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Standard Practice for Pharmaceutical Process Design Utilizing Process Analytical Technology[1]

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INTRODUCTION

Process design is the systematic conversion of information about needs for a product into knowledge about how to manufacture this product. Products and manufacturing processes should be designed using science- and risk-based design strategies to manage variation.

To attain this goal, integration of Process Analytical Technology (PAT) principles and tools during process design will enhance opportunities to build, maintain, and expand science- and risk-based process understanding throughout a product lifecycle. The product lifecycle includes the period in production as well as development.

Process understanding will be the foundation to establish manufacturing (process selection, methodology, implementation, and practice), process control (real-time control on the basis of measured critical quality attributes), effective risk mitigation, and product release concepts.

Process understanding will also enable regulatory strategies in that the level of regulatory scrutiny may reflect the demonstrated level of science- and risk-based process understanding.

1. Scope

1.1 This practice covers process design, which is integral to process development as well as post-development process optimization. It is focused on practical implementation and experimental development of process understanding.

1.2 The term *process design* as used in this practice can mean:

1.2.1 The activities to design a process (the process design), or

1.2.2 The outcome of this activity (the designed process), or both.

1.3 The principles in this practice are applicable to both drug substance and drug product processes. For drug products, formulation development and process development are interrelated and therefore the process design will incorporate knowledge from the formulation development.

1.4 The principles in this practice apply during development of a new process or the improvement or redesign of an existing one, or both.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E1325 Terminology Relating to Design of Experiments

E2475 Guide for Process Understanding Related to Pharmaceutical Manufacture and Control

E2476 Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes for Pharmaceutical Manufacture

E2629 Guide for Verification of Process Analytical Technology (PAT) Enabled Control Systems

[1] This practice is under the jurisdiction of ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products and is the direct responsibility of Subcommittee E55.01 on Process Understanding and PAT System Management, Implementation and Practice.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.