



BridgeSourcing: *A fast, flexible alternative to conventional CMO outsourcing*

For many developers of new biologics, outsourcing clinical or commercial manufacturing with a CMO makes good sense. Dozens of capable CMOs offer ready capacity to companies who can't afford the time, capital or risk involved in building their own biomanufacturing capacity.

Of course, the convenience of instant access to a CMO's infrastructure comes at a steep price: Many CMOs utilize proprietary cell lines, media and other technology that will limit the drug developer's options in the future. Process development work done by the CMO may create barriers to future technology transfer, effectively marrying the drug developer to the CMO indefinitely. This creates a structural disadvantage, resulting in economics that may limit the future value of the drug to its developer.

How to add long-term control to the speed and economics of outsourcing

The FlexFactory® biomanufacturing platform from Xcellerex enables a new level of flexibility to biomanufacturing structure and deployment. When coupled with world class biomanufacturing operations, this platform becomes a complete biomanufacturing solution that features the speed and capital restraint of traditional outsourcing, with the long-term control associated with your own captive biomanufacturing operations. In other words, you can use Xcellerex as your outsourced manufacturing partner on a "bridge" basis (short or long-term), while also maintaining the freedom to TransPlant™ manufacturing operations to your facility anywhere in the world when the time is right for you.

What is FlexFactory?

Xcellerex is built around FlexFactory, a modular, portable biomanufacturing platform that leverages single-use technology, advanced process automation, and compact clean room architecture.

FlexFactory was developed by a team of experienced biomanufacturing professionals who sought to develop a rapid deployment approach to biomanufacturing. By using quality-by-design (QbD) principles, the team designed FlexFactory to eliminate or avoid many of the problems, barriers and other shortcomings of traditional biomanufacturing technologies. FlexFactory is built around three core concepts:



1. 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 contamination or cross-contamination.



2. Compact Clean Room Architecture

We took a fresh look at traditional clean room architecture and the role of contamination in determining manufacturing quality. To avoid the barriers presented by large, expensive and cumbersome conventional clean rooms, Xcellerex designed Controlled Environmental Modules (CEMs) 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.



3. Integrated Automation & Electronic Batch Records

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 “open”, and can tie-in to a client’s existing plant automation architecture, regardless of brand. The user-friendly human interface portion was designed to the latest CFR Part 11 standards, and provides fail-safe 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.

In addition to the core components described above, available FlexFactory services also include facility design (including workflow optimization), process design and optimization for upstream and downstream processing, and a range of other services, including bridge biomanufacturing. Further, clients can choose from a range of FlexFactory configurations, spanning from single-use technology in conventional biomanufacturing space to single-use operations using compact CEM architecture as described above.

Unique Options Enabled by a Unique Business Model

Xcellerex is a technology and equipment company, but our roots are in designing and running biomanufacturing operations. As a result, we structured the company to include expertise and services that we know are essential to smoothing our clients' pathway to new biomanufacturing capacity.

*Xcellerex combines process equipment,
expert services and comprehensive integration
and process knowledge to help drug developers
deploy new biomanufacturing capacity.*



Xcellerex Equipment Platform

Xcellerex offers FlexFactory controlled environmental modules, as well as a line of single-use bioreactors and mixers that have become the standard in the bioprocess industry. Our XDR single-use bioreactors are fully-integrated stirred-tank systems that deliver the performance and scalability of stainless steel systems with the convenience and quality of single-use technology. XDR reactors are fully characterized and feature a process modeling database that enables instantly optimized process scale-up or tech transfer. XDR systems are available with working volumes ranging from 10L to 2000L. Xcellerex also offers XDM Quad Mixers and a full complement of related single-use assemblies.

FlexFactory Services Platform

Xcellerex supports its equipment and platform with a unique portfolio of services. From process design and optimization to facility design to process equipment integration, Xcellerex can help ease the transition to single-use technologies. Through its TransPlant™ services, Xcellerex can “bridge” manufacture a partner’s biomolecule at our GMP facility while the partner’s FlexFactory is constructed, validated and TransPlanted to the partner’s site. This unique model both accelerates time to clinical and commercial manufacturing and allows partners to manage the development and market risk of adding manufacturing capacity.

Xcellerex is uniquely able to help biotech companies produce drug for clinical or commercial use with the same speed and convenience as a conventional CMO, while also helping the client establish the knowledge and infrastructure required to control its long-term destiny.

Clients can select from a spectrum of services offerings based on their unique needs.

Services offerings include:

- ▶ Process design and optimization
- ▶ Process equipment specification and integration
- ▶ Facility design and engineering
- ▶ Automation engineering and integration
- ▶ SOP development, training and bridge GMP operations
- ▶ Quality systems and validation

Our bridge biomanufacturing services are conducted in our new state-of-the-art FlexFactory suite shown below.

