

ADVANCED APPROACHES FOR CELL THERAPY PRODUCT CHARACTERIZATION

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Cell and gene therapy manufacturing process can be complex and have high level of raw material variability. This makes the development of reliable, consistent and cost-effective manufacturing processes a significant challenge. For autologous products, this challenge can be even greater due to the added variability of the patient specific cellular starting material and the lack of real-time process data. These challenges could be addressed through the application of Process Analytical Technologies (PAT) that permit in-line or at-line analysis throughout the manufacturing process. These technologies could allow key variables to be tracked for tighter process control as well as the provision of process information in a time frame enough to allow proactive decision making and the early detection of poor process performance. In this presentation we will show how in-line optical biosensors can be applied for advanced multiparametric monitoring of cell and gene therapy bioprocesses. We will show how real-time process data can be used to support manufacturing decisions and the role these technologies have in supporting a move towards feedback control and adaptive manufacturing.