IPEC FEDERATION

The International Pharmaceutical Excipients Council

General GLOSSARY of Terms and Acronyms

Contents

Acknowledgements

This glossary was developed by representatives of many of the member companies of the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) and the International Pharmaceutical Excipients Council (IPEC) Europe, which are industry associations whose principal members consist of excipient manufacturers and their pharmaceutical users. The company representatives who worked on this guide are listed below:

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IPEC General Glossary of Terms

Term	Definition
21 CFR	Title 21 of the United States Code of Federal Regulations [6]
ACC Responsible Care	The American Chemistry Council has implemented Responsible Care, a voluntary program to achieve improvements in environmental, health and safety performance beyond levels required by the U.S. government. Site and Supply Chain Security Overview [6]
Accelerated testing	Studies designed to increase the rate of chemical degradation or physical change of a drug substance or drug product by using exaggerated storage conditions as part of the formal stability studies. [13]
Acceptable Daily Intake (ADI)	The amount of a substance that can be ingested daily for an entire lifetime without causing appreciable adverse effects. It is expressed in mg/kg body weight/day. [7]
Acceptance criteria	Numerical limits, ranges or other suitable measures of acceptance for test results. [1, 2, 3, 12]
Accountability	The obligation to account for one's conduct and actions, usually to an individual or group, but ultimately to the public. Both individuals and organizations may be accountable. There is some overlap between accountability and transparency (see below). [25]
Accuracy	The accuracy of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found. This is sometimes termed trueness. [4]
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances, intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient of the drug product. 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 or any function of the body of man or animals. (GMP) [1, 3, 4, 5, 6]
Additive	A substance added to the excipient to improve or maintain a characteristic such as a preservative, flow agent, antimicrobial, etc. [4]
ADME	Absorption, distribution, metabolism and excretion
Adulterated Material	Material that has been contaminated with either a foreign material or not manufactured using GMP. This does not pertain to a material that simply does not meet physical or chemical specifications. [1]
AEO	Authorised Economic Operator – status applied to organisations in Europe which permits them to regulatory relief from customs inspections and documentary requirements. Akin to C-TPAT in that it also requires supply chain security measures to be implemented.

Term	Definition
Aflatoxins	The aflatoxins are a group of structurally related toxic compounds produced by certain strains of the fungi Aspergillus flavus and A. parasiticus. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. Aflatoxicosis is poisoning that results from ingestion of aflatoxins in contaminated food or feed. [6]
Agent	A person appointed by a DMF holder to serve as the contact for the holder. [7]
Agreement	Arrangement undertaken by and contractually binding on parties [3, 17, 18]
AIB	The American Institute of Baking
Allergens	A substance that causes an abnormal response by the immune system to certain proteins found in the substance. [6]
Analytical Methods Validation	Documented evidence demonstrating assurance that an analytical method can consistently produce accurate results for the intended analytical performance characteristics.
Analytical Procedure	The analytical procedure refers to the way of performing the analysis. 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, etc. [14]
Animal Sourced	Contains and/or m**anufactured with** starting materials of animal origin. [6]
Annual Report	A report required to be filed with the US FDA within 60 days of the anniversary of the launch of the product into the US market and which provides a sumary of the activities undertaken relating to the product in question during the proceding year. (See also 21 CFR 314.70(d) and 21 CFR 314.81(b)(2).)
API Starting Material	Any material used in the production of the API to create the significant structural fragment or that is purified to produce the API.
Archival System	System used to preserve information considered necessary for future recall or as a legal obligation, using media suitable for storage and retrieval.
Assay (content or potency)	To provide an exact result which allows an accurate statement on the content or potency of the analyte in a sample. [14]
Audit Team Leader	A qualified individual who organizes, coordinates, and is qualified to conduct audits to requisite standard of operation, as applicable.
Auditable Standard	A system, voluntary or mandatory, that imposes a set of operating conditions or specifications, and that can be confirmed by audit.
Auditing	A documented independent, systematic and objective activity designed to assess, evaluate, examine a process, site or organization.
Auditing Program	The organization of audits to confirm that all or part of an organization remains in compliane with the requisite standard, whether voluntary or mandatory.
Authorized Copy	A copy of a procedure either printed or in-an appropriate secured e-format, that has been issued by an orgainzation to a second organization for their use.
Authorized Person	The person recognized by the national regulatory authority as having the responsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the laws and

Term	Definition
	regulations in force in that country. 20
Backup	A local or **remote** copy of computer files for the purpose of restoring the data in the event of a mishap.
Barrier Packaging Materials	Either primary or secondary packaging materials which also have the function of preventing the permeation of gases, moisture or volatile concomitant components into or from the excipient. NOTE: Shipping pallets are not considered secondary packaging
Batch (Lot)	A specific quantity of material produced in a process or series of processes so that it can be expected to be homogeneous. In the case of continuous processes, 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. [1, 3]
Batch Number (Lot Number)	A unique combination of numbers, letters and/or symbols that identifies a batch and from which the production and distribution history can be determined. [1, 2, 3]
Batch Process	A manufacturing process or processing step that produces the excipient from a discrete supply of raw material that is present before the completion of the reaction. [1, 3]
Batch Processing	refer to batch
Batch Record	Documentation that provides a history of the manufacture of a batch of excipient. [1]
Batch/Lot	A specific quantity of material produced in a process or series of processes so that it can be expected to be homogeneous. In the case of continuous processes, 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. [6]
Bill of Lading	A document used when shipping goods that describes the content of the shipment and accompanies it. [4]
Bioavailability	The rate and extent at which the active pharmaceutical ingredient or active moiety is absorbed from a pharmaceutical dosage form and becomes available at the site(s) of action. [25]
Bioburden	The level and type (e.g. objectionable or not) of micro-organisms that can be present in raw materials, ~~API~~ starting materials, excipients, intermediates or APIs. Bioburden should not be considered contamination unless the levels have been exceeded or defined objectionable organisms have been detected. [2]
Bioequivalence	Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives, and their bioavailabilities, in terms of peak (Cmax and Tmax) and total exposure (area under the curve (AUC)) after administration of the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same. [24, 25]
Biological Origin	Any substance produced from animal or vegetable materials including starting materials and processing materials where the latter can come into contact with

Term	Definition
	the excipient,
Biotechnology Derived Excipients	Applies to excipients derived from characterized cells through the use of a variety of expression systems including but not limited to bacteria, yeast, insect, plant, and mammalian cells. [7]
Bioterrorism Act	The United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002. [6]
Bovine Spongiform Encephalopathy (BSE)	A slowly progressive, degenerative, fatal disease affecting the central nervous system of adult cattle. The exact cause of BSE is not known but it is generally accepted by the scientific community that the likely cause is infectious forms of a type of protein, prions, normally found in animals cause BSE. In cattle with BSE, these abnormal prions initially occur in the small intestines and tonsils, and are found in central nervous tissues, such as the brain and spinal cord, and other tissues of infected animals experiencing later stages of the disease. There is a disease similar to BSE called Creutzfeldt-Jacob Disease (CJD) that is found in people. A variant form of CJD (vCJD) is believed to be caused by eating contaminated beef products from BSE-affected cattle. [6]
BP	British Pharmacopoeia
Bracketing	The design of a stability schedule such that only samples on the extremes of certain design factors, e.g., strength, package size, are tested at all time points as in a full design. The design assumes that the stability of any intermediate levels is represented by the stability of the extremes tested. Where a range of strengths is to be tested, bracketing is applicable if the strengths are identical or very closely related in composition (e.g., for a tablet range made with different compression weights of a similar basic granulation, or a capsule range made by filling different plug fill weights of the same basic composition into different size capsule shells). Bracketing can be applied to different container sizes or different fills in the same container closure system. [13]
BRC	British Retail Consortium
Broker / Broking	Brokers resell excipients without conducting physical handling of the product such as warehousing, transport, repackaging etc. [3]
Bulk excipient	Excipient in any transportation or storage equipment (tanks, silos, ISO-Containers, tank/silo trucks etc.) to be filled/repackaged into others (tanks, silos, drums, bags, containers etc.). [3]
Bulk Pharmaceutical Excipient (BPE)	see Bulk Excipient
Bulk product	Any product that has completed all processing stages up to, but not including, final packaging. [20]
Calibration	The demonstration that a particular instrument or **measuring** device produces results within specified limits by comparison with those produced by a reference or traceable standard, over an appropriate range of measurements. [1, 2, 3]

Term	Definition
CAS Number	Unique numerical identifiers assigned by Chemical Abstracts Service to every chemical substance described in the open scientific literature (currently including those described from at least 1957 through the present), including organic and inorganic compounds, minerals, isotopes, alloys and nonstructurable materials (UVCBs, of unknown, variable composition, or biological origin). [27]
Cefic	The European Chemical Industry Council
Certificate	A document that affirms the applicant has met the requirements to be in substantial compliance with the standard or specification.
Certificate of Analysis (COA)	A document listing the test methods, specification and results of testing a representative sample from the batch to be delivered. [1, 3, 4, 8]
Certificate of Conformity (COC)	A document that confirms that the product shipped to the customer, complies with a specific set of requirements or specifications. It does not contain actual test results. [3]
Certificate of Suitability to the European Pharmacopoeia (CEP)	Certificate granted by the European Directorate for the Quality of Medicines (EDQM) to manufacturers of active ingredients or excipients confirming that the applicable Ph Eur monographs and general chapters are adequate to control the chemical purity of the material. Also a CEP can also be granted to confirm a material conforms to the European Pharmacopoeia general chapter 5.2.8 'Minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products', even if the material itself does not have a Ph.Eur monograph.
Certification	The process that leads to confirming the applicant meets the requirements of a Standard.
Change Control	A process used for management review of proposed changes that may impact the quality or regulatory conformance of the excipient. [4]
Change Management	A systematic approach for proposing, evaluating, approving, implementing and reviewing changes. [11]
Chemical Abstracts Service Registry Number (CAS Number)	The CAS Registry is the largest substance identification system in existence. When a chemical substance, newly encountered in the literature, is processed by CAS, its molecular structure diagram, systematic chemical name, molecular formula, and other identifying information are added to the Registry and it is assigned a unique CAS Registry Number. [6]
Chemical Development Studies	Studies conducted to scale-up, optimise, and validate the manufacturing process for a new drug substance. [15[
Chemical Property	A quality parameter that is measured by chemical or physiochemical test methods. [5, 8]
Chemical Reference Substance	The term chemical reference substance, as used in this text, refers to an authenticated, uniform material that is intended for use in specified chemical and physical tests, in which its properties are compared with those of the product under examination, and which possesses a degree of purity adequate for its intended use. [21]
Clean Area	An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants within the area. [20]

