Integrated Design of Facilities and Operations for Autologous Cell Therapies

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Bio

• Aaron Vernon
• VP, Engineering & Supply Chain for Autolus Therapeutics
• 20+ years of experience in supply chain management, manufacturing, business process development, organizational transformation, and facility design/construction at Johnson & Johnson, MedImmune, AstraZeneca, Sucampo, and Autolus.
• At Autolus he is responsible for building the company’s manufacturing and supply network, including the recently announced US manufacturing center in Rockville, Maryland. He lives in Dayton, Maryland with his wife, 3 children, and his dog.
Business Context -
An Explosion of Autologous Cell Therapies

• Since 2012, there has been an explosion of autologous cell therapy assets in early development, but only a handful have been commercialized.

• Sudden onset of demand has led to major capacity crunch – both internal and external (CDMO).

• Drug developers and CDMOs are beginning to invest heavily in capacity.

• How do companies build capacity to meet their near and long-term needs?
Autologous Cell Therapies Are Different

- Circular supply chains
- More network nodes (internal and external)
- Newer, less mature technologies
- Scaling up vs out
- Zero finished goods inventory
- Defined vein to vein cycle times
Autologous Therapies Require An Integrated Service Model

- Ordering
- Scheduling
- Infusion
- Apheresis
- Transportation
- Manufacturing
Their Supply Chains are Complex and Multi-Nodal

- **Hospitals**: Cancer centers of excellence around the country and world
- **Manufacturing Sites**: Centralized or decentralized manufacturing within a region
- **Suppliers**: Raw material suppliers, including tier 2 and tier 3 suppliers
- **Logistics Partners**: 3PLs, warehouses, freezing centers, and customs clearance sites
MONOCLONAL ANTIBODIES

DS supply capacity is **highly dependent** on product/process

DP supply capacity is **dependent** of product/process

ORAL SOLID DOSAGE

DS supply capacity is **dependent** on product/process

DP supply capacity is **independent** of product/process

CELL THERAPIES

DS supply capacity is **highly dependent** on product/process

DP supply capacity is **highly dependent** of product/process

Capacity Depends on Facility and Operational Design
Facility and Operational Designs Are Inextricably Linked
Operational Design Considerations

DIGITAL SYSTEMS
Design should consider what digital business systems to implement and integrate to enable efficient operations.

MATERIALS MANAGEMENT
Design should consider how materials will be delivered, stored, kitted, and moved throughout the facility.

RAW MATERIALS
Raw materials and components should be selected to enable efficient use within facility, minimizing bottlenecks.

SHIFT STRUCTURE
Design shift structure to provide sufficient support considering process requirements. Increased automation and remote monitoring systems may enable decreased staff coverage.

COST OF GOODS
Design should consider cost of goods, including forecasted changes in COGS over time. Increased automation

LOGISTICS
Design should consider how starting materials come to site, how drug product is shipped to patients, and long term storage of retain samples.
Facility Design Considerations

**EFFICIENT MATERIAL FLOW**
Facility design should maximize efficient flow of materials, and waste. With no economies of scale, facility capacity will be limited by material flows.

**DESIGN FOR LEAN SIGMA**
Utilize Design for Lean Sigma to improve efficiency. Maximize use of visual management tools, poke yoke, and value-stream mapping.

**AUTOMATED VS. MANUAL PROCESSES**
Facility and process design should consider the use of automation to reduce variability, lower costs.

**FLEXIBILITY**
Design must balance flexibility for future process changes with cost of that flexibility.

**OPEN VS. CLOSED PROCESS**
Design should attempt to use closed processes in order to minimize impact to room classifications and flows. Aseptic connections should be utilized to minimize use of isolators for additions and extractions.

**BUSINESS CONTINUITY**
Design should consider business continuity and resilience of facility. Focus should be made on risk to operations due to loss of electricity and other utilities.
Design, Verify, Execute Methodology

- **Capacity & Process**
  - Determine desired capacity and process requirements

- **Operational Requirements**
  - Define operating requirements and philosophy

- **Facility Design**
  - Design facility to meet operational and capacity requirements

- **Design Validation**
  - Confirm design meets requirements via discrete event simulation

- **Execution**
  - Build, validate, and operate facility
Thank You.

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