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Standard Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry[1]

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1. Scope

1.1 This terminology covers process analytical technology in the pharmaceutical industry. Terms are defined as they are used relative to the PAT framework in the pharmaceutical industry. Terms that are generally understood and in common usage or adequately defined in other readily available references are not included except where particular delineation to process analytical technology may be more clearly stated.

1.2 This terminology is therefore intended to be selective of terms used generally in process analytical technology as it is applied in the pharmaceutical industry and published in a number of documents, such as those listed in the succeeding sections. The listing is also intended to define terms that appear prominently within other related ASTM standards and do not appear elsewhere.

1.3 The definitions are substantially identical to those published by the U.S. Food and Drug Administration and other authoritative bodies, such as ISO, IEC, ITU, and national standards organizations.

1.4 This terminology supplements current documents on terminology that concentrate on process analytical technology as it is applied in the pharmaceutical industry.

1.5 An increasing number of product designations and designations for chemical, physical, mechanical, analytical, and statistical tests and standards are coming into common usage in the literature, regulatory environment, and commerce associated with process analytical technology in the pharmaceutical industry. Section 2 lists those documents referenced in this terminology.

2. Referenced Documents

2.1 *U.S. Government Publications:*

21 CFR 314.3(b) Applications for FDA Approval to Market a New Drug—General Provisions—Definitions[2]

U.S. FDA PAT Guidance Document, Guidance for Industry PAT—A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance[3]

FDA/ICH Q7A Guidance Document, GMP Guidance for APIs and Its Use During Inspections[3]

2.2 *Other Publication:*

ISO EN 14971 Medical Devices—Application of Risk Management for Medical Devices[4]

3. Terminology

3.1 *Definitions:*

acceptance criteria, *n*—numerical limits, ranges, process signatures, or other suitable measures that are necessary for making a decision to accept or reject the result of a process, in-process variable, a product or any other convenient subgroups of manufactured units.

analyzer, *n*—an instrument designed to measure a property of the process, material, or environmental condition.

at-line measurements, *n*—measurement where the sample is removed, isolated from, and analyzed in close proximity to the process stream.

batch number, *n*—a combination of numbers, letters, and/or symbols that uniquely identifies a batch and from which the production and distribution history can be determined.

computer system, *n*—a group of hardware components and associated software designed and assembled to perform a specific function or group of functions.

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contamination, *n*—the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, API (active pharmaceutical ingredient), or dosage form during production, sampling, packaging, or repackaging, storage, or transport.

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contract manufacturer, *n*—a manufacturer who performs some aspect of manufacturing on behalf of another entity.

cross-contamination, *n*—contamination of a material or product with another material or product.

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[1] This terminology is under the jurisdiction of ASTM Committee E55 on Pharmaceutical Application of Process Analytical Technology and is the direct responsibility of Subcommittee E55.91 on Terminology.

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[2] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

[3] Available from Food and Drug Administration, 5600 Fishers Ln., Rockville, MD 20857.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.