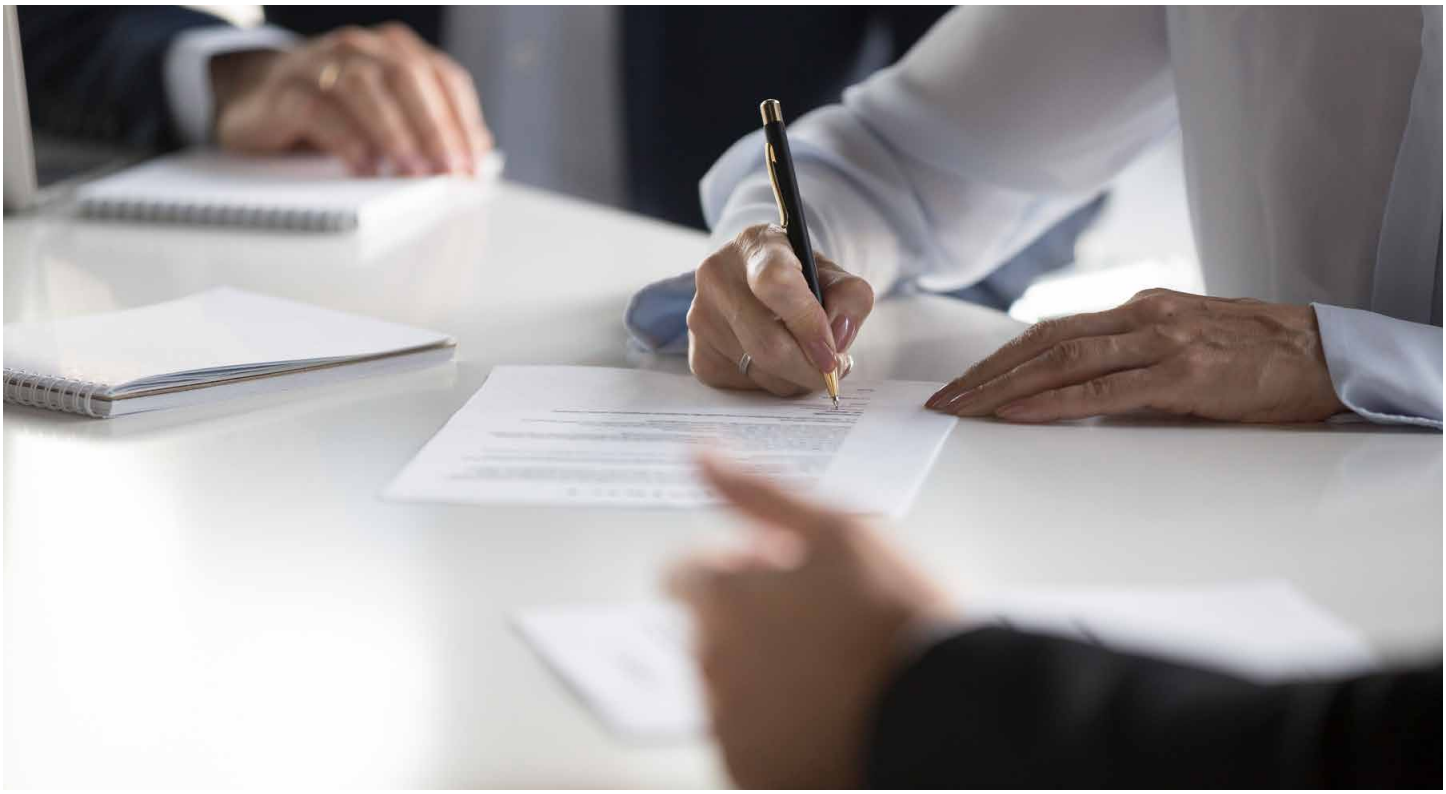
Preparing for the green light: Considerations for post-approval biologics manufacturing

The development process for a vaccine or biologic can be complicated and costly, often involving a lengthy and time-consuming journey spanning several years. Following clinical development and in preparation for approval, it is essential to plan for the commercial manufacturing of your cell culture media. This will allow you to maintain the highest levels of quality and efficiency in your process at a commercial scale. Following approval, this forward-thinking and preemptive planning will help you avoid excessive costs and continue to produce consistently into the future [1].

The following are considerations you should not overlook before, during, and after clinical trials.

Raw materials analysis

Your raw materials may have already been scrutinized and optimized during the clinical phases of your development journey. However, this should not prevent you from analyzing your raw materials post-approval. At commercial volumes, detecting contaminants in raw materials becomes more crucial than ever. Compared to work at a pilot scale, transitioning to larger, commercial batches of raw materials will increase the likelihood of more extensive batch failures due to contamination. This can often be forecasted using digital analytical and statistical (design of experiment) programs to help identify and prevent potential loss of end product as early as possible.



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Your chosen media manufacturer must understand your long-term goals and be willing to follow the necessary steps to facilitate a high-quality raw materials supply chain. Measures such as ongoing monitoring and characterization of raw materials must continue throughout the product life cycle to mitigate risks when fluctuations do occur. This will prevent poor or suboptimal end products from failing QC testing, support the maintenance of your approved status, and help maintain business continuity in the long-term.

Secondary supply

You may have already secured a primary supplier for your cell culture media and process liquids, but qualifying a secondary supplier is a wise risk mitigation practice to avoid supply chain disruptions. If you are increasing quantities beyond your current media manufacturing capacity or that of your current manufacturer, this should be high on your list of post-approval priorities.

While qualifying a secondary supplier may seem like an arduous task, this is outweighed by the vast benefits it brings in terms of business continuity and risk reduction. Secondary or even tertiary suppliers can help increase capacity to continually manufacture large quantities of media while mitigating potential capacity constraints from a primary supplier. Although rare, sudden facility closures are possible during emergencies such as natural disasters or health care crises. As a result, having a preapproved network of additional suppliers will improve the resilience of your unique supply chain.

Strong customer–supplier relationship

A strong relationship with your supplier throughout the process is essential, especially when ordering your liquid or powder formulations in substantial bulk quantities. Good open communication can help mitigate delays in the delivery of your stock to your unique specifications.

Data transfer speed and transparency will also be critical when you enter the commercial stages, allowing for prompt notifications of abnormalities and fluctuations potentially impacting your processes. Examples may include a change of vendor for raw materials, or even a delay in the delivery of your order.

As part of your relationship with your supplier, it is also vital to have a clear understanding of how your intellectual property (IP) will be kept safe. Protecting the unique formulation that you have established throughout your lengthy process development is critical, to help you maintain a competitive advantage in the biopharmaceutical industry [2]. Therefore, it is important to solidify data protection and nondisclosure agreements early on before you begin working with your chosen supplier. Throughout your relationship your supplier should be taking measures to protect your data, such as implementing robust network security systems and training programs, which you can audit.

Considering the above factors is essential in order to help maintain the biologic drug approval status you have spent years working to achieve. Taking these into account as early as possible in your development journey could significantly reduce the risk of supply issues further down the line. This will allow you to smoothly scale up to commercial manufacture and continue to provide the world with life-changing therapeutic products.

References

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2. We Work For Health. Biologics and IP, The Importance of Protecting Intellectual Property. **https://www.weworkforhealth.org/content/biologics-and-ip**.

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