ThermoFisher SCIENTIFIC

Do you really need serum?

Limiting the use of serum in vaccine processes

A liter of medium can require up to 100 mL of serum to support vaccine production. However, as manufacturing processes are scaled up, the amount of serum needed increases as well. A process requiring 20,000 L of growth medium per year requires the qualification, storage, and procurement of 2,000 L of serum. These logistical obstacles can add considerable challenges to what is already an expensive and risky supplement.

Carefully considering the use of serum and its associated challenges is critical to supporting needed vaccine production.

The challenges

Time: Preventing supply disruptions takes considerable planning. Qualifying serum in advance is a key step in mitigating risk; but reserving, shipping, and testing material prior to selection adds time.

Availability: The availability of fetal bovine serum (FBS) can be further limited by competing demands from the growing gene therapy market. In addition, serum suppliers may no longer agree to multiyear supply contracts due to volatility in supply and pricing.

Supply: Supply can be impacted by a number of external factors, such as weather patterns, shipping, cattle cycles, and even feed costs.

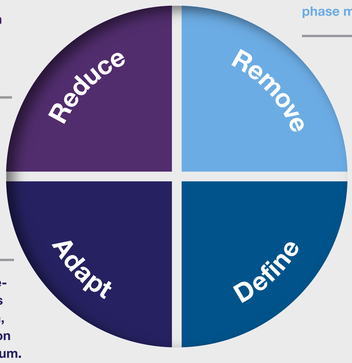
Managing risk: Serum is inherently risky. Managing adventitious agents and lot-to-lot variability requires robust testing and mitigation strategies for consistent performance.

Cost: Since only FBS from New Zealand or Australia is acceptable in most cases, fully formulated vaccine media (including serum) are some of the most expensive media used in biotechnology. Limited supply often makes the cost of a raw material higher and more variable, which ultimately destabilizes vaccine price.

How to limit the use of sera in viral processes

With serum-free or serum-reduced media, you can achieve the same titers, or even higher in some cases, as when using media fully supplemented with serum.

We have outlined four approaches that can help limit the use of serum in viral processes:



Strategies for serum reduction include using enriched basal media and/or bovine serum albumin (BSA) as substitutes.

Consider which steps of the manufacturing process require serum supplementation. While cells grown in adherent conditions may require serum for expansion, the production phase may not require serum at all.

Viral transfer is not adherence-dependent. Adherent cell lines can be adapted to suspension, removing the need for adhesion factors that are present in serum. In fact, many vaccine cell lines can be adapted to suspension using transition media.

Certain vaccine cell lines can be adapted to fully chemically defined (CD) conditions after adaptation to suspension, leading to a completely controlled process.

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

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