Building Scalable Cell Therapy Workflows:

Media, Process, and Automation in Action

FUJIFILM Biosciences
Advanced Therapies Week, 2026

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Value from Innovation

From Early Choices to Commercial Outcomes

- Address the challenges in Mesenchymal Stromal/Stem Cell (MSC) therapy development
- Reduce process variability
- Embed GMP considerations early
- Leverage Automation
- Preparing MSC processes for commercial manufacturing

Build the right foundation.

Welcome to the Workshop

Moderator
Jeff Martin, PhD
Founder
Flyte Bio

Introduction

- Jeff Martin- Moderator
- **Workshop Format**
  - Gather into 4 table groups
  - 5minute table discussions
    - Rotating panelists
  - Summary/Recap
- **Panelist Introduction**
  - Featuring topic insight
- **Table Topics**
  - Quality and Material Control
  - Consistent and Scalable Protocols
  - Automation and Scale-up
  - Supplementation RUO-to-GMP

Consistent and Scalable Protocols

Yosuke Kurokawa
R&D Manager, Cell Therapy
FUJIFILM Biosciences

Priorities for scalable cell therapy workflows

- Balancing performance and clinical scalability
- Managing raw material selection
- Transitioning protocols from bottles to bags

Lesson Learned

- It’s never too early to start planning for scale-up

Takeaway

- Solution providers must work together as partners to offer the best solution to therapy developers

Supplementation RUO-to-GMP

Bill Mirsch
Chief Executive Officer Mill Creek Life Sciences

Priorities for scalable cell therapy workflows

- Develop processes with GMP ready materials
- Perform screening studies at appropriate scale
- Determine appropriate passage/harvest timing

Lesson Learned

- Using rich media can reduce supplementation requirements, increase yield/potency and reduce time in culture

Takeaway

- Start process development with scaled production in mind. Partner with ancillary materials companies that can provide technical support to shorten development timelines

Automation and Scale-up

Dalip Sethi
Senior Commercial Leader, Cell Therapy Technologies
Terumo BCT

Priorities for scalable cell therapy workflows

- Understand the critical quality attributes prior to scaling the production
- Plan for electronic documentation of manufacturing processes
- Understand the process from beginning to end to optimize the workflow

Lesson Learned

- Early automation lowers the burden at later stages for development
- Allocate sufficient time and resources for process transfer

Takeaway

- Automation provides the benefits for cell manufacturing, finding the right technology that is fit for purpose is the key. In addition to the cell culture step, consider the complete workflow to optimize manufacturing.

Quality and Material Control

Jeff Shumway
Regional Account Manager, Life Sciences
Entegris

Priorities for scalable cell therapy workflows

- Raw material selection:
  - Defined purity
  - Controlled particles
  - Clear intended vs. contaminant risk
- Optimized Packaging Solutions
  - "Particle Free"
  - USP 665/1665 Implications
- Closed-system processing
  - Prevent/Detect/Remove Strategy

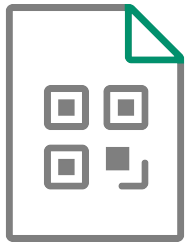
Lesson Learned

- Upstream choices drive downstream quality

Takeaway

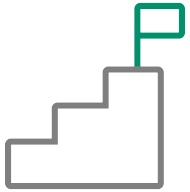
- Quality and scalability start with intentional material selection, packaging and system design

Expert Exchange: Table Topics



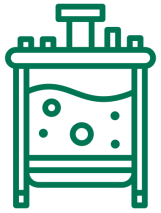
Quality and Material Control

- Contamination and risk
- Filtration and fluid handling
- Quality from day 1



Consistent and Scalable Protocols

- Scalability
- Donor and Raw material variability
- Early standardization



Automation and Scale-up

- Process efficiency
- Bottles to closed-system
- Improves consistency

Supplementation RUO-to-GMP

- Supplement selection
- Consistency and compliance
- Smooth transition

Consistent Themes that Emerged

The need for earlier alignment on scalability and materials selection

The importance of reducing variability through standardized, GMP-ready solutions

The value of partnerships that extend beyond products into data and process support

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