

Today's Biomanufacturing Model is Broken

Fixing the model will open new doors

Introduction

Modern biopharmaceutical production is burdened with problems very different from what the traditional pharma industry faced during its development. Where the pharmaceutical industry was built on the backs of blockbuster drugs, biopharm will grow as a collection of smaller, targeted treatments.

With more than 500 biopharmaceuticals in various stages of clinical development, the market is on the precipice of bursting with products that will outstrip available manufacturing capacity. Many biotherapeutics will hit a dead-end due to the lack of economical production options.

Add the emerging markets for biosimilars (more than \$20 Billion in pending patent expirations), vaccines, and the exploding need for pandemic and bioterror response capacity, and the biopharm industry faces an overwhelming production crisis. Without dramatic innovation in manufacturing strategies and technologies, the industry and the public it serves are in serious trouble.

Conventional Biomanufacturing: Too much time; Too much money

Increasingly, traditional biomanufacturing models – fixed, dedicated facilities and outsourced, contract manufacturing -- have become development and commercial barriers. For example, there are a growing number biomolecules aimed at targeted populations for which manufacturing economics preclude development. In addition, for many companies that have not pursued biomolecules to date, manufacturing expertise represents a major barrier to entry.

The current biomanufacturing model echoes traditional pharma: large, dedicated, fixed-pipe production trains that typically cost \$100 - \$300 million and 3-5 years to build and validate.

The ramp-time required to develop new biomanufacturing capacity demands that enormous investment decisions be made during the riskier early stages of a drug's development. Once capital is committed for such programs, any type of clinical hiccup or delay can be crippling to the sponsor, and the financial burden can bring the whole program, and sometimes the company, crashing down.

The current wave of disposables technologies is a promising step in the right direction, but even those technologies will not be enough if they are simply plugged into the existing paradigm.

The CMO Option: Any port in a storm?

Because of significant timing and investment barriers involved with building new capacity, the manufacturing strategy of choice for many biotechnology firms today is to partner with a contract manufacturer (CMO) for clinical and ultimately, commercial, production.

CMO partnerships can accelerate manufacturing start-up, and can avoid the need for premature capital investments. However, the CMO approach still represents the "lesser of two evils."

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 creates barriers to future technology transfer, effectively

binding the drug developer to the CMO indefinitely. This dynamic creates leverage for the CMO, resulting in economics that may limit the future value of the drug to its developer.

The Fix: FlexFactory® and the Future of Biomanufacturing

To address the challenges facing the industry, Xcellerex has developed a suite of products and technologies that, together, create the “FlexFactory.”

FlexFactory is a bioprocess manufacturing platform built almost exclusively with disposable component technology. The FlexFactory is organized into several discrete modules, each of which is self-contained in its own controlled micro-environment. FlexFactory literally “breaks down the walls” of traditional biomanufacturing,

Utilizing its in-house process development and optimization platform, Xcellerex designs each FlexFactory in close collaboration with a client, then builds, validates and operates the line 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 because the simplified facility takes less time to build, and because the overall build-out process can be dual-tracked.

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

Further, because Xcellerex offers integrated process optimization services and actively operates FlexFactory production for clients and proprietary in-house programs, the company offers comprehensive process knowledge unavailable from typical equipment-only providers.

Conclusion

Xcellerex believes FlexFactory offers the biotechnology industry a unique pathway to prosperity. By treating biomanufacturing as an enabling strategy (vs. a barrier), the industry’s vast promise may in fact materialize.

In fact, Xcellerex is so steadfast in its belief in the platform that the company is actively building its own portfolio of proprietary biomolecules. The viability of each of these molecules has been rescued by the breakthrough economics offered by FlexFactory.



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