

DRUG PRODUCT CHARACTERIZATION: WHAT FORM DO I HAVE?

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The solid form of a drug substance is important when developing a new chemical entity and these forms can include polymorphs, hydrates, salts, cocrystals, amorphous, and amorphous dispersions. The form used in development is significant based on possible manufacturability, solubility, bioavailability, and stability differences between the materials. Drug product samples can be analyzed by a variety of techniques to determine the solid form present or to identify changes that occur during the manufacture of a drug product. This talk will cover how x-ray powder diffraction can be used with other common techniques to characterize drug product samples. The use of x-ray powder diffraction and solid state analyses in understanding and monitoring formulation processes will also be discussed. Case studies will be presented showing the identification of solid phases present in various dosage forms as well as the investigation of process induced changes that can occur upon manufacturing or storage.