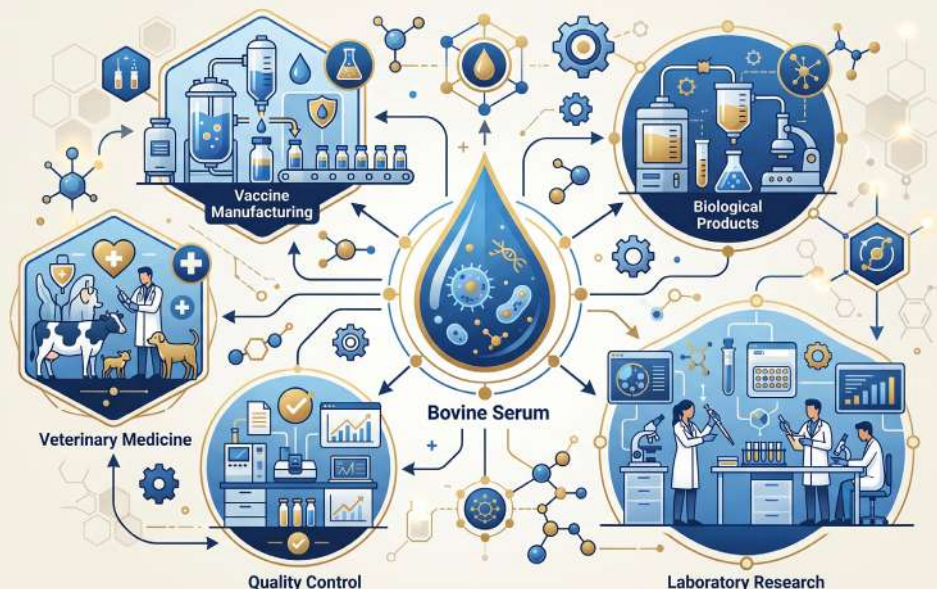


Europe



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E-BOOK

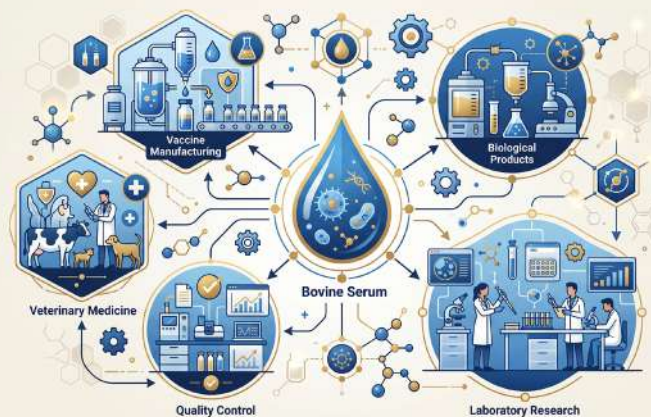
Regulatory Science Conference

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

September 29-30, 2026

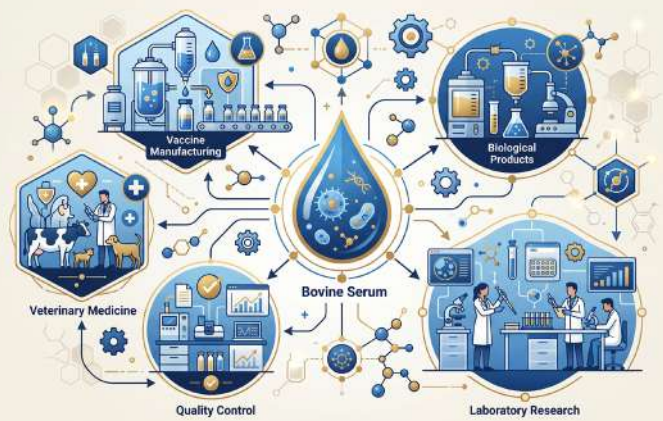
VIRTUAL MEETING

TABLE OF CONTENT

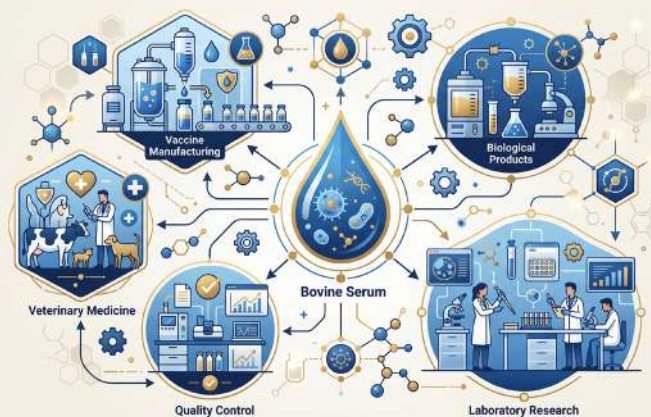


Sponsors	3
About the Conference	4
Scientific and Organizing Committees	5
Scientific Program	6
Upcoming IABS Conferences and Workshops	10
Biosketchs & Abstracts	11

SPONSORS



ABOUT THE CONFERENCE



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).

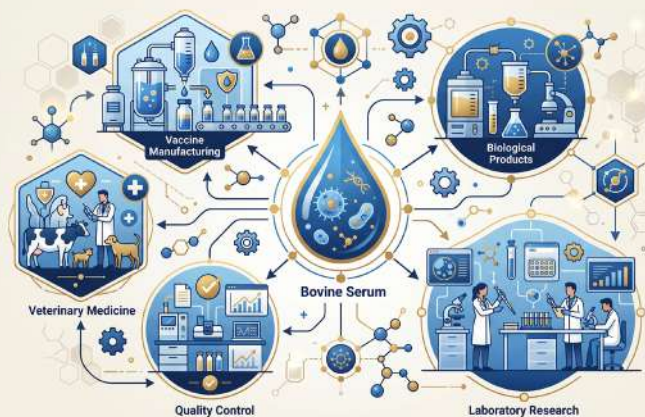
Historically, vaccine manufacturers have relied heavily on serum sourced from Australia and New Zealand due to perceived lower purity risks and BSE-related restrictions. However, recent revisions by the World Organization for Animal Health (WOAH) to include foetal blood as a “safe commodity” may ease 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 COMMITTEES



Scientific and 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

Editorial Committee

Norman Baylor, Editor-in-Chief, Biologicals
Olivier Espeisse, IABS-EU
Carmen Jungbäck, IABS-EU
Etienne Thiry, IABS-EU VBC Chair

SCIENTIFIC PROGRAM

Day 1: Tuesday 29 September, 2026



1:05 pm

Introduction & Pre-meeting Questionnaire Outcome
IABS-EU

Session I – Review of current status and obstacles

Session Chair:

1:15 pm

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 - 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 from WOA
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

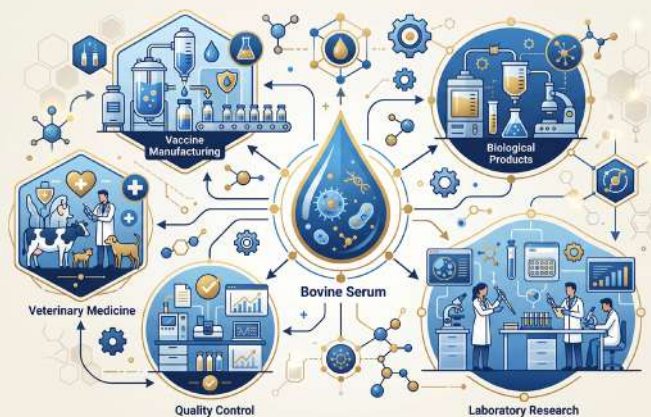
Use of Bovine serum in the the manufacture of human medicinal products – Status and challenges - Florian Zielecki, GSK

3:35 pm

Break

SCIENTIFIC PROGRAM

Day 1: Tuesday 29 September, 2026



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

Viral safety - Is BVDV still an issue? Lessons learnt and effectiveness of inactivation by gamma-irradiation (for BVDV and other bovine extraneous agents)

Viskam Wijewardana, International Atomic Energy Agency

4:25 pm

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?