Term	Definition
Cleaning Validation	Documented evidence to establish that cleaning procedures are removing residues to predetermined levels of acceptability, taking into consideration factors such as batch size, dosing, toxicology and equipment size. [23]
Combination Product	A drug product which contains more than one drug substance. [12]
Combined Sample	Sample resulting from combining all or parts of two or more samples of the material. [26]
Commingling	Unintended blending of traces of carryover material from one batch with another. [3]
Commissioning	Verification that the equipment is suitable for use in a controlled manner.
Commitment Batches	Production batches of a drug substance or drug product for which the stability studies are initiated or completed post approval through a commitment made in the registration application. [13]
Common Technical Document (CTD)	An internationally agreed format for the preparation of applications regarding new drugs intended to be submitted to regional regulatory authorities in participating countries. It was developed by the European Medicines Agency (EMA, Europe), the Food and Drug Administration (FDA, US) and the Ministry of Health, Labour and Welfare (Japan). [28]
Comparator Product	The comparator product is a pharmaceutical product with which the multisource product is intended to be interchangeable in clinical practice. The comparator product will normally be the innovator product for which efficacy, safety and quality have been established. The selection of the comparator product is usually made at the national level by the drug regulatory authority [24]
Competency	The demonstrated personal attributes and ability to apply knowledge and skills in the field of application.
Competitive Tender	A procedure for procuring pharmaceutical products which puts a number of suppliers into competition. Purchasing is done on the basis of quotations submitted by the suppliers in response to a public notice. [25]
Complaint	A request to investigate nonconformance with an aspect of the Excipient GMP Certification program. (SOP 16)
Component	Any material present in the excipient that arises as a consequence of the raw materials and/or manufacturing process. [4]
Composition Profile	A description of all of the components present in the excipient. [4]
Computer System	A group of hardware components and associated software, designed and assembled to perform a specific function or group of functions. [2]
Computer Validation	Documented evidence which provides a high degree of assurance that a computerized system analyses, controls and records data correctly and that data processing complies with predetermined specifications. [23]
Computerized System	A process or operation integrated with a computer system. [2]
Concomitant Component	A substance found in an excipient that is not the intended chemical entity, may be necessary for assuring the proper performance of the excipient in its intended use, and is not an impurity or a foreign substance. (Formerly referred to as minor component.)
Concurrent Validation	Validation carried out during routine production of products intended for sale. [23]

Term	Definition
Confidence Interval	A range, calculated from sample data, within which a population parameter, such as the population mean, is expected to lie, with a given level of confidence. [5]
Consignment (or delivery)	The quantity of a pharmaceutical starting material made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch. [3, 18, 20]
Container	The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product. [17]
Container Closure System	The sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug product. A packaging system is equivalent to a container closure system. Also includes use of tamper evident seals. [13]
Contaminant	An undesired material of a chemical or microbiological nature or foreign matter introduced from a raw material, intermediate, or excipient during production, sampling, packaging, storage or transport. [4]
Contamination	The undesired introduction of impurities of a chemical or microbiological nature or foreign matter into or onto a raw material, intermediate or excipient during production, sampling, packaging or repackaging, storage or transport. [1, 2, 3, 19, 20]
Continual Improvement	Recurring activity to increase the ability to fulfil requirements.
Continuous Process or Processing	A process that continually produces material from a continuing supply of raw material. [1, 3, 5, 8]
Continuous Process Verification	An alternative approach to process validation in which manufacturing process performance is continuously monitored and evaluated. [9]
Continuous Verification	Assuring that during routine production the process remains in a state of control. [29]
Contract	Business agreement for supply of goods or performance of work at a specified price. [3, 17, 18]
Contract Facility	An internal or external facility that provides services to the manufacturer and/or distributor of an excipient. These can include, but are not limited to: manufacturing facilities, laboratories, repackaging facilities (including labeling), warehouses, etc. [8]
Contract Manufacturer	A manufacturer performing some aspect of manufacturing on behalf of the original manufacturer. [2]
Control Strategy	A planned set of controls, derived from current product and process understanding, that assures process performance and product quality. 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) [11]

Term	Definition
Controlled Document	Uniquely identified documents and records, e.g. SOPs, Work Instructions, training records, audit reports, etc., required to demonstrate conformance of the Quality System to established requirements. The issue, revision and withdawal of each version of the document is recorded.
Co-processed Excipients	A co-processed excipient is a combination of two or more compendial or non compendial excipients designed to physically modify their properties in a manner not achievable by simple physical mixing, and without significant chemical change. However in some instances, formation of necessary components may occur, such as in situ salt formation.
Co-processing	The act of manufacturing a co-processed excipient. Several methods may be used, including standard unit operations such as granulation, spray drying, melt extrusion, milling, etc.
Corrective Action	Action to eliminate the cause of a detected non-conformity or other undesirable situation. NOTE: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.
Counterfeit	A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products and may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. [17]
Critical	A process step, process condition, test requirement or other relevant parameter or item that must be controlled within predetermined criteria to ensure that the excipient meets its specification. [1, 2, 3]
Critical Material Attributes	The term critical material attributes is synonymous with critical quality attributes for the components (API and excipients).
Critical Operation	An operation in the manufacturing process that may cause variation in the quality of the excipient or pharmaceutical product or that may affect their regulatory status.
Critical Process Parameter	A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality. [30]
Critical Quality Attributes	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 (this is the ICH definition)
Cross-Contamination	Contamination of a material or product with another material or product. [1, 2, 3]
Current Good Manufacturing Practice (cGMP)	Requirements for the quality system under which drug products and their ingredients are manufactured. Current Good Manufacturing Practices (cGMP) is the applicable term in the United States. For the purposes of this guide, the terms GMP and cGMP are equivalent. [7]
Customer	The organization receiving the excipient once it has left the control of the excipient manufacturer; includes brokers, agents and users. [1, 3]
Customer Risk	The probability that a lot is released by the manufacturer although the product is nonconforming. [4]

Term	Definition
Customs-Trade Partnership Against Terrorism (C-TPAT)	Joint government (US Customs)-business initiative to build cooperative relationships that strengthen overall supply chain and border security. [6]
Date of Manufacture	A date indicating the completion of the final manufacturing process (as defined by the supplier for the particular excipient and process). [4, 8]
Date Retested	The date when retesting is performed by an excipient supplier to extend the length of time that the material may be used. [8]
Decision Maker(s)	Person(s) with the competence and authority to make appropriate and timely quality risk management decision. [10]
Decision Tree	A visual presentation of the sequence of events that can occur, including decision points. [5]
Degradants	Materials resulting from the decomposition of the excipient. [7]
Degradation product	A molecule resulting from a chemical change in the drug molecule brought about over time and/or by the action of e.g., light, temperature, pH, water, or by reaction with an excipient and/or the immediate container/closure system. Also called decomposition product. [12]
Delayed Release	Release of a drug (or drugs) at a time other than immediately following oral administration. [12]
Design of Experiments	A series of planned experiments that uses statistical principles to select variable parameters with the objective of optimizing process performance. [4]
Design Qualification (DQ)	Documented evidence that the facilities and supporting systems, utilities, equipment and processes have been designed in accordance with the requirements of appropriate GMPs and indended use. [23]
Design Space	The multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality. [4, 11]
Detectability	The ability to discover or determine the existence, presence, or fact of a hazard. [10]
Detection Limit	The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value. [14]
Developmental Toxicity	Any adverse effect induced prior to attainment of adult life. It includes effects induced or manifested in the embryonic or fetal period and those induced or manifested postnatally. [7]
Deviation	Departure from an approved instruction or established standard. [1, 2, 3]
Distribution	The division and movement of pharmaceutical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments. [17]
Distributor	All parties in the distribution/supply chain starting from the point at which an excipient is transferred outside the control of the original manufacturer's material management system including parties involved in trade and distribution, (re)processors, (re)packagers, transport and warehousing companies, forwarding agents, brokers, traders, and suppliers other than the original manufacturer.

Term	Definition
	(From Into/Scope of GDP)
Distributor	Those parties involved in trade and distribution, (re)processors, (re) packagers, transport and warehousing companies, forwarding agents, brokers, traders, and suppliers other than the original manufacturer.
DMF Holder	The company or individual who has filed a Drug Master File with a Drug Regulatory Authority (e.g. US FDA, EU EMA, etc.). NOTE: currently regulatory authorities throughout Europe do not have a system to accept EXCIPIENT master files.
Document Control	The set of procedures to ensure documents can be identified as to their status e.g. draft, revised, approved, obsolete, superseded, etc [4]
Document Management System	The system that controls the life cycle of documents; their creation, reviewed, publication, and use, as well as how they are disposed of or retained.
Documented Procedure	A written procedure meeting the requirements of 4.2.3 (document control section of quality standard such as ISO 9001 - section defines requirements for document control to assue that quality related documents affecting work activities show evidence of reivew and approval by authorized personnel prior to issuing new or revised documenation).
Dosage Form	A pharmaceutical product type (e.g., tablet, capsule, solution, cream) that contains a drug substance generally, but not necessarily, in association with excipients. [13]
Drug	Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the terms drug, medicine and pharmaceutical product (see below) are used interchangeably. [25]
Drug Master File (DMF)	Detailed information concerning a specific facility, process, or product submitted to a Drug Regulatory Authority (such as the United States Food and Drug Administration, Health Canada, and the Japanese Pharmaceutical and Medical Devices Agency) intended for incorporation by reference into a new drug application, supplemental new drug application, abbreviated new drug application, investigational new drug application, or biological license application. [7]
Drug Product	A finished dosage form, for example, tablet, capsule, or solution, that contains an active ingredient, generally with excipients, that has been prepared for consumer use and that has undergone all stages of production including packaging and labeling. [7]

