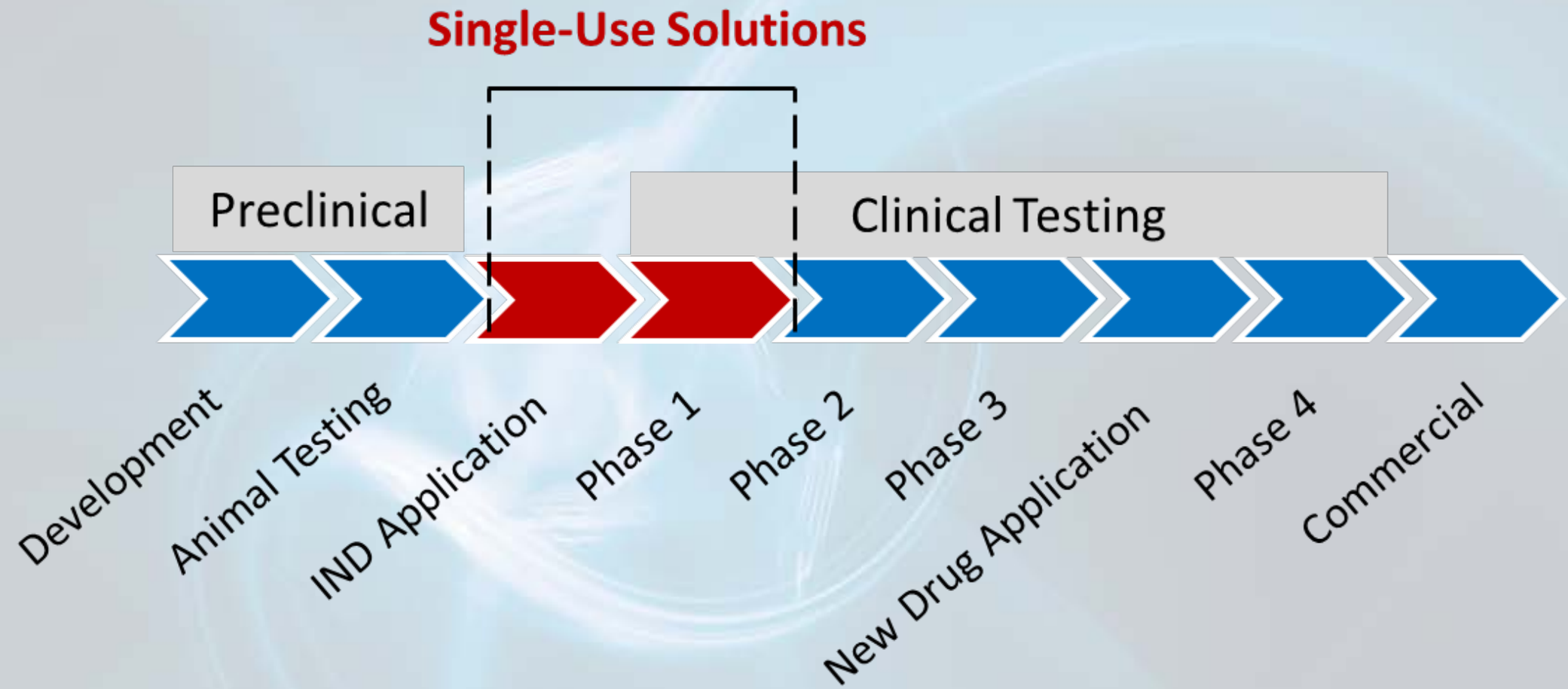
Single-Use Closed-Systems for Cell Therapy

Early stage manufacturing/processing hurdles

- Numerous manual/open steps
- Optimal product dosing and delivery has yet to be established
- Limited batch sizes and need for custom products
- Potential cost of developing custom products can be a deterrent
- In-house personnel “manufacturing” own custom designs
- Not scalable and tend to lack necessary validation
- Regulatory hurdles to be considered

Process changes become more difficult with each clinical phase

When to Close the System



Steps to close your system should be implemented as early as possible

Benefits to Implementing Custom Single-Use Systems

- Improve process flexibility and scalability
- Reduce number of manual steps and minimize opportunities for possible product contamination
- Improve batch to batch consistency by enabling efficient and reproducible processes
- Reduce production times
- Cost effective for early stage smaller scale applications
- Help enable bench to bedside application
- Facilitate plug-and-play process which can be more readily scaled up/out at later stages (ex. Commercial scale automation)

