SARTURIUS

Success Story

How Large Pharma Used Connection Redundancies and Single-Use Systems to Streamline Production

This large pharma manufacturer needed to create a production platform that would be easy to replicate, reduce risk of error or failure in the process, and would streamline their new facilities. By implementing Sartorius connection technology redundancies, this manufacturer mitigated risk, increased site productivity, and improved their tech transfer platform.

Customer Challenge

- Platform needed to be easily replicated in new facilities anywhere in the world.
- Producing multiple products within the same manufacturing space.
- The time required to build new facilities impedes time-to-market.
- Lack of redundancies creates risk of operator error, component failure, etc.

Provided Solution

- Used Opta® as the primary connection technology with a Biowelder® TC as redundancy.
- Mitigated risk of error or failure by designing systems with both aseptic connectors and TPE tubing. This created a fail-safe redundancy in case the primary method failed.
- Platforming allowed the customer to streamline their tech transfer to new facilities.
- Harmonized Standard Operating Procedures (SOPs) and operator training.

Case Profile

Company Type: Large Biopharma

Related Molecule: mAbs

Process Steps:

Cell Culture Media and Buffers, Cell Culture and Seed Expansion, Sterile and Tangential Filtration, Drug Formulation, Fill and Finish, Platform Development

Related Application: Transfer and distribution of fluids (disconnection redundancies)



Before

- An independent process design engineered for each site
- One manufacturing space dedicated to one product
- A single connection technology used



After

- One process design replicated across multiple sites
- One manufacturing space can produce multiple products
- Multiple connection technologies used to create redundancies



Have successfully replicated their platform in a 2nd location.



Produced the same amount of mAb product in a facility with a footprint

one fifth

the size of traditional manufacturing.



Built the facility in half the time of traditional manufacturing.



Reduced operating costs by two thirds of traditional manufacturing.

