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Continuous bio manufacturing of extracellular vesicles

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Interest in microvesicles, exosomes and oncosomes is growing. Applications include 1) Vectors of research or therapeutic cargo, 2) Agents of intercellular communication from stems cells to terminally differentiated tissue to the entire microbiome and 3) Support of clinical diagnostics. There are ongoing efforts to standardize clinically applied vesicle assays and therapeutic cargo vehicles. Reference materials, controls, and performance standards need to be defined for quality assurance in such applications. Sponsors often have their choice of cell platforms, production formats and culture modes for vesicle product and process development. However, commercial success can be dependent upon the discovery of scalable technologies that can produce very large amounts of sufficiently pure and consistent vesicles in a robust, compliant and cost-effective manner in a cGMP environment. In biopharmaceuticals, continuous biomanufacturing promises heightened process flexibility and a reduction in product microheterogeneity; construction costs and schedule extent; utilities requirement; manufacturing suite area and classification. The value of single-use implemented and continuous biomanufacturing methods will be reviewed.

Biography

William G Whitford is Strategic Solutions Leader, GE Healthcare in Logan, UT with over 20 years of experience in biotechnology product and process development. He joined the company as an R&D Leader developing products supporting protein biological and vaccine production in mammalian and invertebrate cell lines. Products he has commercialized include defined hybridoma and perfusion cell culture media, fed-batch supplements and aqueous lipid dispersions. He has published over 250 articles, book chapters and patents in the bioproduction arena.

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