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Process compatibility of hydrogen peroxide vapour disinfection in Aseptic processing.

The most commonly used bio-decontamination agent is hydrogen peroxide vapour. There are process integration and compatibility issues to consider when applied in Aseptic processing. This presentation examines key issues in two project applications:

- The first case study example is in Filling Lines using Isolators and single use product bag systems for both virus based products and non virus based products. The integration and relationship with the disinfection and sterilization processes are considered.
- The second case study example is a Closed RABS Filling line. The Filling Line has gassed in place Feeder hoppers and Feeder bowls together with CIP/SIP for the filling system. The interactions of the disinfection and sterilization processes are considered.

Also for risk reduction in project execution the RABS filling line included initial cycle development, with biological indicator challenges, at the Filling machine manufacturer. The Pharmaceutical company that set this challenge did so knowing cycle parameters would change at site but there would be reduced risk of subsequent engineering challenges and cycle development would only be subject to parameter change. Lessons were learned that can be shared.