



## IABS-EU Meeting on Bovine Serum: challenges and opportunities in the research and development and manufacture of vaccines and other biological products

29 and 30 September 2026 - Budapest, Hungary

### ABSTRACT

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. 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 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 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, biological 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.

### Scientific / Organizing Committee

Johannes **Blümel**, Paul-Ehrlich-Institut  
Frédéric **Descamps**, Co-Chair, Zoetis  
Baptiste **Dungu**, Bonisa Solutions  
Olivier **Espeisse**, IABS-EU  
Benjamin **Hatat**, Boehringer-Ingelheim  
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Donald **King**, Pirbright Institute  
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Catherine **Lebrun**, EDQM  
David **Mackay**, IABS VBC Member  
Etienne **Thiry**, IABS-EU  
Marc **Wintgens**, Global Serum Alliance

## Preliminary Agenda

### Day 1: 29 September, 2026

12:00      *Registration & Welcome Coffee*

12:30      **Introduction**

### Session I – Review of current status and obstacles

- 12:45      **Bovine Serum – What is new in bovine serum production? What is the demand *versus* the offer? What are the obstacles? Perspective from Bovine Serum producers**
- 13:05      **Review of European Pharmacopeia requirements for the use of Bovine serum for the production of human and veterinary medicinal products**
- 13:20      **Review of CVMP & CHMP guidelines applying to the authorization of Bovine serum in human and veterinary medicinal products**
- 13.35      **Bovine Serum and BSE – What is the current status?**
- 13:50      **Review of North-American requirements for the use of Bovine serum in the manufacture of human and veterinary medicinal products**
- 14:10      **Use of Bovine serum in the the manufacture of veterinary medicinal products – Status and challenges**
- 14:30      **Use of Bovine serum in the the manufacture of human medicinal products – Status and challenges**
- 14:50      *Break*
- 15:10      **How can BVDV and other extraneous agents end up into Bovine serum?**
- 15:30      **Viral safety - Is BVDV still an issue? Lessons learnt and effectiveness of inactivation by gamma-irradiation (for BVDV and other bovine extraneous agents)**
- 15:50      **Gamma-irradiation – How does this work? How are decisions made on specific levels of irradiation? How is proof of irradiation gathered? Any capacity concern on the horizon?**
- 16:10      **Q&A on Viral Safety of Bovine Serum**
- 16:40      **Panel Discussion**

17:40 *End of Day 1*

## Day 2: 30 September, 2026

### Session II – Are the current regulatory requirements up-to-date?

8:00 *Registration and Welcome Coffee*

8:30 **Introduction to day 2**

8:40 **Bovine serum industry – A proportionate risk approach: Concrete proposals towards simplification and bureaucracy reduction**

9:00 **How to strengthen consistent supply of safe Bovine serum while keeping admin and logistic burden minimum? Perspective from the Veterinary Pharmaceutical industry**

9:20 **Perspective from Human Pharmaceutical industry**

9:40 **Regulatory requirements in the light of risk assessment for Bovine Serum used in production of medicinal products**

10:00 **Perspective from North-American Regulatory Authorities**

10:20 *Break*

10:50 **Alternatives to Bovine serum as a growth medium for the manufacture of biological medicinal products – Where are we?**

11:10 **Panel discussion**

### Session III – Recommendations and next steps

11:50 All participants

12:50 **Closing remarks**

13:00 *End of Meeting*