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Standard Terminology Relating to Manufacturing of Pharmaceutical and Biopharmaceutical Products in the Pharmaceutical and Biopharmaceutical Industry[1]

This standard is issued under the fixed designation E2363; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This standard covers terminology used by the E55 Committee relating to pharmaceutical and biopharmaceutical industry for manufacture of pharmaceutical and biopharmaceutical products. 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 pharmaceutical and biopharmaceutical manufacturing may be more clearly stated.

1.2 This terminology is, therefore, intended to be selective of terms used generally in the manufacture of pharmaceutical and biopharmaceutical products and published in a number of documents such as those listed in the succeeding section. The listing is also intended to define terms that appear prominently within other related ASTM International standards and do not appear elsewhere.

1.3 The definitions are substantially identical to those published by regulatory agencies such as the U.S. Food and Drug Administration, European Medicines Agency, Pharmaceutical and Medical Devices Agency (Japan), other and national competent authorities (human) as well as other authoritative bodies, such as ICH, ISO, and national standards organizations.

1.4 This terminology supplements current documents on terminology that concentrate on the manufacture of pharmaceutical and biopharmaceutical products.

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 the manufacture of pharmaceutical and biopharmaceutical products.

1.6 *Units*—The values stated in SI units are to be regarded as the standard. No other units of measurement are included in this standard.

1.7 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *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]

E456 Terminology Relating to Quality and Statistics

E869 Test Method for Performance Evaluation of Fuel Ethanol Manufacturing Facilities

E1117 Practice for Design of Fuel-Alcohol Manufacturing Facilities

E1126 Terminology Relating to Biomass Fuels (Withdrawn 2003)[3]

E1285 Guide for Identification of Bacteriophage Lambda (λ) or Its DNA (Withdrawn 2014)[3]

E1286 Guide for Identification of Herpes Simplex Virus or Its DNA (Withdrawn 2014)[3]

E1287 Practice for Aseptic Sampling of Biological Materials (Withdrawn 2008)[3]

E1298 Guide for Determination of Purity, Impurities, and Contaminants in Biological Drug Products (Withdrawn 2014)[3]

E1342 Practice for Preservation by Freezing, Freeze-Drying, and Low Temperature Maintenance of Bacteria, Fungi, Protista, Viruses, Genetic Elements, and Animal and Plant Tissues (Withdrawn 2011)[3]

[1] This terminology is under the jurisdiction of ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products and is the direct responsibility of Subcommittee E55.91 on Terminology.

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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.

[3] The last approved version of this historical standard is referenced on www.astm.org.

E1344 Guide for Evaluation of Fuel Ethanol Manufacturing Facilities
E1493 Guide for Identification of Bacteriophage M13 or Its DNA (Withdrawn 2014)[3]
E1531 Practice for Detection of Mycoplasma Contamination of Cell Cultures by Growth on Agarose Medium (Withdrawn 2014)[3]
E1532 Practice for Detection of Mycoplasma Contamination of Cell Cultures by Use of Bisbenzamide DNA-Binding Fluorochrome (Withdrawn 2014)[3]
E1533 Practice for Indirect Detection of Mycoplasma in Cell Culture by 4'-6-Diamidino-2-2 Phenylindole (DAPI) Staining (Withdrawn 2014)[3]
E1536 Practice for Detection of Mycoplasma Contamination of Bovine Serum by Large Volume Method (Withdrawn 2014)[3]
E1564 Guide for Design and Maintenance of Low-Temperature Storage Facilities for Maintaining Cryopreserved Biological Materials
E1565 Guide for Inventory Control and Handling of Biological Material Maintained at Low Temperatures
E1566 Guide for Handling Hazardous Biological Materials in Liquid Nitrogen
E2500 Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment
E2629 Guide for Verification of Process Analytical Technology (PAT) Enabled Control Systems

2.2 *Federal Standards:*[4]
21 CFR 210.3(b) Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General—Definitions
21 CFR 314.3(b) Applications for FDA Approval to Market a New Drug—General Provisions—Definitions

2.3 *ICH Standards:*[5]
ICH Q2 (R1) Validation of Analytical Procedures
ICH Q6A Guidance for Industry—Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances
ICH Q6B Guidance for Industry—Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products
ICH Q7 Guidance for Industry—Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients
ICH Q8 (R2) Guidance for Industry—Pharmaceutical Development
ICH Q9 Guidance for Industry—Quality Risk Management
ICH Q10 Guidance for Industry—Pharmaceutical Quality System
ICH Q11 Guidance for Industry—Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)
ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

