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.



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

HARVEST



process the target protein is purified and concentrated to final drug substance.



PURIFICATION



FORMULATION & DISPENSING

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
- 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 increased capacity to address bottleneck in manufacturing.

- · 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.

