

POLYMORPHISM AND DRUG DEVELOPMENT: A REGULATOR'S VIEWPOINT

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A general overview will be presented of the typical interactions between a drug company and the FDA during the development of a drug. The physical chemistry of the solid state bulk drug, especially its potential for crystallizing in multiple solid state forms, can significantly influence the development of both the synthetic process and the analytical chemistry of the drug. The drug is marketed and used as a finished drug product, which must be controlled to assure consistent quality. When the drug substance is known to be polymorphic, it can present special analytical concerns for the product. These topics will be discussed from two points of view: the type of information that should be acquired during drug development and how this information relates to issues of drug quality.