Raymond Nims, Syner-G BioPharma Group

4:45 pm

Use of Bovine Serum and High-Throughput-Sequencing-based control of biological products

- Marc Eloit, Pathoquest

5:00 pm

Q&A on Viral Safety of Bovine Serum

5:00 pm

Break

5:40 pm

Panel Discussion

6:30 pm

End of Day 1

SCIENTIFIC PROGRAM

Day 2: Wednesday 30 September, 2026



1:00 pm

Introduction to Day 2
IABS-EU

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

Session Chair:

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? Perspective from the Veterinary Pharmaceutical industry - 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

Alternatives to Bovine serum as a growth medium for the manufacture of biological medicinal products – Where are we? Balint Kupcsulik, Prophyl Ltd

3:25 pm

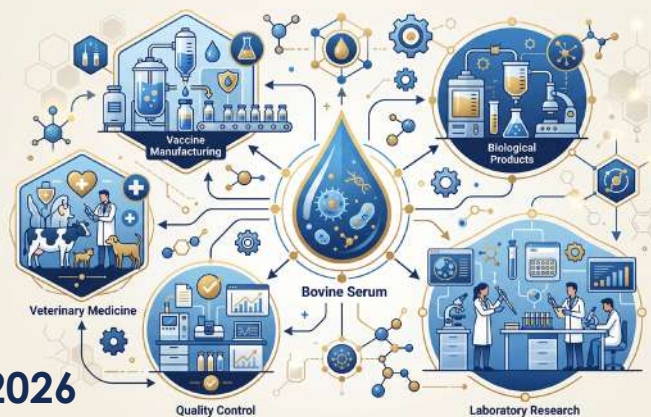
Panel discussion

4:05 pm

Break

SCIENTIFIC PROGRAM

Day 2: Wednesday 30 September, 2026



Session III – Recommendations and next steps

Session Chair:

4:25 pm

All participants

Moderators: Co-Chairs 1 & 2

5:25 pm

Closing Remarks

IABS-EU

5:30 pm

End of Meeting

UPCOMING IABS CONFERENCES & WORKSHOPS



IABS-EU Inno4VAC Final Stakeholder Meeting

*September 28-29, 2026
Leiden, The Netherlands*



12th Statistics Workshop: From Data to Patients – CMC Statisticians Contributions to Quality, Safety, and Efficacy of Pharmaceutical Products

*October 20-22, 2026
Rockville, MD, U.S.A.*



3rd IABS Workshop on Real World Evidence: Pragmatic Randomized Controlled Vaccine Trials: towards global alignment and methodological standards

*November 18-19, 2026
Leiden, The Netherlands*



ASFaVIP FINAL STAKEHOLDER MEETING - ASF: An Analysis of Current Situation of Vaccine Development; Licensing Procedures and Possible Eradication Approaches

*December 3, 2026
Frankfurt, Germany*



5th Controlled Human Infection Model Workshop

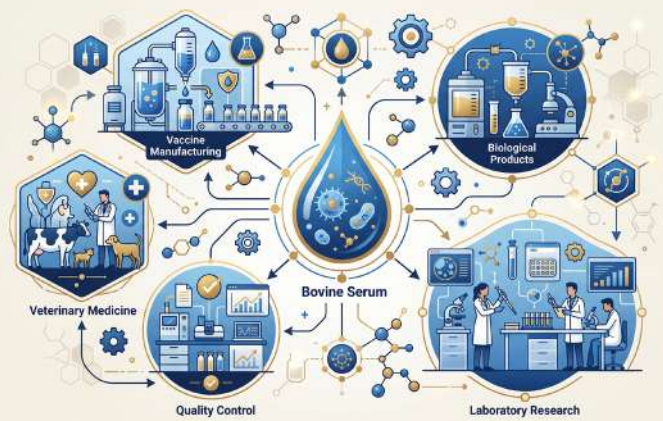
*Spring 2027
Bangkok, Thailand*



Analytics in Cell Therapy: Ensuring Quality in Flow Cytometry established guidelines for Flow Cytometry And QC needs in Cell Therapy

*Autumn 2027
Barcelona, Spain*

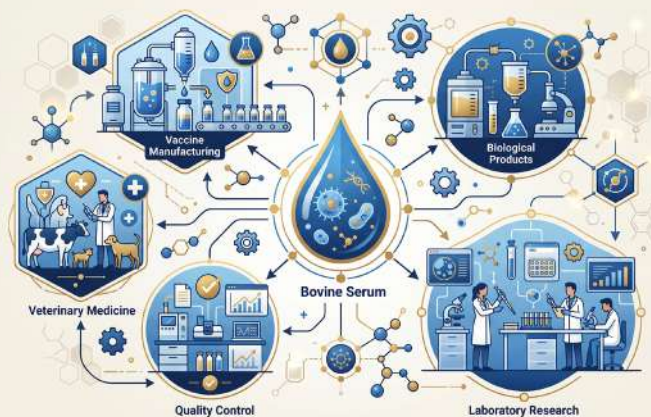
BIOSKETCH



Prof. Dr. Paul Becher, DVM
University of Veterinary Medicine Hannover

Prof. Dr. Paul Becher, DVM: Full professor and Head of the Institute of Virology at the University of Veterinary Medicine Hannover, Germany. Designated WOAHP expert for Classical swine fever (CSF) and Director of the EU and WOAHP Reference Laboratory for CSF. His work has focused on various aspects of the biology of classical swine fever virus, bovine viral diarrhoea virus, and other veterinary-relevant viruses and zoonotic pathogens. This included studies on genetic variability, evolution, and host range of viruses, as well as on viral replication, virus-host interactions, and pathogenesis. Further research activities led to the discovery and characterization of new viruses in domestic and wild animals and have contributed to improved diagnosis and control of viral diseases in animals.

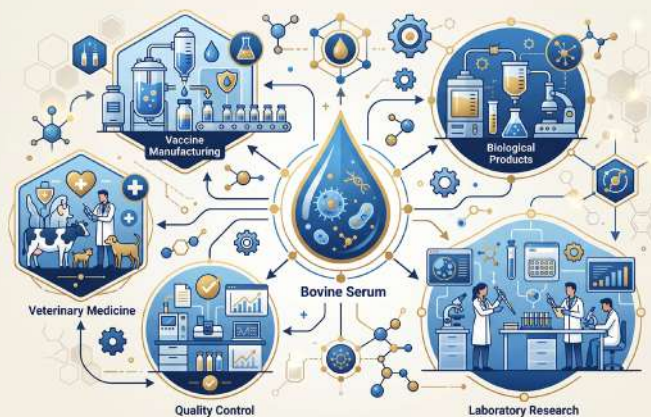
ABSTRACT



How can BVDV and other extraneous agents end up into bovine serum?

Paul Becher, University of Veterinary Medicine Hannover

Bovine serum, particularly fetal bovine serum (FBS), provides unique and important growth promoting factors for optimal cell growth and is frequently used in research and manufacturing of biomedical products, including vaccines. The potential presence of contaminating viruses in bovine serum poses a serious risk to vaccine safety. Bovine viral diarrhea virus (BVDV) has been an illustrative example of viral contaminants in bovine serum which have caused incidents linked to contaminated veterinary vaccines. The presence of BVDV in bovine serum is primarily due to transplacental infection of the fetus between the 40th and 125th day of gestation, which results in highly specific immunotolerance followed by lifelong persistent infection. BVDV and other BVDV-related pestiviruses belong to the genus *Orthopestivirus* within the family *Pestiviridae*. At least five different pestivirus species can infect cattle. While some countries have implemented control programs to eradicate BVDV-1 and BVDV-2, other ruminant pestiviruses are not addressed by these programs, and in many countries, there are no or only limited measures in place to control BVD. It should be noted that there are several other viruses (e.g. bluetongue virus, bovine herpesvirus-1, parainfluenzavirus-3,...) that can contaminate materials of animal origin. The application of advanced molecular methods for virus testing in starting materials and finished products can enable the detection of both known and unknown viruses.

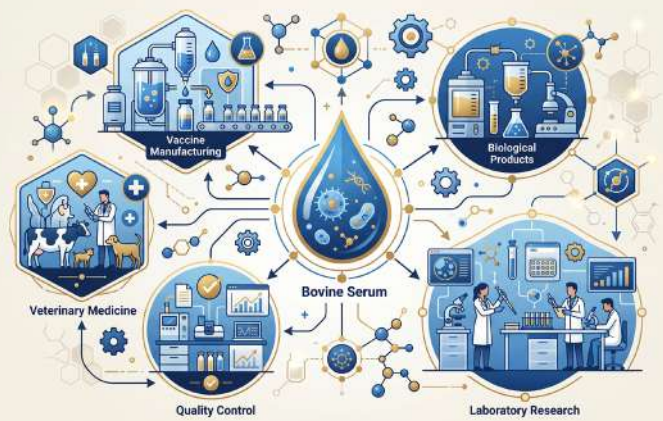


Johannes Bluemel, PhD
Paul-Ehrlich-Institut

Dr. Johannes Bluemel is leading the viral safety section at the Paul-Ehrlich-Institut, Germany. He is assessing virus and TSE safety of blood products, recombinant DNA products, and advanced therapy medicinal products (ATMPs) for clinical trials and marketing authorization. He participated as an expert in the EMA-Biologics Working Party (BWP) and EDQM TSE-certification procedure and contributed to the drafting of numerous Guidelines and Monographs on viral safety. In 2025, he received an award from ICH for revision of guideline ICHQ5A on viral safety of biotechnology products. He is working on several research projects on virus inactivation and detection of viruses by next generation sequencing. He is chairing the group on blood-associated pathogens for the German advisory board "Arbeitskreis Blut" as well as the Ph. Eur. Working Party on High Throughput Sequencing for the detection of viral extraneous agents. Before joining the Paul-Ehrlich-Institut in 1998, Dr. Blümel worked at the University Hospital Bonn. He performed research on virus replication and received qualification in medical virology and virus diagnostics (Fachvirologe).

Dr. Blümel completed his Diploma Study in Biology at the University of Freiburg, Germany where he also received his Ph.D. degree. In 2010 he received a teaching graduation (Habilitation) in Medical Virology from the University of Frankfurt.

