

PROCESS VALIDATION APPROACHES TO CONTINUOUS/CONNECTED DOWNSTREAM PROCESS

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One of the enabling technologies that Novartis has developed for its small and flexible biomanufacturing plant is the continuous/connected downstream process. The major benefit of continuous/connected downstream process is elimination of large product pool tanks (a few 1000L) by introducing small surge tanks (<100L) which greatly reduces plant foot print. The characteristics of continuous/connected downstream process are: 1) multi-unit operations work together in the same time 2) homogenous intermediate product pools are no longer available for typical offline analytical measurements. These new characteristics require process validation approaches to be reexamined.

This talk covers development of representative scale down models for continuous/connected downstream process to efficiently and robustly support process characterization. Viral clearance validation approaches will be also discussed to reflect the requirement of continuous/connected downstream process. Sampling approaches is an integral part of control strategy which needs to be modified as well to ensure successful process validation.