BioReliance®
Pharma & Biopharma
Manufacturing &
Testing Services

Case Study

Building a Fully Single-Use cGMP Biomanufacturing Facility in Martillac, France

Summary

In 2011, MilliporeSigma converted a stainless steel good manufacturing practice (cGMP) bioproduction facility in Martillac, France into a state-of-the-art, fully single-use cGMP facility, providing customers with increased speed to clinic.

Objective

In 2010, MilliporeSigma wanted to demonstrate that state-of-the-art single-use equipment could fully replace stainless steel in a cGMP biomanufacturing facility. Both upstream and downstream processes benefit from single-use systems as they enable increased productivity and flexibility with a reduced cost of goods, among other benefits. This facility would be used to produce therapeutic proteins for customers, particularly small biotechnology companies that lack the process development and clinical manufacturing resources necessary to ensure success of their commercial strategy.

Strategy

Convert Existing Facility

Originally built in 1987, the Biodevelopment Center in Martillac, France predominantly utilized stainless steel equipment for biomanufacturing processes. In 2011, this facility was converted from stainless steel to a fully single-use facility – a process that took six months. Today, the facility houses a total of five state-of-the-art cGMP suites (three upstream, two downstream) for therapeutic protein production.

Build Multi-Disciplinary Project Team

When converting the Biodevelopment Center into a single-use facility, building the right team at the very earliest stages of organization and planning was the key to success. In this case, building the right project team included expert representation from all key functions all working together: engineering, project management, process, regulatory, operations, quality, technology, consumables, etc. Moreover, a critical part of the strategy was to ensure that a strong engineering and project management lead was in place.

Plan for Flexibility

There is tremendous uncertainty in the biopharmaceutical market and it is almost impossible to forecast accurately. In order to successfully adapt to these market changes as well as to last-minute changes in client strategy, flexibility was a key component of the facility design. For example, the facility was designed for rapid and smooth configuration changes so that it would not be limited to one type of process and could undergo rapid changeovers between batches. Thus, equipment can be moved from one suite to another, multiple bioreactors or perfusion processes can be run in parallel, and a USP suite can readily be transformed into a DSP suite.

MilliporeSigma

Results

The Biodevelopment Center was one of the first facilities to attain cGMP compliance utilizing single-use equipment for each unit operation from upstream through downstream processing. The facility was also designed to lower its environmental impact, including a significant decrease in water usage. With the same footprint, the Center doubled its capacity by moving from stainless steel to single-use, as single-use adoption allows a dramatic reduction of bioreactor preparation, allowing more runs and thus more batches per year. Furthermore, almost any change in strategy and market demand can be met because the facility was designed for flexibility, agility, and expansion.

Benefit to Customers

Complete Solution

The Biodevelopment Center in Martillac, France, showcases the first state-of-the-art facility where a provider of biomanufacturing equipment, expendables and consumables uses its own products and years of peer-to-peer collaborative experience to manufacture cGMP batches of therapeutic proteins for drug development companies. The facility includes a biologics manufacturing process that incorporates the latest technologies and innovative products in upstream, downstream and single-use systems. It includes process development and validation services, cGMP-manufacturing of quantities up to clinical Phase II, and technology transfer and scale-up services for Phase III and commercial production.

Agility and Flexibility

The facility was designed for flexibility and agility. Therefore, changes can be made very quickly to adapt to customer needs, such as a change in scope or an unexpected change in commercial strategy.

Open Source Manufacturing

The team at the Biodevelopment Center supports technology transfer after a key milestone if it makes sense for the customer. With the benefits of an 'open source' manufacturing model, customers receive greater control over production as well as the freedom to operate independently. All process knowledge and information is transferred to customers.

Speed to Clinic

The Biodevelopment Center provides access to proven technologies, process development expertise and validation services, making it possible to go from clone selection to cGMP product in only 12 months.

Lessons Learned

There are many important lessons learned from the design, build and ongoing operations of the Biodevelopment Center in Martillac, France, particularly from a business, technology, regulatory, risk management, and engineering perspective. The most important lesson learned – one that cuts across all of these areas – is that the key to success is to design and build a flexible and agile facility.

An in-depth guidebook, entitled, "A Molecule's Journey – Break Down Roadblocks to Commercial Success," captures the lessons learned from the design and build of the Martillac facility to help biopharma executives seeking to navigate through the important considerations necessary to successfully build their own cGMP biomanufacturing facility.

The guidebook can be accessed here:
EMDMillipore.com/molecule-journey-commercial

About BioReliance® End-to-End Solutions

MilliporeSigma is a leading science and technology company in healthcare, life science and performance materials. BioReliance® End-to-End Solutions encompasse service and support for both emerging biotech and major biopharmaceutical companies that seek to accelerate process development, clinical drug production, and conceptual facilities design. We operate our own in-house bioproduction facilities and convey our expertise to clients as they progress on their drug development journey, with an emphasis on single-use technologies and high-performance upstream and downstream systems.

For more information, visit
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