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A HOLISTIC APPROACH TO FACILITY PROTECTION FROM ADVENTITIOUS AGENTS – A CASE STUDY

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The Eli Lilly biologics manufacturing facility in Kinsale, Ireland has been operational since 2010 with a 100% cell culture contamination control success rate. The presentation will review the holistic approach to facility protection from adventitious agents that underpins this success including:

- The risk assessment approach to points of entry and management via detectability and control measures
- The approach to personnel training that considers human factors, increased vigilance and event simulations following strategies that are used in chemical synthesis process safety

The presentation will then focus on control of adventitious virus. The talk will briefly comment on the early warning measures via use of an in process qPCR assay and then move on to place significant emphasis on the application of High Temperature Short Term (HTST) treatment for culture media. The Proof of Concept studies showing applicability to certain media classes and challenges for others will be discussed and then a case study showing detailed laboratory support studies for a number of products will be presented. Finally the challenges of application to clinical and commercial products will be discussed.