2.4 *ISO Standards:*[6]
ISO 9000:2005 Quality Management Systems—Fundamentals and Vocabulary
ISO EN 14971:2012 Medical Devices—Application of Risk Management for Medical Devices
ISO/IEC Guide 51:2014 Safety Aspects—Guidelines for Their Inclusion in Standards
ISO Guide 73:2009 Risk Management—Vocabulary

3. Terminology

3.1 *Definitions:*

acceptance criteria, *n*—numerical limits, ranges, or other suitable measures for acceptance of test results. **ICH Q7**

accuracy, *n*—the accuracy of an analytical procedure expresses the closeness of agreement between the value that is accepted either as a conventional true value or an accepted reference value and the value found. **ICH Q2 (R1)**

active pharmaceutical ingredient, API (or drug substance), *n*—this term identifies the product manufactured in small molecules / synthetics processes. For biologics and large molecules, the term drug substance is mostly used. *See also* **drug substance**.

DISCUSSION—Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body. **ICH Q7**

aerobe, *adj*—organism that can survive and grow in an oxygenated environment.

aerobic fermentation, *n*—fermentation processes that require the presence of oxygen.

anaerobe obligate, *n*—microorganism killed by normal atmospheric concentrations of oxygen.

anaerobic facultative, *n*—microorganism that makes ATP by aerobic respiration if oxygen is present but is capable of switching to fermentation if oxygen is absent.

analytical procedure, *n*—analytical procedure refers to the way of performing the analysis.

DISCUSSION—It should describe in detail the steps necessary to perform each analytical test. This may include, but is not limited to, the sample, the reference standard and the reagents preparations, use of the apparatus, generation of the calibration curve, use of the formulae for the calculation, and so forth. **ICH Q2 (R1)**

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

anhydrous, *adj*—material that does not contain water either absorbed on its surface or as water of crystallization; a water-free product.

[4] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

[5] 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.

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

API, *n*—acronym for Active Pharmaceutical Ingredient.

API starting material, *n*—a raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API Starting Material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced in-house. API Starting Materials are normally of defined chemical properties and structure. **ICH Q7**

aseptic sampling, *n*—sampling process in which no extraneous microorganisms or substances are introduced into the sample or its original bulk material as a result of the sampling system and activity. **E1287**

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

attribute, *n*—characteristic or inherent property or feature.

audit, *n*—systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. **ISO 9000:2005**

audit client, *n*—organization or person requesting an audit. **ISO 9000:2005**

audit conclusion, *n*—outcome of an audit provided by the audit team after consideration of the audit objectives and all audit findings. **ISO 9000:2005**

audit criteria, *n*—set of policies, procedures or requirements. **ISO 9000:2005**

audit evidence, *n*—records, statements of fact, or other information that are relevant to the audit criteria and verifiable. **ISO 9000:2005**

audit findings, *n*—results of the evaluation of the collected audit evidence against audit criteria. **ISO 9000:2005**

audit plan, *n*—description of the activities and arrangements for an audit. **ISO 9000:2005**

audit program, *n*—set of one or more audits planned for a specific time frame and directed towards a specific purpose. **ISO 9000:2005**

audit scope, *n*—extent and boundaries of an audit. **ISO 9000:2005**

auditee, *n*—organization being audited. **ISO 9000:2005**

auditor, *n*—person with the demonstrated personal attributes and competence to conduct an audit. **ISO 9000:2005**

azeotrope, *n*—constant boiling mixture; for ethanol water, the azeotrope of 95.6 % ethanol and 4.4 % water (both percentages by volume) boils at one atmosphere pressure. **E1344**

azeotropic distillation, *n*—use of an organic solvent to create a new constant boiling point mixture; a method used to produce anhydrous ethanol from the ethanol water azeotrope. **E1344**

backset, *n*—liquid portion of the thin stillage that is recycled as part of the process liquid in mash preparation. **E1344**

bacteriophage, *n*—virus that infects bacteria. **E1285**

basic hydrolysis, *n*—chemical addition of water to a compound. **E1344**

batch (or lot), *n*—a specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval **ICH Q7**

batch fermentation—batch of nutrient mixture and microorganisms mixed in a vessel and allowed to ferment. **E1344**

batch number (or Lot number), *n*—a unique combination of numbers, letters, or symbols, or a combination thereof, that identifies a batch (or lot) and from which the production and distribution history can be determined. **ICH Q7**

batch process, *n*—noncontinuous operation in which discrete quantities of material are transformed using individual or sequential steps.

bioburden, *n*—the level and type (for example, objectionable or not) of micro-organisms that can be present in raw materials, API starting materials, intermediates or APIs. Bioburden should not be considered contamination unless the levels have been exceeded or defined objectionable organisms have been detected. **ICH Q7**

bioconversion, *n*—general term describing the use of biological systems to transform one compound into another.