Validated, closed, presterilized process may reduce regulatory scrutiny

Road Blocks to Implementing Closed-System Solutions

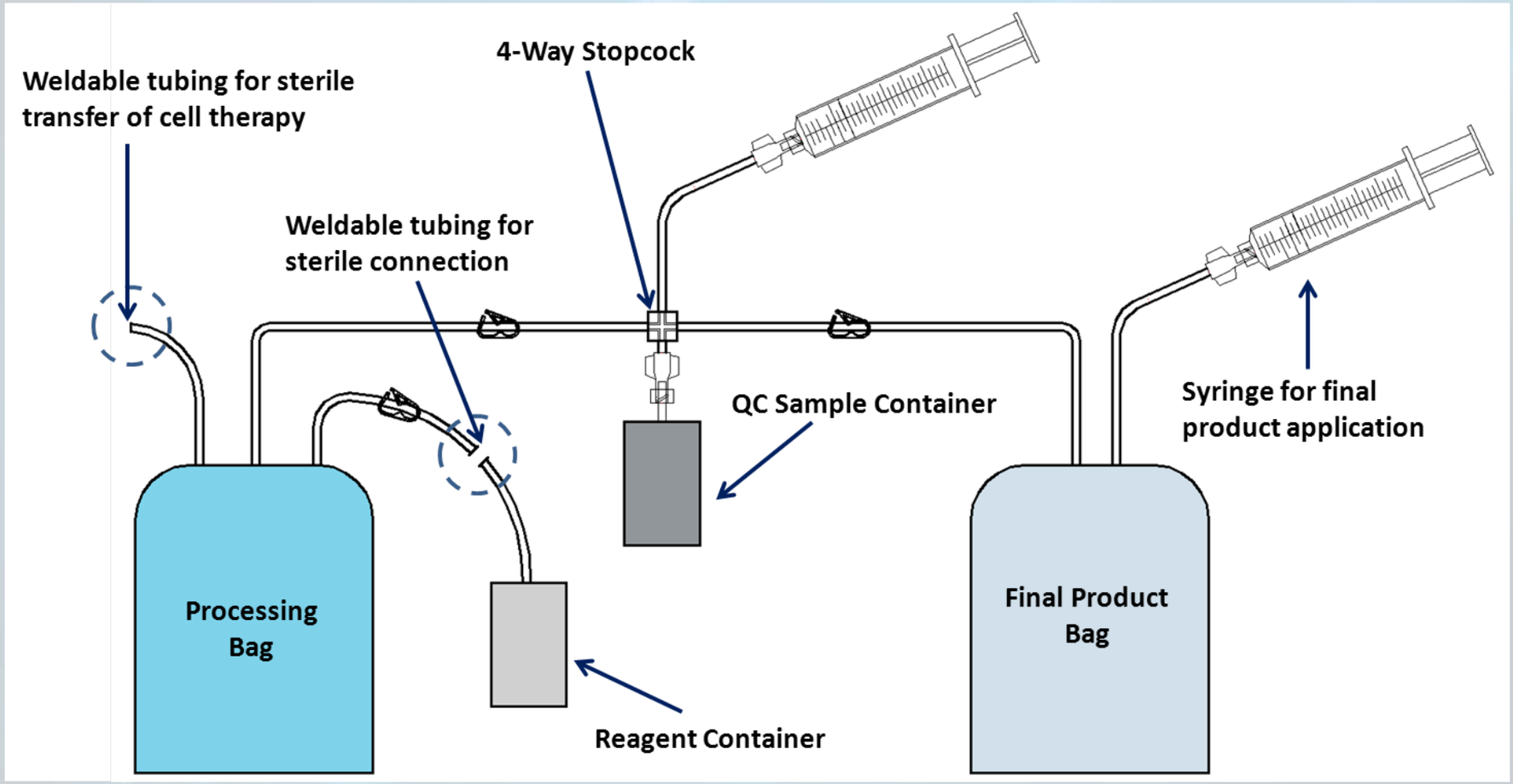
- Reasons for using in-house internal capabilities
  - Early stage doesn't require same process scrutiny
  - Unaware of impending manufacturing scaling challenges
  - Cost of development
  - Cost of goods (CoG)
  - Lack of internal expertise for process development
  - Lack of available manufacturers willing to commit to building custom products due to small batch sizes

In-house customization – temporary solution but isn't best practice

Implementing Custom Solutions for Cell Therapy

- Evaluate processing requirements to transition from early to late stage
  - Helps to understand potential processing scale up/out and where improvements are required
- Establish early relationship with disposables manufacturer
  - Expertise in films/plastics (characteristics, L&E, etc.)
  - Knowledgeable in developing closed systems
  - Perform necessary validation, sterilization, quality assurance
  - cGMP
  - Knowledgeable in regulatory requirements
  - Identify and develop scalable, safe and effective solutions

Custom Solution Example



Developing safe and effective solutions for long-term product success

CharterMedical

THANK YOU

For More Information:

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