Perspective

Pharmaceutical BIOPROCESSING

Continuous Viral Clearance: Advancing Safety in Biomanufacturing

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Introduction

Continuous viral clearance is an emerging approach in biopharmaceutical manufacturing that integrates viral inactivation and removal steps into continuous downstream processing workflows. Viral safety is a critical requirement for biologics produced using mammalian or other susceptible cell lines, as adventitious or endogenous viruses may pose risks to patient safety [1,2[. Traditionally, viral clearance has been achieved through discrete batch operations. Continuous viral clearance aims to enhance process efficiency, robustness, and compatibility with continuous manufacturing platforms while maintaining stringent safety standards.

Discussion

Continuous viral clearance incorporates established viral inactivation and removal techniques, such as low-pH treatment, nanofiltration, and chromatography, into uninterrupted processing schemes. In continuous low-pH viral inactivation, product streams are exposed to acidic conditions for a defined residence time using tubular reactors or hold tanks designed to ensure consistent exposure [3,4]. This approach enables precise control over critical parameters such as pH, temperature, and residence time.

Continuous nanofiltration is another key component of viral clearance strategies. By integrating virus-retentive membranes into continuous downstream workflows, manufacturers can achieve consistent viral removal while supporting steady-state operation. Advances in membrane technology and flow control systems have improved flux stability and minimized fouling, making continuous operation more feasible.

One of the main advantages of continuous viral clearance is improved process integration. Aligning viral clearance steps with continuous upstream and downstream operations reduces hold times, intermediate storage, and manual interventions. This can lead to smaller facility footprints, reduced contamination risk, and improved manufacturing efficiency. Continuous processing also supports real-time monitoring and control, enabling rapid detection of deviations and enhanced process robustness [5].

Despite its benefits, continuous viral clearance presents technical and regulatory challenges. Ensuring equivalent or superior viral clearance performance compared to batch processes requires rigorous validation and residence time distribution studies. Regulatory agencies expect comprehensive demonstration of robustness, consistency, and traceability. Additionally, integration with existing batch-based processes may require hybrid manufacturing strategies during transition phases.

Conclusion

Continuous viral clearance represents a significant advancement in biomanufacturing safety and efficiency. By integrating viral inactivation and removal into continuous processing workflows, it supports modern manufacturing paradigms while maintaining high safety standards. Although technical and regulatory challenges remain, ongoing

innovation and regulatory engagement are driving progress. As the biopharmaceutical industry increasingly adopts continuous manufacturing, continuous viral clearance will play a critical role in ensuring the safe and reliable production of biologic medicines.

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