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PERSPECTIVE

Attribute-Based Design Space: Materials-Science-Based Quality-By-Design for Operational Flexibility and Process Portability

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Abstract In April, 2009, the Pharmaceutical Research and Manufacturers of America (PhRMA) Drug Product Technical Group sponsored an industry workshop to explore the practicality and limitations of defining a design space strictly in terms of material attributes rather than process variables. This material-attribute design space would be independent of scale and configuration of process equipment and the associated process variables. For this reason, it would be portable in the sense that post-approval changes of equipment scale, nameplate, or location would not require regulatory approval. This paper summarizes and expands on the output of the workshop. A key concept that underlies this work is that the performance of a drug product is determined by its structure. The control objective of a manufacturing process is to assemble the components of the product into this structure. This is achieved by controlling the attributes of raw materials and process intermediates from each step in the production train within specified ranges, i.e., by operating within a material-attribute design space. In this paper, we explore the

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