

HYBRID MODELING APPROACHES FOR AUTOLOGOUS CELL THERAPY PROCESS CHARACTERIZATION

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Abstract: It is well known that starting material has a major impact on autologous cell therapy processes and products. As a result, modeling the impact of such attributes on in-process, intermediate and final drug product attributes is an ongoing area of study in autologous cell therapy. This study explored various statistical modeling techniques for process characterization and used both the starting material attributes and experimentally manipulated process parameters as predictors. Linear mixed effects modeling combined with Decision tree models and Principal Component Regression was performed for select critical response variables. In this presentation, these techniques are discussed, and the modeling outputs compared.