



Standard Guide for Specification, Design, Verification, and Application of Single-Use Systems in Pharmaceutical and Biopharmaceutical Manufacturing¹

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1. Scope

1.1 This guide is intended as a complement to Guide [E2500](#).

1.2 This guide is applicable to the range of manufacturing systems described in Guide [E2500](#), specifically all elements of single-use systems, or hybrids of single-use and traditional components, used for the manufacturing of pharmaceutical and biopharmaceutical products, including: materials of construction, components, assembly, manifolds, supporting utilities, associated process monitoring and control systems, automation systems, and controlled environment that have the potential to affect product quality and patient safety.

1.3 This guide is applicable for the implementation of changes to manufacturing system design for existing systems. It may be used for continuous improvement and changes in operation from clinical through to commercial scale.

1.4 For brevity, single-use systems are referred to as SUS throughout the rest of this guide.

1.5 The approach may be applied by the end user, the supplier of SUS, and raw materials sub-suppliers further back in the supply chain.

1.6 This guide is not intended to apply to the use of single-use technology for packaging, primary containers, combination products (products composed of any combination of a drug, device, or biological product) or devices.

1.7 This guide does not address specific local requirements, which remain the responsibility of the end user.

1.8 *This guide does not address employee health and safety, environmental, nor other good engineering and manufacturing practices (GXP) requirements. 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 This guide is under the jurisdiction of ASTM Committee [E55](#) on Manufacture of Pharmaceutical and Biopharmaceutical Products and is the direct responsibility of Subcommittee [E55.03](#) on General Pharmaceutical Standards.

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2. Referenced Documents

2.1 *ASTM Standards*:²

[D4169 Practice for Performance Testing of Shipping Containers and Systems](#)

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

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

2.2 *United States Pharmacopeia*:³

[USP<788> Particulate Matter in Injections](#)

[USP<790> Visible Particulates in Injections](#)

2.3 *International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)*:⁴

[ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients](#)

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

[ICH Q9 Quality Risk Management](#)

[ICH Q10 Pharmaceutical Quality System](#)

2.4 *ISO Standards*:⁵

[ISO 13485:2003 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes](#)

[ISO 14644 Cleanrooms and Associated Controlled Environments](#)

[ISTA 3A General Simulation Performance tests](#)

2.5 *U.S. Food and Drug Administration (USFDA)*:⁶

[Guidance for Industry Process Validation: General Principles and Practices](#)

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 U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.

⁴ Available from International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), ICH Secretariat, 9, chemin des Mines, P.O. Box 195, 1211 Geneva 20, Switzerland, <http://www.ich.org>.

⁵ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁶ Available from U.S. Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993, <http://www.fda.gov>.