

2.1 Critical (Direct Impact) PAT System:

- 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.
- A PAT application used to control or effect an identified critical product and/or quality attribute/parameter or specification

2.2 Key (Indirect Impact) PAT System:

- A PAT system or application whose operation, data, control, alarm or failure is not expected to have an effect on product quality or regulatory compliance and which links or interfaces with a direct impact system, application or test.
- A PAT application used to control or effect an identified key product and/or quality attribute/parameter specification.

2.3 Not Critical (No Impact) PAT System:

- A PAT system or application which will have no effect either directly or indirectly on product quality or regulatory compliance.

Implementation Requirements:

1. General:

- 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.
- When site-specific documents are generated to support PAT implementation, they should adhere to all central notification, review, and approval requirements.

2. Development and Evaluation of PAT technology:

- A PAT system whose category of use is defined as Development and Evaluation of PAT technology should be commissioned as per guidance 098.
- A PAT application method whose category of use is defined as Development and Evaluation of PAT technology does not need to be validated though appropriate demonstration of application suitability for intended use should be performed.
- Questionable results for PAT applications, whose category of use is defined as Development and Evaluation of PAT technology, can be investigated as part of the system or application development activity.

3. Monitoring and Control:

- A PAT system whose category of use is defined as Monitoring and Control and the risk to quality or regulatory compliance is considered critical (direct impact) or key (indirect impact) should be verified (incorporating commissioning and qualification) as per guidance 098.