Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document gives document on the implementation of Process Analytical Technology (PAT) applications at a GMP processing site. Implementation of PAT involves analytical measurement systems with associated methods that are integrated into a manufacturing process. PAT provides more direct information about control points of the manufacturing process and quality attributes of a product than that which is available by traditional analytical methods. Implementation of PAT applications should conform to current Good Manufacturing Practices (cGMPs).

PAT applications should be evaluated and documented according to the intended use and risk to quality and regulatory compliance. Document on the intended use and risk to quality is included in the following sections. The extent of verification testing (incorporating commissioning and qualification), method validation and approach to deviation investigation will depend on the outcome of the risk assessment and should be commensurate with the risk associated with the both the use of the PAT application and the data generated as result of application use.

Classification
Application classification should be based on both the intended use of data and the risk to quality.

1.0 Classification based on Intended Use
Classification should be based on the intended use of the data generated by the PAT application.

1.1 Development and evaluation of PAT technology:
- Includes measurement systems with associated methods under experimental development.
- Includes measurement systems with associated methods used to demonstrate feasibility for a specific use.
- Does not generate data to support acceptability decisions associated with a manufacturing process or product.

1.2 Monitoring and Control
- Includes measurement systems with associated methods used to support acceptability decisions associated with progression of material through a manufacturing process.
- Includes measurement systems with associated methods used to support process optimization.
- Includes measurement systems with associated methods used to used to support process validation.
- Includes measurement systems with associated methods where the data is used to make operational decisions based on non quality attributes (e.g. yield)

2.0 Classification based on Risk to Quality
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.

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.

