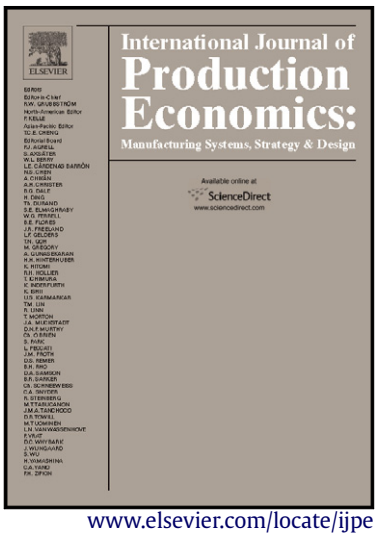

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PII: S0925-5273(13)00275-2
DOI: 10.1016/j.ijpe.2013.06.006
Reference: PROECO5486

To appear in: *Int. J. Production Economics*

Received date: 15 April 2012
Revised date: 9 February 2013
Accepted date: 10 June 2013

Cite this article as: Chih Wei Teng, Lucy Foley, Peter O'Neill, Chris Hicks, An Analysis of Supply Chain Strategies in the Regenerative Medicine Industry – Implications for Future Development, *Int. J. Production Economics,* 10.1016/j.ijpe.2013.06.006

An Analysis of Supply Chain Strategies in the Regenerative Medicine Industry – Implications for Future Development

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Abstract

The pharmaceutical, biotechnology and life sciences industry was worth approximately US$1 trillion in 2010, of which 73.2% was attributed to pharmaceuticals, 25% to biotechnology and the remainder to life sciences. Regenerative medicines, which use live cells to cure previously incurable diseases, are a small, but growing sector of the life sciences industry. Product development here is long, the industry highly regulated and scaling up from lab to volume oriented dispersed production has many challenges. In contrast to most manufacturing environments, it is not possible to change manufacturing processes or supply chains ad hoc, as the entire supply process is specified as part of regulatory approval. It is therefore prudent to plan for the integration of production processes and supply chains during development, as the cost ramifications will seal the success or failure of a therapy at start up. This paper presents a taxonomy, which decomposes regenerative medicine into exemplar cellular therapies that then enables the characterization of their supply chain strategies and structures. Using a case study methodology, we explore the supply chains of five cellular therapies to provide insight into how regenerative medicine supply chains could be configured and managed to get cell therapies to more markets faster, and within an acceptable cost regime.

Keywords: Supply Chain, Effectiveness, Cross Industry, Regenerative Medicine, Umbilical Cord Blood, Pharmaceutical, Cell Therapy, Allogeneic, Autologous, Case Study.