|  |
| --- |
| **术语及缩略语**  **Glossary and Terminology** |

|  |  |  |
| --- | --- | --- |
| **角色Role** | **打印名Print Name** | **部门Department** |
| 作者Author (发起人Initiator) | Ge Min | Global Quality |
| 部门批准人Line Approval  (技术批准人Technical Approval) | Kathy Ji | Head of GQSO |
| 部门批准人Line Approval  (技术批准人Technical Approval) | Gao Jiangfeng | Head of Suzhou Quality |
| 部门批准人Line Approval  (技术批准人Technical Approval) | Ma Xiaomin | Head of Hangzhou Quality |
| 部门批准人Line Approval  (技术批准人Technical Approval) | Yun Kang | GM of Suzhou M1 |
| 部门批准人Line Approval  (技术批准人Technical Approval) | Kaisong Zhou | Head of PD&AS, Suzhou M2 and SC |
| 部门批准人Line Approval  (技术批准人Technical Approval) | Huailiang Zheng | Head of IT |
| 最终批准人Final Approval  (质量批准人Quality Approval) | Wang Dongming | Global Quality Head |

**目录**

**TABLE OF CONTENTS**

[1 目的Purpose 3](#_Toc64882123)

[2 范围Scope 3](#_Toc64882124)

[3 职责Responsibility 3](#_Toc64882125)

[4 要求Requirements 3](#_Toc64882126)

[4.1 General Requirement 3](#_Toc64882127)

[5 术语和缩略语Terminology and Abbreviation 4](#_Toc64882128)

[6 参考资料Reference Documents 4](#_Toc64882129)

[7 表格Form 6](#_Toc64882130)

[8 修订历史Revision History 6](#_Toc64882131)

[9 附录Appendices 6](#_Toc64882132)

[9.1 Glossary List 6](#_Toc64882133)

# 目的Purpose

Establish this procedure is aimed to describe the glossary and terminology of GxP related in order to ensure that the terms and abbreviations applicable to all Innovent and keep consistent, so that all employees have a unified understanding.

# 范围Scope

This procedure is applying to Innovent Corporate, Global functions and all Innovent sites. This glossary refers to the terms definition of NMPA, FDA, EMA GMP and ICH, WHO, PIC/S, ISPE.

# 职责Responsibility

|  |  |  |
| --- | --- | --- |
| 3.1 | Global Quality System and Operation | Responsible for establish and maintain this procedure. |
| 3.2 | Document Author or Initiator | Ensure any documents quote glossary or terminology shall in accordance with this procedure. |
| 3.3 | Document Reviewer and Approver | Review any glossary in reviewed documents is comply with this procedure. |

# 要求Requirements

## General Requirement

### This procedure is applicable to all global documents and site procedure.

### All glossary defined in this procedure covers general terminology and definitions that are used frequently in different lifecycles and departments. If any definition is required to address in any document but not including in this procedure, the definitions shall be specified into the current procedure.

### This procedure shall be periodic reviewed and calibrated every 2 years or when business needs.

### The definitions in this procedure is quote from regulations, guidance or other procedures.

### The definitions are listed alphabetically in appendix 1.

# 术语和缩略语Terminology and Abbreviation

N/A

# 参考资料Reference Documents

| **参考资料Reference** | **标题Title** |
| --- | --- |
| China Ministry of Health No.79 | Good Manufacturing Practice (Revision 2010) |
| FDA 21CFR Part 7 | Enforcement Policy |
| FDA 21CFR Part 11 | Electronic Records, Electronic Signatures |
| FDA 21CFR Part 210 | Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General |
| EU EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 | EU Guidelines to GMP Medicinal Products for Human and Veterinary Use |
| China Ministry of Health No.79 | Good Manufacturing Practice (Revision 2010) |
| PIC/S | Annex 2A Manufacture of Advanced Therapy Medicinal Products for Human Use |
| WHO | Good Manufacturing Practices for pharmaceutical products: main principles |
| ISPE | Glossary of Pharmaceutical and Biotechnology Terminology |
| ICH Q1A(R2) | Stability Testing of New Drug Substances and Products |
| ICH Q1B | Stability Testing: Photostability Testing of New Drug Substances and Products |
| ICH Q2(R1) | Validation of Analytical Procedures: Text and Methodology |
| ICH Q3A(R2) | Impurities in New Drug Substances |
| ICH Q3D Training | Implementation of Guideline for Elemental Impurities |
| ICH Q5A(R1) | Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin |
| ICH Q5B | Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products |
| ICH Q5C | Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products |
| ICH Q5D | Deviation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products |
| ICH Q5E | Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process |
| ICH Q6A | Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances |
| ICH Q6B | Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products |
| ICH Q7 | Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients |
| ICH Q8(R2) | Pharmaceutical Development |
| ICH Q9 | Quality Risk Management |
| ICH Q10 | Pharmaceutical Quality System |
| ICH Q11 | Development and Manufacturing of Drug Substances(Chemical Entities and Biotechnological/Biological Entities) |
| ICH Q12 | Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management |

# 表格Form

N/A

# 修订历史Revision History

|  |  |  |
| --- | --- | --- |
| **版本号**  **Version** | **变更内容**  **Description of Change** | **变更原因**  **Reason for Change** |
| 版本1.0  Version 1.0 | 新增New | 新增本程序，描述术语及缩略语。  Establish this procedure to describe the glossary and terminology in Innovent. |