Term	Definition
Drug Regulatory Authority	A national body that administers the full spectrum of drug regulatory activities, including at least all of the following functions in conformity with national drug legislation: * marketing authorization of new products and variations of existing products (including DMF); * quality control laboratory testing; * monitoring of adverse drug reactions; * provision of drug information and promotion of rational drug use; * good manufacturing practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels; * enforcement operations; monitoring of drug utilization. [25]
Drug Substance	see Active Pharmaceutical Ingredient.
Earliest Expiry/First Out Principle Concept (EEFO)	A distribution procedure to ensure that the stock with the earliest expiry date is distributed and/or utilized before an identical stock item with a later expiry date is distributed and/or utilized. [3, 18]
EDQM	European Directorate for the Quality of Medicines. [6]
Effectiveness	An expression of the degree to which activities have produced the effects planned. [25]
Efficiency	The relationship between the results of activities and the corresponding effort expended in terms of money, resources and time. [25]
Electronic Document	A document that is stored on a computer in an electronic file such as: Portable Document Format (PDF), scanned image (TIF, JPEG, etc.) or Microsoft application such as Word, Excel, or Access.
Enabler	A tool or process which provides the means to achieve an objective. (ICH Q10) [11]
Endotoxin	Lipopolysaccharides (LPS), also known as lipoglycans and endotoxin, are large molecules consisting of a lipid and a polysaccharide found in the outer membrane of Gram-negative bacteria, and elicit strong immune responses in animals. Lipopolysaccharides may be released on destruction of the bacteria, and that the immunogenic response leads to an increase in body temperature.
Equipment	The implements used in the manufacture of an excipient. [5]
Equivalence test	A test that determines the equivalence between the multisource product and the comparator product using in vivo and/or in vitro approaches. [24]
Estimated Daily Dose	see Estimated Daily Intake [7]
Estimated Daily Intake (EDI)	The estimated maximum daily intake (I) of the dosage form (tablets per day) and the concentration (C) of the excipient in each dosage form (mg/tablet) divided by the body weight (BW) in kilograms [7] $EDI = \frac{I*C}{BW}$
Excipient	Substances other than the API which have been appropriately evaluated for safety and are intentionally included in a drug delivery system. [1, 3, 4, 6]

Term	Definition
Excipient Information Package (EIP)	An IPEC initiative to provide standards for the exchange of data between excipient suppliers and excipient users. The EIP is comprised of the Site Quality Overview, Product Regulatory Datasheet, and Site and Supply Chain Security Overview. IPEC's Standardized Excipient Information Protocol User Guide provides information on the preparation of the EIP documents. [4]
Excipient Realization	Development, manufacture, launch and sale of an excipient with the quality attributes appropriate to meet the needs of internal customers, pharmaceutical users, regulatory authorities, health care professionals, and patients.
Expected	Elements of the EIP documents that should be included and addressed in the EIP documents. [6]
Expiration Period	The duration, normally expressed in months or years from the date of manufacture, within which the excipient can continue to be used. [4]
Expiry (Expiration) Date	The date designating the time during which the excipient is expected to remain within specifications and after which it should not be used. [1, 3, 4, 6]
Extended Release	Products which are formulated to make the drug available over an extended period after administration. [12]
Extraneous Contaminant	An impurity arising from any source extraneous to the manufacturing process. [15]
FCC	Food Chemicals Codex [6, 7]
FECC	European Federation of Chemical Distributors
Feedback	The modification or control of a process or system by its results or effects. [11]
Feedback / Feedforward	Feedback/ feedforward can be applied technically in process control strategies and conceptually in quality management. (ICH Q10) [11]
Feedforward	The modification or control of a process using its anticipated results or effects. (Oxford Dictionary of English. Oxford University Press; 2003) [11]
Feedstock	is an alternative name for a raw material used in certain sectors of the chemical industry.
FEMA	Flavor and Extract Manufacturers Association of the United States [7]
Final sample	Sample ready for the application of the test procedure. [26]
Finished product	A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling. [20]
First in/First out Principle Concept (FIFO)	A distribution procedure to ensure that the oldest stock is distributed and/or used before a newer and identical stock item is distributed and/or used. [17]
Forced degradation/Stress testing	Forced degradation studies are used to determine the intrinsic chemical stability of the excipient by investigating and confirming chemical degradation pathways, and to confirm the stability-indicating potential of analytical procedures. ICH Q1A(R2); Stability Testing of New Drug Substances and Products uses the term „stress testing". Such studies are also known as „forced degradation" studies.
Foreign Substance	A component present in the bulk pharmaceutical excipient, but NOT introduced into the excipient as a consequence of its synthesis or purification and not necessary to achieve the required functionality. (formerly referred to as contaminant) [5]

Term	Definition
Formal Experimental Design	A structured, organized method for determining the relationship between factors affecting a process and the output of that process. Also known as "Design of Experiments". [9]
Formal Stability Studies	Long term and accelerated (and intermediate) studies undertaken on primary and/or commitment batches according to a prescribed stability protocol to establish or confirm the re-test period of a drug substance or the shelf life of a drug product. [13]
FPA	The Food Products Association is a trade association serving the food and beverage industry in the United States and worldwide. [6]
Functionality	A desirable property of an excipient that aids and/or improves the manufacture, quality, or performance of the drug product. [4]
GAMP	Good Automated Manufacturing Practices. Minimum requirements for the use of quality management system, methods, and facilities or controls to be used in the automated manufacture, processing, packing, or holding of a drug product and its ingredients.
Generally Recognized as Safe (GRAS)	GRAS is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. [6]
Genetically Modified Organism (GMO)	An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. [6]
Genotoxic Carcinogens	Carcinogens which produce cancer by affecting genes or chromosomes. [16]
Genotoxic Impurities	Impurities present in the finished dosage form that may cause changes to the genome.
Genotoxic Impurities	Impurities present in the finished dosage form that may cause changes to the genome.
Genotoxicity, Genetic toxicity	A broad term that refers to any deleterious change in the genetic material regardless of the mechanism by which the change is induced. [7]
GMA - SAFE	The GMA (Grocery Manufacturers Association) - SAFE assessment is a thorough description of a food production, handling or storage facility's policies and practices, documented by a skilled auditing practitioner and communicated through a web based data management & reporting system that allows individual users of the assessment to determine if the audited facility will meet their own standards.
good distribution practices (GDP)	Requirements for the quality system under which drug products and their ingredients are handled and distributed.
Good Distribution Practices (GDP)	The general principles of good practices in the pharmaceutical starting materials supply chain. [4], including requirements for purchase, receiving, storage and export. GDP regulates the movement of products from the premises of the manufacturer to the end user, or to an intermediate point by means of various transport methods

Term	Definition
Good Documentation Practices	Common documentation expectations for the proper completion of GMP documents. (SOP 20)
Good Engineering Practices (GEP)	Established engineering methods and standards that are applied throughout the project life-cycle to deliver appropriate, cost-effective solutions. [23]
Good Manufacturing Practices (GMP)	Minimum requirements for the quality management system methods, and facilities or controls to be used for the manufacture, processing, packing, or holding of a drug product and its ingredients.
Good Storage Practices (GSP)	Good storage practices are that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof. [17]
Good Trade and Distribution Practices (GTDP)	Good trade and distribution practices are that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the numerous activities which occur during the trade and the distribution process. [17]
Grade	A version of an excipient which is recognised to have the same chemical composition and is covered by the same general monograph, but which differ in one or more attributes that may qualify its performance and use.
HACCP	Hazard Analysis Critical Control Point [6]
Halal	The term indicates that an item is permitted and fit for consumption by Muslims. [6]
Harm	Damage to health, including the damage that can occur from loss of product quality or availability. [10]
Hazard	The potential source of harm (ISO/IEC Guide 51). [10]
Health Establishment	A health establishment is the whole or part of a public or private facility, building or place, whether operated for profit or not, that is operated or de- signed to provide health care services including the supply of pharmaceutical products to the end user. [17]
Herbal Products	Medicinal products containing, exclusively, plant material and/or vegetable drug preparations as active ingredients. In some traditions, materials of inorganic or animal origin can also be present. [15]
Highly Water Soluble Drugs	Drugs with a dose/solubility volume of less than or equal to 250 mL over a pH range of 1.2 to 6.8. (Example: Compound A has as its lowest solubility at 37± 0.5°C, 1.0 mg/mL at pH 6.8, and is available in 100 mg, 200 mg, and 400 mg strengths. This drug would be considered a low solubility drug as its dose/solubility volume is greater than 250 mL (400 mg/1.0 mg/mL = 400 mL). [12]
Historical Norms	The totality of the data set for the excipient and expected range values that have been obtained over time. This includes but is not limited to comparison of chemical & physical properties, microbiological properties, composition profile, stability and/or performance.
HM 232	US Department of Transportation (DOT) Regulation, 49 CFR Part 172, Hazardous Materials: Security Requirements for Offerors and Transporters of Hazardous Materials. [6]

