

## **Summary - Validation of Process Analytical Technology System**

It is recommended that an impact assessment of each PAT system be performed. Those systems that are determined by the impact assessment to have a potential impact on product quality are considered direct impact systems and shall be qualified. Others which are determined to be indirect or no impact are Commissioned.

An impact assessment shall provide a risk-based approach to assess if a PAT system is direct, indirect or no impact, along with the extent of validation required for direct impact systems. Impact Assessments should be performed for all PAT systems. The System Level Impact Assessment (SLIA) shall determine if the system is considered to be Direct Impact, Indirect Impact, or No Impact with respect to its potential impact on product quality.

In the absence of a Component Level Impact Assessment, all components of a direct impact system require validation. Only critical components within a direct impact system require qualification. Non-critical components within a direct impact system are commissioned. For example, a PAT system could be defined as a system by itself. For PAT systems with fixed-installation probes, the most logical system boundary has the probe as part of the process equipment.

For systems that include laboratory instruments as part of the PAT system, the PAT system may first be categorized to determine if it has a direct, indirect or no impact on product quality.

The boundary for the PAT system has therefore been drawn to exclude the product contact components from the PAT system and include those components in the reactor system itself. This PAT system would require commissioning only. The system components in direct contact with product can be included within the scope of the PAT system and qualified as a component of the PAT system, or they can be included within the scope of the reactor system itself and qualified as part of the reactor system.

The boundary for the PAT system has therefore been drawn to exclude the product contact components from the PAT system, and include qualification of those components in the reactor system qualification. This PAT system would require commissioning only.

Quality risk-based, impact assessment of PAT systems and PAT applications is fundamental to establishing the validation strategy.

**[Read More](#)**