Cytovance Biologics White Paper #3

A Strategic Partnership Delivers Innovation, Efficiency In Biotechnology Manufacturing Training

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Biotechnology manufacturing training represents a large, often challenging investment. Developing and implementing an effective training curriculum takes months or years, diverting valuable time and resources away from other projects. Talent acquisition is difficult in many United States regions, with local candidates lacking biotechnology or life sciences manufacturing experience. Unfortunately, undertraining can lead to many operational issues, including production errors, record inconsistencies, and in worst cases, product contamination.

As an experienced contract development and manufacturing organization (CDMO), Cytovance Biologics (Cytovance) creates innovative solutions that deliver value to our customers. Cytovance has a successful training methodology common in smaller biotech, relying heavily on procedural training combined with side-by-side training with subject matter expertise. As Cytovance experienced exponential growth, we realized we needed to streamline the training process to standardize across departments and to reduce the time to proficiency in our manufacturing areas. A cross-functional team set out to find the next step in evolving our training methodology.

This endeavor drove us to partner with the National Center for Therapeutics Manufacturing (NCTM) at Texas A&M to provide a customized training curriculum based on their workforce development curriculum/certification. Compared to estimates for developing the training program in-house, we achieved results in a fraction of the time (three months vs. an estimated 18 months) at a fraction of the cost (33 percent of the estimate).

ADDRESSING KEY CHALLENGES

Cytovance set out to provide the most effective onboarding and training program that would address the rapid growth we were experiencing. We quickly realized that with growth came challenges: transitioning talent pool, organizational consistency, reduced time to autonomy (proficiency), and a high demand on our current subject matter experts (SMEs). Because we are based in Central Oklahoma, our local, entry-level talent pool is relatively small, with very few candidates possessing life science manufacturing experience. Although we were able to staff supervisory roles with experienced candidates from the coastal regions, fully staffing and training an entry-level team using traditional methods became an expensive proposition.

We also had to consider how to create consistency and alignment across departments so that the same foundational information is being conveyed. We noted that many traditional training modules primarily focus on standard operating procedures (SOPs), an approach that functionally trains candidates but provides little environmental context and omits critical hands-on training opportunities, inhibiting deeper learning. Further, training outcomes were not always clear, creating potential confusion over time. Developing a program that could quickly address these challenges would have required more demand on our SMEs, devoting time and effort away from revenue-generating work processes during a very busy, high-growth point in the company.

To overcome these challenges, we partnered with NCTM to pilot a curriculum built on a “basic scientific language” (BSL) framing our technical con-

cepts in an engaging, educational way and augmenting our hands-on training activities.

LEVERAGE A SCIENTIFIC LANGUAGE

As a workforce education and research center serving global life sciences manufacturers, NCTM develops training modules that provide trainees with a foundational education on manufacturing science and its associated regulatory landscape.

By integrating NCTM's world-class educational approach with our SOPs and knowledge base, we created a general manufacturing program that produced functionally capable and fully engaged trainees in record time. Our program included 8+ hours of interactive, professional grade e-learning and 60+ hours of lectures, activities, and assessments (not including lab training).

The specific modules began with two e-learning courses introducing trainees to general pharmaceutical manufacturing, as well as CGMP procedures and documentation. From there, the modules dive deep into relevant topics, such as controlled environments, aseptic technique, chemistry of solution and media preparation, flow filtration, and upstream/downstream processing.

Throughout, we placed heavy emphasis on establishing clear learning objectives and accountabilities for each module, leveraging SMEs to manage and contextualize modules. This is important for several reasons. First, we have already observed the success of leveraging our SMEs to conduct on-the-floor training and to provide guidance on our processes and we wanted to maximize on that strength as a company. Second, having clear learning objectives helps you identify gaps in knowledge, skills, and abilities and a better tracking of retraining and process improvement. Finally, we expect that over time, the learning objectives will help to reduce error rates and time to proficiency and improve outcomes, employee retention, and development across a diverse range of projects.