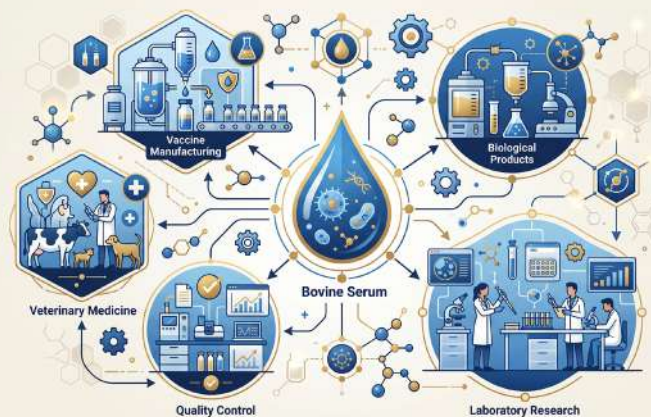
BIOSKETCH



Dr Frederic Descamps
Zoetis

Frédéric Descamps graduated as Veterinarian from the Faculty of Liège, Belgium, and obtained his PhD on the pathogenesis and immunology of *Microsporum canis* in cats in the same faculty. He has been working in the field of Veterinary Regulatory Affairs since 2003, first in the public sector where he has been acting as Senior Assessor at the Belgian Medicine Agency and as Belgian alternate CVMP member at the European Medicines Agency. Then he moved to the Veterinary pharmaceutical Industry in 2011. He is now Senior Director of Regulatory Affairs at Zoetis. He is also Chair of the Biological Working Party of AnimalHealthEurope. His primary responsibility is to develop new biological products (vaccines in particular) and maintain existing products on the market.

BIOSKETCH



Baptiste Dungu
University of Kinshasa

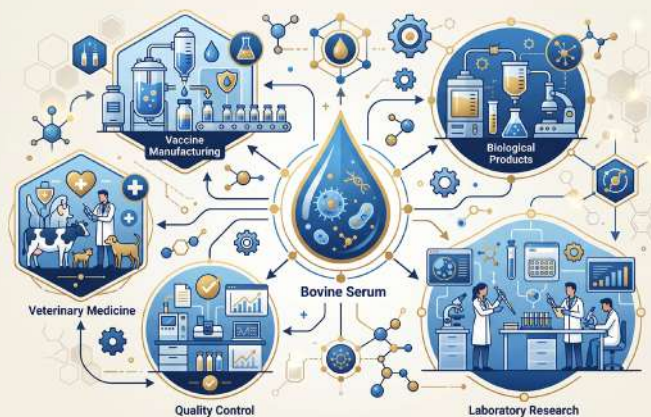
Baptiste DUNGU is a veterinarian with a PhD in vaccinology and more than 30 years of experience in the research, development, manufacturing, regulation, quality and marketing of vaccines and other animal disease control tools. Currently an Associate Professor of Infectious Diseases and Immunology at the University of Kinshasa, DRC, he further leads a program on neglected zoonotic diseases and, through his UK and South Africa registered company, Bonisa Solutions Ltd., is involved in several related activities on all continents. He has also worked as a veterinarian and vaccinology specialist in different animal health institutions in South Africa (OVI-FMD laboratory, OBP, Afrivet, Design Biologix), Morocco (MCI Animal Health), Saudi Arabia (UDF) and the United Kingdom (GALVmed, VetIntel). His work experience has spanned different areas of biotechnology, mainly vaccines, diagnostics, and biopharmaceuticals, locally and internationally, in the commercial, governmental, academic, development, and international sectors, holding research, technical, management, and leadership positions.

Through Bonisa Solutions Ltd. in the UK and South Africa, Dr. Dungu has conducted assignments for the World Bank, ILRI and the FAO on vaccine projects in Asia and the Middle East. He is also working with FAO South Africa to develop programmes targeting various transboundary animal diseases, including avian influenza, foot-and-mouth disease (FMD), and rabies.

He is currently one of 6 members of the WOAHS Scientific Commission. Until April 2024, he was a panellist of the One Health High Level Expert Panel (OHHLEP, established by the WHO, FAO, WOAHS and UNEP). Prof. Dungu also serves on the board of the International Veterinary Vaccinology Network (IVVN), and the Board of AfricaBio; he is a member of the Group of Experts on Animal Health for the African Union, and sits on the steering committee of the AU's Pan-African Vaccine Centre (PANVAC).

He has published more than 40 peer reviewed scientific publications, hold a patent, and authored few book chapters in the field of vaccinology.

ABSTRACT



Bovine Serum, BSE and Extraneous Agents: Updates on WOHAI Standards

Baptiste Dungu, Bonisa Solutions Ltd

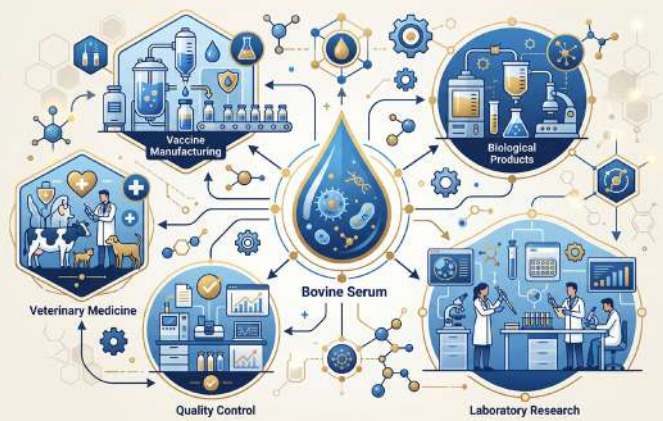
The WOHAI Terrestrial Code and Manual constitute the principal international reference framework governing the safety assessment and regulatory status of bovine-derived starting materials used in vaccine and biological product manufacture. This presentation reviews recent revisions to both instruments and their implications for the serum sector.

The 2023 revision of Terrestrial Code Chapter 11.4 replaced prior country-based classification with a fully risk-based BSE assessment framework. Critically, fetal blood was added to the safe commodities list under Article 11.4.2, permitting trade without BSE-related conditions regardless of the exporting country's risk status — potentially widening the qualified supplier base beyond historically preferred sources.

On extraneous agents, the revised Manual Chapter 3.4.7, adopted in May 2024, updates bovine pestivirus taxonomy and validated diagnostic methods underpinning donor-herd screening and batch release. A dedicated Code Chapter 11.X on bovine pestivirus infection remains pending adoption following unresolved concerns on case-definition criteria.

Key technical challenges persist: non-uniform BVDV inactivation kinetics under gamma-irradiation, divergent testing approaches across regions, and the absence of a harmonised global specification reconciling WOHAI, European Pharmacopoeia and USDA-CVB requirements — all directly relevant to the ongoing EDQM monograph revision.

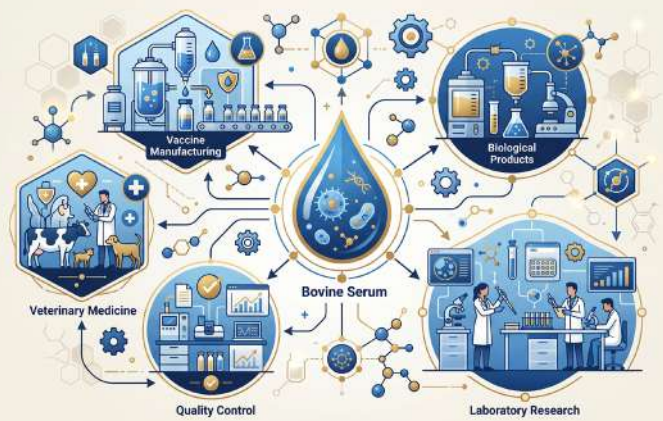
BIOSKETCH



Marc Eloit, Prof.
Pathoquest

Marc Eloit is a veterinarian specializing in infectious diseases and a former Professor of Virology at the National Veterinary School of Alfort. He previously served as Director of the Virology Unit before going on to lead the Pathogen Discovery Laboratory at the Institut Pasteur until 2023. His academic research has focused on the identification of novel or unexpected viruses in patients, as well as on viruses circulating at the human–wildlife interface. For 20 years, he was a member of the Virus Safety Committee of the French Medicines Agency. In 2010, he founded PathoQuest, a spin-off from the Institut Pasteur dedicated to testing biological products using next-generation sequencing (NGS). He currently serves as a scientific adviser to the company.

ABSTRACT

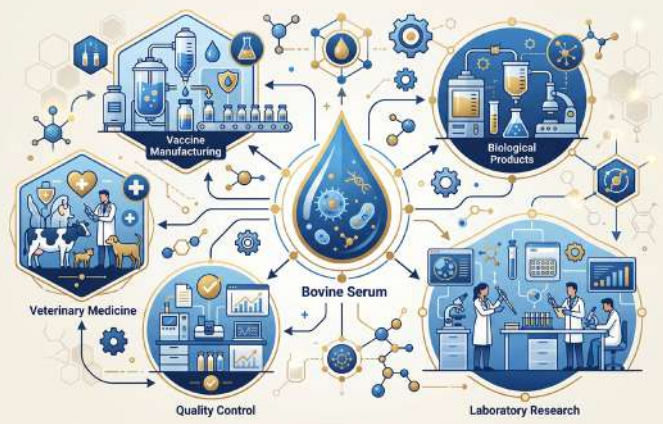


Use of Bovine Serum and NGS testing of drug products: mitigation of inert viral sequences while controlling the risk of viral contamination

Marc Eloit, Pathoquest

The use of bovine serum (BS) in the production of biological products may introduce live viral contaminants or residual viral nucleic acids detectable by NGS. This presentation discusses risk mitigation strategies, including NGS testing of BS batches as an ancillary study of potency tests by the drug manufacturer prior to use, and/or quantitative PCR screening for common contaminants. When viral sequences are detected in drug products, quantitative analyses can help distinguish true viral replication from inert background material. Together, these approaches support robust viral risk control and more reliable interpretation of NGS results in BS-containing manufacturing processes.

