

# Capacity Planning Considerations for Autologous Cell Therapies

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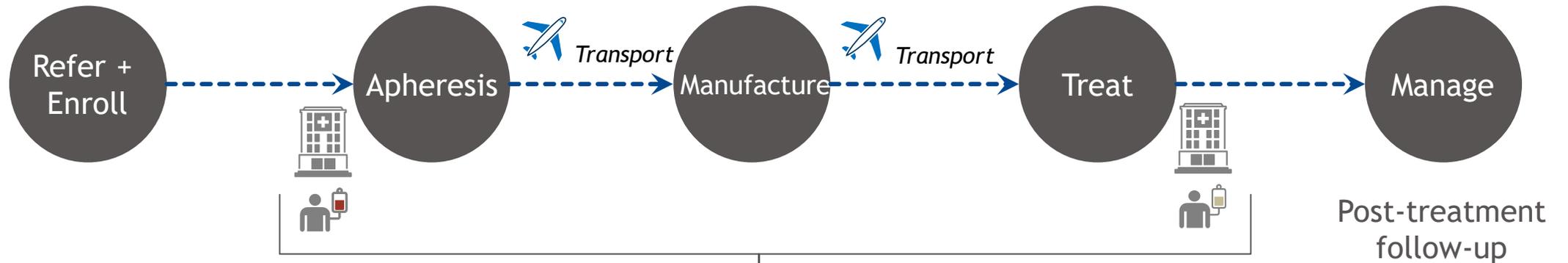
Alicia Collins

Executive Director, Cell Therapy Global Patient Operations

# Agenda

- 3 general challenges that make capacity difficult
- Unique challenges for autologous cell therapy
- Addressing the challenges

# Patient Cell Journey – Autologous therapies



## Time to Treatment

In general, ~3-4 Weeks between aph and treatment

# General Challenges

- Inventory
- Scaling
- Communication

# What's one the most foundational differences? - Inventory buffer

Inventory Type	Individualized Therapies	Biologics/Small Molecules
Raw Materials	✓	✓
Drug Substance	X*	✓
Drug Product	X	✓
Finished Goods	X	✓
Channel	X	✓

\*Planning, alignment, and communication are critical

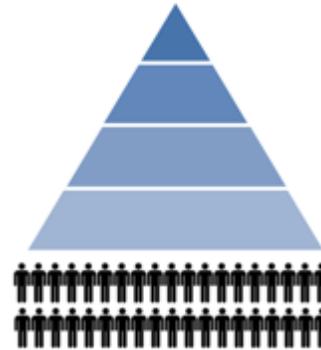
# Scaling: Fundamental difference in make to order vs make to stock

