



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**

Title: Barrier treatments for bovine serum to prevent introduction of viral contaminants into a user's cell cultures – Raymond Nims - Syner-G BioPharma Group

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.

