Article

Cell culture

The power of communication and transparency

Qualifying secondary cell culture media supply

Whether you need to reduce risk from supply chains or require a greater capacity when scaling up, there will be times when an alternative supply of your cell culture medium is required to streamline and safeguard your biopharmaceutical development. Securing a secondary supply of your medium is essential to support these needs, but it's also important that you have full confidence in your back-up.

For instance, your selected secondary supplier must provide assurance that your proprietary formulation can be manufactured to the same specifications at a secondary site. The key to achieving a successful secondary supply qualification and the commencement of an effective collaboration is establishing confidence and trust between you and your supplier, built on a foundation of close communication and transparency.

Understanding the task at hand

In this unpredictable world, sudden changes can result in major impacts to supply chains. From weather events to global conflicts, these changes can lead to disruptions, causing sudden shortages or stoppages in the supply of your critical goods. To help ensure the manufacture of consistent formulations at different sites, your supplier must have a robust and multifaceted equivalency program between its facilities, including equipment validations, staff training, and raw materials supply. Thermo Fisher Scientific offers you a global footprint and redundancy in key capabilities to help de-risk your workflow, providing a reassuring, uninterrupted worldwide supply. This network capability provides you with confidence that you can maintain the security of your raw materials, both in terms of consistent quality and the quantities required.

Reassurance through robust data

To help assure you that these issues have been considered and secondary site equivalency has been achieved, vendors must maintain open communication and transparent data sharing. As biopharmaceutical developers wanting to reach the clinic as fast

as possible, you require extensive information to confirm that manufacturing facilities are harmonized for streamlined technology transfers.

A data package will include comprehensive information on a range of equivalency parameters, including the homogeneity of mixtures, qualification procedures, and testing protocols. This package will also advise you of supply chain security and the quality of raw materials achieved through a strict supplier qualification program, batch testing, and regular audits. Thermo Fisher also offers trace element testing, upon request, to help increase visibility, control, and mitigation of any potential raw material variability.

A further important consideration for biopharmaceutical developers is whether the same high quality can be achieved at the vendor's manufacturing facilities. In order to achieve this, vendors must operate equivalent quality management systems and provide evidence that the facilities are certified to the same standards, with validated methodologies based upon current FDA or EMA guidelines.

Prior to qualification, it is imperative that test batches be prepared in order to validate equivalency, and that the correct formulation specifications can be achieved at the secondary site. Relationships can also be strengthened by supporting you at an early stage of your project through pre-CGMP prototyping services.

Rapid turnaround of small-scale prototypes can significantly shorten timelines and, when undertaken with scale-up in mind, can provide results that mirror later CGMP manufacture. Combined with the confidence achieved through successful harmonization of manufacturing sites, this approach helps reassure you that there are multiple steps in place to prevent unnecessary delays if a secondary supply is required.

Achieving smooth communication and transparency

Timely and transparent communication between a customer and vendor is critical for the success of a supply collaboration. Trust must be developed at the early stages of the project, prior to the technical transfer, and maintained as the project moves forward.

Your supplier must provide you with confidence that it can maintain the security of raw materials, in terms of both consistent quality and the quantities required.

Your vendor should take the time to understand you as a customer and connect you with the right point of contact for support. You should expect to see strong internal communications between manufacturing sites and efficient, accurate information flow. With Thermo Fisher, you will have a single point of contact to help maintain lines of communication while reducing the likelihood of misunderstandings. Regularly scheduled meetings, along with transparency around lead times and inventory, help to proactively manage expectations.

The use of electronic data capturing systems can facilitate effective communication and greater transparency between you and your media manufacturer. By sharing interlinked operating and information management systems online, you can instantaneously receive information to evaluate batch tests and the manufacturing process as the project proceeds.

Certificates of Analysis (COAs) are important documents used to support authenticity and traceability, confirming regulatory compliance and providing key data (e.g., osmolality, pH, performance assay results, etc.) specific to your lot. Some suppliers are now offering digital CoAs, such as Thermo Fisher Scientific's VeriCert Exchange™ program, allowing you to quickly and easily access this data.

A good supplier should also drive continuous improvements. This can include investing in innovative tools like automation and user-friendly portals, but also by listening to your feedback and acting on it. They should offer real-time support that responds at your pace and demonstrates superior engagement with your specific project needs.

Creating confidence

Altogether, successful secondary supply qualification requires a comprehensive demonstration of site equivalency and that a high probability of comparable performance has been established. The transfer of a project to CGMP manufacturing can be a challenging time for biopharmaceutical developers, and reassurance through robust data is required every step of the way. Media manufacturers, such as Thermo Fisher, that approach projects with openness can help supply you with the confidence needed at this critical stage of your drug development journey.

Learn more about streamlining media manufacturing, no matter the stage or scale, at **thermofisher.com/media-manufacturing**

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