



company profile

Defining the future of biomanufacturing

Xcellerex is revolutionizing the way biomolecules are developed, manufactured and commercialized. The company's unique single-use technology platform transforms biomanufacturing economics, enabling the development of biotherapeutics and vaccines, and dramatically improving the ability of Xcellerex and its partners to deploy manufacturing capacity.

The Opportunity

The biotherapeutic and vaccine markets are undergoing enormous growth and change. More than 500 products, including therapeutic proteins, monoclonal antibodies, and vaccines are in clinical development and approximately 100 are on the market today.

The vaccine industry is undergoing a renaissance driven by scientific advances, the commercial success of new products, and an urgent need for new products to meet the twin threats of pandemic influenza and bioterrorism. In addition, the industry is undergoing a shift from egg-based to cell-based fermentation.

In this environment, biomanufacturing and the ability to deploy it rapidly and cost-effectively is becoming a strategic capability that is enabling to new biomolecule development and commercialization.

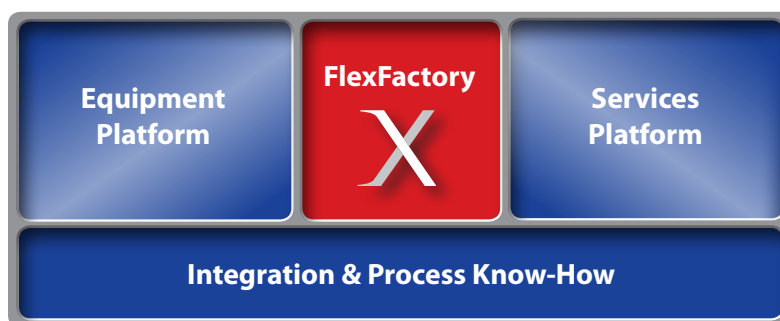
Increasingly, traditional biomanufacturing models — fixed, dedicated facilities and outsourced, traditional contract manufacturing (CMO) — have become development and commercial barriers. For the growing number of biomolecules aimed at specific subpopulations within a disease class, traditional manufacturing economics will not yield acceptable returns-on-investment. In addition, for many companies that have not pursued biomolecules to date, manufacturing expertise represents a major barrier to entry. Outsourcing is not an option due to the lack of CMO capacity and capability and “limited control of destiny.”

A traditional commercial manufacturing facility for a single product requires an investment of \$100-\$300 million and three to five years for construction and validation of its systems. Much of the cost is due to the infrastructure to maintain sterile conditions in reaction vessels and large scale environmental controls to maintain air quality in manufacturing suites.

In addition, the long lead time required to build a new facility increases development risk because manufacturing capacity decisions must be made early, well before it is known whether a product will succeed in the clinic and reach the marketplace. The CMO model presents significant challenges in efficiency, scalability, timing and control.

The Xcellerex Solution

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 a unique blend of expertise and services that we know to be essential to smoothing our clients' pathway to 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 TransPlantSM 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.

MANAGEMENT

GUY BROADBENT

President & Chief Executive Officer
(Thermo Fisher Scientific)

PARRISH GALLIHER

Founder & Chief Technology Officer
(Millennium, LeukoSite, Biogen,
Alpha-Beta Technology)

JOHN CHICKOSKY

Chief Commercial Officer
President, Biosystems Division
(Sepracor, CARR, Kendro)

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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.

Management and Organization

Xcellerex has built a management team with world class expertise in biologics manufacturing and outstanding track records in growing life science organizations. Guy Broadbent, CEO, brings a wide range of commercial, corporate and business development experience from a 30-year career at Thermo Fisher Scientific. Parrish Galliher, Chief Technology Officer, founded Xcellerex in 2002 after an extensive career that included positions as head of manufacturing at Biogen and Millennium Pharmaceuticals.

Xcellerex has developed an international team of technical sales professionals to serve customer demand in all major global markets. The company maintains 60,000 square feet of laboratory and manufacturing space at its headquarters location in Marlborough, Massachusetts, USA.

The company has raised over \$55 million to date from investors including VantagePoint Venture Partners, Kleiner Perkins Caufield & Byers, and SCG Capital.

Recent Milestones & Developments

▶ Xcellerex was awarded an \$11 million Phase 2 contract by the U.S. Defense Threat Reduction Agency (DTRA), to develop technology for accelerated monoclonal antibody and vaccine manufacturing.

▶ Xcellerex is launching its expanded line of bioreactors designed to **grow bacteria and other high density, high productivity cell lines.** Testing to date has yielded unparalleled results that have not been approached by other single-use bioreactor systems.

Current data demonstrates performance equivalent to stainless steel systems for:

- Pseudomonas OD (optical density) 260
- Yeast OD of 170
- e. Coli OD of 140
- Neurospora cell mass of 40 g/l dry cell weight.

Additional data for additional cell lines, including picchia and blue-green algae will be published soon.

▶ The biopharmaceutical division of a major pharma organization presented detailed results of a **head-to-head comparison between the Xcellerex XDR single-use bioreactor and an existing stainless steel bioreactor system.** Several evaluation runs were conducted in both batch refeed and fed-batch modes.

At the 500 liter scale, the Xcellerex system demonstrated comparable performance for cell density, viability and metabolic profiles. The titer was found to be comparable, and product quality was found to be equivalent to internal reference materials.

▶ Xcellerex launched the **world's first 2,000 liter single-use bioreactor** to complement its 50, 200, 500 and 1000 liter models.

▶ Xcellerex will deliver a validated **FlexFactory for clinical trials to a client in Europe in seven months**, which includes a GMP run performed by a newly trained customer team at the Xcellerex facility.