Integrated Design of Facilities and Operations for Autologous Cell Therapies

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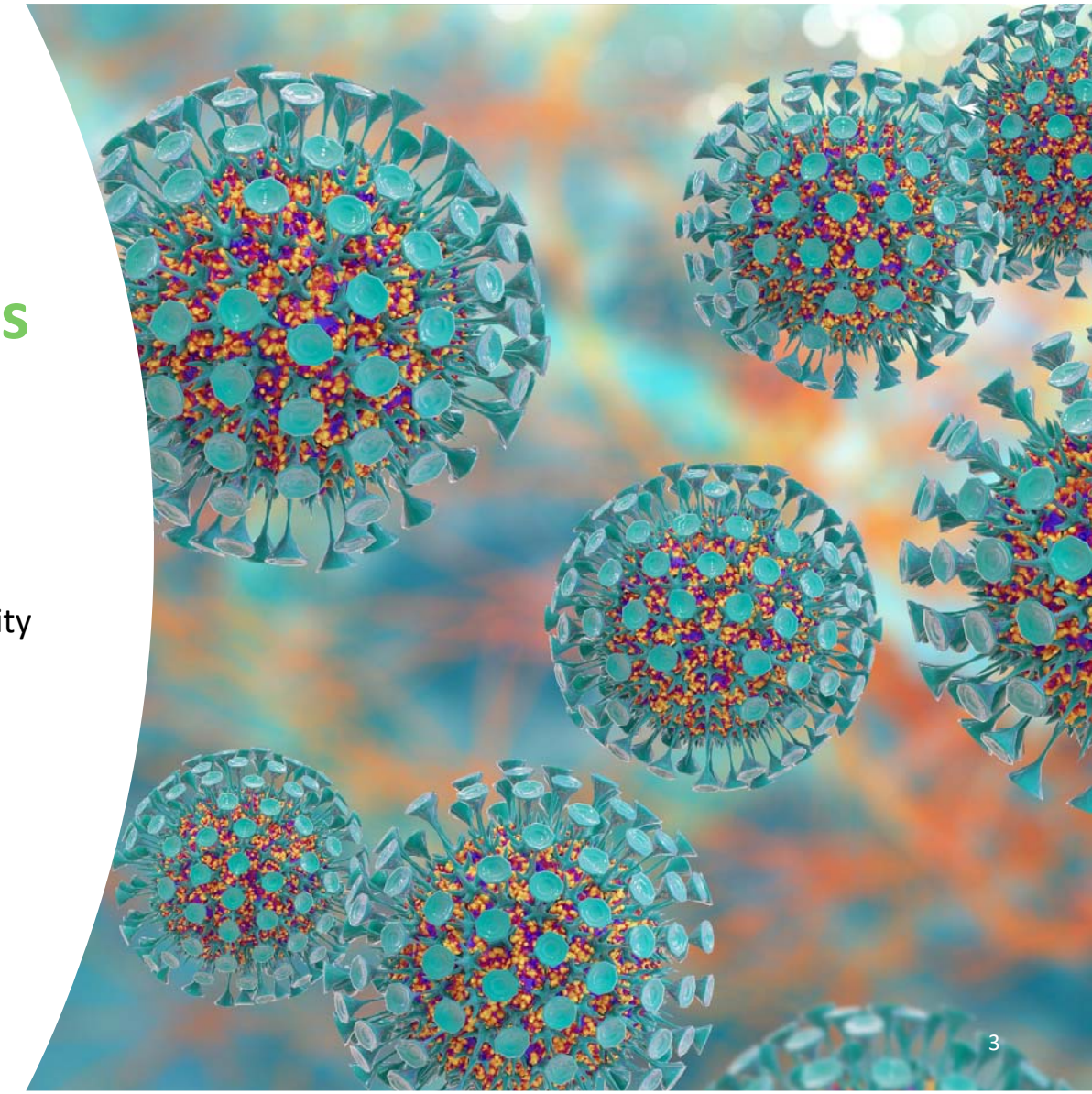
Bio

- 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.