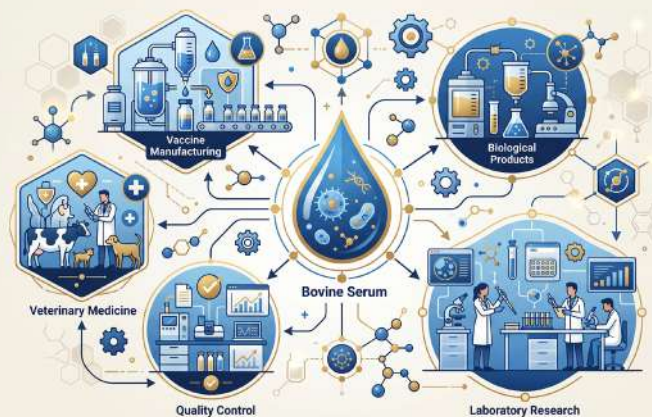
BIOSKETCH



Dr Olivier Espeisse
IABS-EU

Olivier Espeisse (DVM, Maisons-Alfort, and MBA, Bowling Green State University) practiced dairy veterinary medicine in Normandy before moving to the veterinary pharmaceutical industry, where he has been particularly involved in association work at global and European level. He is a member of the IABS VPC.

BIOSKETCH



Kendall Graber

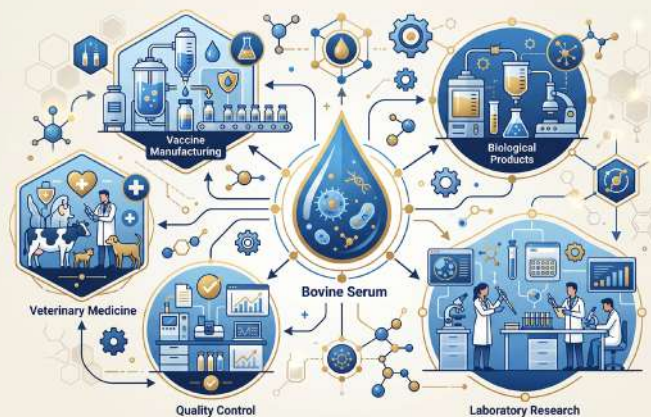
USDA's Center of Veterinary Biologics

Kendall Graber – Inspection Section Leader, USDA Center for Veterinary Biologics.

Following graduation from South Dakota State University in 1986, Mr. Graber began working in the veterinary biologic industry, including just under 20 years with Fort Dodge Animal Health. He has held positions in R&D, Quality Control, Production, and Quality Assurance. His knowledge of industry grew following Pfizer's acquisition of Fort Dodge and subsequent sale to Boehringer Ingelheim Vetmedica, Inc.

Mr. Graber has been with the Center for Veterinary Biologics in Inspection and Compliance since 2010, where he currently serves as the Section Leader of Inspection. His experiences have afforded him the opportunity to participate in and review a wide range of inspections, internal audits, investigations and root cause analysis evaluations.

BIOSKETCH



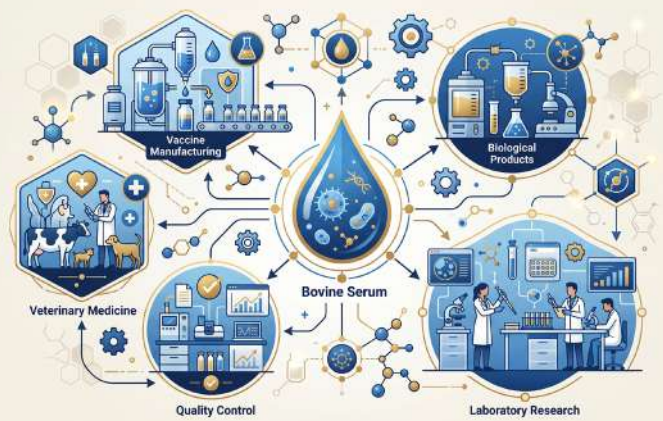
Gergely Hamar
AnimalHealthEurope

Gergely Hamar holds a BSc in Agricultural Engineering with a specialization in Animal Breeding and an MSc in Agricultural Engineering and Management. His university training covered a broad range of disciplines, including animal breeding, livestock production, animal health, nutrition, and agricultural economics as well management.

With more than 26 years of experience in the animal health industry, Gergely currently serves as a Director for Regulatory Affairs at Ceva Santé Animale. He leads global regulatory strategy and scientific advocacy activities across a diverse portfolio of veterinary medicinal products, with particular experience in veterinary biologicals.

His areas of interest include regulatory innovation and science, international harmonization, and facilitating access to novel animal health technologies.

ABSTRACT

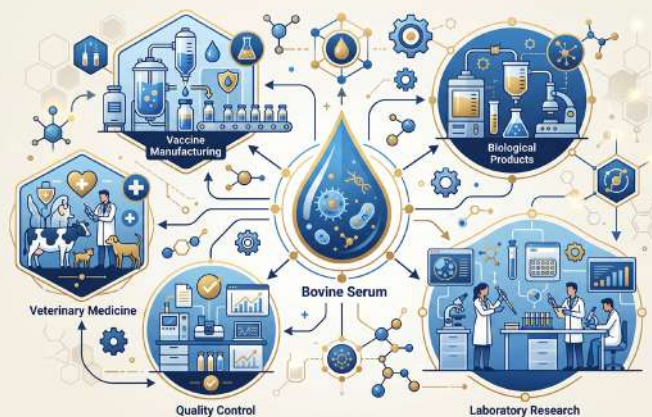


How to strengthen consistent supply of safe Bovine serum while keeping admin and logistic burden minimum. Opportunities for Improvements

Gergely Tibor Hamar, AnimalHealthEurope

The targeted aim is to achieve the same science and safety expectations with fewer administrative barriers and a more resilient vaccine supply. This requires international reliance on serum supplier dossiers, global consensus on irradiation, and further promotion of risk-based approaches focused on the actual risk, biological characteristics of the agent, intended use of the serum, and effectiveness of manufacturing processes. These measures aim to reduce duplicate assessments and supply logistics complexity while maintaining safety expectations.

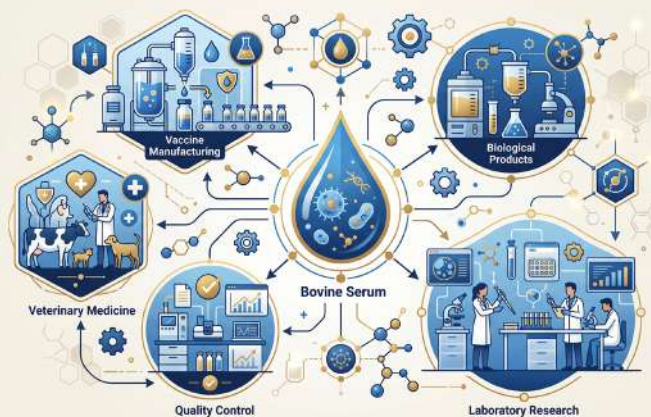
ABSTRACT



Use of Bovine serum in the manufacture of veterinary medicinal products Status and challenges

Benjamin Hatat, Boehringer-Ingelheim

Bovine serum remains a critical raw material for veterinary vaccine production; however, serum supply is challenged by evolving disease situations, lengthy qualification and import processes, and only partially harmonized global regulatory requirements. Different documentation, testing, irradiation and risk-assessment expectations increase administrative burden, reduce sourcing flexibility and may impact vaccine availability. While the industry fully supports the objective of maximizing safety, there is a need for a more pragmatic and proportionate demonstration of safety that preserves supply resilience.

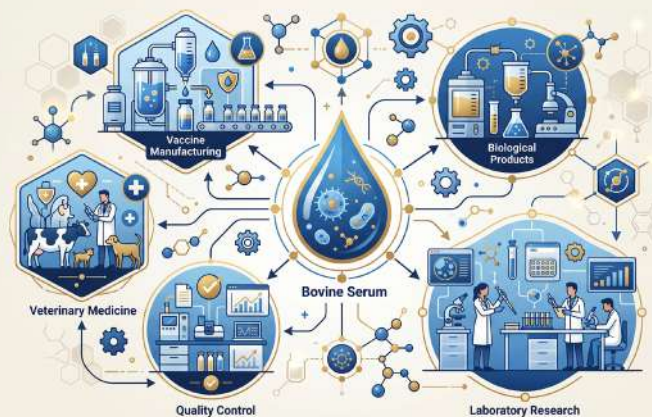


Dr Carmen Jungbäck
IABS-EU

Dr Carmen Jungbäck graduated from the Tierärztliche Hochschule, Hannover with a degree in Veterinary Medicine. In 1981, after a few years as an animal surgeon she joined the Paul-Ehrlich-Institut, (Federal Agency for Sera and Vaccines), Langen, Germany, where she was Head of the section Veterinary Virology 1 until retirement in 2016. The section's area of activities comprises vaccinelicensing and testing, with special expertise in viral vaccines for poultry. In this context, the practical testing of vaccines during licensing and for official batch release is one of the major responsibilities.