Term	Definition
Homogeneity	A material is regarded as homogeneous when it is all of the same origin (e.g. from the same batch) and as nonhomogeneous when it is of differing origins. [26]
Homogeneous Material	Material of uniform consistency and composition throughout a batch. [1] [3, 18]
Hypersensitivity	A violent reaction by the immune system to a substance that is normally considered harmless. [6]
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
Identification Threshold	A limit above (>) which an impurity should be identified. [15]
Identified Impurity	An impurity for which a structural characterization has been achieved. [12, 15]
Identity	The uniqueness of an excipient demonstrated by its physio-chemical properties. [7]
Immediate Container	The receptacle used solely for the transportation of the inert ingredient commodity in bulk or in quantity to manufacturers, packers, processors or distributors. [7]
Immediate Release	Allows the drug to dissolve in the gastrointestinal contents, with no intention of delaying or prolonging the dissolution or absorption of the drug. [12]
Impermeable Containers	Containers that provide a permanent barrier to the passage of gases or solvents, e.g., sealed aluminum tubes for semi-solids, sealed glass ampoules for solutions. [13]
Importation	The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone). [17]
Impurity	An undesirable material found in an excipientas a consequence of the raw materials, excipient manufacturing process, or excipient degradation.
Impurity Profile	A description of the impurities present in the excipient.
In-vitro Equivalence Test	An in vitro equivalence test is a dissolution test that includes comparison of the dissolution profile between the multisource product and the comparator product in three media: pH 1.2, pH 4.5 and pH 6.8. [24]
In-vitro Quality Control Dissolution Test	A dissolution test procedure identified in the pharmacopoeia, generally a one time point dissolution test for immediate-release products and a three or more time points dissolution test for modified release products. [24]
Inactive Ingredient Database (IID)	An FDA database containing information on excipients present in FDA approved drug products. [4]
INCI Name	International Nomenclature of Cosmetic Ingredients as defined in the Cosmetic, Toiletry and Fragrance Association's (CTFA) publication, the Cosmetic Ingredient Dictionary and Handbook. [6]
Indicator	Criterion used to measure changes, directly or indirectly, and to assess the extent to which the targets or objectives of a programme or project are being attained. Indicators should meet the criteria of clarity, usefulness, measurability, reliability, validity (see below) and acceptance by key stakeholders. [25]
Innovation	The introduction of new technologies or methodologies. [11]

Term	Definition
Innovator Pharmaceutical Product	Generally the pharmaceutical product which was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality according to requirements at the time of the authorization. When a substance has been available for many years, it may not be possible to identify an innovator pharmaceutical product. [24]
In-process Control / Testing	Checks performed during production to monitor and, if appropriate, to adjust the process to ensure that the intermediate or excipient conforms to its specification. [1, 3]
In-process Tests	Tests performed during the manufacture of an excipient, drug substance or drug product, rather than the tests that are conducted for finished product release.
Installation Qualification (IQ)	Confirmation the item is installed to the supplier or user requirements or expectations.
Intended Range	The range set based on the desired target.
Interchangeability	Functional equivalent in all respects to the original source material. [4]
Intermediate	Material that must undergo further manufacturing steps before it becomes an excipient. [1, 3]
Intermediate Precision	Intermediate precision expresses within-laboratories variations: different days, different analysts, different equipment, etc. [14]
Intermediate Product	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product. [17, 20]
Intermediate Testing	Studies conducted at 30°C/65% RH and designed to moderately increase the rate of chemical degradation or physical changes for a drug substance or drug product intended to be stored long term at 25°C. [13]
International Chemical Reference Substance	International Chemical Reference Substances (ICRS) are primary chemical reference substances established on the advice of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. They are supplied primarily for use in physical and chemical tests and assays described in the specifications for quality control of drugs published in The International Pharmacopoeia or proposed in draft monographs. The ICRS may be used to calibrate secondary standards. [21]
International Nonproprietary Name	The shortened scientific name based on the active ingredient. WHO is responsible for assigning INNs to pharmaceutical substances. [25]
Intramuscular (i.m.)	A route of administration where the drug product is injected into a muscle. [7]
Intraperitoneal (i.p.)	A route of administration where the drug product is injected into the abdominal cavity. [7]
Intravenous (i.v.)	A route of administration where the drug product is injected into a vein. [7]
IPEA	International Pharmaceutical Excipients Auditing, Inc. [6]
IPEC	International Pharmaceutical Excipients Council
IPEC PQG	International Pharmaceutical Excipients Council and the Pharmaceutical Quality Group
ISO	International Organization for Standardization. [6]
ISO 14000	The International Organization for Standardization's family of standards on environmental management Site and Supply Chain Security Overview – Section 4

Term	Definition
	[6]
JP	Japanese Pharmacopoeia [6]
JPE	Japanese Pharmaceutical Excipients [6]
JSFA	Japanese Standards for Food Additives
Justified	Documented explanation in support of a conclusion or decision.
Knowledge Management	Systematic approach to acquiring, analysing, storing, and disseminating information related to products, manufacturing processes and components. (ICH Q10) [11]
Kosher	The term indicates that an item is fit for consumption according to Jewish law. [6]
Label	The display of written, printed or graphic matter on the Immediate container of the excipient (inactive ingredient) product. [7]
Labeling	The process of applying the correct label to the container following completion of line-clearance.
Labeling	All written, printed or graphic matter accompanying an excipient at any time while it is in-transit to the customer or being held for sale after shipment or delivery to the customer. [7]
Large-volume Parenterals	Sterile solutions intended for parenteral application with a volume of 100ml or more in one container of the finished dosage form. [20]
Letter of Access	A written statement by the CEP holder permitting a customer to refer to the CEP information in a Marketing Authorization application.
Letter of Authorization	A written statement by the holder or designated agent or representative permitting FDA to refer to information in the DMF in support of another company's submission. [7]
Lifecycle	All phases in the life of a product from the initial development through marketing until the product's discontinuation. [9]
Ligand	An agent with a strong affinity to a metal ion. [15]
Linearity	The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample. [14]
Long Term Testing	Stability studies under the recommended storage condition for the re-test period or shelf life proposed (or approved) for labeling. [13]
Lot	A batch or a specific identified portion of a batch. (see "batch")
Lot Number	See Batch Number
Low- to medium-shear Process	The limits within which a tool or process operates based upon minimum variability as governed by the prevailing circumctances. [31]
Lowest-Observed Effect Level (LOEL)	The lowest dose of substance in a study or group of studies that produces biologically significant increases in frequency or severity of any effects in the exposed humans or animals. [16]
Management Review	A documented review by the Top Management to assure the quality management system continues to be suitable, adequate, and effective, including stated policies and objectives related to the fulfillment of the organizations objectives.
Manufacture	Various operations, such as processing, packaging, labeling, and testing.

Term	Definition
Margin of Safety	An indicator of the magnitude of the difference between an exposed dose to a human population and the highest no observed adverse effect dose determined in test animals. [7]
Marketing Authorization (Product License, Registration Certificate)	A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life. [20]
Mass Balance	The sum of the quantifiable material present in the excipient. [5]
Master Batch Record	Documentation of the steps necessary to produce a finished excipient by batch processing. [4]
Master Formula	Documents specifying the materials to be used along with their quantities, the packaging materials, and a description of the procedures and precautions required to produce a specified quantity of a finished product.
Master Process Flow	Documentation that describes excipient manufacture from raw material to final purification using continuous processing. [4]
Master Process Log	Record of the operating conditions used for the manufacture of the excipient using continuous processing. [4]
Master Production Instruction (Master Production and Control Record)	Documentation that describes the manufacture of the excipient from raw materials to completion. [1]
Master Production Record	Record of the manufacture of the lot/batch of the excipient from raw material to completion using batch manufacturing methodology.
Master Record	A document or set of documents that serve as a basis for the batch documentation (blank batch record). [20]
Material	A general term used to denote raw materials (starting materials, reagents and solvents), process aids, intermediates, excipients, packaging and labeling materials. [1, 2, 3]
Matrixing	The design of a stability schedule such that a selected subset of the total number of possible samples for all factor combinations is tested at a specified time point. At a subsequent time point, another subset of samples for all factor combinations is tested. The design assumes that the stability of each subset of samples tested represents the stability of all samples at a given time point. The differences in the samples for the same drug product should be identified as, for example, covering different batches, different strengths, different sizes of the same container closure system, and, possibly in some cases, different container closure systems. [13]
Mineral Based	Contains starting materials of mineral origin. [6]
Mixed Excipient	A mixed excipient is defined as a simple physical mixture of two or more compendial or non-compendial excipients produced by means of a low- to medium-shear process where the individual components are mixed but remain as discrete chemical entities, i.e. the nature of the components is not chemically changed.

Term	Definition
Mixtures	Products resulting from the physical combination of multiple excipients, often through a mixing operation and the nature of the processing is such that the materials are not co-processed together. [7]
Model Product	A product that represents a group of similar products with respect to composition, functionality or specification. [1]
Modified Release	Dosage forms whose drug-release characteristics of time course and/or location are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms such as a solution or an immediate release dosage form. Modified release solid oral dosage forms include both delayed and extended release drug products. [12]
Mother Liquor	The residual liquid that remains after crystallization or isolation processes. [1]
MSDS	Material Safety Data Sheet [6]
NACD	National Association of Chemical Distributors (NEW)
Neat Excipient	The pure excipient, containing no other materials. [7]
Neurotoxicity	The ability of a substance to cause adverse effects on the nervous system. [16]
New Drug Product	A pharmaceutical product type, for example, tablet, capsule, solution, cream, etc., which has not previously been registered in a region or Member State, and which contains a drug ingredient generally, but not necessarily, in association with excipients. [12]
New Drug Substance	The designated therapeutic moiety, which has not previously been registered in a region or Member State (also referred to as a new molecular entity or new chemical entity). It may be a complex, simple ester, or salt of a previously approved drug substance. [12, 15]
New Excipient:	An excipient used for the first time in a drug product or a new route of administration. [7] Equivalent to 'Novel Excipient'.
New Molecular Entity	An active pharmaceutical substance not previously contained in any drug product registered with the national or regional authority concerned. A new salt, ester, or non-covalent-bond derivative of an approved drug substance is considered a new molecular entity for the purpose of stability testing under this guidance. [13]
Nominal Component	refers to the component by which a particular excipient is named.
Nonconformance	A non-fulfillment of a requirement defined within a quality management system.
Non-conforming Material	Material that does not meet the manufacturer's specifications or has not been manufactured according to applicable GMPs. [3]
Non-Official Method (Non-Official Source)	An analytical technique not found in compendia or other listings of official analytical methods. [7]
No-Observed-Adverse-Effect Level (NOAEL)	The highest dose of a substance that, in a given toxicity test, causes no biologically significant effects in the exposed test animals. [7]
No-Observed-Effect Level (NOEL)	The highest dose of substance at which there are no biologically significant increases in frequency or severity of any effects in the exposed humans or animals. [16]
Normal Variability	The variability expected to be obtained for the excipient during typical processing and evaluation when the process operates in a state of control with no special causes of variation.

