

Media by Design Services

Cell culture

Benefits of working with a custom media development collaborator

Cell culture media is a fundamental driver of process productivity during biopharmaceutical manufacturing. Utilizing a medium with an optimal formulation is critical when trying to meet bioproduction process targets.

During the early phases of clinical development, when speed is a priority, using a catalog medium can be sufficient. However, as you move closer to commercial production, optimizing process parameters such as product titer, cell growth, and viability becomes increasingly important. At this point, you may find that an off-the-shelf medium does not have the most suitable composition to meet the productivity requirements of your chosen cell line or process that are necessary for commercial manufacturing.

As a result, you may opt to improve process performance by choosing a custom cell culture media formulation instead. At this stage, there remains a significant strategic decision—whether the custom medium should be developed in-house or with a third-party media development collaborator.

Choosing to outsource any process during biopharmaceutical development and manufacturing can initially be seen as an unnecessary expense when you need to minimize costs. However, working with a media development collaborator comes with a range of benefits that can offset the initial investment.

To decide whether you should choose an external collaborator, it is vital to consider your requirements alongside these potential benefits.

Additional resource capacity and capabilities

The choice between in-house or outsourced media development will firstly be dictated by resource utilization. A third-party collaborator can help alleviate the in-house resource demands of developing a custom medium. This can free up internal capacity to be reallocated to other projects or process development tasks, potentially accelerating overall development timelines.

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Alongside increasing internal capacity, collaborators can also offer access to additional equipment, knowledge, and experience. Successful development of a suitable cell culture media formulation relies on effective assessment of the components that are driving productivity and critical quality attributes within the medium. A collaborator is likely to have access to key tools and techniques to identify these crucial components, with the expertise to interpret analytical results and provide actionable insights to optimize their levels.

Techniques such as spent media analysis, proteomic and metabolomic analyses (together known as multi-omics), and key driver identification methodologies can provide detailed information about the cell culture environment. This can help you understand which specific components in a medium formulation are driving cell culture performance the most, and ultimately help you arrive at a formulation that maximizes productivity.

Optimizing scale-up

Scale-up is a crucial phase of process development, and challenges at this stage can present unexpected hurdles that can reduce your speed-to-market. For example, failed conversion of the formulation to a dry media format for large-scale manufacturing can result in significant delays.

With a media development collaborator, you can benefit from formulation expertise that considers both the media format and the components themselves. This knowledge can help reduce the risk of scalability and manufacturability challenges arising during scale-up and into the future.

Some collaborators can also offer rapid prototyping services to help you further avoid challenges during scale-up. With swift turnaround times, the manufacturability and scalability of batches can be quickly assessed without incurring the high expense of trialing cGMP production. Rapid prototyping can also test various raw materials to determine which one is most suitable for the process, allowing quick and well-informed decisions to be made.

Managing raw materials

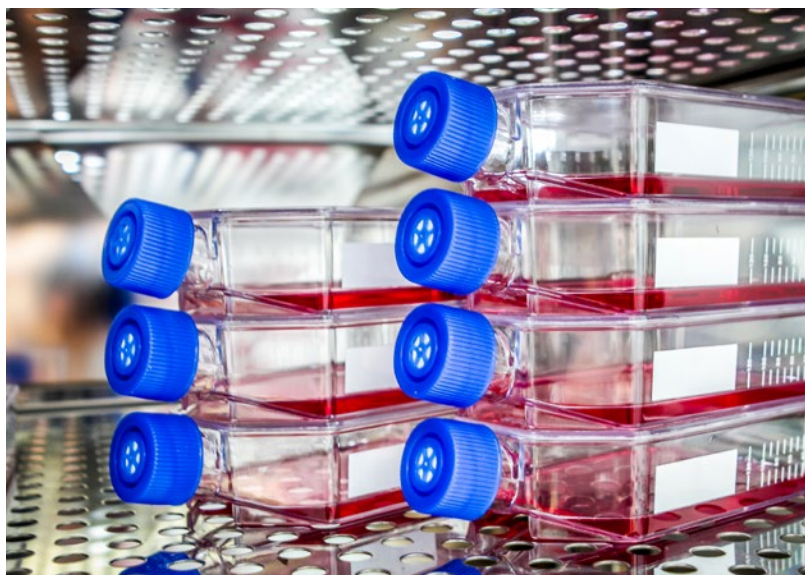
Achieving consistent process performance is also contingent on the quality and consistency of the raw materials from which the medium components are derived. Impurities such as trace metals can have a significant impact. Controlling raw material variability can be a challenge, particularly as raw materials are often sourced from various suppliers.

A knowledgeable media development collaborator can offer proprietary methods and troubleshooting capabilities to help mitigate the risk of raw material variability and minimize the

incidence of process inconsistency. A collaborator's strict qualification requirements for raw material suppliers can help minimize batch-to-batch inconsistencies. This is especially advantageous for processes that are particularly sensitive to trace element contamination. This insight can also assist in identifying any raw material defects or trace elements that could negatively impact scale-up, that can be easily overlooked with insufficient in-house analysis.

Reducing risk in the long term

In addition to developing the medium itself, media development collaborators can also provide ongoing support. Once a suitable medium has been developed, further challenges can arise during commercial manufacturing. Continued access to the R&D team that designed the medium formulation can potentially help manage future batch-to-batch process inconsistency that may occur and help resolve problems in a timely manner.



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Alongside the manufacturing benefits, regulatory burdens can also be eased. Qualified and documented data on all elements of the custom formulation can help reduce the risk of delays during regulatory filing.

Supporting a range of projects

Although catalog media options for traditional bioproduction processes are now comprehensive, options for newer modalities can be limited. Even when using a custom formulation, successful production of many of these modalities, such as adeno-associated viral vector-based gene therapies, can be challenging as they rely on using a highly optimized and consistent medium.

Media development collaborators have teams of experienced research and development scientists that are actively working to understand and identify key productivity drivers for these advanced modalities. By continually expanding its knowledge base in preparation for future industry trends, a collaborator can provide media development solutions that meet evolving bioproduction requirements.

Choosing a media development collaborator

Media development collaborators are experienced organizations that can effectively guide you through the custom media development process. A seemingly daunting project can be simplified by a collaborator's wealth of expertise and access to critical resources that can help reduce costs and accelerate development timelines.

When choosing to work with a media development collaborator, it is key to assess both the short- and long-term benefits that can be gained. During the initial development phase, this decision can help you develop a formulation that achieves your bioproduction process requirements. Additional expertise and experience in enhancing process productivity is invaluable in creating more economical processes and, through this, more affordable therapies for patients. Moreover, a collaborator can provide the support required to help you efficiently scale up and maintain consistent commercial production into the future.

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