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Virus filtration for biosimilar manufacturing: From needs to solutions

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Manufacturers of biologicals are required to demonstrate that their downstream processes are capable of clearing adventitious or endogenous viruses in order to insure against the incidence of viral contamination. Virus filtration is routinely used in downstream processing as a virus clearance step as it is considered robust, easy to use and entails relatively simple validation requirements. In this lecture, we examine the regulatory landscape as it applies to virus filtration of biologics as well as discuss the critical operating parameters that impact viral filter process implementation. The session will specifically cover current practices relating to virus filter validation, expected clearance requirements, typical performance for a robust filter operation, scale-up & operational considerations to ensure robust viral clearance assurance.

Biography

Tathagata Ray is Manager leading India Biomanufacturing Sciences Network Group, working for the last eight years in Merck Millipore. His expertise includes optimizing downstream unit operations and providing scale up solutions to biological manufacturers. He is Master's in Biotechnology and has publications in national and international journals.

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