The partnership with NCTM afforded us several benefits, including:

- The creation of a highly versatile, highly knowledgeable team with potential for retention and advancement
- The preservation of time and resources that would otherwise be used to develop a curriculum from scratch
- The ability to leverage content during our region's peak recruiting window, facilitating speed
- The implementation of important validity checks and benchmarks

These benefits quickly translated into direct value to our client. Cytovance's analysis determined that a 40-hour training program could take between 100 - 900 hours to develop, depending on complexity and expected outcomes. Furthermore, the expenditures of paying curriculum designers and using SME time to develop curriculum could put your costs well in to the $200,000 range and take a year to two to develop. This was not feasible to Cytovance as training content was needed quickly to meet growth demands at a time when we were already dedicated to working long hours on client projects. The partnership with NCTM, who had at least 80 percent of the content already developed, allowed Cytovance to customize and supplement the content in roughly 90 days, reducing the development time by two-thirds.

EXPANDING DEVELOPMENT

Following our initial success with the General Biomanufacturing Processes training program, Cytovance is leveraging several other ways to utilize the content, including rolling out other modules that have been customized, such as:

1. Upstream Biomanufacturing Processes
2. Downstream Biomanufacturing Processes
3. Biomanufacturing Processes Lecture Series
4. Regulatory Lecture Series

We have found that finding a strong partner with a similar purpose has created a mechanism to enhance and improve what we offer to our employees as well as provide cost-effective curriculum design. This may not be the best method for every biotech, but it is a partnership that has been a tremendous success for Cytovance. If you are considering doing this in your organization, here are some of the steps we took to help us be successful:

- Find the right partner. Usually a workforce development program, technology center, or university.
- Work through the logistics, intellectual property, training consents, etc.

- Get a cross-functional curriculum team: training, science, manufacturing, etc.
- Create the business case with clear cost-benefit analysis for senior management.
- Establish clear learning objectives to drive training analytics.
- Work with stakeholders and managers to help them understand the objectives.
- Train managers first so they know what others will be trained on, as well as expectations for employees when they come out of training.
- Allow for ways to continually review and update the training with the partner and managers.

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ABOUT CYTOVANCE BIOLOGICS

Cytovance® Biologics is a leading biopharmaceutical contract development and manufacturing organization (CDMO) that excels in the rapid and cost-effective development and manufacture of large molecule active pharmaceutical ingredients (APIs) from both mammalian cell culture and microbial fermentation such as monoclonal antibodies, fragment antibodies, bispecifics, enzymes, fusion proteins, vaccines, and other biological products, including plasmid DNA and cell-based therapeutics.In addition to our clinical and commercial CGMP API manufacturing services, Cytovance offers well-integrated development services supporting the entire product life cycle, including cell line development, cell banking, microbial strain development, process and analytical development, and process characterization. A centralized, responsive program management team coordinates all critical chemistry, manufacturing, and controls (CMC) activities for each client program around raw materials management, QC testing, ICH stability studies, and regulatory support. Our 140,000 sq. ft., state-of-the-art facility in Oklahoma City is designed to meet U.S., EU, and other global regulatory standards.

Cytovance® offers deep industry expertise and unique customized services for the scale-up and cGMP manufacture of protein-based therapeutics from early-stage preclinical development to commercial production, for both mammalian and microbial. Further information can be found at www.cytovance.com.

ABOUT THE NATIONAL CENTER FOR THERAPEUTICS MANUFACTURING (NCTM)

The National Center for Therapeutics Manufacturing is an interdisciplinary workforce education and research center serving the global biopharmaceutical and vaccine manufacturing industries. A member of the Texas A&M Engineering Experiment Station, the NCTM develops and delivers customizable instructor-led, computer-based, and hands-on learning to expose the student to various aspects of cell culture and basic molecular biology, aseptic processes and microbiology, upstream and downstream processing of biological materials including viruses, monoclonal antibodies and other recombinant proteins, as well as industrial bioanalytical methods.

NCTM also provides enabling technologies to academic/medical researchers and start-ups through its blended infrastructure of academic, scientific, and industrial expertise and complete range of bench-to-pilot and Phase 1 scale bioprocess and analytical equipment. Our capabilities include:

- Media screening to improve cell line productivity
- Expression systems including bacteria/yeast/mammalian/algae/insect lines
- Protein expression and purification
- Process development/optimization support
- Analytical methods development and characterization