

Patient-Specific Cell Therapy

# Getting to the Factory of the Future

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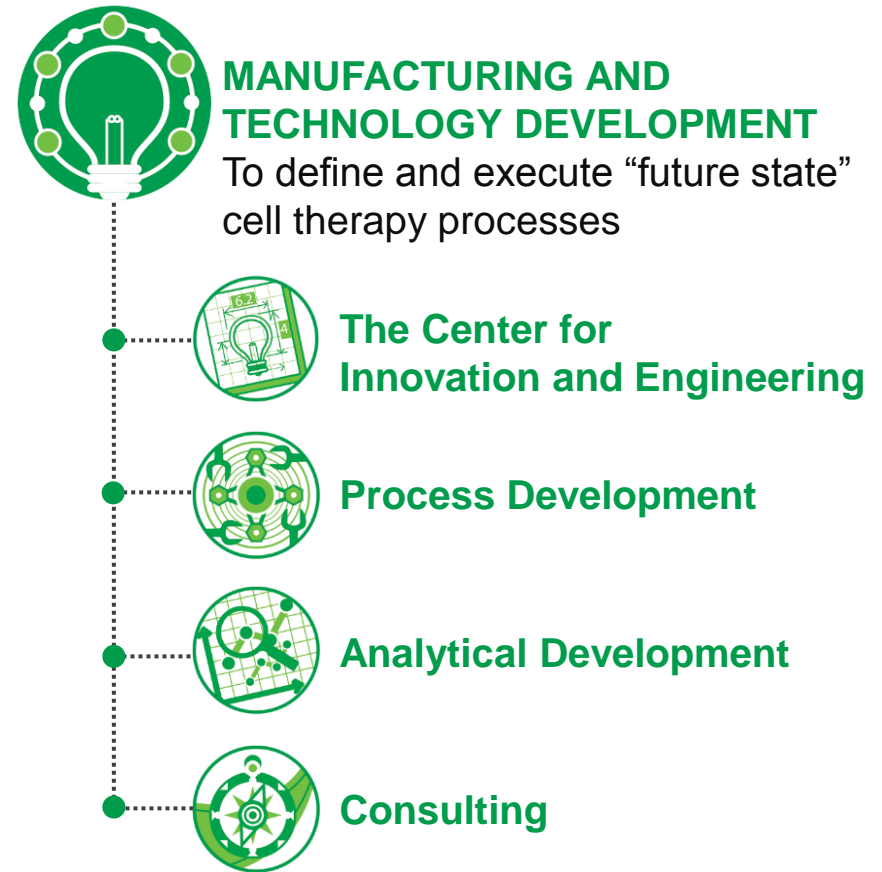
The National Academy of Sciences Engineering  
Medicine  
**Washington, DC**  
June 26, 2017

PCT Cell Therapy Services, LLC

A Hitachi Group Company

# PCT: Unparalleled track record of exclusive focus on cell and cell-based gene therapy

18+ years delivering expert service and operational capabilities



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**Hitachi** Chemical



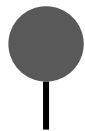
Mountain View, CA



Allendale, NJ



## Creating a global commercial enterprise with deep engineering expertise



May 2017: Hitachi Chemical purchased 100% of PCT



Intention to pursue PCT/Hitachi European joint venture



Plan to launch Yokohama, Japan CDMO facility April 2018

# Our cell therapy partners are clearly asking for a solution

Minimize cost  
and timeline for  
implementation

Greater operational  
flexibility and  
adaptability

Expedited training  
of technical staff

“Plug-n-Play”  
manufacturing  
processes

Reduced cost  
of outsourcing  
manufacturing

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# The end goal of cell therapy product developers is to achieve **Commercially Viable Manufacturing**

Our industry is currently experiencing high levels of **complexity** in manufacturing, which is leading to the creation of inefficiencies through custom product and service solutions.



How can we, as a community, begin to establish **consistency** in these products and services to drive towards the creation of platform solutions and enable a reduced cost of goods?

