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

**September 29-30, 2026**
**Virtual Meeting**

**Risk assessment of bovine viruses unable to replicate in production cell culture – A scientific approach -** Dr. 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 therfore compare two case-studies.