# VIRAL CLEARANCE VALIDATION FOR A FULLY CONTINUOUS MANUFACTURING PROCESS FOR PHASE 1 STUDIES

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Over the past years, BiosanaPharma has developed a fully continuous process for the manufacturing of antibodies. The objective is to have a continuous production platform for biosimilars. Recently, a phase 1 study was initiated for a biosimilar that was produced using this continuous platform.

Using high cell density perfusion, two BioSMB (chromatography) steps, continuous nanofiltration and UFDF, a production campaign was performed under GMP to produce multiple drug substance batches. Given some unorthodox design choices, validation of the viral clearance capacity of this continuous process revealed some interesting challenges. The viral clearance validation focused on three steps: low pH virus inactivation, a membrane anion exchange step and nanofiltration. In this talk, justification for the scale down model is presented alongside with the results of the viral clearance study to demonstrate the safety of the product for a phase 1 study.