

The importance of raw materials for protein quality and consistency

Maintaining quality is an important consideration for biopharmaceutical developers transitioning to commercial manufacturing. When producing biologic drugs, it is vital that attributes affecting quality, such as glycosylation, charge variation, and aggregation, are controlled when moving to a commercial scale.

The key to this is the supply of quality raw materials. The purity of raw materials can have a significant impact on protein quality attributes and batch-to-batch consistency, ultimately affecting the efficacy and safety of your end product.

How can you ensure end-product consistency?



Raw material sourcing

Quality begins with supply from established markets and a robust raw material sourcing procedure.



Raw material characterization

The raw material components should be rigorously assessed and impurities investigated through trace element analysis.



Deep analytics

When variability is detected, deep analytics is an essential tool for investigating consistency, or lack thereof, and discovering the root cause of the irregularity.

Investigating inconsistency

The problem

A formulation has successfully been transferred to a commercial media manufacturing facility, but the protein profile does not appear to be consistent when produced at scale.



The explanation

Lot-to-lot variability in the raw materials can cause unexpected differences in formulations.

Cell culture media components are strictly chosen during the formulation stage to improve the product's end performance and scalability. However, the manufacture of certain raw materials can lead to wide trace element variability in the final media solution.

In this case, the formulation developed at the R&D lab inadvertently contained trace amounts of copper and manganese, which altered the protein glycosylation pattern of the end product.



The solution

With the mystery solved, the media manufacturers worked with the bioproduction developers to control the trace element profile of the media solution for future cGMP production.



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