COMPLEX NEW MODALITIES REQUIRE ADVANCED BIOMANUFACTURING PLATFORMS: THE CASE OF EXOSOME BIOTHERAPEUTICS

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Exosome-based therapeutics are rapidly evolving as a high potential new modality in multiple clinical areas such as oncology, immuno oncology, neurology and tissue regeneration, among others. As these indications involve large patient populations, the implementation of exosome therapeutics requires robust manufacturing processes yielding large quantities of highly purified material. However, the complexity and heterogeneity of exosomes pose significant R&D challenges. Here, we present the successful development of a large-scale manufacturing process using engineered human cells grown in a high-density continuous culture. The upstream process is followed by a sequence of purification steps yielding material of high purity and quality. The related analytical and characterization methods are also discussed.