

# **The Role of PXRD in QbD and PAT**

- Possibilities and Limitations

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With the introduction of Food and Drug Administration's (FDA) recent "Quality by Design (QbD)" and "Process Analytical Technology (PAT)" initiatives, empirical approaches to the pharmaceutical manufacturing process have been de-emphasized. The rationale contained in these initiatives states that quality cannot be tested into products but should be designed into the process.

A number of analytical technologies have demonstrated potential for use in supporting both the QbD and PAT strategies. Due to instrumental complexities, including source and detector configurations, as well as safety reasons, PXRD has not been widely considered as a potential PAT tool. This presentation will include a discussion of general PAT instrumental requirements, the role of single crystal XRD and PXRD in establishing crystal form identification to ensure process control, and applications to illustrate the possibilities and limitations of using on-line PXRD.