



# INSTRUCTION MANUAL FOR TURNITIN SIMILARITY

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**INTRODUCTION**

In recent years, the Food and Drug Administration (FDA) has emphasized “Quality by Design” (QbD) as a current Good Manufacturing Practices (cGMP) initiative for the twenty-first century. Despite numerous presentations and publications by FDA officials and leading pharmaceutical researchers (1, 2, 3, 4, 5, 6, 7, 8, 9, 10), several pilot programs (11,12), and the adoption of QbD by the International Conference on Harmonization, misunderstanding about QbD is still prevalent throughout pharmaceutical, biotechnology, and medical device industries. This article points out the basic components of QbD and application of QbD concepts to develop formulations and optimize manufacturing processes for topical dermatologic products.

The basic premise of QbD is that a product cannot be tested or inspected into a quality product and quality attributes should be designed *via* the thorough understanding of raw materials, formulation, and manufacturing process into a drug product. Additionally, under quality by testing (QbT), the sample size for each stage of testing is generally insufficient to ensure acceptable quality attributes for an entire batch. Hence, under QbD, testing confirms acceptable quality attributes, without extensive sampling. Specifications from raw materials, active ingredients, in-process testing, and drug product are only part of the quality control strategy. The quality needs to be designed into a drug product based upon a systematic understanding of how critical material attributes (CMAs) of drug substance and excipients, and critical process parameters (CPPs) used during manufacturing affect critical quality attributes of the drug product. This type of understanding can be achieved using various QbD

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