
APS1012 Management of Innovation – Final Team Projects, Fall 2011**Innovations in Biotechnology**

Biotechnology is the next major revolution in regenerative medicine and will transform medical care as we know it. It encompasses cutting-edge innovative technologies that will benefit society as soon as 5-10 years from now. Three main areas of the biotech industry are reviewed:

- Cell and tissue production
- Gene therapy
- Drug screening on disease models

After examination of current cellular products in clinical trials, and analysis of the political, economic, engineering, scientific and manufacturing constraints, recommendations are proposed for changes to management of the cellular biotechnology sector in order to promote future innovation and advancement.

The current regulatory path for cellular product approval is unclear and tedious. Policy shortcomings concerning the definition of stem cells and their usage is leading to difficulty in translating basic scientific research to a marketable product. Current clinical trials predict increased exploitation of the pharmaceutical value chain infrastructure to push cellular therapies through the manufacturing pipeline.

Biotech start-ups are abundantly motivated and have many economic avenues for growth, but the clinical translation of their products is being impeded by several engineering and scientific limitations. Regulatory bodies need to provide stimulus policies, such as incentives for increased collaboration between established pharmaceutical companies and the small biotech entrants, to ensure the economic and societal benefits of these therapies are fully realized.