Term	Definition
Nutritional Information	The declaration of specific nutritional components such as total calories, calories from fat , total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, iron. [6]
Official Distributor(s)	Distributor(s) with which the manufacturer has a business relationship; usually a formal distribution agreement.
Official Method (Official Source)	An analytical technique found in a compendia or other listing of official analytical methods. [7]
OHSAS 18001	International occupational health and safety management system specification.
Operating Characteristic (OC) Curve	A graphical technique for showing the performance of an accept/reject plan. [4]
Operational Qualification (OQ)	Documented verification that the system or subsystem performs as intended over all anticipated operating ranges. [23]
Optional	Suggested topics that should be considered for inclusion in an EIP document. [6]
Oral (p.o)	A route of administration where the drug product is taken by mouth (per os). [7]
Organic (organically grown)	Specific practices addressing livestock breeding, cultivation of crops, the level of processing and the production of food. [6]
Original Manufacturer	Person or company manufacturing a material to the stage at which it is designated as a pharmaceutical starting material. (GDP Guide/WHO Good Trade and Distribution Practices) [3, 4, 18]
Original sample	Sample collected directly from the material. [26]
Other Components	Materials present in an excipient that arise as a consequence of the raw materials and/or manufacturing process and are not concomitant component. [4]
Out of Trend (OOT)	A result that is not expected based on an examination of previous data when presented in chronological order, but remains within specification. A result showing a distinct offset from the rest of the data set.
Outsourced Activities	Activities conducted by a contract acceptor under a written agreement with a contract giver. (ICH Q10) [11]
OVI	Organic Volatile Impurities, USP/NF General Chapter <467> [6]
Packaging	The container and its components that hold the excipient for storage and transport to the customer. [8, 5]
Packaging Material	A material intended to protect an intermediate or excipient during storage and transport. [1, 2 3, 4]
Packaging Operations	Those manufacturing processes which place the finished excipient into the container and its components designed to hold the excipient for storage and transport to the customers. [7]
Pedigree	Documentation that provides traceability of the material throughout the supply chain.
Performance Indicators	Measurable values used to quantify quality objectives to reflect the performance of an organisation, process or system, also known as “performance metrics” in some regions. (ICH Q10) [11]
Performance Qualification (PQ)	Documented verification that the equipment or system consistently produces the intended output.

Term	Definition
Periodic Testing Program	See "Skip-Lot Testing". [8]
Permissible Daily Exposure (PDE)	The maximum daily acceptable intake of a substance. [7]
Permitted Daily Exposure	The maximum acceptable intake per day of residual solvent in pharmaceutical products. [16]
Ph. Eur.	European Pharmacopoeia [6]
Pharmaceutical Alternatives	Products are pharmaceutical alternative(s) if they contain the same molar amount of the same active pharmaceutical moiety(s) but differ in dosage form (e.g. tablets versus capsules), and/or chemical form (e.g. different salts, different esters). Pharmaceutical alternatives deliver the same active moiety by the same route of administration but are otherwise not pharmaceutically equivalent. They may or may not be bioequivalent or therapeutically equivalent to the comparator product. [24]
Pharmaceutical Equivalence	Products are pharmaceutical equivalents if they contain the same molar amount of the same active pharmaceutical ingredient(s) in the same dosage form, if they meet comparable standards, and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or the manufacturing process and some other variables can lead to differences in product performance. [24]
Pharmaceutical Excipient	Substances, other than the active ingredient, which have been appropriately evaluated for safety and are included in a drug delivery system to: - Aid in the processing of the drug delivery system during its manufacture; #NAME - Assist in product identification; or - Enhance any other attribute of the overall safety and effectiveness of the drug during storage or use [22]
Pharmaceutical Quality System (PQS)	Management system to direct and control a pharmaceutical company with regard to quality. [11]
Pharmaceutical Starting Material	A pharmaceutical starting material is an active pharmaceutical ingredient (API) or an excipient intended or designated for use in the production of a pharmaceutical product. [3, 18]
Pharmacopoeial Reference Standards	The specificity of pharmacopoeial reference substances has been addressed in the introduction of ISO Guide: General requirements for the competence of reference material producers. “Pharmacopoeial standards and substances are established and distributed by pharmacopoeial authorities following the general principles of this Guide. It should be noted, however, that a different approach is used by the pharmacopoeial authorities to give the user the information provided by certificate of analysis and expiration dates” [21]
Physical Form	The state, at ambient conditions, in which the excipient is found; solid, liquid or gas. [7]
Physical Property	A quality parameter that can be measured solely by physical means. [5, 8]
Physiological Effect	Any effect on the normal health of the human body. [5]

Term	Definition
Pilot Scale Batch	A batch of a drug substance or drug product manufactured by a procedure fully representative of and simulating that to be applied to a full production scale batch. For solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100,000 tablets or capsules, whichever is the larger. [13]
Pivotal Scale	A scale of cGMP pharmaceutical product manufacture less than full commercial scale but greater than $1/10^{th}$ commercial scale. Studies using such manufacture (e.g. product stability) may be used to support the marketing application. [4]
Polymorphic Forms	Different crystalline forms of the same drug substance. These can include solvation or hydration products (also known as pseudo-polymorphs) and amorphous forms. [15]
Polymorphism	The occurrence of different crystalline forms of the same drug substance. This may include solvation or hydration products (also known as pseudopolymorphs) and amorphous forms. [12]
Precision	The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision may be considered at three levels: repeatability, intermediate precision and reproducibility.
Pre-formulation	Those studies preceding formal formulation design that are used to investigate the physical, chemical and biopharmaceutical properties of the API. [4]
Prequalification	The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of good manufacturing practice (GP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the decision. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture/registration, but the amount and type of information requested from the supplier for assessment by the procurement agency may differ. [25, 26]
Preventive Action	Action to eliminate the cause of a potential non-conformity or other undesirable potential situation. NOTE: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. (ISO 9000:2005) [11]
Primary Batch	A batch of a drug substance or drug product used in a formal stability study, from which stability data are submitted in a registration application for the purpose of establishing a re-test period or shelf life, respectively. A primary batch of a drug substance should be at least a pilot scale batch. For a drug product, two of the three batches should be at least pilot scale batch, and the third batch can be smaller if it is representative with regard to the critical manufacturing steps. However, a primary batch may be a production batch. [13]

Term	Definition
Primary Chemical Reference Substance	A designated primary chemical reference substance is one that is widely acknowledged to have the appropriate qualities within a specified context, and whose assigned content when used as an assay standard is accepted without requiring comparison with another chemical substance. [21]
Primary Packaging Materials	Packaging materials which have direct contact with the excipient. NOTE 1 Examples of primary packaging materials are glass, plastics, aluminium films, foils. They may be combinations of different materials/components. NOTE 2 Primary packaging materials may be directly printed or decorated.
Primary Reference Standard	A substance that has been shown by an extensive set of analytical tests to be authentic material that is of high purity and to which all like standards are traced and qualified or certified. This standard is preferably obtained from an officially recognized source. If no official recognized source is available, the reference standard selected shall be appropriately characterized. A substance that has been shown by an extensive set of analytical tests to be of defined quality; generally of high purity and to which all like standards are traced and qualified or certified. This standard is preferably obtained from an officially recognized source. If no official recognized source is available, the reference standard selected shall be appropriately characterized.
Procedure	Written, authorized instruction for performing specified operations. [3]
Process	The combination of operating steps including synthesis, isolation, purification, packaging, etc. that produce the finished excipient. [4, 5, 8]
Process Aids	Materials, excluding solvents, used as an aid in the manufacture of an intermediate or API that do not themselves participate in a chemical or biological reaction (e.g. filter aid, activated carbon, etc). [2]
Process Analytical Technology (PAT)	A system for designing, analyzing, and controlling manufacturing through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality. [6, 9]
Process Capability	A statistic which describes the performance of the process with respect to the specification limits.
Process Capability Index (Cp)	A statistical measurement that can be used to assess whether or not the process is adequate to meet specifications. A “State of Statistical Control” can be said to exist if the random variation in test results for a process parameter is such that the calculated process capability is greater than 1.33 [8]
Process Control	See In-Process Control. [2]
Process Parameter	A measurable operating condition. [4, 5]
Process Robustness	Ability of a process to tolerate variability of materials and changes of the process and equipment without negative impact on quality. [9]
Process Step	A documented instruction to the **pharmaceutical** excipient manufacturing personnel directing that an operation be done. [4]
Process Validation	A documented program that provides a high degree of assurance that a specific process will consistently produce a result meeting predetermined acceptance criteria.

Term	Definition
Processing	Operations to change product characteristics by mainly physical treatment through e.g. milling, sieving, distilling, filtration, blending. [3]
Processing Aid	A material added to a manufacturing step for the purpose of facilitating the completion of that step or subsequent step. [4]
Procurement	The process of purchasing or otherwise acquiring any pharmaceutical product, vaccine, or dietary supplements or component of such productsfor human use.
Procurement Agency	Any organization purchasing or otherwise acquiring any pharmaceutical product, vaccine, dietary supplements or component of such products for human use.
Producer Risk	The probability that a lot is rejected by the manufacturer although the product is conforming. [4]
Product Information	In the context of this document, product information means information on pharmaceutical products submitted by manufacturers or suppliers in any of the formats specified in the procurement agency's guidelines (including product dossiers, product questionnaires or other formats) to obtain prequalification for the products. [25]
Product Lifecycle	All phases in the life of the product from the initial development through marketing until the product's discontinuation. [10]
Product of Biotechnology	A product derived from any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
Product of Fermentation	A substance produced and secreted by living organisms, and harvested for use or subsequent processing.
Product Realization	Achievement of an excipient with the quality attributes appropriate to meet the needs of patients, health care professionals, regulatory authorities (including compliance with marketing authorisation) , and internal customers' requirements. [IPEC]
Product Recall	Product recall is a process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product. The recall might be initiated by the manufacturer, importer, distributor or a responsible agency. [17]
Production	Operations involved in the preparation of an excipient from receipt of materials operations through processing and packaging of the finished excipient. [1, 2, 3, 18, 19, 20, 26]
Production Batch	A batch of a drug substance or drug product manufactured at production scale by using production equipment in a production facility as specified in the application. [3]
Production Specification	A list of tests, references to analytical procedures, and appropriate criteria for a material as manufactured. [4]
Proposition 65	The California Safe Drinking Water and Toxic Enforcement Act of 1986, better known by its original name of Proposition 65, is "right to know" legislation regarding substances known to the State of California to cause cancer or birth defects or other reproductive harm. [6]
Prospective Validation	Validation that should be successfully completed before the product is offered for sale.