She was also member of a number of advisory boards to the EDQMOMCL Network, Ph.Eur Group 15V and CVMP-IWP and JEG3R at EMA dealing with IVMPs under various aspects. At IABS she is member of the board and Chair of the Veterinary Biologicals Committee and Vice-President of IABS - EU. She is organizing IABS meetings focusing on the veterinary field. As member of IABS-EU she is involved in the IMI projects (ZAPI and Vac2Vac).

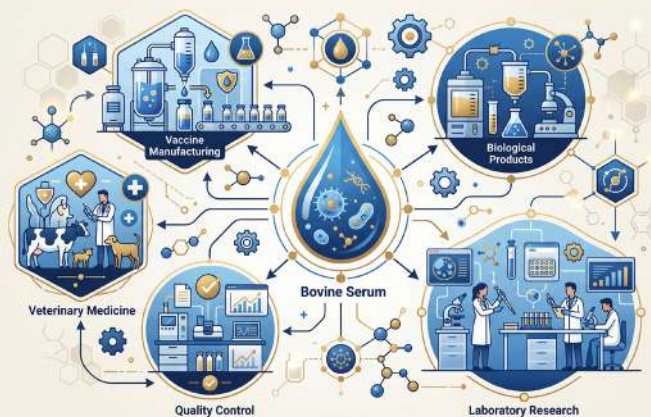
BIOSKETCH



Donald King
Pirbright Institute

Dr. Don King is an elected member of the WOAHP Biological Standards Commission and a WOAHP (World Organization for Animal Health) expert for foot-and-mouth disease (FMD) and swine vesicular disease. Dr King leads the Food and Agriculture Organization (FAO) World Reference Laboratory for FMD (WRLFMD) and coordinates international reference surveillance and vaccine evaluation activities undertaken by the global WOAHP/FAO FMD Laboratory Network which includes partnerships with other international FMD Reference Laboratories.

He has a background in veterinary virology and immunology (University of Leeds, UK and University of California, Davis, USA) and has research interests in understanding the processes that drive the evolution of positive-stranded viruses such as FMD virus. From a practical perspective, his group pioneers and applies new technologies for the detection and characterization of important livestock disease agents. These methods are deployed for routine diagnostic work and are also used to monitor the global patterns of disease, to recognize new emerging viral lineages that pose new and exotic threats.

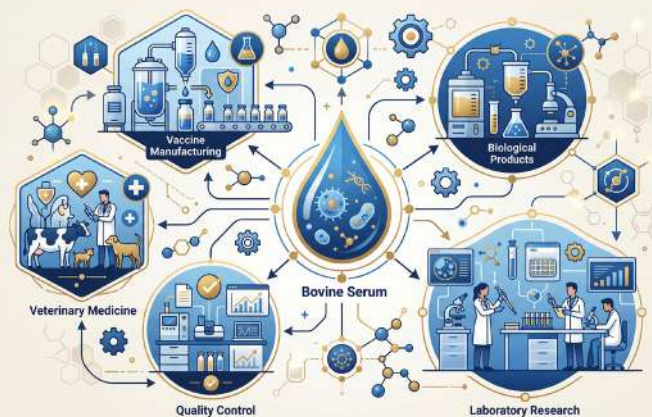


Bálint Kupcsulik, PhD, MBA
GSK's Gödöllő

Bálint Kupcsulik, PhD, MBA, is Manufacturing Science and Technology Lead at GSK's Gödöllő site. He has more than 20 years of experience in vaccine and biopharmaceutical development, manufacturing, industrialization, technology transfer, and process improvement in international environments. Before joining GSK, he served as Biopharmaceutical Production Director at Prophyl Ltd. from May 2025 to September 2026, and previously held several leadership roles at Ceva Santé Animale and Ceva-Phylaxia, including Research and Technology Assessment Manager, Manufacturing Science and Technology Director, and Industrial Development Director. His experience includes technology scouting, scale-up, process transfer, GMP manufacturing, Quality by Design, and the implementation of novel biological production platforms.

He holds a PhD in Applied Chemical Engineering Sciences, an MBA, and an MSc in Biochemical Engineering from the Budapest University of Technology and Economics. He is also active in academia as an honorary lecturer and serves as secretary of the Bioengineering Working Committee of the Hungarian Academy of Sciences.

ABSTRACT



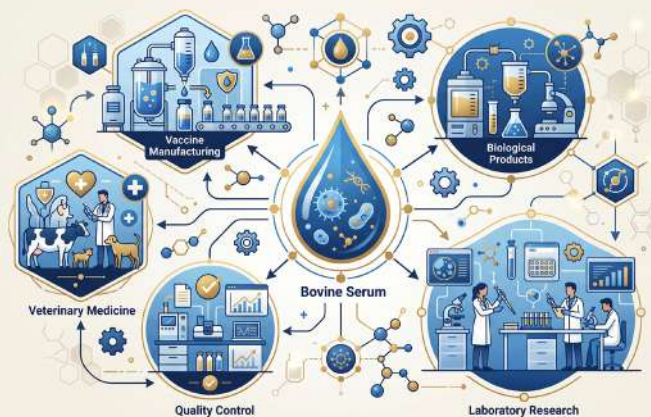
Alternatives to Bovine serum as a growth medium for the manufacture of biological medicinal products – Where are we?

Bálint Kupcsulik, PhD, MBA

Bovine serum remains a widely used supplement in biological production systems, despite the growing availability of serum-free and chemically defined alternatives. Its replacement is challenging because serum provides multiple functions simultaneously, including nutrients, growth and differentiation signals, transport proteins, protection from cellular stress, and attachment factors. Consequently, successful serum reduction cannot rely on a universal substitute but must be tailored to the specific cell substrate, product, and manufacturing process.

This presentation reviews practical strategies for serum reduction and removal, including gradual adaptation, Design of Experiments–based media optimization, spent-media analysis, intracellular metabolomics, secretome analysis, and multi-omics modelling. Combining these approaches can enable the development of robust serum-free processes, although the required time, technical expertise, validation effort, and cost can be substantial.

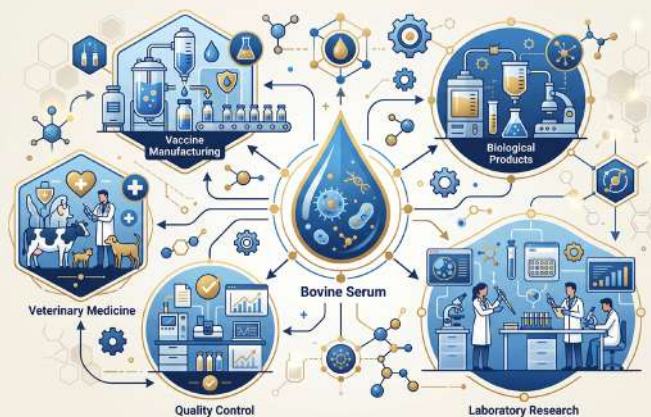
Serum-free production is already well established for recombinant-protein platforms and several cell-based processes, while viral-vaccine substrates, primary cells, and some advanced therapies still require application-specific development and comparability work. Overall, further serum reduction is technically feasible, but its implementation depends strongly on biological complexity, process requirements, and economic viability.



Dr Gabor Kulcsar
National Food Chain Safety Office

Gábor Kulcsár graduated at the University of Veterinary Medicine in Budapest in 1993. He specialized as a veterinary microbiologist and he earned his PhD from the same university.

He has been working on the field of authorization and control of veterinary immunologicals since 1994. He was appointed as the head of the Hungarian regulatory agency in 2008. Among other national and international memberships he is the Hungarian member of the CVMP at the European Medicines Agency and the chairperson of the Standing Committee on Prequalification of Vaccines against FAST diseases at the FAO EuFMD.

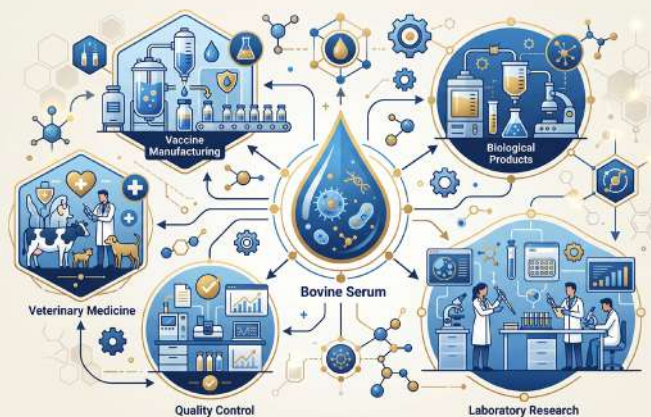


Ms Catherine Lebrun
EDQM

Catherine Lebrun holds a master's degree in sciences (Biochemistry) from the University of Strasbourg (1992), a master's degree in quality, safety and environment management (2001) and a DESS in Applied Microbiology from the Pharmaceutical University of Strasbourg (1993). She began her career in the pharmaceutical industry in 1994 as a researcher in the R & D laboratory of a large food company. Later she was Head of the microbiological quality control laboratory for several years, responsible for quality control and batch release, before working in quality, safety and environment management of a large pharmaceutical company.

