

FlexFactory® Biomanufacturing Platform

Introduction

The FlexFactory® biomanufacturing platform is a proven, innovative approach to vaccine and biopharmaceutical production that enables a new level of flexibility, speed, capital efficiency and manufacturing quality never before seen in biomanufacturing.

FlexFactory vanquishes historical design tradeoffs

Conventional biomanufacturing facilities are enormous and complex, with miles of stainless steel pipe for cleaning and sterilization, multiple high-maintenance clean rooms and deeply entrenched barriers to efficiency. In developing FlexFactory, Xcellerex examined the challenges presented by conventional bioproduction architecture and developed innovative but fundamentally proven solutions to each.

► Step 1: Leverage the advantages of single-use technology

Xcellerex designed FlexFactory as a 100% single-use platform. This eliminates the need for costly CIP/SIP infrastructure, eliminates time-consuming sterilization and validation procedures, and greatly reduces the chance for cross contamination.

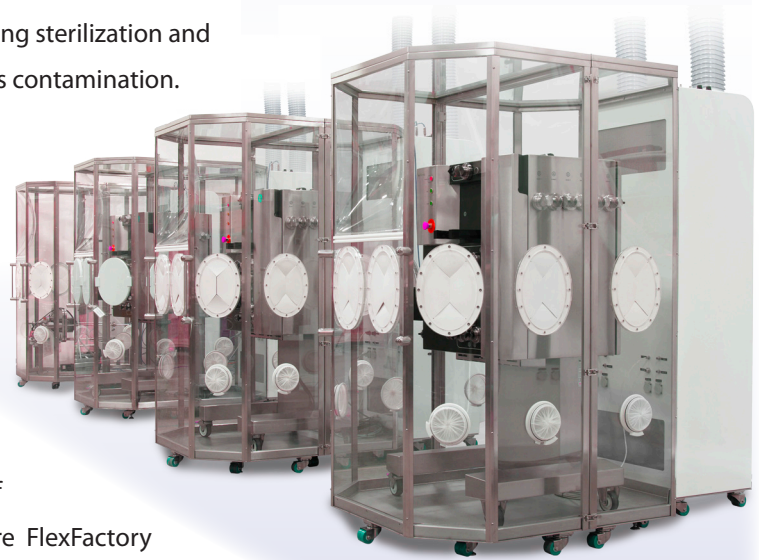
► Step 2: Rethink clean room architecture

We took a fresh look at traditional clean room architecture and the role of contamination in determining manufacturing quality. Rather than employ large, expensive and cumbersome conventional clean rooms, Xcellerex designed CleanCube™ Controlled Environmental Modules that effectively shrink the clean room around each unit operation while removing the operator—the single largest source of contamination—from the clean room. This means that an entire FlexFactory biomanufacturing line can be co-located in a single inexpensive Class 300,000 clean room, and that a single team of operators can move freely from one unit operation to the next without the burden of multi-level gowning and degowning.

► **Step 3: Embrace plant automation** To enhance manufacturing quality, plant efficiency and to embrace Quality-by-Design principles, Xcellerex developed the eFactory plant automation platform. The backbone of this platform is technology neutral, and can tie-in to a client's existing plant automation architecture, regardless of brand. The user-friendly human interface portion was

Major FlexFactory Advantages

- 60%+ reduction in capital investment
- 40% less space needed (simplified space)
- 85% reduction in water and waste
- 55% reduction in carbon footprint
- 32% reduction in COGS
- Faster deployment: 7-12 months vs. 3-5 years
- Accommodate simultaneous multi-drug production in same facility
- One team of operators can move freely across entire line without gowning and degowning
- Integrated automation package ensures quality control and speeds batch release

