LOW-COST PRODUCTION AND PURIFICATION OF CYTOKINES AND GROWTH FACTORS FOR CELL THERAPY PRODUCTS

Reducing costs for critical cell growth components

NIIMBL® The National Institute for Innovation in Manufacturing Biopharmaceuticals

Before the NIIMBL project, our business model has been to license technology. Post-NIIMBL project, we may become a manufacturer. Being involved with a group of people who live, eat, and breathe manufacturing, it has been transformative to be involved in a project like this.

PHIL BRYAN
Potomac Affinity Proteins

POTOMAC AFFINITY PROTEINS

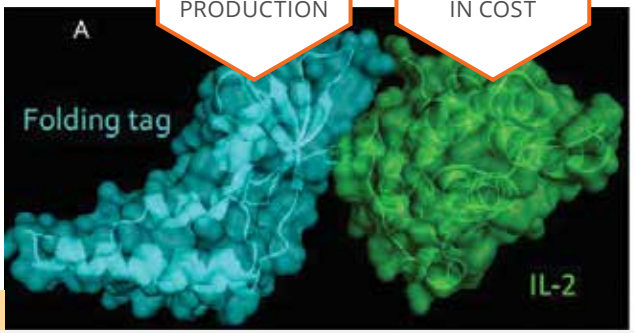
North Potomac, MD

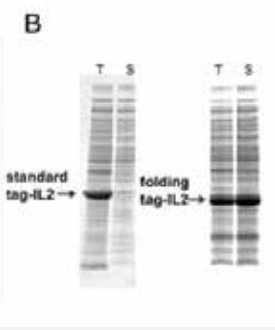
Type:
Small-Med Size Company

Participating Organizations:
University of Maryland College Park

2,000% INCREASED PRODUCTION

>90% REDUCTION IN COST





INDUSTRY NEED

Cytokines are proteins used in cell culture to support cell growth, survival and differentiation. While they are a vital component of cell therapy manufacturing, they are also the most expensive with costs ranging from $1K to $50K for a single milligram per cytokine. The industry would greatly benefit from a new approach to manufacture cytokines for cell growth that is more cost effective.

SOLUTION

Focusing on IL-2 and FGF2 cytokines, Potomac Affinity Proteins teamed with the University of Maryland to scale cytokine production reliably and at a fraction of the cost. The team aimed to use Potomac Affinity Proteins' e. Coli expression system to create a platform process for cytokine production and purification that integrates molecular machinery into traditional manufacturing technologies. The process would allow for greater scale up potential at a reduced cost, while expanding flexibility for the industry to adopt the novel purification process for other critical cytokines or proteins.

OUTCOME

The results of this project exceeded expectations. Initial projections were ≥50mg per run. Impressively the team was able to produce and validate 1 gram of IL-2 and FGF2 cytokines respectively from 5 Liters of cell culture. In addition to the nearly 2,000% increase over expected production, the team achieved a significant cost reduction of 90% - 99.8%, from $1k - $50k per mg to less than $100 per mg. This basic methodology can be applied across additional cytokines beyond IL-2 and FGF2. However, the real game-changer for the industry is that it can be scaled-up to manufacture significantly higher quantities reducing cost to only dollars per mg, potentially resulting in significant manufacturing cost savings.

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