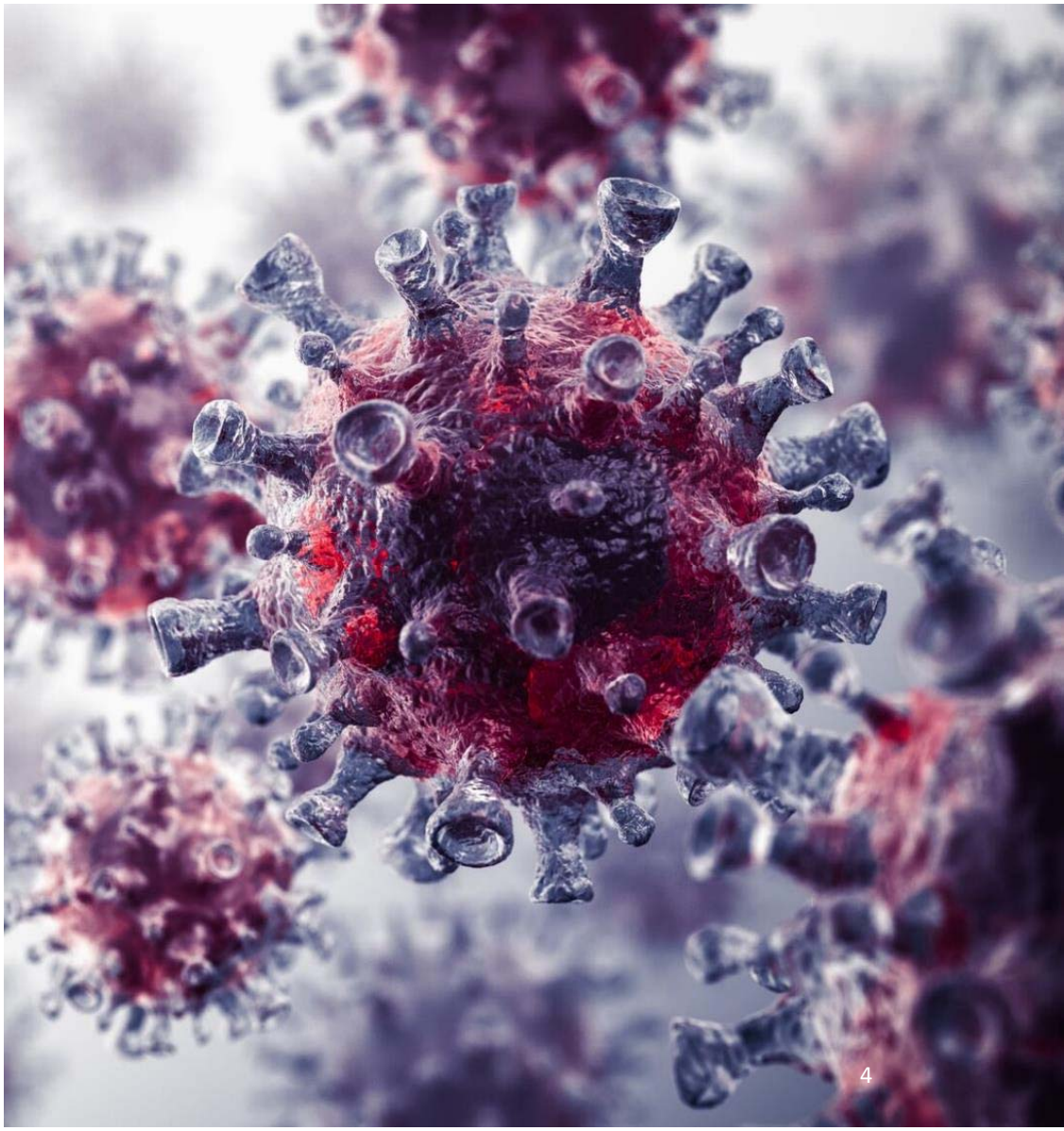
Business Context -
An Explosion of Autologous Cell Therapies

- 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?



