Patient-Specific Cell Therapy

Getting to the Factory of the Future

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The National Academy of Sciences Engineering Medicine
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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

CLINICAL MANUFACTURING
To deliver operational excellence

Technology Transfer

Technology Transfer

cGMP Manufacturing, Infrastructure and Systems

Global Logistics and Storage

MANUFACTURING AND TECHNOLOGY DEVELOPMENT
To define and execute “future state” cell therapy processes

The Center for Innovation and Engineering

Process Development

Analytical Development

Consulting

PCT Cell Therapy Services, LLC
A Hitachi Group Company
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
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?
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

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<tr>
<th>Quality</th>
<th>Scalability</th>
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<tr>
<td>• High variation in donor material</td>
<td>• Conventional approaches to economies of scale are limited</td>
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<td>• Delivery of production lot to wrong patient can be life-threatening</td>
<td>• Separate batch record and lot release for each patient in PSCT</td>
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<td>• Severe product testing constraints (MOA, time, sample volume, cost)</td>
<td>• Severe “fresh product” scheduling constraints (In &amp; Out)</td>
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<tr>
<th>Sustainability</th>
<th>Cost of Goods</th>
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<td>• Failure of production lot = failure to treat patient</td>
<td>• Highly manual, open processes requiring skilled labor.</td>
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<td>• Complex product ⇒ challenging comparability assessment</td>
<td>• Complexity of supply chain and logistics</td>
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<td>• Reagent and disposable supply chains have not been established</td>
<td>• High cost of idle manufacturing capacity</td>
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<td>• Use of “super donors” in off-the-shelf therapies</td>
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Challenges to achieve a commercial future for cell therapy
Solutions to achieve a commercial future for cell therapy

Strategic Commercialization Manufacturing Plan

The Right Business Model

Factory of the Future

Current State of Manufacturing

Idle Capacity

Scalability

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