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Process Analytical Technology Enabling Continuous Drug Product Manufacturing

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Continuous processing offers many advantages in pharmaceutical manufacturing. Low capital investment from a small factory foot print, removal of scale-up issues during process development and support of agile /lean supply chain being key economic benefits.

Process analytical technology is a key enabler of continuous processing of pharmaceuticals. The ability of rapid on-line measurement technologies reduces the risk of continuous mixing systems, and can support a QbD approach to control and lead to adoption of Real Time Release strategies for the product.

This paper will describe the on-line PAT systems developed for, and installed in Pfizer's first commercial scale continuous drug product manufacturing facility. The focus will be on design of sample interfaces and the measure capability related to the product specifications. The paper will also include a discussion on method validation philosophies for on-line real time technologies applied to pharmaceutical processes.
