

CASE STUDY: RAMAN IMPLEMENTATION FOR PROCESS LIFECYCLE MANAGEMENT IN FERMENTATION BASED PROCESSES

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Existing metabolite analyzers for several inline fermentation based vaccine processes are becoming obsolete in upcoming years. Analyzers are used to support classified parameters and attributes as well as characterization of the fermentation processes. A PAT solution is preferred as a replacement as it would allow for enhanced process understanding and control. Raman spectroscopy has been aligned as a core technology for implementation with varying challenges based on media, organism, processing parameters and attributes being measured. Implementation requires a highly collaborative approach across functions and sites to ensure effective implementation with no interruption to supply. Using a standardized approach to Raman model development and validation, robust models have been developed for 2 product lines with implementation scheduled over the next three years.