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Continuous Manufacturing of Complex Parenterals such as mRNA Vaccines and Liposomes

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This presentation will focus on the development of a continuous manufacturing platform for complex parenterals. Currently there are 15 US FDA approved products produced *via* continuous manufacturing. However, all of these products are in the solid oral space. Our laboratory has been developing continuous processing for complex parenterals. Following the Covid 19 pandemic, it has become even more apparent that such an approach is necessary for injectable products. The benefits associated with continuous manufacturing can; reduce cost, increase quality through online process analytical technology (PAT), and increase throughput, to achieve rapid production of high-quality products. Liposomes as well as polymeric micelles, and lipid nanoparticles (LNPs) will be discussed. Key aspects in the development of these novel therapeutics will be addressed together with insights into critical issues in the manufacturing process. Our laboratory has developed a novel continuous manufacturing platform for complex parenteral dosage forms which allows precise control over particle size and can also ensure monodisperse particles. This platform is fully equipped with PAT to ensure all aspects of product quality. An overview of this manufacturing platform will be presented. The platform is based on co-flow technology and employs the formation of a turbulent jet at the site where the two flows mix, promoting vesicle formation. Case studies on different therapeutics prepared using this technology will be discussed as well as the utilization of this technology for quality standards preparation.

Keywords: (continuous manufacturing, complex parenterals, microspheres, liposomes, long acting injectables)