DISCUSSION—Examples are digestion of organic wastes or sewage by microorganisms to produce methane.

biomass, *n*—total weight of living matter in a given volume.

calibration, *n*—the demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements. **ICH Q7**

capability, *n*—ability of an organization, system, or process to realize a product that will fulfil the requirements for that product. **ISO 9000:2005**

capability of a process, *n*—ability of a process to realize a product that will fulfil the requirements of that product.

DISCUSSION—The concept of process capability can also be defined in statistical terms.

ISO 9000:2005, ICH Q10

change management, *n*—systematic approach to proposing, evaluating, approving, implementing, and reviewing changes. **ICH Q10**

characteristic, *n*—distinguishing feature. **ISO 9000:2005**

chemical transformation step, *n*—for chemical entities, a step involved in the synthesis of the chemical structure of the drug substance from precursor molecular fragments.

DISCUSSION—Typically, it involves C-X or C-C bond formation or breaking. **ICH Q11**

competence, *n*—demonstrated personal attributes and demonstrated ability to apply knowledge and skills. **ISO 9000:2005**

computer system, *n*—group of hardware components and associated software designed and assembled to perform a specific function or group of functions. **ICH Q7**

computerized system, *n*—a process or operation integrated with a computer system. **ICH Q7**

conformity, *n*—fulfillment of a requirement. **ISO 9000:2005**

consequence, *n*—outcome of an event affecting objectives. **ISO 73:2009**

containment, *n*—the action of confining a biological agent or other entity within a defined space.

contaminants, *n*—any adventitiously introduced materials (for example, chemical, biochemical, or microbial species) not intended to be part of the manufacturing process of the drug substance or drug product. **ICH Q6B**

contamination, *n*—undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, API, or dosage form during production, sampling, packaging, or repackaging, storage, or transport. **ICH Q7**

continual improvement, *n*—recurring activity to increase the ability to fulfill requirements. **ICH Q10, ISO 9000:2005**

continuous fermentation, *n*—nonstop flow of nutrients into a fermenting vessel with the simultaneous outflow of products, organisms, and by-products. **E1344**

continuous process—process in which material is added, processed, and removed in an uninterrupted manner.

continuous process verification, *n*—alternative approach to process validation in which manufacturing process performance is continuously monitored and evaluated. **ICH Q8 (R2)**

contract, *n*—binding agreement. **ISO 9000:2005**

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

control, *n*—measure that is modifying risk. **ISO 73:2009**

controlled area, *n*—an area constructed and operated in such a manner that some attempt is made to control the introduction of potential contamination (an air supply approximating to grade D may be appropriate), and the consequences of accidental release of living organisms. The level of control exercised should reflect the nature of the organism employed in the process. At a minimum, the area should be maintained at a pressure negative to the immediate external environment and allow for the efficient removal of small quantities of airborne contaminants. **ISO 14644**

control model, *n*—procedure or mathematical expression (algorithm) that uses the outputs of the process model combined with any other data inputs required to calculate values for the critical control parameters for the process; it uses input data from the process to generate an actionable command or commands that are issued to the control system. **E2629**

control number, *n*—see **lot number**.

control strategy, *n*—planned set of controls, derived from current product and process understanding, that assures process performance and product quality.

