

## ASK THE EXPERT

# Rethinking Cell Therapy Logistics From the Ground Up

with Kevin McHugh

The biopharmaceutical industry is undergoing a fundamental transformation as manufacturing shifts from protein biologics to highly personalized cell therapies. That evolution represents a significant departure from the historically centralized, linear production models that characterized the past few decades of bioproduction. Whereas traditional manufacturing focuses on scale, repeatability, and efficiency through homogeneous batch production, cell therapies introduce unprecedented operational complexity by requiring individualized treatments tied directly to specific patients. In a May 2026 Ask the Expert webinar, Kevin McHugh (process expert for product excellence automation at Sartorius) described how the new paradigm of cell-therapy manufacturing necessitates adoption of advanced tools for process orchestration.

### The Cell-Therapy Manufacturing Journey

The operational journey for cell therapies involves numerous interconnected touchpoints, each introducing distinct dependencies and risks. Such factors include treatment urgency, collection variability during apheresis, manufacturing-capacity constraints, cryogenic-shipment integrity, potential for release delays, and highly coordinated patient-specific delivery. Unlike traditional supply chains designed around forecast-driven inventory and standardized distribution, cell-therapy operations require dynamic scheduling coordination, individualized traceability, and multiparty orchestration.

The solution lies in transitioning from fragmented coordination models to connected operations platforms that distribute process information in real time across apheresis centers, drug manufacturers, couriers, quality teams, and treatment centers. Such an approach — which McHugh calls a “ground-up orchestration approach” — creates digital workflows, end-to-end traceability, and

automated response systems for operational events such as temperature excursions, documentation gaps, and equipment availability issues.

For example, a temperature excursion is detected during a cryogenic shipment. Typically, resolving this might include phone calls, email chains, manual investigation, and delayed coordination. In a connected operations model, the response becomes orchestrated and workflow-driven. The system detects the issue in real-time, triggers automated alerts, engages stakeholders, initiates investigation workflows, and coordinates operational adjustments.

By implementing workflow-enforced chain of identity verification and dynamic rescheduling capabilities, organizations can achieve real-time operational visibility, faster coordination, and more stable commercial operations. Such systems, including the Biobrain Operate manufacturing execution system (powered by Tulip’s digital platform), create a foundation for scalable cell-therapy delivery at commercial scale.

### Questions and Answers

**Can Sartorius customize applications based on customer need?** Yes, and we also can create applications on demand. We can interface different instruments and cater to your facility needs.

**Is knowledge of computer coding required to use the Biobrain Operate system?** The Biobrain Operate system is a no-code interface. Additionally, customers can customize the interface on their own. The idea is to give users the means to customize as needed.



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