In 2001, she joined the EDQM as a Scientific Programme Manager in the European Pharmacopeia Department, supporting the work of Expert Groups in the area of biologicals, including Groups 15 and 15V (Vaccines and sera for human and veterinary use). She has a large experience at the EDQM as a Scientific Programmed Manager to various groups of experts (human blood and blood products, human and veterinary sera and vaccines, working parties for Botulinum toxin, Bovine serum etc).

ABSTRACT

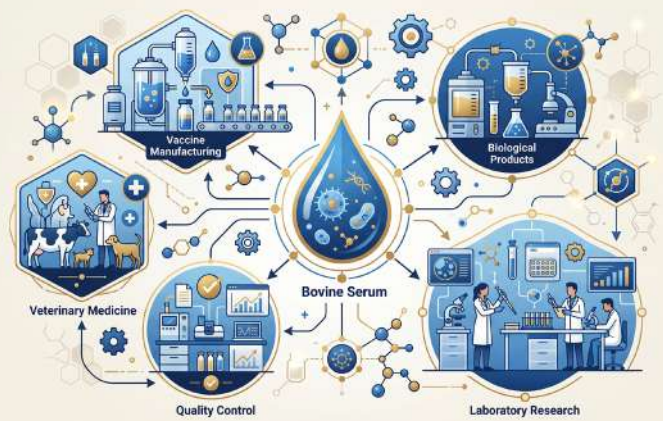


Review of European Pharmacopeia requirements for the use of Bovine serum for the production of human and veterinary medicinal products

Catherine Lebrun, EDQM

The European Pharmacopoeia Commission has initiated a general revision of the European Pharmacopeia monograph on Bovine Serum (2262) to reflect current practices. A background on the development of the monograph will be provided as well as a "Pharmeuropa teaser", for example general questions on how the monograph should best be revised may be shared with the audience. Participants will be invited to submit comments on the revised draft monograph, which will be published in Pharmeuropa subsequent to the conference.

BIOSKETCH

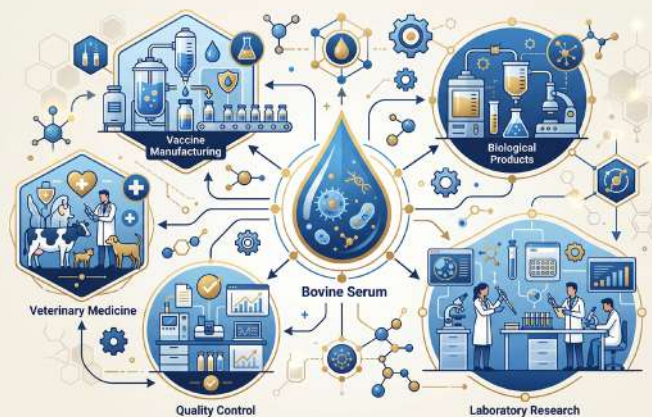


Ray Nims

Syner-G BioPharma Group

Raymond Nims has, since 2009, served as a viral safety consultant to the biopharmaceutical industry, first with RMC Pharmaceutical Solutions, Inc. and since 2023 with Syner-G Biopharma. From 2006 to 2009, Ray was a subject matter expert at Amgen, directing outsourced viral and mycoplasma testing of raw materials and products, and was a business process owner for Amgen's global contract analytical testing lab outsourcing program. From 1994 to 2006, Ray was employed by BioReliance, directing viral safety, endotoxin, and cell line identity studies for biologics cell line characterization, raw material testing, and product lot release testing.

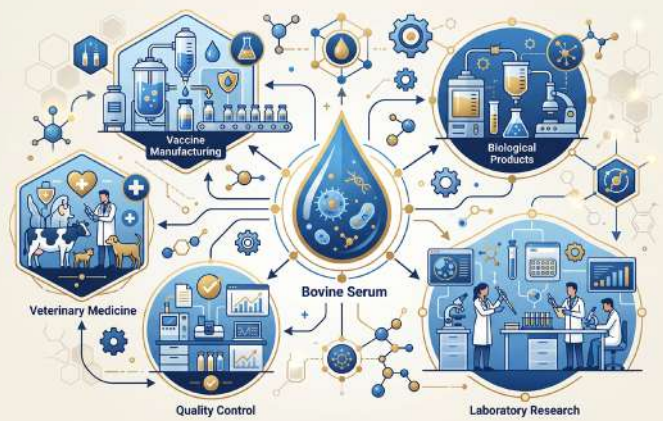
ABSTRACT



Barrier treatments for bovine serum to prevent introduction of viral contaminants into a user's cell cultures

Ray Nims

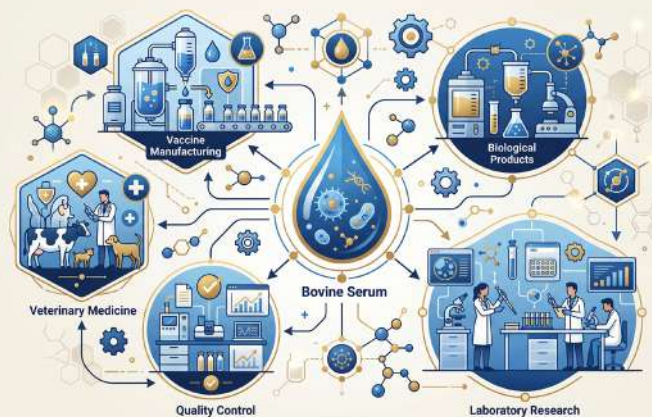
United States Pharmacopeia and European Pharmacopoeia each have chapters mandating the use of barrier treatments for inactivating viral contaminants that might be present in bovine serum. The use of serum that has not been subjected to viral inactivation treatments has led to viral contamination events in the past (e.g., Cache Valley virus, epizootic hemorrhagic fever virus, reovirus). The pharmacopoeia chapters therefore specify that use of non-barrier-treated serum for regulated manufacturing applications such as biologics or vaccine manufacture must be justified. Barrier treatments can include gamma irradiation of deeply frozen serum in the commercial bottles, heat inactivation at 56°C for 30 or more minutes applied to the thawed serum, or ultraviolet irradiation of the liquid product stream during serum manufacturing. The most commonly applied and most effective treatment is gamma irradiation, although it must be understood that each of the barrier treatments has limitations. The efficacies of each treatment for various families of viruses and limitations of the various barrier treatments in terms of minimum and maximum fluences or temperatures will be discussed in this presentation. The efficacies of the various barrier treatments for viral inactivation are typically first-order, meaning that increasing inactivation efficacy is obtained with increasing temperature or fluence. However, the possibility of detrimental impacts on serum performance in a user's cell culture application may represent a practical limit to how stringent a barrier treatment can be applied. The latter must be determined on a case-by-case basis by individual users, as different primary or continuous cell lines exhibit different susceptibilities to performance impacts of treated sera.



Prof Etienne Thiry
IABS

Etienne Thiry was born on the 4th of April 1957 in Etterbeek (Brussels). He was graduated as doctor in veterinary medicine in 1980 and in veterinary sciences (PhD) in 1985. He is retired diplomate member of the European College for Veterinary Public Health. From 1st October 2022 he is ordinary professor emeritus of veterinary virology and viral diseases, Liège University, Belgium. He is also professor emeritus of veterinary virology at the Free University of Brussels. He won the International Pfizer award by the international committee of the World Buiatrics Society in 1996. He won the Gaston Ramon award by the French Academy of Veterinary Medicine in 2008. He was recognized by the European Society for Veterinary Virology as honorary member in 2009. He received the award Prix de la Francophonie by the Fédération des Associations francophones des vétérinaires d'Animaux de Compagnie (FAFVAC) in 2011. The French Veterinary Technical Groups (GTV 52) awarded him the Jean-Jacques Tondreau Excellence Prize in 2012.

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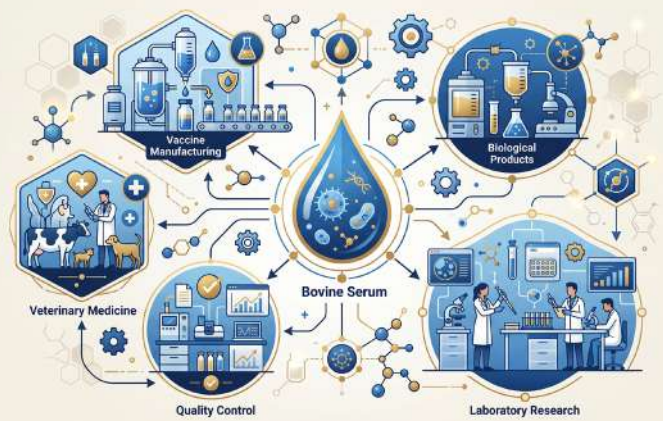


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Etienne Thiry is member of the Royal Academy of Medicine of Belgium. He is also member of the National Committee for Microbiology of the Belgian Royal Academy. He is vice-chairman of the Veterinary Biologicals Committee of the International Alliance for Biological Standardization. He is consulting member, previously acting- and vice-chairman, of the European Advisory Board on Cat Diseases. He is formze vice-chairman of the board of directors of the federal scientific institute Sciensano (2018-2024); former chairman of the scientific committee at the Belgian Food Safety Agency (Afsca) (2014-2021); former chairman of the Risk Assessment Group Covid Animals (2020-2021); former chairman of the expert committee for animal health and welfare at the French Agency for Food, Environmental and Occupational Health and Safety (Anses) (2012-2018). He was also chairman of the board of directors of the nonprofit association Formavet active in veterinary continuing education.

