Europe

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

VIRTUAL MEETING

29 and 30 September 2026

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
Carmen **Jungbäck**, IABS-EU
Donald **King**, Pirbright Institute
Gabor **Kulcsar**, Nébih
Catherine **Lebrun**, EDQM
David **Mackay**, IABS VBC Member
Etienne **Thiry**, IABS VBC Chair
Marc **Wintgens**, Global Serum Alliance

Meeting Program

Times are indicated CET

Day 1: 29 September, 2026

1:00 pm *Technical and Organizational matter*
IABS Secretariat

1:05 pm **Introduction**
Etienne **Thiry**, IABS-EU, Chair of the IABS Veterinary Biologicals Committee
Frédéric **Descamps**, Zoetis, Member of the IABS Veterinary Biologicals Committee

1:10pm **Pre-meeting Questionnaire Outcome**
Frédéric **Descamps**, Zoetis

Session I – Review of current status and obstacles

Moderator: Frédéric Descamps

1:15 pm **Bovine Serum: Enabling Human and Animal Health Through Science-Based, Sustainable Supply**
Marc **Wintgens** - Global Serum Alliance

1:35 pm **Review of European Pharmacopeia requirements for the use of Bovine serum for the production of human and veterinary medicinal products**
Catherine **Lebrun** – European Directorate for the Quality of Medicines

1.50 pm **Review of CVMP & CHMP guidelines applying to the authorization of Bovine serum in human and veterinary medicinal products**
Johannes **Blümel -** Paul-Ehrlich-Institut

2:10 pm **Bovine Serum, BSE and extraneous agents – Updates on WOAH Standards**
Baptiste **Dungu**, Bonisa Solutions

2:25 pm **Break**

2:35 pm **Review of USDA-CVB requirements for the use of Bovine serum in the manufacture of veterinary medicinal products**
Kendall **Graber**, USDA's Center of Veterinary Biologics

2:55 pm **Use of Bovine serum in the the manufacture of veterinary medicinal products – Status and challenges**
Benjamin **Hatat** - AnimalHealthEurope

3.15 pm **Use of Bovine serum in the the manufacture of human medicinal products – Status and challenges**
Florian **Zielecki**, GSK

3:35 pm	**Break**
3:45 pm	**How can BVDV and other extraneous agents end up into Bovine serum?** Paul **Becher**, University of Veterinary Medicine Hannover
4.05 pm	**Establishing Gamma Irradiation Parameters for Pathogen Inactivation in Vaccine Production and their Application to Serum Inactivation** Viskam **Wijewardana**, International Atomic Energy Agency
4.25 pm	**Barrier treatments for bovine serum to prevent introduction of viral contaminants into biologics** Raymond **Nims**, Syner-G BioPharma Group
4.45 pm	**Use of Bovine Serum and NGS testing of drug products: mitigation of inert viral sequences while controlling the risk of viral contamination** Marc **Eloit**, Pathoquest
5.00 pm	**Q&A on Viral Safety of Bovine Serum** All Facilitator: Gabor Kulcsar
5.30 pm	**Break**
5.40 pm	**Panel Discussion** **All speakers** *Moderator: Frédéric Descamps*
6:30 pm	*End of Day 1*

Day 2: 30 September, 2026

1:00 pm	**Introduction to day 2** Frédéric **Descamps**, Zoetis, Member of the IABS Veterinary Biologicals Committee

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

Moderator: Frédéric Descamps

1.10 pm	**Bovine serum industry – A proportionate risk approach: Concrete proposals towards simplification and bureaucracy reduction** Marc **Wintgens** - Global Serum Alliance

1.30 pm **How to strengthen consistent supply of safe Bovine serum while keeping admin and logistic burden minimum? Opportunities for Improvements**
Gergely **Hamar** – AnimalHealthEurope

1.50 pm **Risk assessment of bovine viruses unable to replicate in production cell culture – A scientific approach**
Florian **Zielecki**, GSK

2.10 pm **Regulatory requirements in the light of risk assessment for Bovine Serum used in production of medicinal products**
Johannes **Blümel** - Paul-Ehrlich-Institut

2.30 pm **Break**

2.45 pm **Perspective from the USDA-CVB**
David **White**, USDA's Center of Veterinary Biologics

3.05 pm **Technical Possiblities of Serum Reduction in Biological Production Systems**
Balint **Kupcsulik** – GSK

3.25 pm **Panel discussion**
All speakers
Moderator: Frédéric Descamps

4.05 pm **Break**

Session III – Recommendations and next steps

Moderator: Frédéric Descamps

4.25 pm **Panel discussion**
All speakers

5.25 pm **Closing remarks**
Olivier **Espeisse**, IABS-EU President

5.30 pm *End of Meeting*