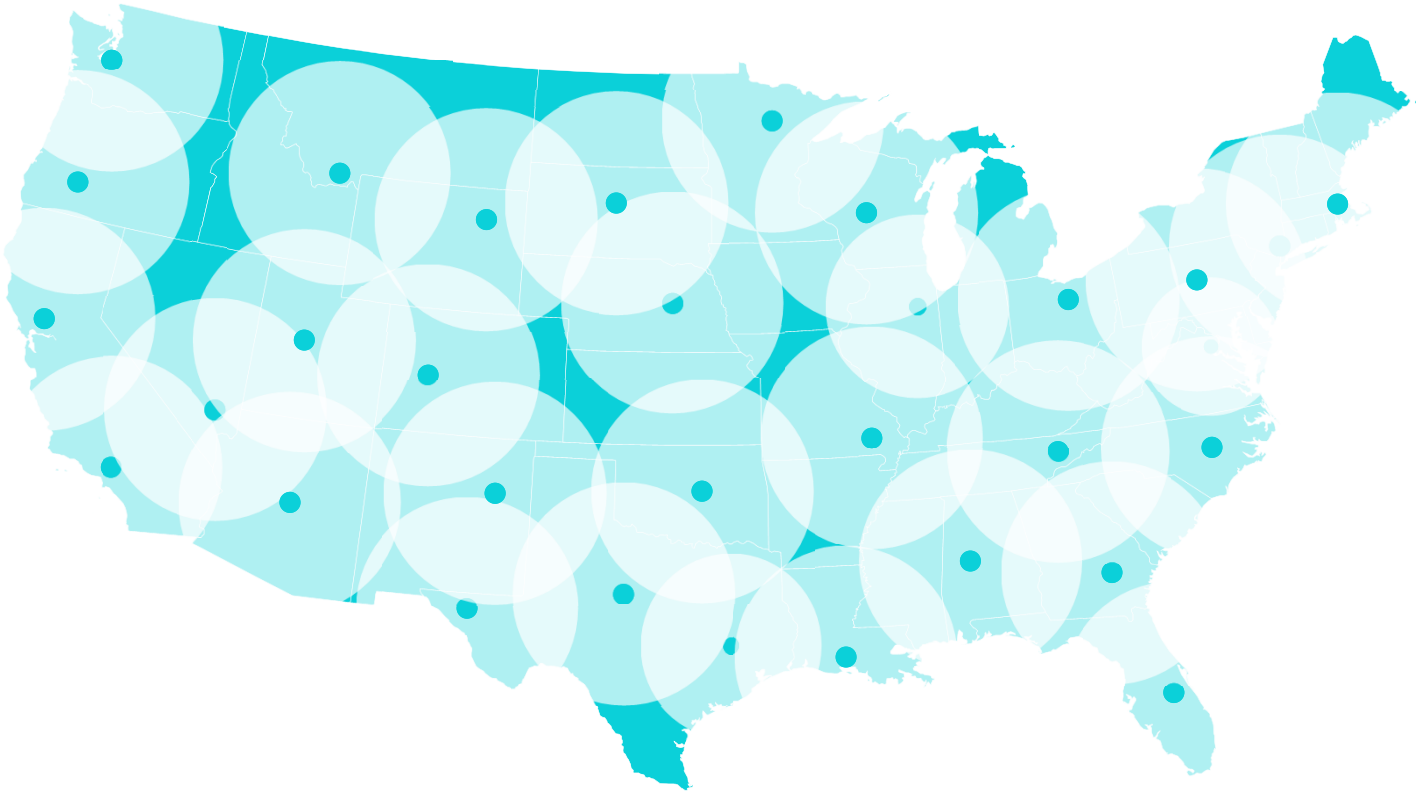
Autologous Cell Therapies Are Different

- 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

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

Capacity Depends on Facility and Operational Design

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

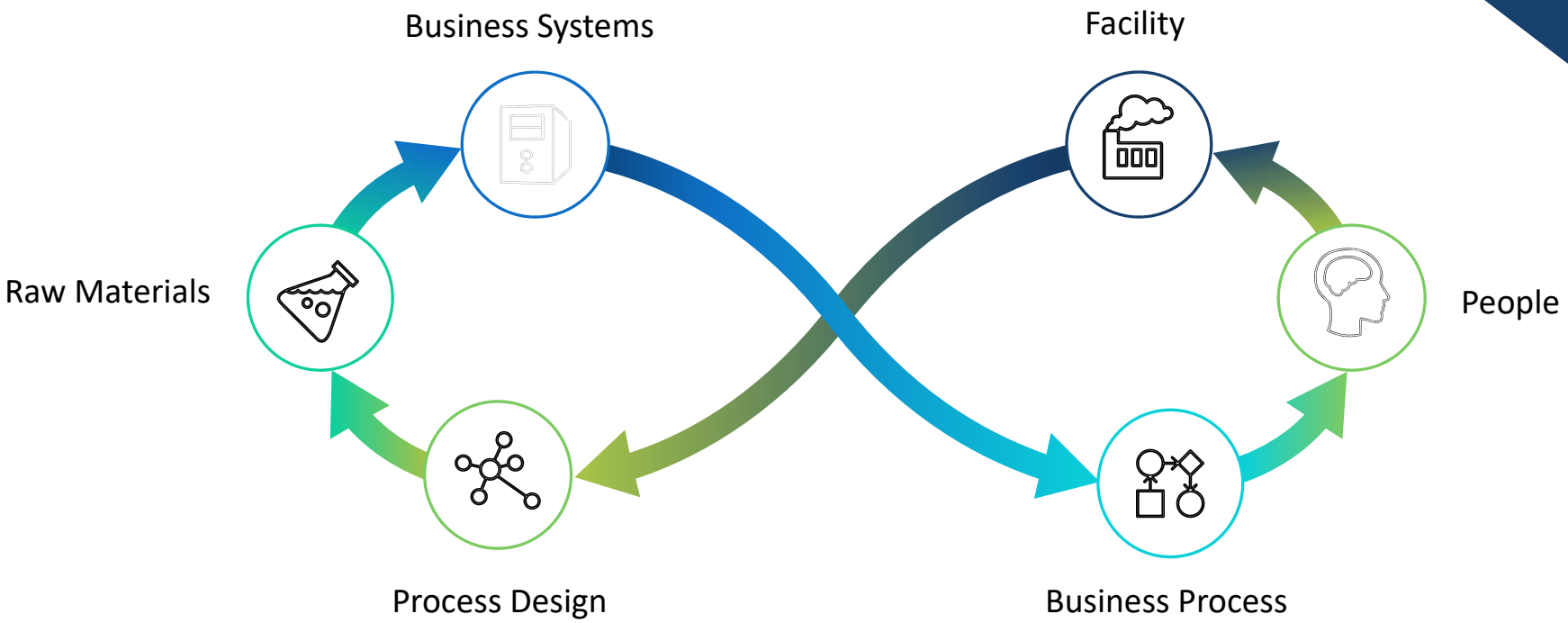
DP supply capacity is **independent** of product/process

CELL THERAPIES

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

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

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.

FLEXIBILITY

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

DESIGN FOR LEAN SIGMA

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

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.

