

Summary - Implementation of Process Analytical Technology

Implementation of PAT involves analytical measurement systems with associated methods that are integrated into a manufacturing process. Implementation of PAT applications should conform to current Good Manufacturing Practices (cGMPs).

Classification should be based on the intended use of the application, including the use of data generated. Subsequent impact to product quality and regulatory compliance should be incorporated into the classification assessment.

A PAT system or application whose operation, data, control, alarm or failure is expected to have an effect on product quality or regulatory compliance.

A PAT application that will produce, monitor, evaluate, store or report data used to accept or reject product or material, or data used to support regulatory compliance.

Each Site PAT application should be approved for use at the site by the Site Quality Team, including a review of its potential impact upon the quality systems at the site.

For PAT applications whose category of use is defined as Monitoring and Control, associated manufacturing and quality documentation should be revised in accordance with local change control policies in order to implement the PAT application at the site.

For critical (direct impact) and key (indirect) PAT methods, whose use is defined as Monitoring and Control, reliability of PAT applications should be periodically verified (based on risk) with a scientific and statistically-justified approach.

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