His research interests cover several aspects of animal virology, especially the study of animal virus-host interactions and the evolution of viral populations in noroviruses and hepeviruses; in applied research, virucidic activity and the quality of personal protective equipments, especially in the context of the Covid-19 pandemic. These scientific activities generated more than 500 papers in specialised scientific journals (hindex Scopus 48). He is the author of the four books in the collection Clinical Virology at the Editions du Point Vétérinaire on clinical virology of ruminants, dog and cat, swine and equids.

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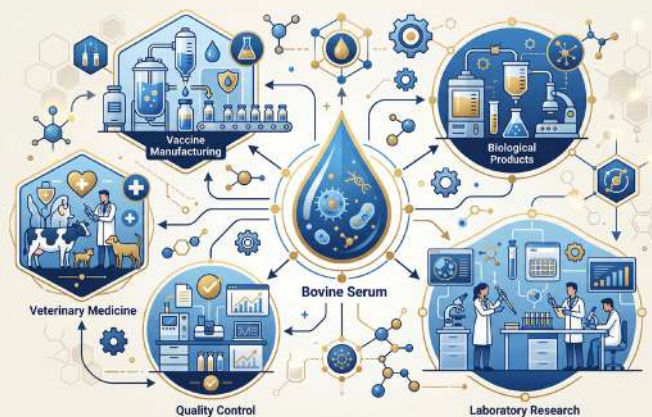


David White

USDA's Center of Veterinary Biologics

Dr. White is the Director of Policy, Evaluation, and Licensing at the USDA's Center for Veterinary Biologics. Dr. White was previously the Safety and Security Unit Lead, and was formerly the Biosafety Manager, of the National Centers for Animal Health in Ames, IA. Previously, Dr. White has worked as a researcher in containment facilities for the USDA-Agricultural Research Service and the Centers for Disease Control and Prevention. Before leaving the CDC, he was a Team Lead at CDC's Division of Select Agents and Toxins. Dr. White received his B.S. (Environmental Health), DVM, and PhD (Virology) from Colorado State University, and is a Diplomate of the American College of Veterinary Microbiologists and was a Registered Biosafety Professional from 2017-2023.

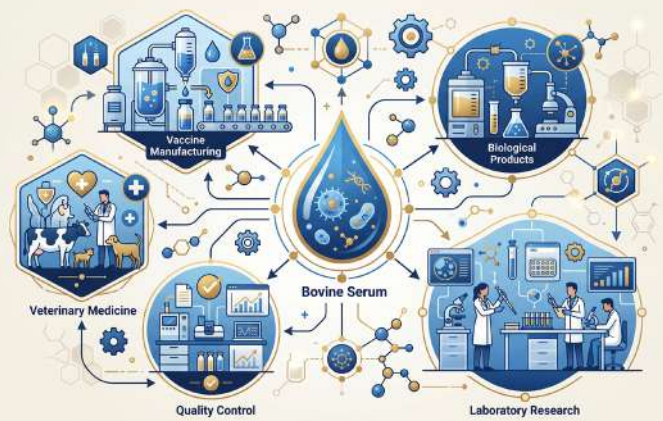
ABSTRACT



Barrier treatments for bovine serum to prevent introduction of viral contaminants into a user's cell cultures

Ray Nims

United States Pharmacopeia and European Pharmacopoeia each have chapters mandating the use of barrier treatments for inactivating viral contaminants that might be present in bovine serum. The use of serum that has not been subjected to viral inactivation treatments has led to viral contamination events in the past (e.g., Cache Valley virus, epizootic hemorrhagic fever virus, reovirus). The pharmacopoeia chapters therefore specify that use of non-barrier-treated serum for regulated manufacturing applications such as biologics or vaccine manufacture must be justified. Barrier treatments can include gamma irradiation of deeply frozen serum in the commercial bottles, heat inactivation at 56°C for 30 or more minutes applied to the thawed serum, or ultraviolet irradiation of the liquid product stream during serum manufacturing. The most commonly applied and most effective treatment is gamma irradiation, although it must be understood that each of the barrier treatments has limitations. The efficacies of each treatment for various families of viruses and limitations of the various barrier treatments in terms of minimum and maximum fluences or temperatures will be discussed in this presentation. The efficacies of the various barrier treatments for viral inactivation are typically first-order, meaning that increasing inactivation efficacy is obtained with increasing temperature or fluence. However, the possibility of detrimental impacts on serum performance in a user's cell culture application may represent a practical limit to how stringent a barrier treatment can be applied. The latter must be determined on a case-by-case basis by individual users, as different primary or continuous cell lines exhibit different susceptibilities to performance impacts of treated sera.



Marc Wintgens
Global Serum Alliance

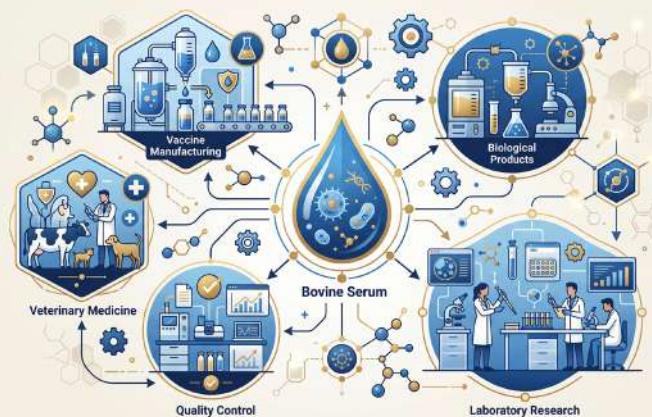
Marc Wintgens (BSc) is leading the Global Serum Alliance. His focus is on facilitating the international trade of safe serum for cell culture applications for production of human and animal therapeutics and diagnostics as well as in academic and industrial research. At the same time, he's an international consultant, giving advise in the cell culture sector at the levels of management, regulatory affairs and global sales.

For the past 46 years, he's been active with several of the larger companies (Gibco, HyClone, ThermoFisher, Selborne, VWR, Biowest) in the areas of cell culture and molecular biology. Since 2000, Marc Wintgens is actively negotiating international regulation related to import/export and safe use of animal sera, on behalf of the global serum sector.

In 2006, he became the lead of the European regional advisory team of ISIA in the US.

In 2018, he joined the Global Serum Alliance (former ESPA), where his focus is on expanding the global international network of the association, to help simplifying the serum rules, while increasing the safe use of animal sera and to guarantee supply chain security.

ABSTRACT



Bovine Serum: Enabling Human and Animal Health Through Science-Based, Sustainable Supply

Marc Wintgens - Global Serum Alliance

Bovine serum has played a fundamental role in the development and manufacture of biological medicinal products for more than seven decades, beginning with the introduction of the Salk inactivated polio vaccine in 1955.

Today, bovine serum remains an important component of cell culture systems used in the development and production of human and veterinary vaccines, biological medicines, diagnostics and emerging advanced therapies.

This presentation examines the current role of bovine serum from the perspective of both serum producers and serum users.

It brings together scientific, regulatory, supply-chain, animal-welfare and sustainability considerations to provide, a fact-based perspective, on the continued use of bovine serum in biomanufacturing.

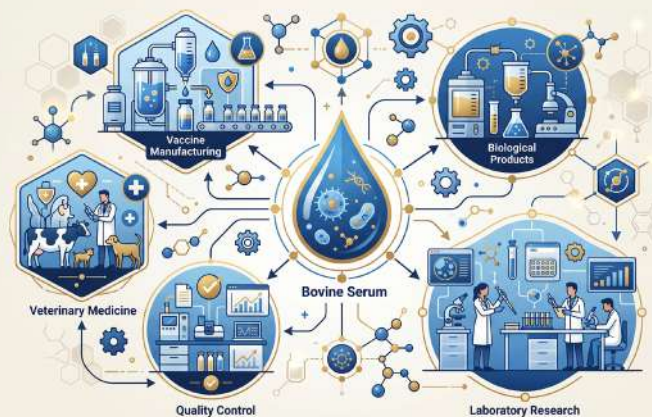
As an example of the importance of bovine serum applications, particular attention is given to the contribution of animal vaccination to disease prevention, animal welfare, antimicrobial-use reduction and the avoidance of unnecessary animal losses.

The presentation also addresses the complexity of international trade in bovine serum. Import requirements differ substantially between jurisdictions, reflecting different approaches to animal health, mitigation of transmissible-agents, geographical sourcing, processing and optimisation of safety.

These differences can create unnecessary barriers to international trade and may affect both supply security and the sustainability of global serum supply chains.

Rather than considering animal-derived materials solely as hazards to be eliminated, the presentation proposes a proportionate, science- and evidence-based approach in which potential issues are identified, characterized and appropriately controlled.

