

IMPLEMENTATION OF AUTOMATED PROCESS MONITORING AND DATA CAPTURE

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Kite Pharma is implementing an automated data capture and visualization tool for automated continued process verification (CPV) to align with FDA best practices on process validation. The increased volume and variety of data associated with autologous therapies add significant scalability challenges for traditional process monitoring workflows. The tool's intent is to reduce the time spent sourcing, aggregating, and transforming the data into a form ready for consumption by operations management, and provides unified views of joint patient/process data for improved knowledge management. The system utilizes an enterprise data lake cloud solution in combination with a variety of big data technologies to ingest and integrate data from disparate source systems, transform the data per defined business rules, and finally load the data into a publishing layer for consumption by various visualization and analytical tools. The platform will be fully GMP compliant and meet 21 CFR Part 11 guidelines with full audit capability. The visualization tools will dashboard key analytics against control limits, with the capability of providing timely alerts to enable earlier identification of process deviations leading to faster response. The tool is built upon advanced analytics platform, which will be capable of machine learning, predictive analytics, and pattern recognition. A series of case studies will support the key advances achieved from this approach.