IMPLEMENTATION OF A PROCESS-SCALE ADENOVIRUS PURIFICATION WITH A SINGLE-USE PLATFORM

Amélie Boulais, Sartorius Stedim Biotech amelie.boulais@sartorius-stedim.com Maria Mellado, Sartorius Stedim Biotech Miyako Hirai, Sartorius Stedim Biotech Cristina Peixoto, IBET

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Adenovirus vectors are finding increasing application within the vaccine and gene therapy industries. Companies developing adenovirus-based biopharmaceuticals will benefit from single-use process platforms that are quick and easy to install and have been demonstrated previously to produce purified adenovirus. The platform can be adapted to new adenovirus products with a minimum investment of time and resource in process development activities. We have assembled a platform from existing and proven technologies, available from lab to production scale, that meet the quality requirements of the vaccine industry. The platforms includes clarification, ultrafiltration/diafiltration, chromatography and sterile filtration steps. The approach has been successfully demonstrated for the purification of an Adenovirus serotype 5 vector, at the 20 L scale. It allows the complete purification of the vaccine in one day.