From Cells to Life Changing Medicines

Adhering to the Highest Standards of Biologics Manufacturing



CELL LINE EXPANSION

At the start of the process cells are grown and multiplied from a single vial of identical cells.

PRODUCTION

In a controlled bioreactor, the cells continue to grow and produce an optimal amount of the target protein.



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HARVEST

Using depth filtration, the harvest step separates protein and media from cellular debris.

PURIFICATION

In a multi-step process the target protein is purified and concentrated to final drug substance.





While maintaining the protein concentration, formulation buffers are added. Then the product is transferred into storage containers.



Vials or syringes are filled with formulated drug substance, labeled and packaged as drug product.





Hopewell Manufacturing Facility Highlights

- Hybrid modular facility (2,000L x 8 capacity) 90% stainless steel (SS) + 10% single use (SU). Lower cost (higher automation and less consumables) compared to 100% SU facility; shorter construction time compared to 100% SS stick-building facility; lower possibility of contamination (upstream SU).
- Drug Substance (DS) and Drug Product (Liquid/Lyophilization) 2 million vials per year.
- 70,000L buffer hold capacity per suite, DS has 2 suites equaling 140,000L.
- Increased Water for Injection (WFI) capacity combined with large buffer hold capacity allows for up to 8g/L at 2-day cadence. 2x10 ton WFI generators, increased capacity addresses bottleneck in manufacturing.

- New technology Online TOC & Flow VPX (Online Protein Concentration)

 real time data; reduce manpower & human error.
- Automation Distributed Control System (DCS): enhance data integrity, compliance, equipment integration and automation control.
- Automated Storage and Retrieval Systems (ASRS) automated warehouse to maintain efficient material management process; improve efficiency.
- · Vapor Compression System (VCS) lower energy consumption.

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