1 product lot



1 patient

1 product lot

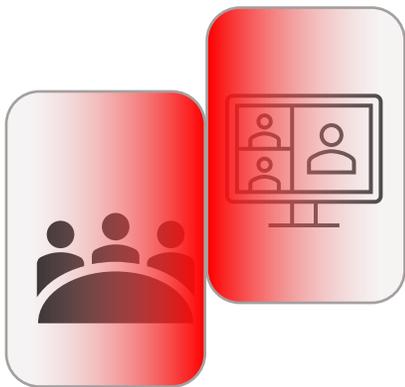


Many patients

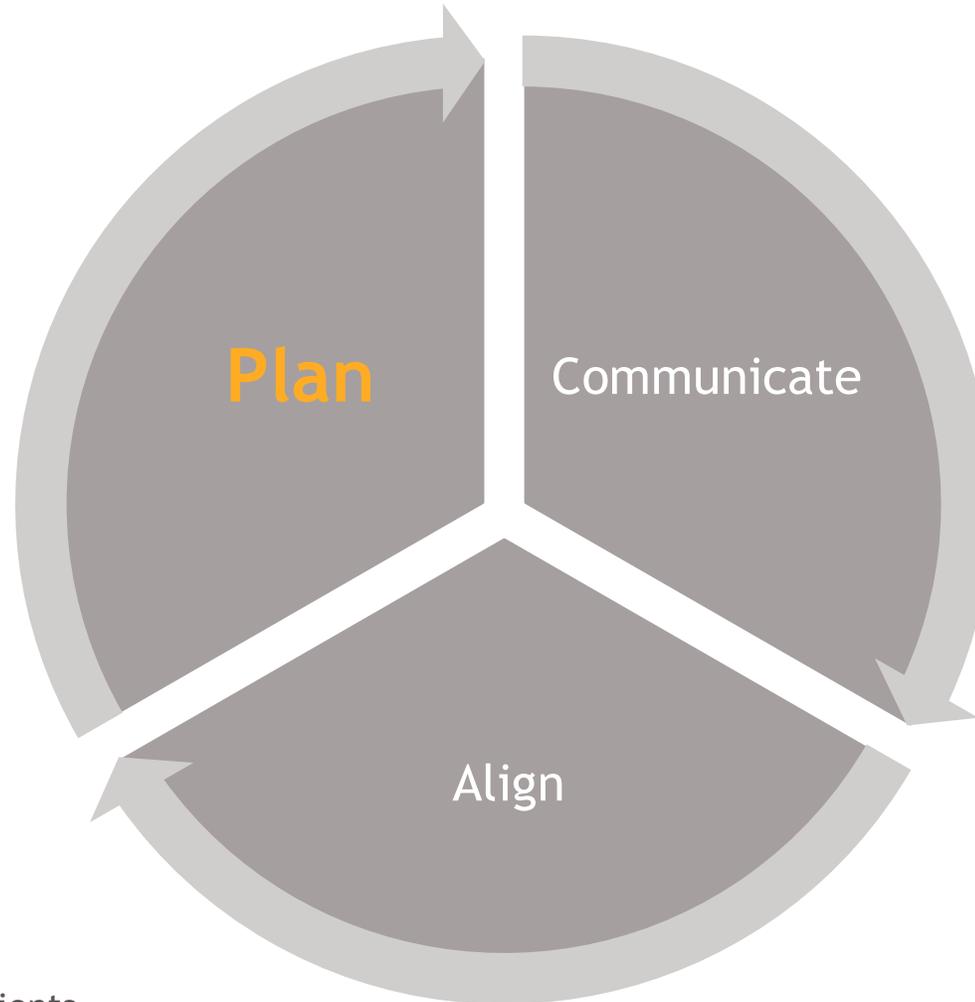
# Foundational things you've always done must be more tightly integrated than ever before



Small blips can make huge waves



Mis-alignment can directly impact patients



*It will be more complex than you think*

*It will take longer than you plan*

*Unexpected things will happen*

# Unique challenges that can impact autologous cell therapy capacity

## Turnaround Time

- Patient is part of Supply Chain
- Time from vein to vein is critical: white glove service needed
- Hospital/treatment center capacity constraints become yours
- Tied to your Mfg capacity

## Systems & Interfaces

- Must have strong integration between systems
- Manual operations will reduce capacity and be costly

## People

- People capacity will be consumed by execution tasks
- Burnout

## Manufacturing & Materials

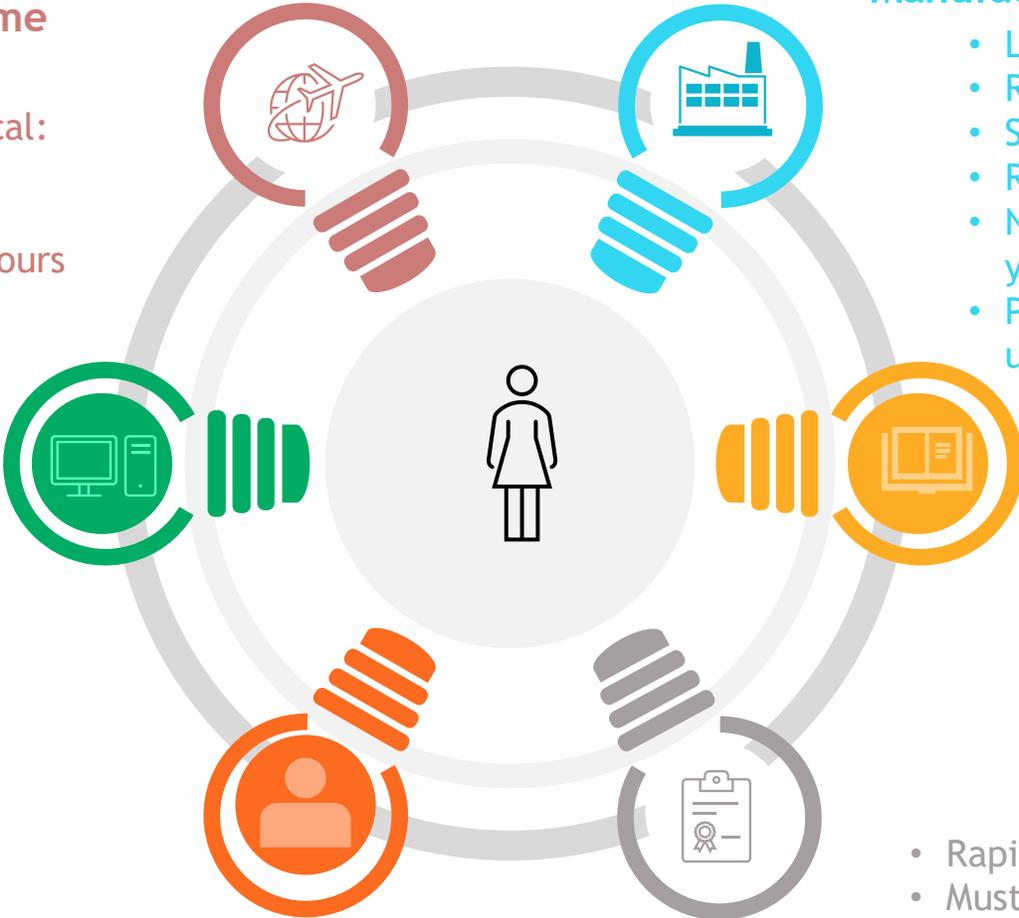
- Labor intensive & manual
- Ramping capacity requires long lead time
- Storage capacity is critical
- Robust supply chain needed
- Nascent suppliers/CMOs - their capacity is your capacity
- Patient's cells are starting material with unknown variability