Term	Definition
Protocol	A detailed plan describing the conduct of a study.
Purity	The extent to which the excipient is free of foreign materials such as impurities and contaminants. [7]
Purity Tests	Test to ensure that all the analytical procedures performed allow an accurate statement of the content of impurities of an analyte, i.e. related substances test, heavy metals, residual solvents content, etc. [12]
Pyrogen-Free	A specification parameter that stipulates that the substance or product will not induce elevation in body temperature if administered to, or included in a product to be administered to, a patient.
Qualification	Action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation. [2]
Qualification Threshold	A limit above (>) which an impurity should be qualified. [15]
Quality	The suitability of an excipient for its intended use as indicated by relevant physical, chemical, and microbiological properties and as assured by compliance with this standard.
Quality Agreement	A formal agreement between the excipient manufacturer and their pharmaceutical customer that stipulates the responsibilities of each party in meeting the regulatory requirements for sale and use of the excipient in a dosage form. [4]
Quality Assurance (QA)	The sum total of the organized arrangements made with the object of ensuring all excipients are of the quality required for their intended use and that quality systems are maintained. [1, 2, 3]
Quality Assurance/Quality Control	The disciplines having the responsibility and authority to assure the excipient conforms to its' specifications and is produced under appropriate GMPs. [7]
Quality by Design (QbD)	A philosophy built on the premise that "Quality cannot be tested into a product or operation, it must be built in during the whole development and manufacturing cycle."
Quality Control (QC)	Checking or testing that specifications are met. [1, 2, 3]
Quality Critical	Describes a material, process step or process condition, test requirement or any other relevant parameter that directly influences the quality attributes of the excipient and which must be controlled within predetermined criteria. [1, 3]
Quality Document	Any document, such as a procedure, record, policy, or form that is used in support of the IPEA Quality Management System. (SOP 0)
Quality Management System (QMS)	A management system that directs and controls how the organization implements quality policies and achieves quality objectives.
Quality Manual	Document specifying the quality management system of an organisation. (ISO 9000:2005) [11]
Quality Objectives	A means to translate the quality policy and strategies into measurable activities. (ICH Q10) [11]

Term	Definition
Quality Planning	Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives. (ISO 9000:2005) [11]
Quality Policy	Overall intentions and direction of an organisation related to quality as formally expressed by senior management.(ISO 9000:2005) [11]
Quality Record	A document that demonstrates conformance to a procedure or work instruction that is part of the quality system. (Quality Manual)
Quality Risk Management	A systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle. [10]
Quality System	See “quality management system”
Quality Target Product Profile (QTPP)	A prospective summary of the quality characteristics of a drug product that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the drug product (ICH definition)
Quality Unit(s)	An organizational unit independent of production which fulfills both Quality Assurance (QA) and Quality Control (QC) responsibilities. This can be in the form of separate QA and QC units or a single individual or group, depending upon the size and structure of the organization. [2]
Quality-critical	Describes a material, process step or process condition, test requirement or any other relevant parameter that directly influences the quality attributes of the excipient and which must be controlled within predetermined criteria.
Quantitation Limit	The quantitation limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy. The quantitation limit is a parameter of quantitative assays for low levels of compounds in sample matrices, and is used particularly for the determination of impurities and/or degradation products. [14]
Quarantine	The status of materials isolated physically or by other effective means pending a decision on their subsequent approval or rejection. [1, 2, 3, 18]
Random Sample	Sample in which the different fractions of the material have an equal probability of being represented. [26]
Random Variation	Variation in the measured property whose distribution of results shows no predictable pattern. [4]
Range	The range of an analytical procedure is the interval between the upper and lower concentration (amounts) of analyte in the sample (including these concentrations) for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy and linearity. [14]
Rapidly Dissolving Products	An immediate release solid oral drug product is considered rapidly dissolving when not less than 80% of the label amount of the drug substance dissolves within 15 minutes in each of the following media: (1) pH 1.2, (2) pH 4.0, and (3) pH 6.8. [9]
Raw Material	A general term used to denote starting materials, reagents and solvents intended for use in the production of intermediates or excipients. [1, 2, 3] Raw material and starting material are not equivalent as starting material has a different meaning in a regulatory context.

Term	Definition
Reagent	A material that is used to chemically modify a starting material or intermediate during the manufacture of an excipient.
Recall (USA: see Retrieval)	A process for withdrawing or removing a pharmaceutical material from the distribution chain because of defects in the materials or complaints of a serious nature. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency. [3, 18]
Recommended Re-Evaluation Date	That date beyond which the bulk pharmaceutical excipient should not be used without further appropriate reexamination. [6]
Recommended Re-evaluation Interval	The period beyond which the bulk pharmaceutical excipient should not be used without further appropriate re-examination.
Reconciliation	A comparison between the theoretical quantity and the actual quantity. [20]
Record	Document stating results achieved and/or providing evidence of activities performed. The medium may be paper, magnetic, electronic or optical, photographic etc. or a combination thereof. [1, 3]
Recovery	The introduction of all or part of previous batches (or of redistilled solvents and similar products) of the required quality into another batch at a defined stage of manufacture. It includes the removal of impurities from waste to obtain a pure substance or the recovery of used materials for a separate use. [20]
Reduced Frequency Testing Program	See "Skip-Lot Testing". [8]
Re-evaluation Date/(Retest Date)	The date beyond which the bulk pharmaceutical excipient should not be used without further appropriate re-examination to ensure that it is still in conformance with the specification. [1, 3, 7]
Re-evaluation Interval	The duration, normally expressed in months or years from the date of manufacture, throughout which the excipient should continue to conform to the specification and after which should be tested to confirm it continues to meet specification. [4]
Reference Standard, Primary	A substance that has been shown by an extensive set of analytical tests to be authentic material that should be of high purity. This standard can be: (1) obtained from an officially recognised source, or (2) prepared by independent synthesis, or (3) obtained from existing production material of high purity, or (4) prepared by further purification of existing production material. [2]
Reference Standard, Secondary	A substance of established quality and purity, as shown by comparison to a primary reference standard, used as a reference standard for routine laboratory analysis. [2]
Relabeling	The process of putting a new label on the material (see also labeling). [3, 18]
Reliability	An expression of the degree to which a measurement performed by different people at different times and under different circumstances produces the same results (see also validity). [25]
Reliable Quantification of Drug Needs	A careful evaluation of the quantities needed of each drug, based on either adjusted past consumption or anticipated pattern of diseases and standard treatment, which can be expected to match actual needs reasonably well. [25]
Repackaging	The action of changing the packaging of the material. [3, 8, 18]

Term	Definition
Repeatability	Repeatability expresses the precision under the same operating conditions over a short interval of time. Repeatability is also termed intra-assay precision . [14]
Replacement in Kind	Manufacturing equipment that uses the same operating principle and is of similar construction or packaging components made with the same materials of construction and sealed in a similar manner. [5]
Reporting Threshold	A limit above (>) which an impurity should be reported.
Representative Sample	A quantity of the excipient taken according to a prescribed rationale so as to accurately portray the material being sampled (e.g., a batch).
Reprocessing	Repetition of an activity that is a normal part of the manufacturing process and that has been documented previously. [1]
Reproducibility	Reproducibility expresses the precision between laboratories (collaborative studies, usually applied to standardization of methodology). [14]
Requirements	The explicit or implicit needs or expectations of the governing standards.
Residual Solvents	Residual solvents are defined as organic chemicals that are used or produced in the manufacture of active substances or excipients, or in the preparation of medicinal products. ICH Q3C Impurities: Residual Solvents [6]
Resources	Material, process, equipment or personnel required to perform an activity or service
Responsible Care	A voluntary program to achieve improvements in environmental, health and safety performance. Adopted by most Chemical Industry associations worldwide.
Retained Sample	Representative sample of a batch/delivery that is sufficient quantity to perform at least **2** full quality control analyses and will be kept for a defined period of time.
Retest Date	The date when a **specific batch of** material **must** be re-examined to ensure that it is still suitable for use.
Retest Interval	(Re-evaluation Interval) [4]
Re-test Period	The period of time during which the drug substance is expected to remain within its specification and, therefore, can be used in the manufacture of a given drug product, provided that the drug substance has been stored under the defined conditions. After this period, a batch of drug substance destined for use in the manufacture of a drug product should be re-tested for compliance with the specification and then used immediately. A batch of drug substance can be re-tested multiple times and a different portion of the batch used after each re-test, as long as it continues to comply with the specification. For most biotechnological/biological substances known to be labile, it is more appropriate to establish a shelf life than a re-test period. The same may be true for certain antibiotics. [13]
Retest/Re-evaluation Interval	The duration, normally expressed in months or years, from the date of manufacture, throughout which the excipient is expected to continue to conform to the specification and after which must be tested to confirm it continues to meet the specifications.
Retrieval	Process for the removal of an excipient from the distribution chain. [1, 3]
Retrospective Validation	Validation based upon historical records that demonstrates the process can achieve the desired output.

