

## **252a Pharmaceutical Coating Operations: Challenges and Opportunities in the Changing Regulatory Paradigm**

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Several recent reports indicate the need to enhance product and process understanding. Research in the recently identified FDA's critical path areas and PAT guidance provide enormous help to those who seek to apply innovative technologies in their laboratories and manufacturing practices. A good process understanding is likely to yield products with desired qualities and enhanced manufacturing efficiencies. An important aspect of process understanding to move towards "desired state" is the utilization of mathematical models by designed set of experiments to obtain empirical relationships between the product and process variables with desired responses. Once these relationships are developed, sound scientific principles can be applied to explain those relationships and set meaningful specifications. Such studies are expected to yield products of predictable responses, and provide a risk-based approach to understanding the critical variables within the "designed space." While some companies are actively utilizing these strategies, others need more examples and case studies. The present discussion will highlight the role of these strategies in drug product development.