



Standard Guide for Verification of Process Analytical Technology (PAT) Enabled Control Systems¹

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1. Scope

1.1 This guide describes the verification of process analytical technology (PAT) enabled control systems using a science- and risk-based approach. It establishes principles for determining the scope and extent of verification activities necessary to ensure that the PAT-enabled control system is fit for purpose, properly implemented, and functions as expected.

1.2 In this guide, a PAT-enabled control system is considered to be the system that adjusts the manufacturing process using timely measurements (that is, during processing) of attributes of raw and in-process materials to determine responses that assure the process remains within specified boundaries and minimizes variability in the output material. The overall aim of the PAT-enabled control system is to ensure product quality. The PAT-enabled control system of a manufacturing process provides the capability to determine the current status of the process and drive the process to ensure the output material has the desired quality characteristics. The control system should be able to respond to process variations in a timely manner, providing corrections that ensure that the process follows the desired process trajectory to reach the desired outcome. PAT-enabled control systems may use process models based on first principles understanding or empirical models derived from experimental investigations or both. In addition to automated controls, a PAT-enabled control system may include components where there is manual intervention.

1.3 Principles described in this guide may be applied regardless of the complexity or scale of the PAT-enabled control system or whether applied to batch or continuous processing, or both.

1.4 The principles described in this guide are applicable to a PAT-enabled control system and also to its component subsystems. This guide does not cover the requirements for continuous quality verification of the overall process, which are covered in Guide [E2537](#).

¹ This guide is under the jurisdiction of ASTM Committee [E55](#) on Manufacture of Pharmaceutical Products and is the direct responsibility of Subcommittee [E55.01](#) on PAT System Management, Implementation and Practice.

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1.5 For information on science- and risk-based approaches in the pharmaceutical industry, reference should be made to ICH Q8(R2), ICH Q9, and ICH Q10. For guidance on PAT systems in the pharmaceutical industry, reference should be made to FDA Guidance for Industry—PAT and FDA Guidance for Industry—Process Validation.

1.6 *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.*

2. Referenced Documents

2.1 ASTM Standards:²

[E122](#) Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

[E2363](#) Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry

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

[E2500](#) Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment

[E2537](#) Guide for Application of Continuous Quality Verification to Pharmaceutical and Biopharmaceutical Manufacturing

2.2 Other Standards:

[ICH Q2\(R1\)](#) Validation of Analytical Procedures: Text and Methodology³

[ICH Q8\(R2\)](#) Pharmaceutical Development³

[ICH Q9](#) Risk Management³

[ICH Q10](#) Pharmaceutical Quality System³

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.

³ Available from International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), ICH Secretariat, c/o IFPMA, 15 ch. Louis-Dunant, P.O. Box 195, 1211 Geneva 20, Switzerland, <http://www.ich.org>.