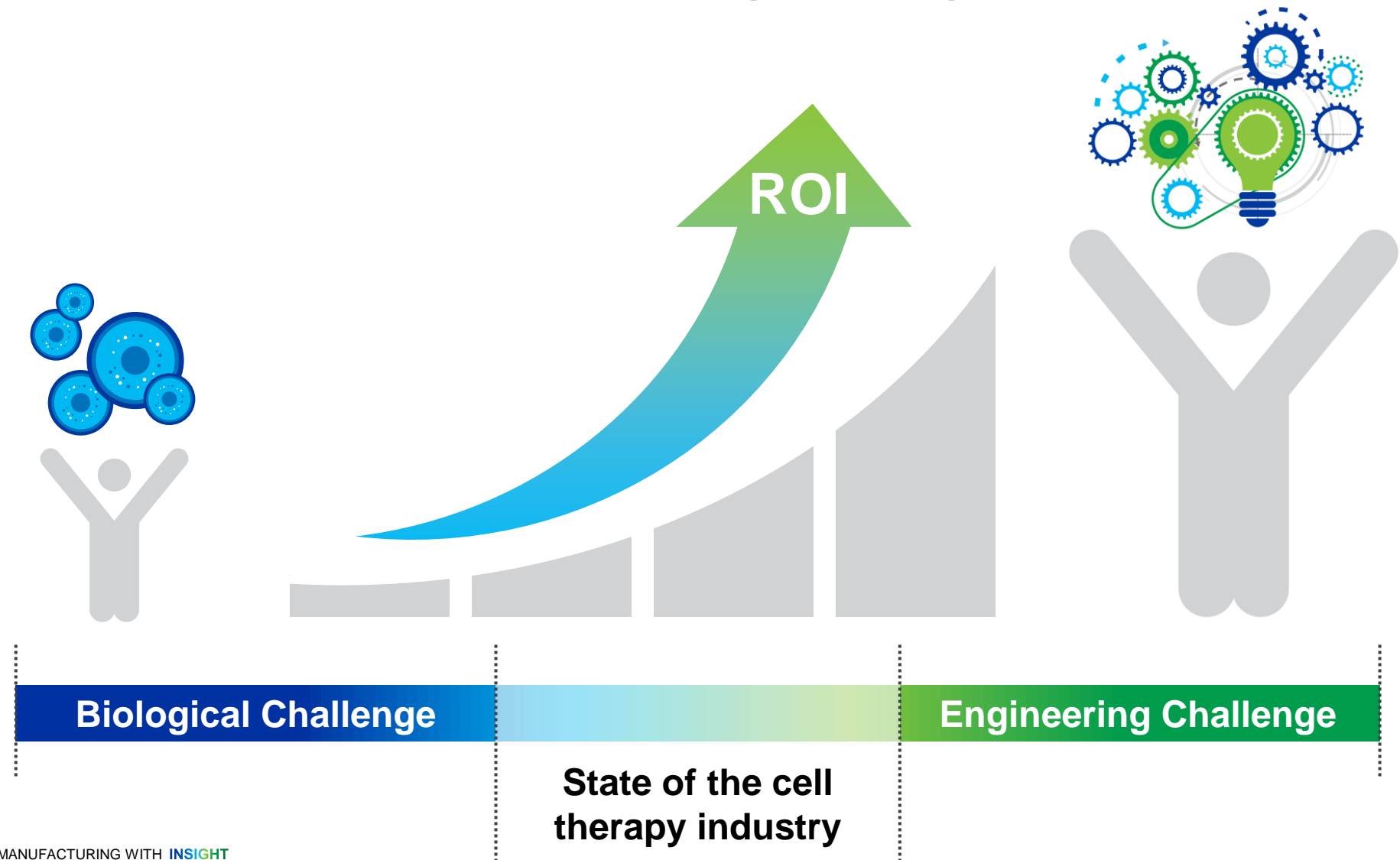
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## There are a number of key assertions driving this narrative

- Cell therapy industry is currently experiencing **high complexity** in manufacturing and development due, in part, to a **lack of consistency** in product and service solutions
- The industry needs a strategy and infrastructure to enable **consistent solutions**, recognizing that service providers are not yet able to fully standardize manufacturing platforms
- The unit operation approach provides a methodology to begin development of this **delivery platform** for product development companies to leverage and approach an optimal cost of goods
- **Automation** and other tactics should be used to further reduce the cost of goods associated with the delivery platform, rather than on an individual product or process basis

