International Alliance for Biological Standardization

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

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Virtual Meeting

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

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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.