Term	Definition
Revalidation	Repeated validation of an approved process (or a part thereof) to ensure continued compliance with established requirements. [23]
Reversible Toxicity	The occurrence of harmful effects that are caused by a substance and which disappear after exposure to the substance ends. [16]
Reworking	Subjecting previously processed material that did not conform to standards or specifications to processing steps that differ from the normal process. [1, 2]
Risk	The combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51). [10]
Risk Acceptance	The decision to accept risk (ISO Guide 73). [10]
Risk Analysis	The estimation of the risk associated with the identified hazards. [10]
Risk Assessment	A systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards. [10]
Risk Communication	The sharing of information about risk and risk management between the decision maker and other stakeholders. [10]
Risk Control	Actions implementing risk management decisions (ISO Guide 73). [10]
Risk Evaluation	The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk. [10]
Risk Identification	The systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description. [10]
Risk Management	The systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating and reviewing risk. [10]
Risk Reduction	Actions taken to lessen the probability of occurrence of harm and the severity of that harm. [10]
Risk Review	Review or monitoring of output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk. [10]
Robustness	The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage. [14]
Route of Exposure/Administration	The method by which the drug product containing the excipient is administered to the patient. [7]
Sales Specification	A list of tests, references to analytical procedures, and appropriate criteria for a material as offered for sale. [4]
Sample	A portion of a material collected according to a defined sampling procedure. The size of any sample should be sufficient to allow all anticipated test procedures to be carried out, including all repetitions and retention samples. If the quantity of material available is not sufficient for the intended analyses and for the retention samples, the inspector should record that the sampled material is the available sample (see Sampling record) and the evaluation of the results should take account of the limitations that arise from the insufficient sample size. [26]
Sampler	Person responsible for performing the sampling operations. [26]

Term	Definition
Sampling	Operations designed to obtain a representative portion of a pharmaceutical starting material based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments, batch release, etc. [3, 17, 18]
Sampling Method	That part of the sampling procedure dealing with the method prescribed for withdrawing samples. [26]
Sampling Plan	Description of the location, number of units and/or quantity of material that should be collected, and associated acceptance criteria. [26]
Sampling Procedure	The complete sampling operations to be performed on a defined material for a specific purpose. A detailed written description of the sampling procedure is provided in the sampling protocol. [26]
Sampling Record	Written record of the sampling operations carried out on a particular material for a defined purpose. The sampling record should contain the batch number, date and place of sampling, reference to the sampling protocol used, a description of the containers and of the materials sampled, notes on possible abnormalities, together with any other relevant observations, and the name and signature of the inspector. [26]
Sampling Unit	Discrete part of a consignment such as an individual package, drum or container. [26]
Scale	An increase or decrease in the batch size in batch processing or the throughput capability for continuous processing whether or not different equipment is used. [5]
Secondary Chemical Reference Substance	A secondary chemical reference substance is a substance whose characteristics are assigned and/or calibrated by comparison with a primary chemical reference substance. The extent of characterization and testing of a secondary chemical reference substance may be less than for a primary chemical reference substance. Although this definition may apply inter alia to some substances termed “working standards”, part B of these guidelines is intended to apply to secondary reference substances supplied as “official”, e.g. regional/national standards, and not to manufacturers’ or other laboratories’ working standards. [21]
Secondary Packaging Materials	Packaging materials which do not have direct contact with the excipient. NOTE 1: Examples of secondary packaging materials are printed or unprinted cartons, labels, over-wraps, and transit containers such as folding boxes, glass, plastics, aluminium films, and foils. They may be combinations of different materials/components. NOTE 2: Secondary packaging materials may be directly printed or decorated. NOTE 3: Shipping pallets are not considered secondary packaging materials.
Secondary Reference Standard	A substance of established quality and purity, as shown by comparison to a primary reference standard, used as a reference standard for routine laboratory analysis.
Selected Sample	Sample obtained according to a sampling procedure designed to select a fraction of the material that is likely to have special properties. A selected sample that is likely to contain deteriorated, contaminated, adulterated or otherwise unacceptable material is known as an extreme sample. [26]

Term	Definition
Self-contained Area	Premises which provide complete and total separation of all aspects of an operation, including personnel and equipment movement, with well established procedures, controls and monitoring. This includes physical barriers as well as separate air-handling systems, but does not necessarily imply two distinct and separate buildings. [20]
Semi-permeable Containers	Containers that allow the passage of solvent, usually water, while preventing solute loss. The mechanism for solvent transport occurs by absorption into one container surface, diffusion through the bulk of the container material, and desorption from the other surface. Transport is driven by a partial-pressure gradient. Examples of semi-permeable containers include plastic bags and semi-rigid, low-density polyethylene (LDPE) pouches for large volume parenterals (LVPs), and LDPE ampoules, bottles, and vials. [13]
Senior Management	Person(s) who direct and control a company or site at the highest levels with the authority and responsibility to mobilise resources within the company or site. (ICH Q10 based in part on ISO 9000:2005) [11]
Severity	A measure of the possible consequences of a hazard. [10]
Shelf Life	The length of time during which the excipient meets specification (see also expiration period, re-evaluation interval and retest interval). [4]
Short Duration	in the context of mixed excipients refers to a process that is typically timed in minutes and does not alter the physical or chemical characteristics of the components being processed.
Signed (signature)	The record of the individual who performed a particular action or review. This record can be initials, full handwritten signature, personal seal, or authenticated and secure electronic signature.
Significant Change	Any change that has the potential to alters an excipient's physical, chemical, or microbiological property from the norm, and/or that may alter the excipient's performance in the dosage form.
Simple Physical Mixture	refers to the blending of two, or more, different materials in a way that is not intended to change the physical or chemical characteristics of the components. The blending process is generally low shear and of short duration, with limits dependent on the nature of the components being mixed. The process usually involves the use of mechanical agitation which can include paddles within a vessel, or the tumbling of the vessel that contains the different materials.
Site	A defined location of the equipment in which the excipient is manufactured. It may be within a larger facility. A change in site may be to a different part of the existing facility, but in a different operational area, or to a remote facility including a contract manufacturer.

Term	Definition
Skip Lot (periodic) Testing	The performance of specified tests at release on pre selected batches and/or at predetermined intervals, rather than on a batch-to-batch basis, with the understanding that those batches not tested must still meet all the acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified, presented to, and approved by, the regulatory authority before implementation. When tested, any failure of the starting material to meet the acceptance criteria established for the periodic (skip lot) test should be handled by proper notification of the appropriate regulatory authority (authorities). If these data demonstrate a need to restore routine testing, then batch-by-batch release testing should be reinstated. [3, 18]
Skip-Lot Testing Program	Periodic or intermittent testing performed for a particular test parameter, which is justified by historical data demonstrating a state of statistical process control. [8]
Solvent	An inorganic or organic liquid used as a vehicle for the preparation of solutions or suspensions in the manufacture of an **excipient.** [2]
Specific test	A test which is considered to be applicable to particular new drug substances or particular new drug products depending on their specific properties and/or intended use. [12]
Specification	A list of tests, references to analytical procedures and appropriate acceptance criteria that are numerical limits, ranges or other criteria for the tests described for a material, that the material is required to meet.
Specification	A list of tests, references to analytical procedures and pre-established numerical limits, ranges or other criteria for the tests described, that the material is required to meet.
Specification – Release	The combination of physical, chemical, biological, and microbiological tests and acceptance criteria that determine the suitability of a drug product at the time of its release. [13]
Specification - Shelf life	The combination of physical, chemical, biological, and microbiological tests and acceptance criteria that determine the suitability of a drug substance throughout its re-test period, or that a drug product should meet throughout its shelf life. [13]
Specificity	The ability to assess unequivocally the analyte in the presence of components that may be expected to be present. Typically these might include impurities, degradants, matrix, etc.
Specified impurity	An identified or unidentified impurity that is selected for inclusion in the new drug substance or new drug product specification and is individually listed and limited in order to assure the quality of the new drug substance or new drug product. [12]
SQC	The plotting of sequential test results to show their variation relative to the specification range and their normal variation. [5]
Stability	Continued conformance of the excipient to its specifications. [1, 3, 7]
Stability Test Method	A stability indicating method that investigates whether or not a particular characteristic of the excipient changes relative to specification over time.

Term	Definition
Stable Process	A process is considered stable when the output of the process, regardless of the nature of the processing (batch or continuous), can be demonstrated, by appropriate means, to show a level of variability which consistently meets all aspects of the stated specification, (both pharmacopeia and customer specific) and is thus acceptable for its intended use. [8]
Stakeholder	Any individual, group or organization that can affect, be affected by, or perceive itself to be affected by a risk. Decision makers might also be stakeholders. For the purposes of this guideline, the primary stakeholders are the patient, healthcare professional, regulatory authority, and industry. [10]
Standard Operating Procedure (SOP)	An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). Certain SOPs may be used to supplement productspecific master and batch production documentation. [17, 20, 23]
Starting Material	A raw material or intermediate defined at the starting point for excipient GMPs and used in the production of an excipient that is incorporated as a significant structural fragment or that is purified to meet the quality requirement for an excipient.
State of Control	A condition in which the set of controls consistently provides assurance of continued process performance and product quality. (ICH Q10) [11]
Statement of Commitment	A declaration by the excipient manufacturer certifying that the DMF is current and that the DMF holder will comply with the statements made there in. [7]
Statistical Control	A process that results in product that exhibits random variation of its property. [4]
Statistical Process Control	A statistical techniques involving ongoing evaluation of measurements to monitor and analyze the variation in processes.
Statistical Quality Control (SQC)	The plotting of sequential test results to show their variation relative to the specification range and their normal variation.
Sterile	Completely free from microorganisms such that, after inoculation of a suitable nutrient medium under aseptic conditions with the material, and followed by incubation at an appropriate temperature for 14 days, no growth of microorganisms is seen. [4]
Storage	The storing of pharmaceutical products up to the point of use. [17, 19]
Storage Condition Tolerances	The acceptable variations in temperature and relative humidity of storage facilities for formal stability studies. The equipment should be capable of controlling the storage condition within the ranges defined in this guideline. The actual temperature and humidity (when controlled) should be monitored during stability storage. Short term spikes due to opening of doors of the storage facility are accepted as unavoidable. The effect of excursions due to equipment failure should be addressed, and reported if judged to affect stability results. Excursions that exceed the defined tolerances for more than 24 hours should be described in the study report and their effect assessed. [13]

