

Sartorius & RoosterBio to advance downstream purification for exosomes manufacturing

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A step further to commercialise the exosome production and purification process

Germany-headquartered Sartorius has extended a strategic collaboration partnership agreement with US-based RoosterBio Inc. to address purification challenges and establish scalable downstream manufacturing processes for exosome-based therapies.

Through this collaboration, Sartorius and RoosterBio will provide best-in-class solutions and expertise for a human mesenchymal stem/stromal cell (hMSC) - based exosome production platform that delivers industry-leading yield, purity, and potency.

Additionally, this collaboration will focus on the development of comprehensive analytical techniques for the characterisation of exosomes and the entire spectrum of extracellular vesicles (EVs) to establish quantitative strategies for quality control of exosome purification intermediates and final drug product.

Sartorius and RoosterBio will develop scalable platform purification processes using Sartorius' comprehensive toolbox of solutions to maximise exosome productivity while maintaining therapeutic attributes. Sartorius' Biostat STR® manufacturing bioreactor platform, process analytical technologies (PAT) toolbox, along with RoosterBio's hMSC banks, RoosterNourish™ hMSC cell growth medium, and RoosterCollect™ EV production medium will be used for upstream manufacture of exosomes at large scale. For the development of downstream purification methods, Sartorius's scalable filtration equipment, Sartoflow® Smart and Sartoflow® Advanced will be leveraged for clarification, concentration, and formulation of exosomes in combination with column chromatography unit operations.