

# Regulatory Science Conference

Europe



## Bovine Serum: challenges and opportunities in the research and development and manufacture of vaccines and other biological products

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Bovine serum, particularly foetal bovine serum (FBS), remains a critical starting material in the manufacture of many biological medicinal products, especially vaccines for both human and veterinary use. Foetal Bovine serum is also used in research and development activities, both at academic and industry levels. Despite industry interest in transitioning to animal-origin-free alternatives, bovine serum's unique growth-promoting properties for a wide range of microorganisms cell types, including microbial and mammalian cells, make its replacement technically challenging. The sourcing and use of bovine serum are subject to stringent regulations in the European Union and globally, aimed at (among others) minimizing risks of contamination by extraneous agents such as Bovine Viral Diarrhoea Virus (BVDV) and Bovine Spongiform Encephalopathy (BSE).

Historically, vaccine manufacturers have relied heavily on serum sourced from Australia and New Zealand due to perceived lower purity risks and BSE-related restrictions. However, recent revisions by the World Organization for Animal Health (WOAH) to include foetal blood as a "safe commodity" may ease some geographic sourcing constraints. Concurrently, serum manufacturers report unprecedented demand, raising concerns about potential supply shortages that could impact vaccine availability. Additional challenges include evolving regulatory requirements around the world, variability in testing methods and limitations in BVDV inactivation kinetics, all of which complicating the establishment of optimal specifications and potentially affecting logistics and ultimately vaccine supply.

The European Directorate for the Quality of Medicines & HealthCare (EDQM) has initiated a review revision of the Bovine Serum monograph in the European Pharmacopeia, presenting a timely opportunity for a focused scientific meeting. This meeting aims to convene a broad spectrum of stakeholders—including regulatory authorities, serum producers, biologicals products manufacturers, academia, and public health officials—to review the regulatory history, current risks, supply challenges and technical considerations related to bovine serum and potential alternatives.

Key topics will include supply constraints, regulatory requirements, gamma irradiation efficiency, contamination risks for BVDV and other viral extraneous agents, and BSE, and perspectives from global regulatory agencies and industry. The meeting seeks to foster dialogue on optimizing regulations and guidance to safeguard supply of vaccines and other biological products without compromising their safety.

By addressing these critical issues, the meeting aspires to support the sustainable availability of this critical biological raw material and promote collaborative solutions at the international level.

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