# The ideal investment in a business for maximum returns is one that resolves an engineering constraint

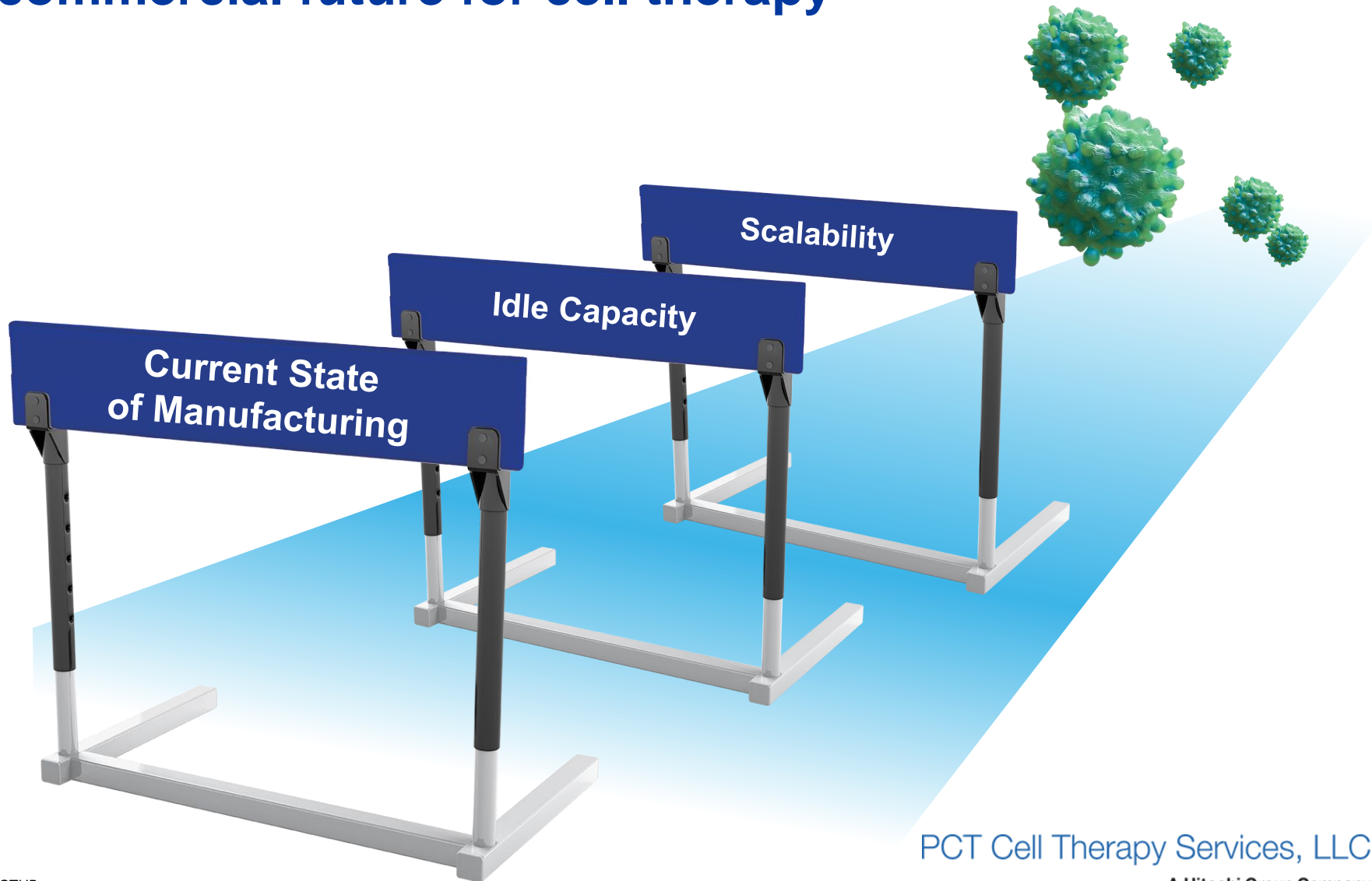


# Current challenges in the cell therapy industry

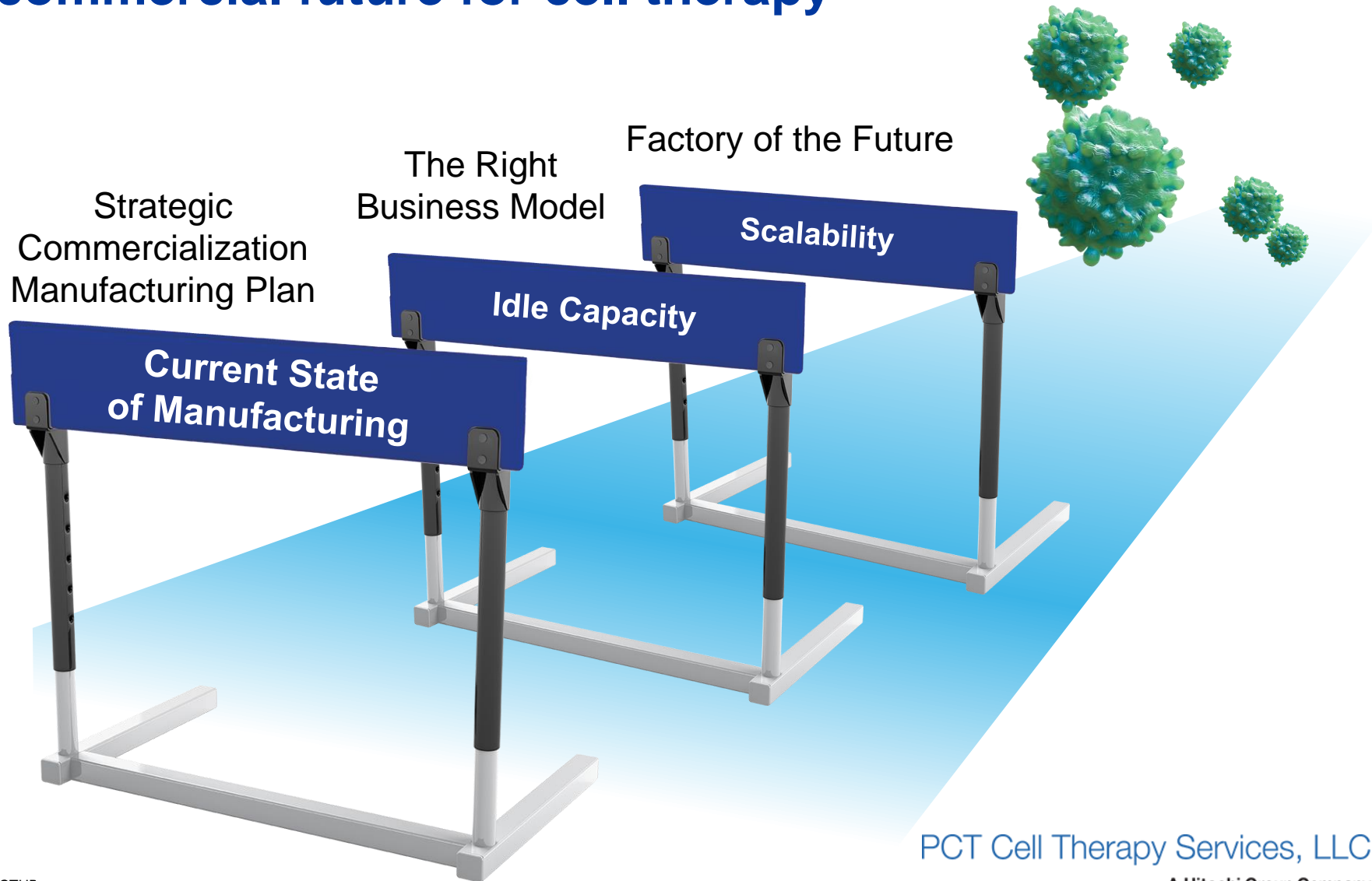
Quality	Scalability
<ul style="list-style-type: none"><li>• High variation in donor material</li><li>• Delivery of production lot to wrong patient can be life-threatening</li><li>• Severe product testing constraints (MOA, time, sample volume, cost)</li></ul>	<ul style="list-style-type: none"><li>• Conventional approaches to economies of scale are limited</li><li>• Separate batch record and lot release for each patient in PSCT</li><li>• Severe “fresh product” scheduling constraints (In &amp; Out)</li></ul>
Sustainability	Cost of Goods
<ul style="list-style-type: none"><li>• Failure of production lot = failure to treat patient</li><li>• Complex product ⇒ challenging comparability assessment</li><li>• Reagent and disposable supply chains have not been established</li><li>• Use of “super donors” in off-the-shelf therapies</li></ul>	<ul style="list-style-type: none"><li>• Highly manual, open processes requiring skilled labor.</li><li>• Complexity of supply chain and logistics</li><li>• High cost of idle manufacturing capacity</li></ul>



# Challenges to achieve a commercial future for cell therapy



# Solutions to achieve a commercial future for cell therapy



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