Term	Definition
Stress Testing (drug product)	Studies undertaken to assess the effect of severe conditions on the drug product. Such studies include photostability testing (see ICH Q1B) and specific testing on certain products, (e.g., metered dose inhalers, creams, emulsions, refrigerated aqueous liquid products). [13]
Stress Testing (drug substance)	Studies undertaken to elucidate the intrinsic stability of the drug substance. Such testing is part of the development strategy and is normally carried out under more severe conditions than those used for accelerated testing. [13]
Strongly Suspected Human Carcinogen	A substance for which there is no epidemiological evidence of carcinogenesis but there are positive genotoxicity data and clear evidence of carcinogenesis in rodents. [16]
Subcontractor	A third party for outsourced work or services that contribute in whole or in part to the manufacture, testing, distribution and storage of excipients.
Subcutaneous (s.c.)	A route of administration where the drug product is injected beneath the skin. [7]
Suitability	Demonstration that a process or technique provides expected output.
Supplier	Person or company providing pharmaceutical starting materials on request. Suppliers may be distributors, manufacturers, traders, etc. (GDP Guide/WHO Good Trade and Distribution Practices) [3, 17, 18]
Supply Chain	Supply chain is defined as all steps in the entire chain of distribution starting from the point at which an excipient is transferred outside the control of the original manufacturer's material a management system downstream to the final user of the excipient. [3]
Supporting Data	Data, other than those from formal stability studies that support the analytical procedures, the proposed re-test period or shelf life, and the label storage statements. Such data include (1) stability data on early synthetic route batches of drug substance, small scale batches of materials, investigational formulations not proposed for marketing, related formulations, and product presented in containers and closures other than those proposed for marketing; (2) information regarding test results on containers; and (3) other scientific rationales. [13]
Synthetic	Products which are not derived from starting materials sourced from plants, animals or minerals and that are not products of fermentation. Note: Also see specific regional or national organic food legislation for additional information on the use of the term synthetic. [6]
Tamper Evident	Describes a means to reveal any interference with the integrity of the finished packaged excipient and designed to make improper opening of an excipient's packaging evident to the purchaser.
Teratogenicity	The occurrence of structural malformations in a developing fetus when a substance is administered during pregnancy. [16]
Therapeutic Equivalence	Two pharmaceutical products are considered to be therapeutically equivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and after administration in the same molar dose, their effects, with respect to both efficacy and safety, are essentially the same when administered to patients by the same route under the conditions specified in the labeling. This can be demonstrated by appropriate bioequivalence studies, such as pharmacokinetic, pharmacodynamic, clinical or in vitro studies. [24]

Term	Definition
Top Management	A person or group of people who direct and control an organization at the highest level. The highest level may either be at the site or corporate level and will depend on how the quality management system is organized.
Traceability	Ability to determine the history, application or location that is under consideration, for example, origin of materials and parts, processing history or distribution of the product after delivery. [1, 3]
Trader / Trading	See Broker/Broking. [3]
Transit	The period during which pharmaceutical products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination. [17]
Transmissible Spongiform Encephalopathy (TSE)	TSE's are rare forms of progressive neurodegenerative disorders that affect both humans and animals and are caused by similar uncharacterized agents that generally produce spongiform changes in the brain. Specific examples of TSE's include: scrapie, which affects sheep and goats; BSE, which affects cattle; transmissible mink encephalopathy; feline spongiform encephalopathy; chronic wasting disease (CWD) of mule deer, white-tailed deer, black-tailed deer, and elk; and in humans, kuru, Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome, fatal familial insomnia, and variant Creutzfeldt-Jakob disease (vCJD). [6]
Transparency	The term transparency means: — defining policies and procedures in writing and publishing the written documentation; and — giving reasons for decisions to the public (see also accountability above). [25]
Trend	A statistical term referring to the direction or rate of change of a variable. [10]
Typical Usage Level	The quantity of excipient expected to be found in drug products based upon excipient functionality. [7]
Unidentified Impurity	An impurity for which a structural characterisation has not been achieved and that is defined solely by qualitative analytical properties (e.g., chromatographic retention time). [15, 12]
Uniformity	A starting material may be considered uniform when samples drawn from different layers do not show significant differences in the quality control tests which would result in non-conformity with specifications. The following materials may be considered uniform unless there are signs to the contrary: organic and inorganic chemicals; purified natural products; various processed natural products such as fatty oils and essential oils; and plant extracts. The assumption of uniformity is strengthened by homogeneity, i.e. when the consignment is derived from a single batch. [26]
Universal Test	A test which is considered to be potentially applicable to all new drug substances, or all new drug products; e.g., appearance, identification, assay, and impurity tests. [12]
Unspecified Impurity	An impurity that is limited by a general acceptance criterion, but not individually listed with its own specific acceptance criterion, in the new drug substance specification. [15]
User	A party who utilizes an excipient in the manufacture of a drug product or another excipient. [8]

Term	Definition
USP/NF	United States Pharmacopeia/National Formulary [6]
Validation	A documented program that provides a high degree of assurance that a specific product, method, procedure (e.g., cleaning), or system will consistently produce a result meeting predetermined acceptance criteria.
Validation	A documented program that provides a high degree of assurance that a specific process, method or system will consistently produce a result meeting predetermined acceptance criteria.
Validation Master Plan (VMP)	The VMP is a high-level document that establishes an umbrella validation plan for the entire project and summarizes the manufacturer's overall philosophy and approach, to be used for establishing performance adequacy. It provides information on the manufacturer's validation work programme and defines details of and timescales for the validation work to be performed, including a statement of the responsibilities of those implementing the plan. [23]
Validation Protocol (or Plan) (VP)	A written plan stating how validation will be conducted and defining acceptance criteria. For example, the protocol for a manufacturing process identifies processing equipment, critical process parameters/operating ranges, product characteristics, sampling, test data to be collected, number of validation runs, and acceptable test results. [2]
Validation Readiness Check	not yet defined
Validation Report (VR)	A document in which the records, results and evaluation of a completed validation programm are assembled and summarized. It may also contain proposals for the improvement of processes and/or equipment. [23]
Validity	An expression of the degree to which a measurement performed actually measures the characteristic which the investigator wishes to measure (see also reliability above). [25]
Vegetable Sourced	Contains starting materials of plant origin. [6]
Verification	The application of methods, procedures, tests and other evaluations to provide objective evidence that the output of a particular operation meets the specified requirements for that operation
WHO	World Health Organization
WHO-type certificate	A certificate of pharmaceutical product of the type defined in the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. [World Health Organization. WHO Certification Scheme on the quality of pharmaceuticals products moving in international commerce. Geneva, World Health Organization, 2000. WHO/EDM/QSM/2000.] [25]
Worst Case	A set of conditions encompassing processing limits, circumstances, equipment, etc., which pose the greatest chance of a failure in a process, to a product, or in a procedure, when compared to ideal conditions or those stipulated in a procedure. Such conditions do not necessarily induce product, process, or equipment failure. [4, 23]
Yield, Expected	The quantity of material or the percentage of theoretical yield anticipated at any appropriate phase of production based on previous laboratory, pilot scale, or manufacturing data. [2]

Term	Definition
Yield, Theoretical	The quantity that would be produced at any appropriate phase of production, based upon the quantity of material to be used, in the absence of any loss or error in actual production. [2]

IPEC General Glossary of Acronyms

Acronym	Definition
21 CFR	Title 21 of the United States Code of Federal Regulations [6]
ACC	The American Chemistry Council
ADI	Acceptable Daily Intake
API	Active Pharmaceutical Ingredient
ADME	Absorption, distribution, metabolism and excretion
AEO	Authorised Economic Operator
AIB	The American Institute of Baking
BP	British Pharmacopoeia
BRC	British Retail Consortium
COA	Certificate of Analysis
COC	Certificate of Conformity
CEP	Certificate of Suitability to the European Pharmacopoeia
CAS Number	Chemical Abstracts Service Registry Number
CTD	Common Technical Document
cGMP	Current Good Manufacturing Practice
DQ	Design Qualification
EEFO	Earliest Expiry/First Out Principle Concept
EDQM	European Directorate for the Quality of Medicines. [6]
EDI	Estimated Daily Intake
EIP	Excipient Information Package
FCC	Food Chemicals Codex [6, 7]
FECC	European Federation of Chemical Distributors
FEMA	Flavor and Extract Manufacturers Association of the United States [7]
FIFO	First in/First out Principle Concept
FPA	Food Products Association
GAMP	Good Automated Manufacturing Practices
GRAS	Generally Recognized as Safe
GMO	Genetically Modified Organism
GMA	Grocery Manufacturers Association
GDP	Good Storage Practice
GEP	Good Engineering Practices
GMP	Good Manufacturing Practices
GSP	Good storage practices
GTDP	Good Trade and Distribution Practices
HACCP	Hazard Analysis Critical Control Point [6]

Acronym	Definition
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
IID	Inactive Ingredient Database
INCI	International Nomenclature of Cosmetic Ingredients and Handbook. [6]
IQ	Installation Qualification
IPEA	International Pharmaceutical Excipients Auditing, Inc. [6]
IPEC	International Pharmaceutical Excipients Council
IPEC PQG	International Pharmaceutical Excipients Council and the Pharmaceutical Quality Group
ISO	International Organization for Standardization. [6]
ISO 14000	The International Organization for Standardization's family of standards on environmental management Site and Supply Chain Security Overview – Section 4 [6]
JP	Japanese Pharmacopoeia [6]
JPE	Japanese Pharmaceutical Excipients [6]
JSFA	Japanese Standards for Food Additives
LOEL	Lowest-Observed Effect Level
MSDS	Material Safety Data Sheet [6]
NACD	National Association of Chemical Distributors (NEW)
NOAEL	No-Observed-Adverse-Effect Level
NOEL	No-Observed-Effect Level
OHSAS 18001	International occupational health and safety management system specification.
OC	Operating Characteristic
OQ	Operational Qualification
OOT	Out of Trend
OVI	Organic Volatile Impurities, USP/NF General Chapter <467> [6]
PQ	Performance Qualification
PDE	Permissible Daily Exposure
Ph. Eur.	European Pharmacopoeia [6]
PAT	Process Analytical Technology
Cp	Process Capability Index
QA	Quality Assurance
QbD	Quality by Design
QC	Quality Control
QMS	Quality Management System
QTPP	Quality Target Product Profile
SOP	Standard Operating Procedure
SQC	Statistical Quality Control
TSE	Transmissible Spongiform Encephalopathy

Acronym	Definition
USP/NF	United States Pharmacopeia/National Formulary [6]
VMP	Validation Master Plan
VP	Validation Protocol
VR	Validation Report
WHO	World Health Organization

IPEC General Glossary References

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