

QUESTION-BASED REVIEW. LINKING REGULATORY EVALUATION OF SOLID STATE PROPERTIES TO PHARMACEUTICAL QUALITY

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The Office of Generic Drugs (OGD) is launching a question-based review (QbR) for the Chemistry, Manufacturing, and Controls (CMC) evaluation of an Abbreviated New Drug Application (ANDA) that is focused on critical pharmaceutical quality attributes. This new paradigm will transform the CMC review into a modern, science and risk-based pharmaceutical quality assessment that will transform the way CMC information for generic drugs is submitted and reviewed in the U.S. The QbR incorporates the principles of quality by design and better focuses the CMC review on the design, development and manufacturing of pharmaceuticals, resulting in more science-based and effective regulatory decisions. This presentation will discuss 1) what QbR is, 2) why QbR is necessary, 3) how QbR was developed, and 4) what the benefits of QbR are. This presentation will also discuss significant roles of solid state properties in implementing quality by design principles.