What to look for in a cell culture media supplier: key considerations to reduce risks and manage costs

Cell culture media is an essential component of biopharmaceutical manufacturing, directly influencing cell growth and function. Given the foundational role of media in determining process productivity, choosing a supplier is a critical decision when scaling up production to commercial volumes.

When evaluating any potential vendor, whether for a catalog or custom medium formulation, it is important to ensure it can meet your unique needs. These include achieving maximum cell culture media quality and consistency, meeting lead time and cost requirements, and providing the support you need to secure continued success. A vendor failing to meet your requirements can result in significant disruption, reducing the long-term productivity of your workflow and increasing overall manufacturing costs.

It is worth considering the advantages of working with an experienced global vendor with a large overall manufacturing capacity and advanced quality control processes either as your primary or secondary supplier.

Through its multisite network and expanded capabilities, a global supplier may be able to provide increased supply security, more consistent media, and other benefits that can help you achieve long-term efficiency.

When considering a global supplier, it is still vital to carefully assess its capabilities and validate if it can meet both your current and future needs. To help you streamline your evaluation process and maximize confidence in your media supply, there are five key factors you should consider.

1) Robust quality systems and raw material risk reduction

High-quality media is crucial to consistently achieving optimal process performance. As a result, validating that your supplier has robust quality systems and established processes to reduce variability risks is critical during the selection process.

When evaluating a supplier, ensuring regulatory compliance is paramount—both to protect patient health and avoid costly fines. Within this area, regular quality audits and detailed protocols to maintain compliance are key features to assess. When working with a global supplier, you should also confirm it adheres to the regulatory guidelines of your country of operation.

Suppliers should have strict raw material sourcing and analysis programs in place, as well as qualified secondary, and even tertiary, supplies of critical materials. When considering raw material quality, control of trace element contamination is

especially key. Even small deviations in the trace element profile of your media can dramatically impact product quality and lower productivity.

Microbiological contamination is another potential source of variability that your supplier should have dedicated protocols to control.

2) Global capabilities and supply assurance

Maximizing supply assurance is central to reducing the risk of costly manufacturing delays. Supply disruption can arise due to a range of different factors. Even relatively small disruptions could potentially cause significant productivity losses, so assessing the strength of a vendor's supply chains should be a key priority.

To limit the risk of delays caused by late or unfulfilled orders, choosing a supplier with a global manufacturing network and built-in redundancies can be highly beneficial. Through its ability to provide redundant capacity, the supplier can act quickly to mitigate any disruption, as equivalent products can be produced and shipped from another site within its network.

Likewise, having capabilities across multinational sites results in the ability to source raw materials globally, helping the supplier strengthen its raw material supply chains and increase overall supply assurance.

3) Media customization and CGMP proprietary media manufacturing options

Suppliers with media development capabilities, media customization options, and small-scale pilot media prototyping services can enable you to test and improve the manufacturability and scalability of a custom formulation. Novel components can be added, and components not driving cell culture performance can be reduced or removed. An experienced production team can help ensure your formulation is consistent and may accelerate a streamlined transfer to CGMP manufacturing when you are ready.

If you are considering outsourcing CGMP media manufacturing for your own formulation, a major benefit of working with a proven manufacturer is access to multiple format options and experience in media format conversion. Custom packaging can also be tailored to the needs of your project to help reduce risks and improve operational efficiency. In the end, outsourcing your media manufacturing may allow you to purchase media in larger quantities than could potentially be produced in-house, without increased investment.

If your new therapy is intended to serve patients across the world, there is also no substitute for having as much experience as possible on your side—including the global expertise in regulatory filing offered by a worldwide media manufacturer.

4) Optimal lot-to-lot consistency

Batch-to-batch media inconsistency has the potential to have a significant impact on process performance and increase costs. Many different factors can introduce variability into media—from raw material impurities to out-of-specification manufacturing equipment. It is crucial to select a manufacturer with dedicated procedures to control these factors.

If you are working with a global supplier with multiple manufacturing sites, a fully harmonized network can give you confidence in the consistency of your media, no matter which site it is produced at. When evaluating whether a potential supplier can achieve this, looking for a comprehensive site-to-site equivalency program should be prioritized.

Ask your potential media manufacturer to provide details on harmonization across critical areas, such as raw material sourcing and analysis, manufacturing processes and equipment, and finished product QA/QC testing. Additionally, evidence that the supplier is continuing to invest in maintaining equivalency at new facilities is another indicator of a supplier that can help you optimize consistency.

5) Analytical support

Even after optimizing for quality, supply assurance, and consistency, challenges may still arise during commercial manufacturing. In the event of process disruption, rapid responses are critical to help minimize downtime. Working with a supplier with the analytical capabilities and knowledge to investigate any process variability efficiently and thoroughly can have many benefits.

A supplier with broad analytical capabilities can help resolve manufacturing challenges ranging from inconsistent product quality to more complex issues such as precipitates, extractables, and leachables. Furthermore, having access to experienced consultation to interpret analytical results and provide actionable insights can help you optimize your workflow and streamline production.

gibco

Maximizing success with a global supplier

No matter the supplier you choose, carefully evaluating its capabilities within these five areas can help you maximize confidence in your media supply and optimize productivity.

An experienced supplier with a global footprint and extensive capabilities can support you in achieving manufacturing success—often with long-term savings and efficiencies that would not otherwise be possible.

With over 60 years of cell culture experience, in-depth quality systems, and comprehensive support services, Thermo Fisher Scientific can help you optimize your process.

Thermo Fisher expands media manufacturing to China site

Thermo Fisher has recently increased its local technical support, sales, and manufacturing presence by launching Gibco™ Rapid Prototyping Services in China.

Located in the Huqiu District of Suzhou City, Jiangsu Province, this expansion offers greater speed and efficiency to biopharmaceutical customers in China. Through this service, small-scale, non-CGMP production of customized cell culture media, feeds, supplements, and buffers can be rapidly sourced for research use and process development.

The Suzhou facility complements two other global Gibco Rapid Prototyping Services sites and works closely with the entire Gibco™ cell culture network of CGMP media production sites. It provides simplified technology transfers and media scale-up under harmonized process controls and quality management standards.

This local resource provides fast and flexible responses and fosters technical collaborations between customers in China and Thermo Fisher's global bioprocessing specialists to help deliver an enhanced customer experience.

Learn more about Gibco Rapid Prototyping Services, or request information, today.

Learn more at **thermofisher.com/mediamanufacturing**

gibco

For Research Use or Further Manufacturing. Not for diagnostic use or direct administration into humans or animals.
© 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **EXT6025 1123**