

AUTOMATIC PROCESSING AND PERFORMANCE QUALIFICATION (PQ) IN PHARMACEUTICAL APPLICATIONS

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Powder X-ray Diffraction (XRD) is a widely used technology to analyze crystalline materials. Until recently, XRD was largely in the domain of isolated research labs. Today XRD is often used as a routine quality control tool for in-line process control. Every step of the measurement process can be fully automated, starting with sample preparation and ending with a customized report printed on a remote computer.

Research laboratories can also benefit from automatic data processing. Often, the emphasis is on the result, not the method. Researchers tend to spend a lot of time using XRD, because it is an extremely powerful and flexible tool. However, automatic processing can help focus the method on the application. It is possible, for instance, with one mouse click to measure a sample and print a report of the identified crystalline phases.

Automatic processing can enhance productivity for performance qualification (PQ) in FDA regulated environments. A timer will start the performance qualification at pre-determined intervals. This may include standard sample loading, measurement, analysis (e.g. background determination, peak search, scan corrections, search-match, comparison to standard measurement), report generation and automatic report printout.

The power to automatically process measured data has increased dramatically with newly available software. For instance, it is now possible to obtain quantitative results on pharmaceutical samples. A practical application which will be presented is the quantification of amorphous lactose in a crystalline lactose matrix.

Poster abstract

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