DISCUSSION—The controls can include parameters and attributes related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control. **ICH Q10**

control system, *n*—system that responds to inputs signals from the process, its associated equipment, other programmable systems, or an operator, or combinations thereof, and generates output signals causing the process and its associated equipment to operate in the desired manner. **E2629**

correction, *n*—action to eliminate a detected nonconformity. **ISO 9000:2005**

corrective action, *n*—action to eliminate the cause of a detected nonconformity or other undesirable situation. **ISO 9000:2005**

critical, *adj*—describes a process step, process condition, test requirement, or other relevant parameter or item that shall be controlled within predetermined criteria to ensure that the API or drug product meets its specification. **ICH Q7**

critical material attribute, *n*—a physical, chemical, biological or microbiological property or characteristic of a raw material that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

critical quality attribute, *n*—a critical quality attribute (CQA) is a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality. **ICH Q8 (R2)**

critical process parameter, *n*—a Critical Process Parameter (CPP) is a term used in pharmaceutical production for process variables which have an impact on a critical quality attribute (CQA) and, therefore, should be monitored or controlled to ensure the API or drug product obtains the desired quality. **ICH Q8 (R2)**

cross-contamination, *n*—contamination of a material or product with another material or product. **ICH Q7**

cryogenic temperatures, *n*—temperatures below or equal to -100 °C. **E1564, E1565, E1566**

cryoprotectant, *n*—chemical substance used to protect cells during freezing and rewarming. **E1342**

CGMP, *n*—acronym for current Good Manufacturing Practices.

CGMP regulations, *n*—current regulations published by the U.S. Food and Drug Administration (FDA) regarding manufacturing, processing, packaging, and storing of drug and biological products. **E1287**

customer, *n*—organization or person that receives a product. **ISO 9000:2005**

customer satisfaction, *n*—customer's perception of the degree to which the customer's requirements have been fulfilled. **ISO 9000:2005**

decision maker(s), *n*—person(s) with the competence and authority to make appropriate and timely quality risk management decisions.

defect, *n*—non-fulfillment of a requirement related to an intended or specified use. **ISO 9000:2005**

deleterious impurities, *n*—impurities that are a health or safety concern, particularly with respect to toxicity, carcinogenicity, or immunogenicity.

DISCUSSION—Deleterious impurities shall be controlled, and their levels determined using suitable analytical methods. **E1298**

dependability, *n*—collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance, and maintenance support performance. **ISO 9000:2005**

design and development, *n*—set of processes that transforms requirements into specified characteristics or the specification of a product, process or system. **ISO 9000:2005**

design of experiments, DoE, *n*—a structured, organized method for determining the relationship between factors affecting a process and the output of the process. **ICH Q8 (R2)**

design reviews, *n*—planned and systematic reviews of specifications, design, and design development and continuous improvement changes performed as appropriate throughout the life cycle of the manufacturing system.

DISCUSSION—Design reviews evaluate deliverables against standards and requirements, identify problems, and propose required corrective actions. **E2500**

design space, *n*—the multidimensional combination and interaction of input variables (for example, material attributes) and process parameters that have been demonstrated to provide assurance of quality. **ICH Q8 (R2)**

detectability, *n*—ability to discover or determine the existence, presence, or fact of a hazard. **ICH Q9**

detection limit, *n*—detection limit of an individual analytical procedure is the lowest amount of analyte in a sample that can be detected but not necessarily quantitated as an exact value. **ICH Q2 (R1)**

deviation, *n*—departure from an approved instruction or established standard. **ICH Q7**

deviation permit, *n*—permission to depart from the originally specified requirements of a product before realization. **ISO 9000:2005**

direct detection of mycoplasma, *n*—detection of mycoplasma by cultivation in culture media.

document, *n*—information and its supporting medium. **ISO 9000:2005**

drug product, *n*—the dosage form in the final immediate packaging intended for marketing. (Reference Q1A). **ICH Q7**

drug substance, *n*—term used to specify the API in biologics and large molecules manufacturing. The term API is mostly used in small molecules / synthetics manufacturing. *See also* **API**. **ICH Q7**

dry basis moisture control, *n*—of biomass, cells, or product fuels, the ratio of the weight of the water in a sample to the weight of the dry material.

DISCUSSION—It is expressed as a percent.

durability, *n*—quality of a component to perform as designed for its design life.

effectiveness, *n*—relationship between the result achieved and the resources used. **ISO 9000:2005**

enabler, *n*—tool or process that provides the means to achieve an objective. **ICH Q10**

envelope, *n*—layer of cell membrane-derived lipoprotein that surrounds the protein coat (capsid) of some viruses. **E1286**

enzyme, *n*—biological catalyst that is protein in nature. **E1344**

establishing the context, *v*—defining the external and internal parameters to be taken into account when managing risk and setting the scope and risk criteria for the risk management policy. **ISO 73:2009**

eutectic temperature, *n*—temperature below which all liquid portions of an aqueous suspension have entered the solid phase. **E1342**

event, *n*—occurrence or change of a particular set of circumstances. **ISO 73:2009**

expiry date (or expiration date), *n*—the date placed on the container/labels of an API designating the time during which the API is expected to remain within established shelf life specifications if stored under defined conditions, and after which it should not be used. **ICH Q7**

exposure, *n*—extent to which an organization or stakeholders or both are subject to an event. **ISO 73:2009**

external context,, *n*—external environment in which the organization seeks to achieve its objectives. **ISO 73:2009**

F pilus, *n*—protrusion on *E. coli* that is necessary for mating.