## Regulatory

- Prior Approval required to increase capacity (add identical unit operations)
- Need plans in place to manage out-of-specification drug product

## Quality

- Rapid release is essential
- Must be Right First Time
- Quality operations must ramp in step with Mfg.



# How to address the challenges

## Turnaround Time

- Treat as a value stream
- Know what's achievable now vs. future
- Find predictive tools: proactive vs. reactive

## Systems & Interfaces

- System implementations & builds must happen quickly and be well integrated
- Must have strong integration between IT/Commercial/Operations

## People

- Need ops execution as a stand-alone organization
- Org design & programs for business continuity
- Automate

## Manufacturing & Materials

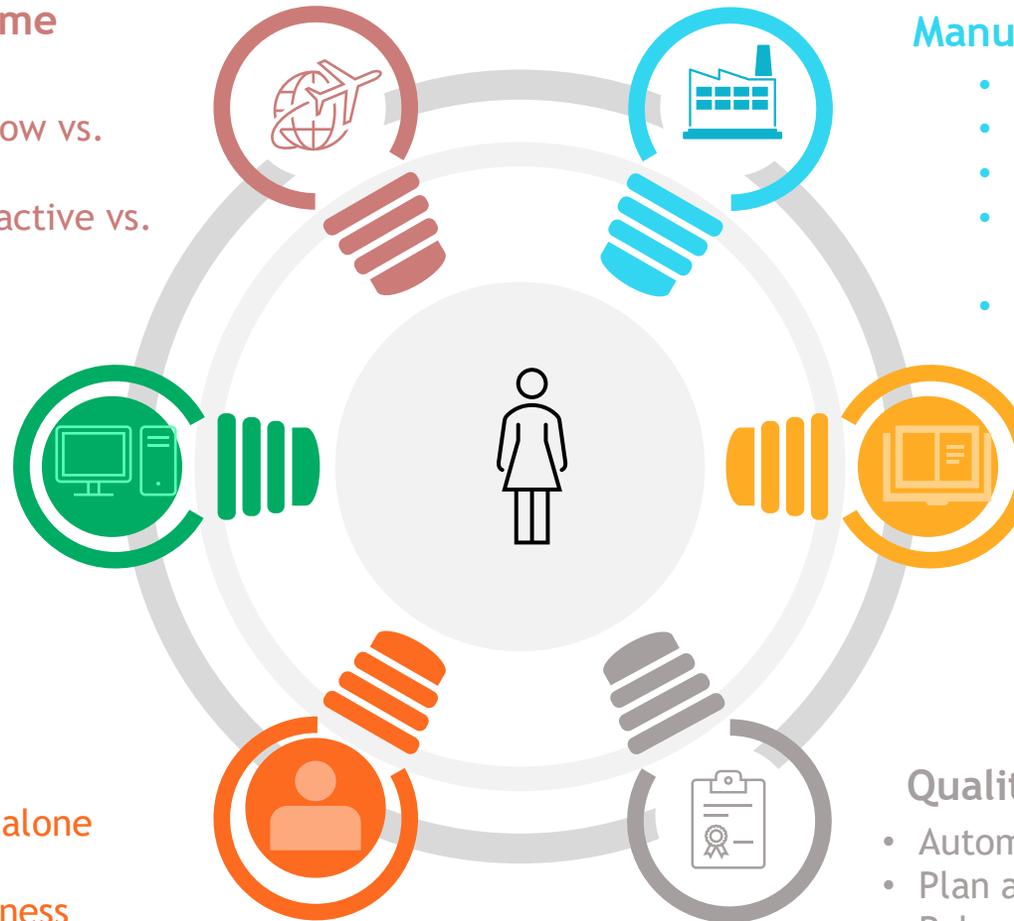
- Automation & manage capacity as a program
- Select the right suppliers & materials early
- Share forecasts & partner
- Design your manufacturing facilities for the highest level of flexibility
- PLAN & hire early