ABSTRACT



It highlights the importance of close cooperation between serum producers, medicinal-product manufacturers, regulators and other stakeholders to optimize safety, ensure supply-chain resilience, facilitate international trade and minimize unnecessary environmental impacts.

The presentation concludes with a call for greater international cooperation and harmonization, where scientifically justified, to ensure continued access to safe, high-quality bovine serum for the production of life-saving and preventive medicinal products while maintaining high standards of animal welfare, sustainability and public health.

Bovine Serum: Science, Safety and Sustainability

For more than 70 years, bovine serum has supported the development and manufacture of human and veterinary biological medicinal products, from vaccines to innovative cell-based therapies.

Despite its continued importance, the use and international movement of bovine serum are increasingly influenced by concerns regarding animal-derived materials, adventitious agents, animal welfare, sustainability and regulatory complexity.

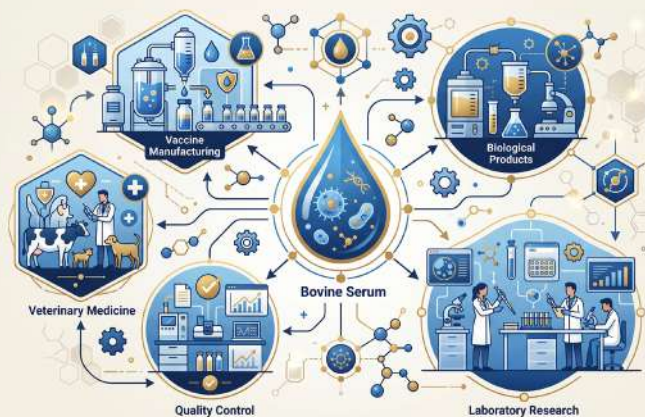
This presentation brings together the perspectives of serum producers and serum users to examine the current and future role of bovine serum in biomanufacturing. It considers the contribution of serum to human and animal health, including its role in vaccine production and the resulting benefits for disease prevention, animal welfare and antimicrobial-use reduction.

Particular attention is given to differences in international import requirements and their implications for safety, supply-chain security, sustainability and access to appropriately qualified serum.

The presentation advocates a proportionate, evidence-based approach to risk management and greater international cooperation between industry and regulatory authorities.

The objective is to promote constructive dialogue on how safe serum can continue to support global human and animal health while optimizing regulatory consistency, supply security and environmental sustainability.

ABSTRACT



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

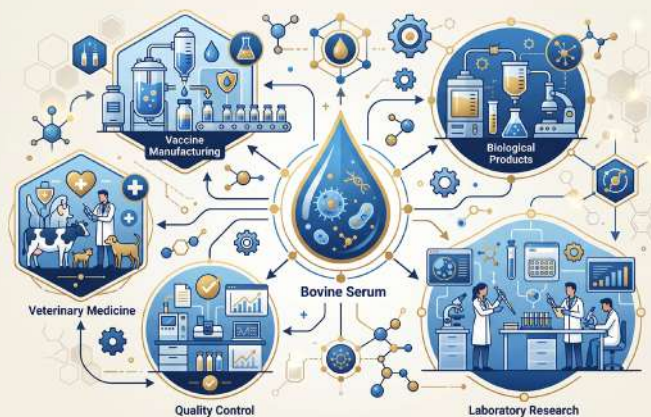
Marc Wintgens - Global Serum Alliance

Text The manufacture of vaccines and other biological medicinal products frequently relies on bovine serum as a critical raw material. Ensuring its microbiological safety requires a scientifically justified and proportionate risk assessment, that protects patients, while maintaining the availability of life-saving products. This presentation proposes a structured framework for serum risk assessment, based on the principles of ICH Q9 quality risk management, where the level of control is proportionate, with the actual level of risk, rather than driven by theoretical hazards alone. Using fetal bovine serum (FBS) as a case study, a stepwise approach is presented to progressively reduce the list of relevant biological hazards of interest.

The framework integrates six complementary elements:

- (1) Veterinary inspections at the farms and slaughterhouses,
- (2) consideration of the placental barrier and its influence on vertical transmission of viruses,
- (3) traceability of serum to the collection region and evaluation of regional animal health status,
- (4) assessment of the relevance and limitations of classical testing methods,
- (5) implementation of validated viral inactivation measures such as gamma irradiation,
- (6) strategic testing targeted to the residual viruses, that remain relevant, after the preceding risk reduction steps.

The presentation also discusses the importance of interpreting test results within their biological context. For example, conventional testing for bovine viral diarrhoea virus (BVDV) may have limited value for untreated serum, whereas molecular methods can provide greater added value for demonstrating the absence of other regionally relevant viral pathogens. Emerging technologies, including next-generation sequencing based testing, are highlighted as promising tools for differentiating viable from non-viable viral material and further strengthening evidence-based risk assessment. Overall, the proposed proportionate risk assessment strategy should enable manufacturers and regulators to focus control measures where they provide the greatest benefit, supporting both product safety and continuity of supply for biological medicines while avoiding unnecessary restrictions on the use of bovine serum.



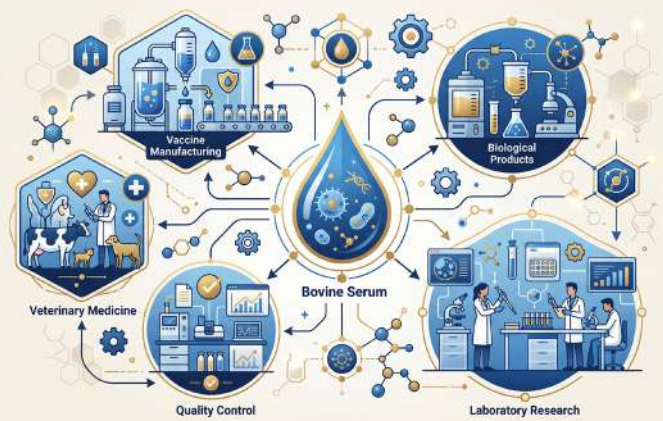
Dr. rer. nat Florian Zielecki
GSK Vaccines, global MSAT

Dr. Florian Zielecki is a Viral Safety Scientific Manager with more than 12 years of experience in virology, viral safety, and vaccine manufacturing. He conducted his PhD at the Robert Koch Institute in Berlin studying highly pathogenic H5N1 influenza viruses, followed by four years of postdoctoral research at the Institute of virology of the Philipps University Marburg investigating the innate immune response to highly pathogenic viruses under BLS4 conditions.

Back in 2014 Dr. Zielecki joined the pharmaceutical industry, first at Novartis and since 2016 at GSK, where he has held scientific and leadership positions in MSAT Process Science leading process characterization, manufacturing support, and lifecycle management activities in small scale format for cell culture based viral vaccines.

Since 2018 he has joined the global viral safety team. In his current role as Viral Safety Scientific Manager, Dr. Zielecki provides scientific leadership in viral safety, with a particular focus on viral risk assessment, virus clearance of animal derived raw materials, and regulatory compliance for biopharmaceutical products.

ABSTRACT

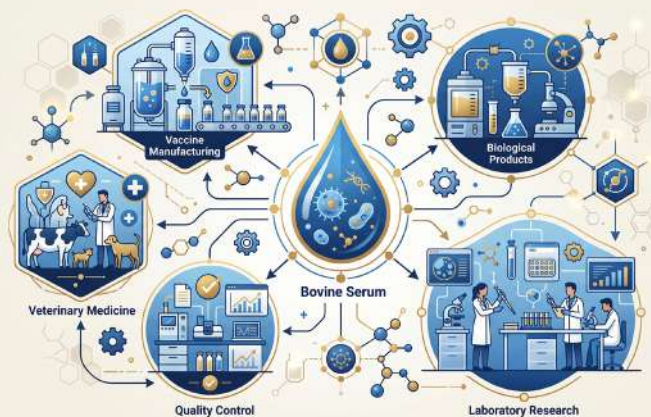


Use of Bovine Serum in the manufacture of human vaccines – New challenges and risk control - A virological perspective

Florian Zielecki, GSK

A review of published high-throughput sequencing studies highlights the increased detection of novel viruses in bovine serum, challenging traditional viral safety concepts for this critical raw material. Indeed, these viruses can be undetectable using the conventional Quality Control assays and resist to viral inactivation treatments. The objective of the presentation is to initiate a discussion about the quality and safety risks represented by these viral agents and the strategy to manage the risk in term of risk reduction or acceptance.

ABSTRACT



Risk assessment of bovine viruses unable to replicate in production cell culture – A scientific approach

Florian Zielecki, GSK

The objective of this second session is to present a structured scientific approach to perform viral safety risk assessment for bovine serum in the light of high-throughput sequencing data reporting multiple viral sequences, but lack the demonstration of infectivity, disease association, or fulfilment of Koch's postulates. These cases still require systematic risk evaluation. Building on ICH Q9 quality risk management, the proposed framework integrates knowledge management with stepwise viral risk identification, analysis, evaluation, and risk control/acceptance. Viruses with differences in pathogenicity, detectability, and γ -irradiation sensitivity will lead to distinct decisions of "controlled" versus "accepted" risk for Fetal Bovine Serum, with the option to add quantitative risk assessment providing additional safety margin where needed. The session will therefore compare two case-studies.