

Development of a scalable production process for the manufacturing of exosome-based biotherapeutics

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Exosomes have emerged as a therapeutic platform that could allow for the development of highly potent and directed therapeutics. As efforts accelerate to translate exosome biology into new medicines, clear technology gaps have emerged between the current state of the art for producing extracellular vesicles, including exosomes, and the capabilities necessary to support large scale clinical and commercial manufacturing. Codiak BioSciences has created a scalable exosome production platform based on chemically-defined, suspension cell culture with purification using conventional downstream unit operations. In this presentation, the potential of exosome-based therapeutics and the bioprocessing technologies for their future commercialization will be discussed in the context of the capabilities and limitations of the existing biomanufacturing platforms. The development strategy employed by Codiak BioSciences will be described and supported by case studies from process development. This will include examples of challenges specific to working with large macromolecular complexes.