



Feasibility Study

Cell Microfactories:

Re-distributed Manufacture of Cell-Based Therapeutics

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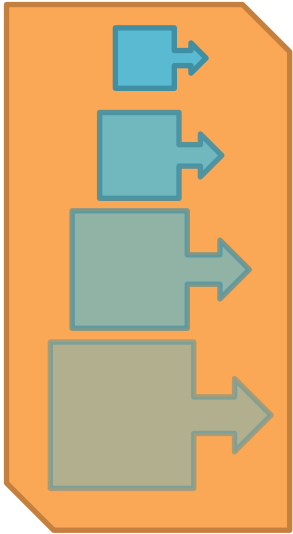


Problem Statement

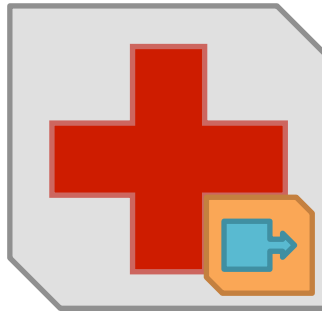
- Regenerative medicine has been identified by the Government as a priority technology for UK competitiveness¹
- Progress is slow as investors are reluctant to invest in unorthodox equipment and/or processes
- Cost of supply chain from a centralised facility is prohibitive
- **Alternative:** small semi-automated units, proven in the laboratory, reducing the business risk
 - Regulatory, legal, financial and operational hurdles to overcome
 - Products are sensitive to temperature and timing of supply.

Feasibility Study

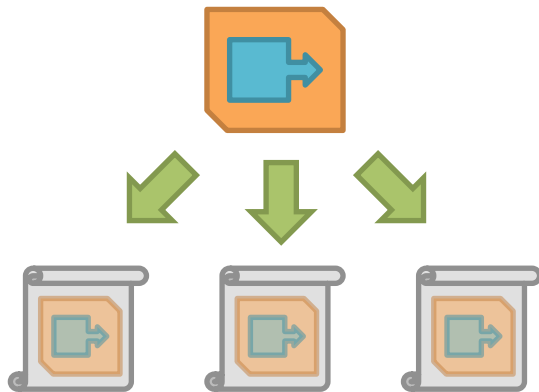
- ‘To examine a range of alternative models of re-distributed manufacturing for both autologous and allogeneic cell- and tissue-based therapeutics (CATBTs) and identify those that offer the highest probability of success for future business’
- Such as;



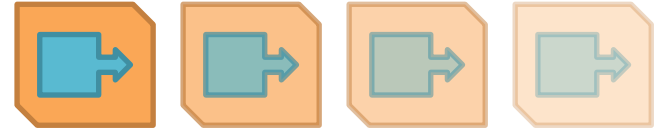
Scale Up
(Vertical)



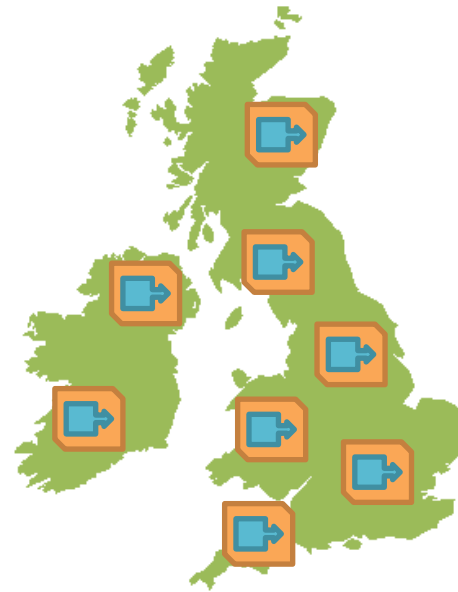
In-Hospital



Franchise



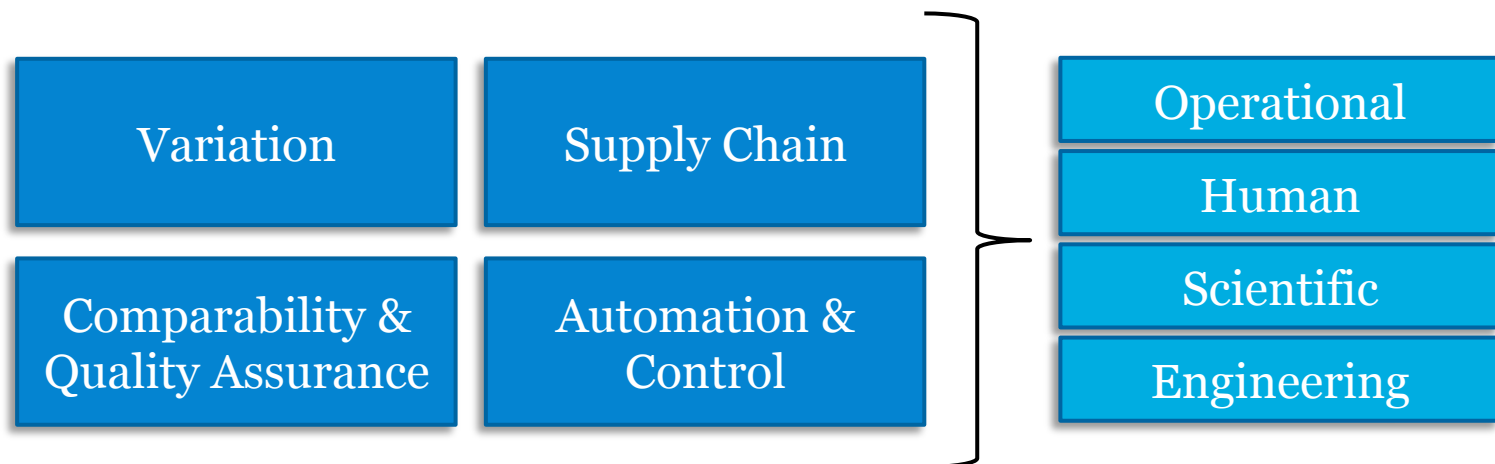
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Local Hubs

Methodology

- On-the-ground surveys of current practise
- Technical confirmation of conditions of cell supply and yield
- Consideration of the likely variability of source material
- Examine four main characteristics in order to discern which features warrant focused study;



Work Packages

- Regulatory Route to Supply with Confidence
 - *Jacqueline Barry*
 - Operational responsibility and process' chain of custody

- Business Models
 - *Andrew Webster*
 - Manufacturing modes of operation that would be possible and economical



Work Packages

- **Technical / Machine Aspects**
 - *Qasim Rafiq, Aston University*
 - Investigate standardisation of equipment
 - Comparative studies;
 - Automated & manual culture
 - Controlled & uncontrolled culture
- **Accommodation of Variation**
 - *Jon Petzing, University of Loughborough*
 - Build upon previous work, particularly the effect of master and working cell banks



Deliverables

- Potential business models with costing
- Framework models of operation (IDEFo)
- Detailed research proposals that illustrate cost and value release
- Technology gaps for adoption of particular business models

- White Paper outlining business/technical models and limitations
- RiHN report with economic/technical/legal/regulatory gaps and solutions
- Peer reviewed journal papers
- Conference paper for public impact
- EPSRC / MRC / Innovate UK full project proposal