DISCUSSION—The F pilus also contains the receptor for phage M13.

Feedback, *n*—the modification or control of a process or system by its results or effects. **ICH Q10**

Feedforward, *n*—the modification or control of a process using its anticipated results or effects. **ICH Q10**

fermentation, *n*—biochemical reaction process in which microorganisms in a nutrient medium convert a feedstock to a product. **E1344**

flashpoint, *n*—temperature at which a combustible liquid ignites. **E1344**

freeze drying, *v*—also known as lyophilization; sublimation of water from a frozen aqueous suspension. **E1342**

freezing, *v*—lowering the temperature of an aqueous suspension to a point at or below the temperature of ice crystal formation. **E1342**

frequency, *n*—number of events or outcomes per defined unit of time. **ISO 73:2009**

genome (of a virus), *n*—genetic material consisting of nucleic acid (RNA or DNA). **E1286**

glucose, *n*—most prominent simple sugar (six-membered $C_6H_{12}O_6$) produced from starches and cellulose material by hydrolysis. **E1344**

good engineering practices, *n*—include design practices and criteria accepted in professional societies (ASTM, AIChE, ASME, ACS, and so forth), proved by experience, verified by actual data, and so forth, that will meet the process, safety, and environmental requirements of the system.

grade, *n*—category or rank given to different quality requirements for products, processes, or systems having the same functional use. **ISO 9000:2005**

harm, *n*—damage to health, including the damage that can occur from loss of product quality or availability or injury or damage to the health of people or damage to property or the environment. **ICH Q9, ISO 51:2014**

hazard, *n*—potential source of harm. **ICH Q9, ISO 14971:2019, ISO 73:2009, ISO 51:2014**

hazardous biological materials, *n*—biological materials, and products derived therefrom, that pose a potential threat to human health.

hazardous event, *n*—event that can cause harm. **ISO 51:2014**

hazardous situation, *n*—circumstance in which people, property, or the environment is/are exposed to one or more hazards. **ISO 14971:2019, ISO 51:2014**

Hfr, *n*—strain of E. coli in which the F+ factor is inserted into the chromosome. **E1493**

hydrolysis, *n*—act of cleaving or splitting of complex molecules by the chemical addition of a water molecule.

DISCUSSION—Acid hydrolysis is defined as the chemical addition of water to a compound. **E1344**

impurity, *n*—any component present in a raw material, intermediate, API, or dosage form that is not the desired entity. **ICH Q7**

impurity profile, *n*—description of the identified and unidentified impurities present in a raw material, intermediate, API, or dosage form.

in-line measurements, *n*—measurement in which the sample is not removed from the process stream and can be invasive or non-invasive.

in-process control (or process control), *n*—checks performed during production in order to monitor and, if appropriate, to adjust the process or to ensure that the intermediate or API conforms to its specifications, or both. **ICH Q7**

in-process material, *n*—any material(s) fabricated, compounded, blended, or synthesized using a chemical, physical, or biological process that is produced for and being used in the preparation of an intermediate, drug substance, or drug product.

in-process tests, *n*—measurements performed during manufacturing and pertaining to the process or in-process material within the process.

indirect detection of mycoplasma, *n*—detection of mycoplasma by DNA staining or any method other than cultivation.

induction, *n*—relief of repression of transcription of lysogenic phage genes encoding the functions for lytic growth so that the phage will grow lytically. **E1285**

information, *n*—meaningful data. **ISO 9000:2005**

infrastructure, *n*—system of facilities, equipment, and services needed for the operation of an organization. **ISO 9000:2005**

inherently safe design, *n*—measures taken to eliminate hazards or reduce risks or both by changing the design or operating characteristics of the product or system. **ISO 51:2014**

innocuous impurities, *n*—impurities that are not a health or safety concern in the product.

