Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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# Standardized Platform Process With In-Line Cell Lysis Purifies Plasmid DNA Using A Single Chromatographic Step For Cell And Gene Therapy.

Plasmid DNA (pDNA) serves as a critical starting material for the production of advanced therapy medicinal products (ATMPs) in the field of cell and gene therapy. The growing demand for pDNA requires the development of manufacturing processes that can meet aggressive timelines while maintaining cost-effectiveness. Here we present a robust single-use process that enables seamless scale-up from research and development (R&D) to good manufacturing practice (GMP) grade, as well as the associated challenges.

This process involves bacterial cell growth in fermenters, alkaline cell lysis, and a streamlined chromatographic step. A key aspect of this approach is the implementation of a controlled cell lysis step, ensuring the production of high-quality pDNA that complies with regulatory agency standards. Notably, this process achieves efficient purification and polishing with just a single chromatographic step, simplifying the manufacturing process as well as reducing costs.

We will provide an overview of the platform process, what were the challenges and benefits of a standardized process and then share results on the quality attributes obtained through its implementation. Our findings demonstrate the effectiveness of this approach in generating pDNA that meets quality requirements set by regulatory agencies.