## Regulatory

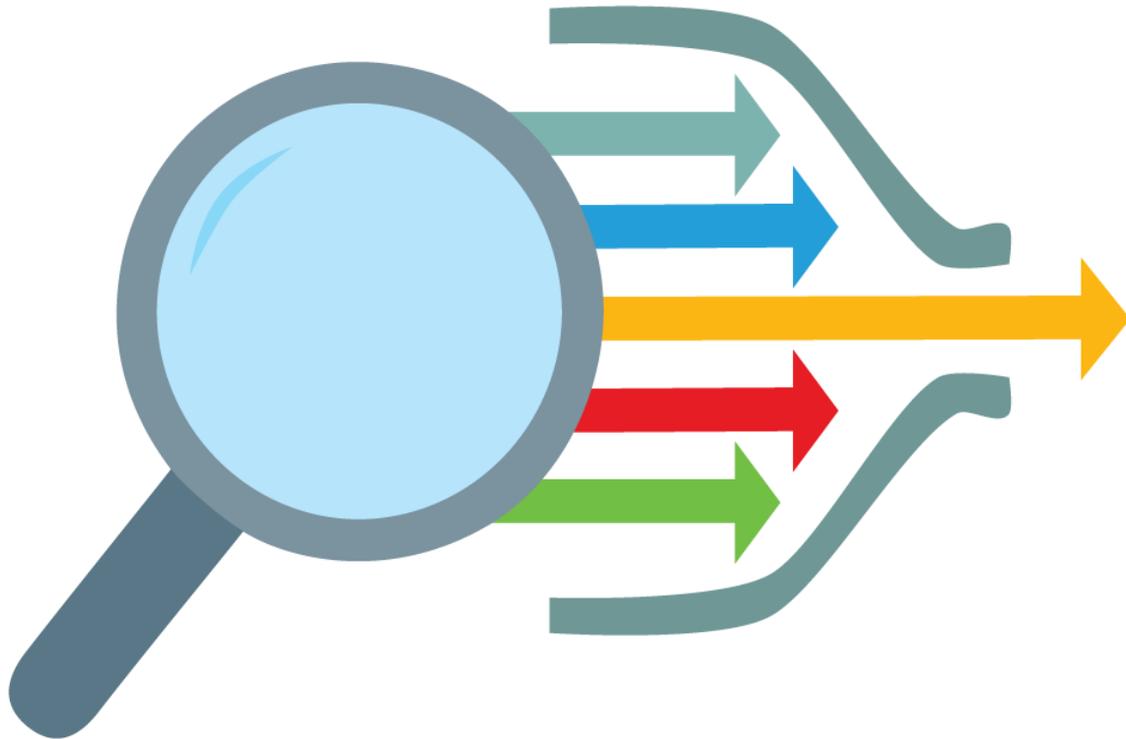
- Incorporate clear, complete Post Approval Change Management Protocol for capacity into BLA
- DP OOS: Seek approval for Expanded Access Protocol (EAP) in parallel with BLA review

## Quality

- Automate
- Plan and hire early
- Robust testing chain required



# What's the next bottleneck?



- Harmonize and have consistency across nodes as you increase your capacity or that will impede ability to scale & grow.
- Complexity is here now, even if you think you have time to figure it out.

*It will be more complex than you think*

*It will take longer than you planned*

*Unexpected things will happen*

## In Summary:

- PLAN & Re-plan
- Communicate and Align to plans
  - Create programs to govern and drive things like manufacturing capacity ramps & turnaround times
  - Hire early
  - Be realistic, employ defensive pessimism
  - Always do what's best for patients