DISCUSSION—The route of administration of the drug may be a significant criterion in the determination of whether an impurity is innocuous. **E1298**

innovation, *n*—introduction of new technologies or methodologies. **ICH Q10**

inspection, *n*—conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing, or gauging. **ISO 9000:2005**

intended use, *n*—use in accordance with information provided with a product or system, or, in the absence of such information, by generally understood patterns of usage. **ISO 51:2014**

interested party, *n*—person or group having an interest in the performance or success of an organization. **ISO 9000:2005**

intermediate, *n*—a material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API. Intermediates may or may not be isolated. **ICH Q7**

intermediate precision, *n*—intermediate precision expresses within-laboratories variations: different days, different analysts, different equipment, and so forth. **ICH Q2 (R1)**

knowledge management, *n*—systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes, and components. **ICH Q10**

level of risk, *n*—magnitude of a risk or combination of risks expressed in terms of the combination of consequences and their likelihood. **ISO 73:2009**

life cycle, *n*—series of all phases in the life of a pharmaceutical product from the initial conception to final decommissioning and disposal **ISO 14971:2019**

likelihood, *n*—chance of something happening. **ISO 73:2009**

linearity, *n*—linearity of an analytical procedure is its ability (within a given range) to obtain test results that are directly proportional to the concentration (amount) of analyte in the sample. **ICH Q2 (R1)**

liquid nitrogen freezers, *n*—freezers that operate by a refrigeration system in which cooling is provided by a refrigerant such as liquid nitrogen. **E1565**

liquid nitrogen storage, *n*—storage directly in liquid nitrogen or in the vapor phase above liquid nitrogen. **E1566**

lot, *n*—batch, or a specific identified portion of a batch, having uniform character and quality within specified limits or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits. **21 CFR 210.3(b)**

lot number, control number, or batch number, *n*—any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined. **21 CFR 210.3(b)**

low-temperature preservation, *n*—stabilizing viable or biologically active material by freezing or freeze-drying. **E1342**

lysogen, *n*—bacterial strain that has a phage stably maintained.

DISCUSSION—In the case of lambda, the phage is integrated into the host genome. The integrated phage is called a prophage. **E1285**

management, *n*—coordinated activities to direct and control an organization. **ISO 9000:2005**

management system, *n*—system to establish policy and objectives and to achieve those objectives. **ISO 9000:2005**

manufacture, *n*—all operations of receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control, release, storage, and distribution of APIs and related controls. **ICH Q7**

manufacturer, *n*—natural or legal person with responsibility for the design or manufacture, or both, of a pharmaceutical product with the intention of making the pharmaceutical product available for use under his name whether or not such a pharmaceutical product is designed or manufactured, or both, by that person himself or on his behalf by another person(s). **ISO 14971:2019**

manufacturing process, *n*—set of activities or operations performed to deliver a desired output.

Manufacturing systems—elements of pharmaceutical and biopharmaceutical manufacturing capability, including facility equipment, process equipment, supporting utilities, associated process monitoring and control systems, and automation systems that have the potential to affect product quality and patient safety. **E2500**

Material, *n*—general term used to denote raw materials (starting materials, reagents, and solvents), process aids, intermediates, APIs, drug products and packaging and labeling materials. **ICH Q7**

material specification, *n*—set of criteria to which a material shall conform to be considered acceptable for its intended use.

measurement management system, *n*—set of interrelated and interacting elements necessary to achieve metrological confirmation and continual control of measurement processes. **ISO 9000:2005**

measurement process—set of operations to determine the value of a quantity. **ISO 9000:2005**

measurement system, *n*—system of sensors, instruments, analyzers, or combinations thereof that collects signals generated by passive or active interaction with process material or process equipment and converts those signals into data. **E2629**

measuring equipment, *n*—measuring instrument, software, measurement standard, reference material, auxiliary apparatus, or combination thereof necessary to realize a measurement process. **ISO 9000:2005**

metrological characteristic, *n*—distinguishing feature that can influence the results of measurement. **ISO 9000:2005**

metrological confirmation, *n*—set of operations required to ensure that measuring equipment conforms to the requirements for its intended use. **ISO 9000:2005**

metrological function, *n*—function with administrative and technical responsibility for defining and implementing the measurement management system. **ISO 9000:2005**

moisture content, *n*—amount of water contained in product expressed as either a percentage of the mass of the oven-dry biomass or of the wet biomass, moisture content, dry basis.