Pharma Intelligence

The Need To Re-Establish CDMO Relationships In A Changing Landscape

POWERED BY SCRIP

IN ASSOCIATION WITH NORTHWAY® BIOTECH

Pharma Intelligence

The Need To Re-Establish CDMO Relationships In A Changing Landscape

POWERED BY SCRIP

IN ASSOCIATION WITH NORTHWAY® BIOTECH

The Need To Re-Establish CDMO Relationships In A Changing Landscape

BY VLADAS BUMELIS, PROF.

The Pandemic Storm

The COVID-19 pandemic continues to change the landscape for the global pharmaceutical industry. While there are certainly procedural and technological improvements as a result, continuing lockdowns are creating additional delays. Currently, countries pivotal to manufacturing – such as China – are still enforcing severe COVID lockdowns. Pharmaceutical companies are having to reconsider their options to take part in any person(s) in plant (PIP) activities, which remain essential even with all of the remote technology improvements. Understandably, companies are feeling the strain of such delays, but particularly biotechs – where a delay could cause a financial shutdown – are the most anxious.

During COVID-19, multiple problems created significant delays. Depending on the lockdown, employees were either unable to enter the biomanufacturing plant or staffing is reduced to ensure safety by enforcing social distancing. PIP activities, for example during technology transfers, also proved to be costly, from the delays encountered in entering the plants to the quarantining of the designated PIP employees.

All of the above scenarios created interruptions as the workforce was partly unable to complete tasks in a timely fashion. Delays, however, didn't stop there. Transport became an issue. Substance and product shipment delays were common because port workforces were greatly reduced to keep employees safe. Additionally, couriers depending on commercial

flights also experienced issues with shipping delays and had to store products as they waited for flights to become available.

Changing Landscape Leads to Growing Pains

The market changed, starting at the regulatory level. Agencies waived regulations to try to assist streamlining the process. As an example, the European Union waived monoclonality for certain COVID-19 applications. This presented new problems for manufacturers as it pushed the envelope and forced contract development and manufacturing organizations (CDMOs) to rethink and become innovative in their strategies.

With these changes, both large and small pharma companies started working preferably with local CDMOs, with a preference towards them being almost in sponsors' backyards, particularly in the United States, which influenced Northway Biotech's decision to open a facility outside of Boston, one of the major hubs in the global biotechnology industry. Additionally, when a pandemic strikes, funding is awarded to treat the pandemic, as happened in the United States and Europe. Therefore, sponsors need to look for CDMOs with the flexibility to change assets and meet manufacturing requirements required by this funding.

This, too, however, created new issues as local CDMOs were flooded with clients on a first come, first served basis, and often sponsors did not have the time to do the proper due diligence. As a result, many CDMOs were booked to capacity for anywhere from a year to two years. Not only were spots difficult to find, but switching to a new CDMO came with its own challenges, as another arduous and even costly search for spare capacity would be needed.

Evaluation and Escape Strategy

It is important to figure out early if a CDMO fits a sponsor's needs, especially when establishing new working relationships. To avoid future delays, sponsors must now evaluate if a CDMO can handle all of their needs. Some CDMOs are suitable for early development but do not have the capacity to fit their needs in later clinical and/or commercial launch stages. While no longer an urgent need, many sponsors are now left searching for a better fit for their projects – one that is flexible and innovative enough for all of their workstreams.

The question for sponsors already facing having to switch CDMOs is when to do so. There are many factors to consider when moving, but it largely comes down to risk management. Some CDMOs are not particularly conducive to technology transfers, so the potential for data loss can become a big issue. Additionally, there may be proprietary information – such as a cell line or process – that will not transfer. Thus, the sponsor may have to start again from scratch. Such factors need to be discussed between the backup CDMO and the sponsor to find an optimal time to switch.

"It is important to figure out early if a CDMO fits a sponsor's needs, especially when establishing new working relationships."

To be successful in switching, clients should work with CDMOs that adopt to the client process, and not vice versa, using a cus-

tomized approach. The discussions between a sponsor and CDMO should be full of questions regarding the project, but this becomes even more important with a backup CDMO. Typical discussions should inform sponsors of current and future slot capacity, the types of slots available, and an understanding not only of the type of projects but also of the client type that a CDMO has experience with. A smaller sponsor, such as a biotech, could be overlooked in some cases.

CDMO Strategic Planning

Another important consideration largely overlooked in sponsor and CDMO discussions is the CDMO's strategic planning. To increase capacity, the CDMO needs to be looking at future demand. As an example, if there is a need for additional equipment, such as bioreactors, the delivery considering typical lead times could easily take up to a year. All of this comes prior to setting up and commissioning such equipment.

Additionally, changes within the CDMO's workforce and training also need to be part of the strategic planning. Maintaining staff while reducing turnover is a key part of a sound business. The need for a positive work environment becomes imperative. Retention rates are important to sponsors, as high personnel turnover only causes confusion and creates delays. A CDMO's strategic planning has to have already anticipated such changes months – and sometimes years – in advance to have everything in place at the right time.

> "To be most effective in this market, CDMOs that have everything under the same roof in addition to being up to date with the latest technologies can offer a one-stop-shop project advantage."

CDMOs Today

To be most effective in this market, CDMOs that have everything under the same roof in addition to being up to date with the latest technologies can offer a one-stop-shop project advantage. Northway Biotech wants to be the best CDMO partner for its clients, to make their lives easier and instill confidence during an anxious time for the industry.

Justifiably, anxiety is a consequence of COVID-19, but with it came a change to how sponsors conduct their business. Understanding that another pandemic could easily impact the world, it is now standard practice for sponsors to reach out to multiple CDMOs as backups. When evaluating the current landscape, sponsors – especially biotechs – are more conscious of potential issues and of evaluating CDMOs for quality and flexibility over costs. Additionally, to reduce gaps in the process and data loss from technological transfers, the trend is moving toward CDMOs with capacities to scale up as needed and with customized and flexible approaches to conducting such tech transfers. It is all about strategy and finding the right balance between immediate and long-term needs for both the sponsors and CDMOs.

Vladas Algirdas Bumelis, Prof.

Vladas Algirdas Bumelis, Prof., is the Founder and CEO of Northway Biotech. He holds PhDs in both chemistry and biotechnology from Vilnius University and is a full member of the Lithuanian Academy of Sciences. Prof. V. Bumelis has extensive experience in the pharmaceutical and biotech industries, having previously served in senior management positions at international companies in the biopharma industry such as Teva Pharmaceuticals, Sicor Inc., Biofa, and Biotechna. His illustrious career has been recognized many times. In 2004, Prof. V.Bumelis received the Science Award of Lithuania in recognition of his achievements in the development and production of recombinant proteins, while in 2012, he was named CEO of the year in Lithuania.

Scrip
Pharma Intelligence

NORTHWAY®
BIOTECH

About Northway Biotech

Northway Biotech is a leading contract development and manufacturing organization (CDMO) supporting customers worldwide. Its highly experienced, professional team executes projects at any stage, from cell line construction and process development to cGMP manufacturing of biopharmaceutical products. The company's wide-ranging expertise and vertically integrated service offering translate to the ability to rapidly execute multiple projects from its state-of-the-art GMP facilities while ensuring full process and product compliance at all stages of research, development and commercial manufacturing. Northway Biotech is a privately owned company founded in 2004 and located in Vilnius, Lithuania; London, United Kingdom; and in Waltham, Mass., U.S.

Learn more at www.northwaybiotech.com