

Large scale production and characterization of exosomes

Konstantin Konstantinov, Codiak BioSciences

Exosome-based therapeutics are rapidly evolving as a new modality with a promising potential in multiple clinical areas. Successful implementation requires development of robust large-scale processes for the manufacture of highly purified material. However, the complexity and heterogeneity of exosomes pose significant R&D challenges. Here, we present the successful development of a manufacturing process using immortalized human cells, currently operating at commercial scale. Contrary to traditional ultracentrifugation approaches for exosome production, our process is based on modern biochemical engineering principles, resulting in a robust and scalable operation. The related analytics and characterization methods are also discussed.