

SPS-XRPD Workshop



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Applications of XRPD for Phase Identification throughout Pharmaceutical Product Development

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Small molecule APIs can exist in a variety of distinct solid-state forms with drastically different physicochemical properties. During development of these APIs, many factors are considered during form selection, such as stability, manufacturability, bioavailability, and intellectual property. If solid-state changes are observed during development, these selection factors can be negatively impacted, which can have detrimental effects to the development process and timeline. The “gold standard” tool to characterize solid-state forms is XRPD, which is used to ensure product quality from the late stages of Discovery as well as throughout Product Development, Commercialization, and Life Cycle Management.

We will discuss several case studies in order to illustrate the use of XRPD in screening of solid forms of APIs and in determining the impact of DS and DP unit operations on the solid-state form of APIs. We will further discuss the use of XRPD to troubleshoot processing or stability failures due to contamination or raw material variability. Throughout the presentation, comparisons to other solid-state characterization techniques, such as Raman, NIR, IR, and ssNMR, will be discussed to illustrate gaps in areas of implementation of XRPD.

Primary author: Dr PATEL, Anisha (Bristol-Myers Squibb)

Presenter: Dr PATEL, Anisha (Bristol-Myers Squibb)

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