Construction and commissioning of this FlexFactory suite at Xcellerex headquarters was completed in less than six months, demonstrating the rapid deployment speed possible with the FlexFactory platform.



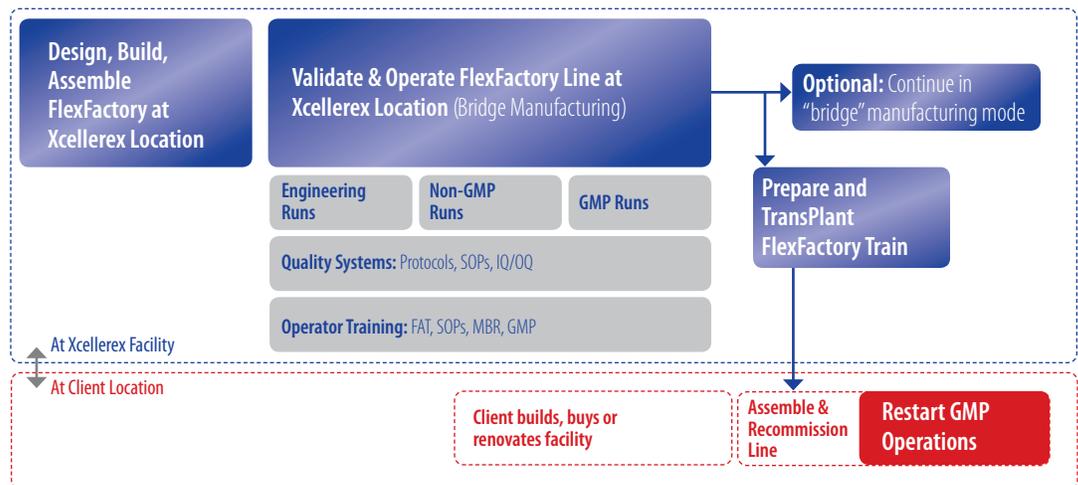
Integration and Process Know-How

Xcellerex is unique among equipment manufacturers in that we offer years of biomanufacturing operations experience and we use our equipment every day. Our team's experience in designing processes, integrating hardware and software, and designing optimized single-use facilities enables us to help our customers streamline their road to new capacity, while avoiding many of the first-time mistakes that lurk around every corner. More than our innovative equipment design and services offerings, it is this hands-on knowledge that our current customers value most in our partnerships.

A Typical BridgeSourcing Project with TransPlant Operation

A typical engagement will involve Xcellerex working closely with a client to define or transfer a process into pre-clinical, clinical or commercial scale production. Xcellerex will design and build a FlexFactory biomanufacturing train for the client, commission it, and operate it at an Xcellerex location, providing product and data for the client.

The client meanwhile can choose to build or remodel their own biomanufacturing facility at the outset, or later after some clinical or commercial milestone has been met. Once the client's facility is ready, and the timing is right for the client, Xcellerex TransPlants the production train and recommissions it at the customer location where it can begin making product again within weeks of relocation.



What TransPlant enables

With Xcellerex BridgeSourcing and TransPlant options, a client can:

- ▶ Gain **rapid access** to biomanufacturing capacity
- ▶ **Postpone investment** in their own facility until risk milestones are met
- ▶ **Train their operating team** at the Xcellerex site so they are ready to ramp-up quickly after the TransPlant
- ▶ Build their facility in parallel with the production train to **compress total deployment time**
- ▶ **Maintain long-term control** of their manufacturing economics and process

Summary: Strategic Advantages

The selection of the FlexFactory® biomanufacturing platform delivers unrivaled gains in speed, economics, risk mitigation and flexibility:



Speed

- ▶ 6-18 months vs. 3-5 years for new capacity
- ▶ Enables more informed investment decisions
- ▶ Faster product changeovers
- ▶ Rapid expansion of manufacturing capacity



Flexibility

- ▶ Compact clean room architecture: Modular, Portable
- ▶ Operator can access entire line
- ▶ Multiple product manufacturing
- ▶ Ability to TransPlant™ to customer
- ▶ Avoid long-term CMO lock-up



Less Risk

- ▶ Enables more informed capital investment decisions
- ▶ Pre-trained operating team avoids start-up mistakes
- ▶ Automation of quality assurance
- ▶ Operators removed from clean room
- ▶ Disposables minimize contamination



Economics

- ▶ Lower total capital cost (50%-75%)
- ▶ Lower operating costs (20%)
- ▶ Higher asset utilization
- ▶ Shorter timeline to product revenue
- ▶ Improved environmental impact

Interested in Learning More?

To learn more about how FlexFactory and the Xcellerex BridgeSourcing model might work for your organization, please contact us:

By email: bridge@xcellerex.com
Phone: 1.866.Xcellerex or +1 508.480.9235

Our team will schedule a review with you to understand your process and business needs, to describe our recommended approach and to answer any questions you might have.

