

# Serum Savvy:

## Navigating the World of Pharma and Biotech Manufacturing Suppliers

Quality, consistency, reliability, and traceability



Animal-derived serum, including Fetal Bovine Serum (FBS), is essential for many pharmaceutical and biotech manufacturing processes. You need a serum supplier you can rely on even during times of constrained global inventory.

Choose a serum supplier that will consistently deliver the high quality product you need. Quality, consistency, reliability, and traceability are key considerations.

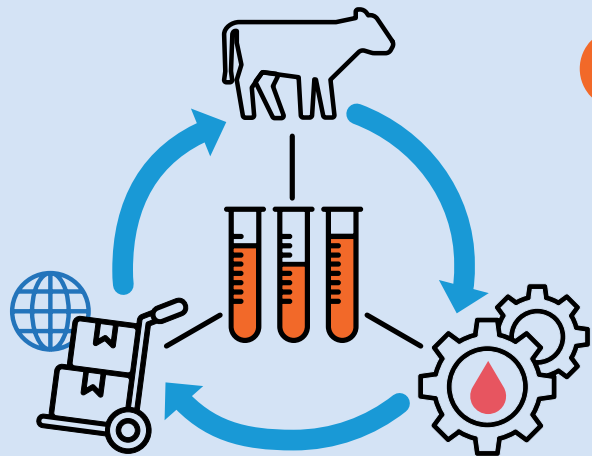
### Serum Quality and Consistency

#### Quality

- Endotoxin originates from bacterial cell walls. High levels can reflect poor handling during serum collection or processing.
- Hemoglobin in serum stems from red blood cell lysis during separation. High levels of hemoglobin can reflect problems in the separation process.
- Look for a supplier that tests all serum lots to rigorous standards for endotoxin and hemoglobin levels.

#### Consistency

- High variability can impact manufacturing processes. Ask for samples and perform lot validation before purchasing serum from a new lot.



### Supply Chain Reliability

Disruptions to abattoirs or the beef industry due to pandemics or other factors can impact serum supplies.

- Look for a supplier that has a robust supply chain through direct relationships with abattoirs and a fully integrated supply chain.

### Traceability and Certifications

Traceability and proper certification ensure that you can trust the serum you purchase.

#### ISIA Traceability Certification

- The International Serum Industry Association (ISIA) provides traceability certification based on rigorous independent audits of the entire supply chain.
- By working with an ISIA-certified supplier, you ensure that there is an unbroken chain of custody from the source to the end user.

#### EDQM Certification

- A Certificate of Suitability (CEP), provided by the European Directorate for the Quality of Medicines and Healthcare (EDQM), shows that a serum product meets European Pharmacopoeia (EP) criteria, including the requirement to minimize the risk of bovine spongiform encephalopathy (BSE). For therapeutics sold in Europe, a CEP is critical.



**Corning checks all the boxes as a quality serum supplier.**

Corning has long-term supply assurance through its direct relationships with abattoirs in the United States and brokers outside of the US. Serum collection and processing are performed under strict control and using Corning-approved processes at every step.

Seeking a new serum supplier? Check out Corning's line of ISIA-certified, quality-tested products from a reliable supply chain.

[www.corning.com/serum](http://www.corning.com/serum)

# CORNING

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