

## **BESPOKE CELL THERAPY MANUFACTURING PLATFORMS - A CONTRADICTION IN TERMS?**

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Advanced biological therapies, such as cell and viral therapeutics, will have a transformative effect on healthcare. In many cases these therapies are curative rather than palliative and aim to treat a wide range of diseases including malignancies, cardiovascular, immune, and metabolic disorders.

As cell therapies begin to enter commercialization stages, some of the bigger challenges that need to be addressed include bottlenecks in production and high cost of goods. At the same time, switching to manufacturing platforms that might allow scale-up (allogeneic) and scale-out (autologous) to allow commercialization at an acceptable cost of goods could result in changes to the cell product critical quality attributes.

For the field to move forward, it is imperative to enable the use of production platforms that allow commercialization, yielding high quality and quantity of cells at acceptable costs. Yet, as opposed to the highly commercialized mammalian cell protein manufacturing, in which the same cell types and processes are used to produce many different proteins, the diversity of cell types and processes in cell therapy may require significantly different manufacturing methods.

Does this mean that a multitude of different manufacturing platforms is needed and feasible for cell therapy manufacturing?

Or is the development of a one-size-fits-all platform a superior and possible approach?

How would an optimal bespoke platform approach look like, and would it work for different modalities (allogeneic vs. autologous), and a diversity of cell types and processes?

These questions will be addressed and possible considerations and solutions presented.