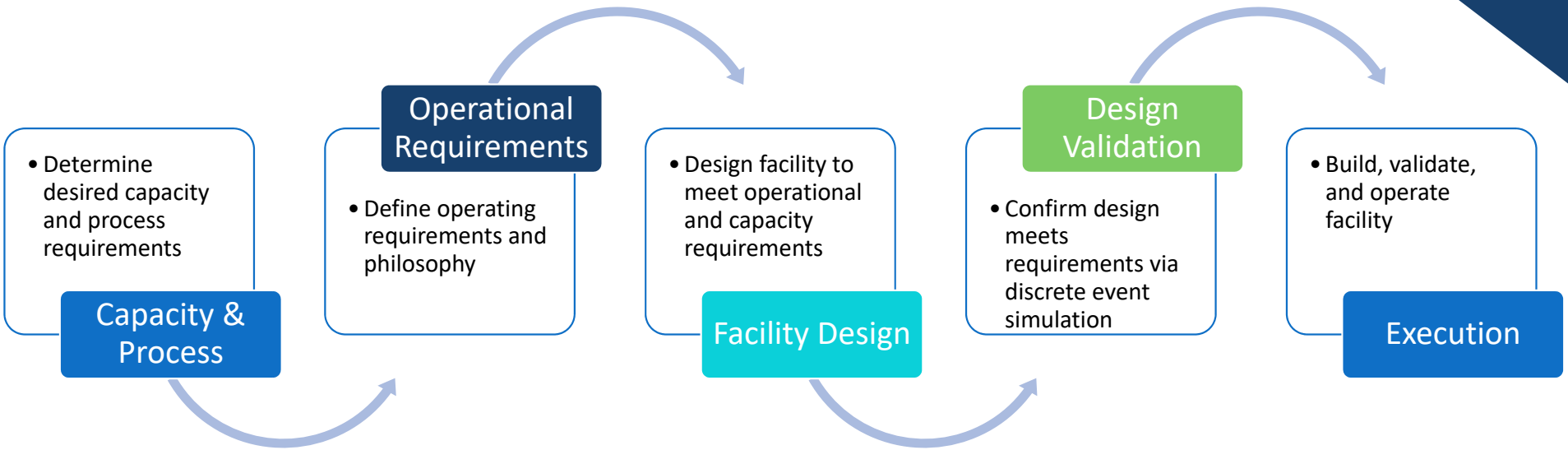
AUTOMATED VS. MANUAL PROCESSES

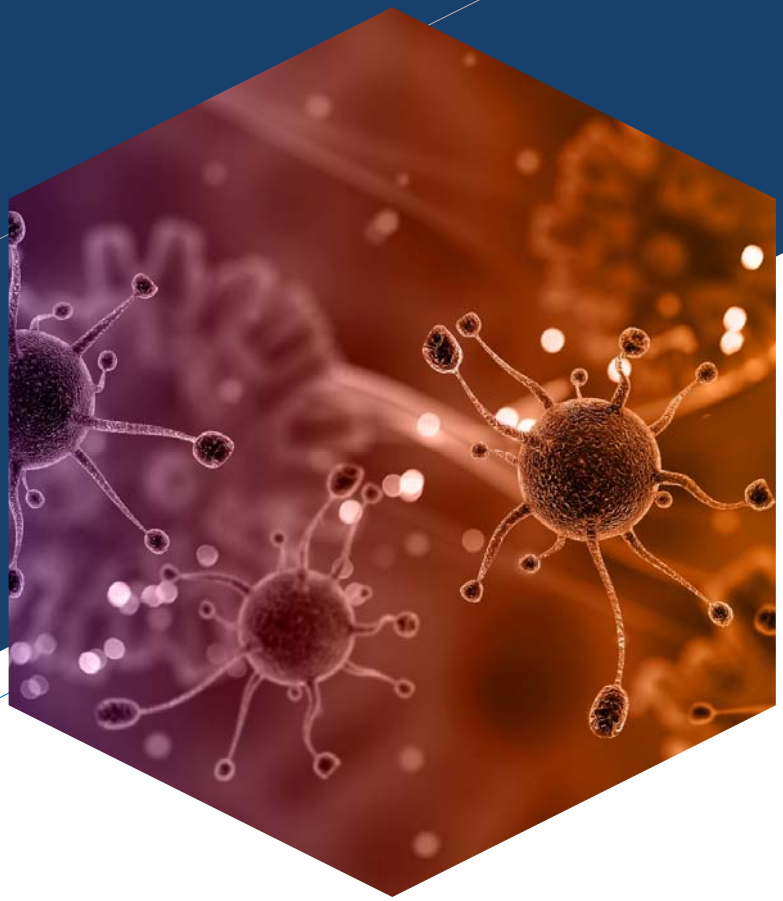
Facility and process design should consider the use of automation to reduce variability, lower costs,

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





Thank You.

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