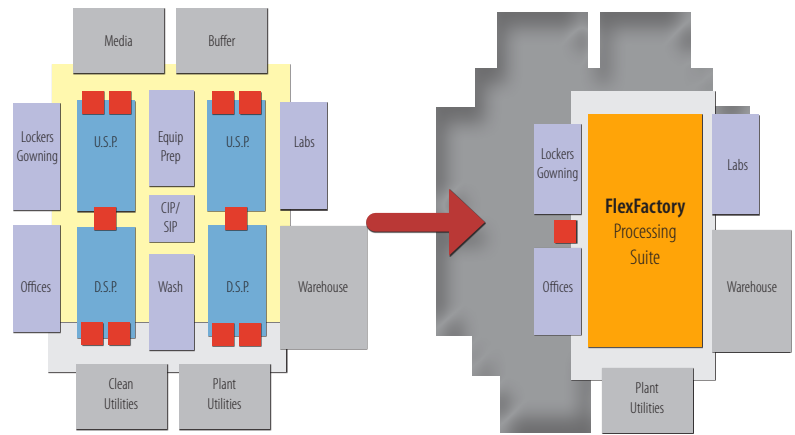


▲ FlexFactory downstream modules

designed to the latest CFR Part 11 standards, and provides failsafe controls to enforce operating and quality protocols. An electronic watchdog feature protects against unauthorized actions and provides instant alerts when a protocol is breached. This enables the operator to take remedial action immediately, often in time to save a batch. eFactory also provides powerful menu-based data trending that enables plant engineers and operators to monitor performance in real time. At the end of a batch, review-and-release can be accomplished by reviewing just the exceptions and deviations, without having to laboriously review the entire record.

► Step 4: De-Risk and Accelerate Start-Up

Finally, Xcellerex coupled FlexFactory with a service operation designed to further enhance the start-up process. In a typical scenario, Xcellerex's biomanufacturing team can operate a FlexFactory to produce GMP materials for clinical trials for a client who is still deciding whether it makes sense to build their own new capacity or until their trials justify the investment in a facility. For a company already committed to production, while the client constructs its new manufacturing facility, Xcellerex can assemble the FlexFactory at an Xcellerex location, validate it, train the client's operators, operate the FlexFactory, and then **TransPlant™** the entire GMP operation to the client's location when ready. The pre-validated, transplanted operation can restart with pre-trained operators within weeks.



▲ **Plant footprint is cut by 40% or more. Capital investment reduced by 65%.**
A typical FlexFactory configuration requires only 25,000 square feet of simplified floor space, versus approximately 40,000 sq. ft. or more for a conventional biomanufacturing operation of the same scale.

A revolution built on familiar technology

With FlexFactory, Xcellerex succeeded in creating a transformational approach to biomanufacturing, but we were also mindful that biologics manufacturers are risk averse. Therefore, we built FlexFactory by creatively adapting technologies that are already familiar to plant operators, and also well-accepted by the FDA, EMEA and other important regulatory bodies.

As experienced bioproduction operators, we also understood that every biologics process is unique, and that every process step must be optimized to the satisfaction of the operator. Therefore it was imperative that we design a platform that preserved technology neutrality, so that every process step could be optimized with the *best available technology sourced from the world's premier hardware providers*. The result is FlexFactory.

Accessing FlexFactory

To assist clients and partners in their adoption of FlexFactory, Xcellerex offers a suite of world-class products, services and business practices. These include:

1. XDR Single-Use Bioreactors & XDM Quad Mixers:

Fully-integrated XDR systems that deliver stirred-tank cell-culture and microbial productivity equivalent or better than conventional stainless steel systems. XDM mixers provide mixing power and convenience throughout your process.

2. FlexFactory TransPlant™ Services: Xcellerex offers a portfolio of expert services to assist clients in the adoption of FlexFactory. Services include process development, tech transfer, integration, validation, protocol development,

BridgeSourceSM manufacturing, operator training, and Trans-Plant of the FlexFactory line to the client facility. These services dramatically accelerate the time to GMP manufacturing.

3. Facility Design and Integration: As part of our bridge manufacturing service, Xcellerex has been at the forefront of operating single-use biomanufacturing lines. We've developed a deep understanding of facility requirements to help you optimize material and personnel flows and space efficiency to get the most from your facility investment.