

Xcellerex, FlexFactory® and the Future of Biomanufacturing

Introduction

When Parrish Galliher founded Xcellerex in 2002, he and his team brought with them years of experience building and operating biopharmaceutical production plants. Having lived through the myriad challenges that biopharm executives still face today, they also brought with them a clear vision of what the future of biomanufacturing should look like. Today, at its headquarters in Marlborough, Massachusetts, Xcellerex has turned that vision into reality.

Strategic Biomanufacturing Challenges

With a finite supply of cash and a capricious timeline, biotech managers must invest to accelerate the path to commercialization, while taking great care to not deplete the financial runway before liftoff. One of the most complex investment decisions involves selecting a manufacturing strategy that provides manageable risks and robust economics. Biotechs face two basic manufacturing options: do-it-yourself or contract it out. Each comes with its own challenges.

Companies that choose to build their own manufacturing capacity often do so to optimize long-term control and economics. However, it typically costs tens if not hundreds of millions of dollars and takes 3-5 years to build, equip and validate a traditional biomanufacturing plant. This means significant capital must be committed during the riskier early stages of a molecule's development. Not only do these companies risk building plants for drugs that may never reach market, they also may find themselves with a plant that may not be suitable for manufacturing other products.

The other route preferred by many biotechs today is to partner with a CMO for clinical and ultimately, commercial, production. The CMO partnership can accelerate manufacturing start-up, and can avoid the need for premature capital investments. However, many CMOs will utilize proprietary cell lines, media and other technology that will limit the biotech's options in the future. The economics of the CMO relationship will often limit the future value of the drug to its developer.

FlexFactory and the Future of Biomanufacturing

To address these challenges, Xcellerex has developed a suite of products and technologies that, together, create the "FlexFactory." FlexFactory is a bioprocessing manufacturing platform built almost exclusively with disposables technology. The FlexFactory is organized into several discrete modules, each of which is self-contained in its own controlled environment. Xcellerex designs the FlexFactory with a client, then builds, validates and operates it in the Xcellerex production facility. Simultaneously, the client can build or renovate its own production space. When the time is right, the FlexFactory line can be TransPlanted™ into the customer's site and restarted within weeks.

The FlexFactory manufacturing strategy delays the biotech's facility build-out for as long as possible and greatly reduces investment risk (overall investment is significantly reduced too due to the simplified facility requirements). Overall time to commercial production is reduced by 70% or more.

In addition, because of its modular design and the disposable platform, the FlexFactory can easily be adapted for multi-product manufacturing. In effect, FlexFactory delivers the speed and capital efficiency benefits of the CMO approach with the control and long-term economics of company-controlled manufacturing.



Xcellerex, Inc.
170 Locke Drive
Marlborough MA 01752

1-866-Xcellerex
www.xcellerex.com