

Microsymposium

MS075.001

Regulatory classification of cocrystals and its implications on drug development

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Although cocrystallization is not a new phenomenon, its application to improve important pharmaceutical properties including manufacturability generated significant interest across pharmaceutical industry in recent years. While cocrystals can provide an exciting opportunity for pharmaceutical scientists to engineer solid-state form with right properties, there was no regulatory paradigm existed until 2011. In 2011, FDA issued a draft guidance for new drug applications and abbreviated new drug applications on regulatory classification of cocrystals as drug product intermediates and the information required to support cocrystal product application. In this presentation, initial regulatory classification, comments and suggestions provided both industry and academia regarding the draft guidance, final FDA guidance and subsequent IQ consortium sponsored cocrystal working engagement with FDA will be discussed.

None

Keywords: [Cocrystal](#), [regulatory](#), [FDA](#)