# 附录Appendices

## Glossary List

| **首字母 Beginning with** | **术语和缩略语 Terminology and Abbreviation** | **定义**  **Definition** |
| --- | --- | --- |
| A | Acceptance Criteria | Numerical limits, ranges, or other suitable measures for acceptance of test results. |
| A | Action Limit | Established criteria indicating that the critical variables of a system are out of acceptable range, and requiring investigation and corrective action. |
| A | Active Pharmaceutical Ingredient (API) (or Drug Substance) | Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) 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 and function of the body. |
| A | Actual Yield | the quantity that is actually produced at any appropriate phase of manufacture, processing, or packing of a particular drug product. |
| A | Air Lock | An enclosed space with two or more doors, and which is interposed between two or more rooms (e.g. of differing class of cleanliness), for the purpose of controlling the air-flow between those rooms when people or materials need to enter or exit. An air-lock is designed for and used by either people or materials. |
| A | Alert Limit | Established criteria giving early warning of drift of the critical variables of a system from normal conditions, while not reaching the action limit, which are not necessarily grounds for definitive corrective action. |
| A | 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. |
| A | At Rest State | The “at rest” state is the condition where the installation is complete with equipment installed, but with no operations and personnel present. |
| A | 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 regulations in force in that country. |
| B | Batch (or Lot) | A defined quantity of starting material, packaging material or finished product processed in one process or series of processes so that it could be expected as homogeneous. To complete certain stages of manufacture, it may be necessary to divide a batch into a number of subbatches, which are later brought together to form a final homogeneous batch. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval. For example, the homogeneous product that solid or semi-solid preparations for oral or topical use are produced within the same blender by one blending prior to molding or filling should be regarded as one batch. The homogeneous product that liquid preparations for oral or topical use are produced by final mixing prior to filling (sealing) should be regarded as one batch. |
| B | Batch Record | All relevant documents and records for the disposition of a batch and includes processing, quality analysis and release review information. Such documentation can be used to trace all history and information related to the quality of finished product. |
| B | Bioburden | The level and type (i.e. objectionable or not) of micro-organism present in raw materials, media, biological substances, intermediates or products. Regarded as contamination when the level and/or type exceed specifications. |
| B | Biologic License Application (BLA) | Biological products are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires a firm who manufactures a biologic for sale in interstate commerce to hold a license for the product. A biologics license application is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical affects of the biologic product. If the information provided meets authority agency requirements, the application is approved and a license is issued allowing the firm to market the product. |
| B | Biological Product | Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources — human, animal, or microorganism — and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available. |
| B | Biosafety level (BSL) | The containment conditions required to safely handle organisms of different hazards ranging from BSL1 (lowest risk, unlikely to cause human disease) to BSL4 (highest risk, cause severe disease, likely to spread and no effective prophylaxis or treatment available). |
| B | Blow/Fill/Seal Equipment | Blow/fill/seal units are purpose built machines in which, in one continuous operation, containers are formed from a thermoplastic granulate, filled and then sealed, all by the one automatic machine. |
| B | Brand Name Drug | A brand name drug is a drug marketed under a proprietary, trademark-protected name. |
| B | Bulk Product | Any product which has completed all processing stages up to, but not including, final packaging. |
| C | Calibration | The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring, recording or controlling instrument or system (especially weighing), or values represented by a material measure, and the corresponding known values of a reference standard. |
| C | CAPA | Corrective Action and Preventive Action – System that focuses on investigating, understanding, and correcting discrepancies while attempting to prevent their occurrence |
| C | Capability of a Process | Ability of a process to realise a product that will fulfil the requirements of that product. The concept of process capability can also be defined in statistical terms. |
| C | Cell Bank | Cell bank system: A cell bank system is a system whereby successive batches of a product are manufactured by culture in cells derived from the same master cell bank. A number of containers from the master cell bank are used to prepare a working cell bank. The cell bank system is validated for a passage level or number of population doublings beyond that achieved during routine production. Master cell bank: A culture of [fully characterised] cells distributed into containers in a single operation, processed together in such a manner as to ensure uniformity and stored in such a manner as to ensure stability. A master cell bank is usually stored at - 70°C or lower. Working cell bank: A culture of cells derived from the master cell bank and intended for use in the preparation of production cell cultures. The working cell bank is usually stored at - 70°C or lower. |
| C | Cell Culture | The result from the in-vitro growth of cells isolated from multicellular organisms. |
| C | Change Management | A systematic approach to proposing, evaluating, approving, implementing and reviewing changes. |
| C | Clean Area | A room (or an area) with defined environmental control of particulate and microbial contamination, constructed, outfitted and used in such a way as to reduce the introduction, generation and retention of contaminants within the room or area. |
| C | Cleaning Validation | There are documents and records that prove that the approved cleaning procedures can effectively clean the equipment to meet the requirements of pharmaceutical production. |
| C | Closed System | Where an active substance or product is not exposed to the immediate room environment during manufacture. |
| C | Combination Product | A drug product which contains more than one drug substance. |
| C | Comparable | A conclusion that products have highly similar quality attributes before and after manufacturing process changes and that no adverse impact on the safety or efficacy, including immunogenicity, of the drug product occurred. This conclusion can be based on an analysis of product quality attributes. In some cases, nonclinical or clinical data might contribute to the conclusion. |
| C | Component | any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. |
| C | Computer System | A group of hardware components and associated software, designed and assembled to perform a specific function or group of functions. |
| C | Computerized System | A system including the input of data, electronic processing and the output of information to be used either for reporting or automatic control. |
| C | Computerized System Life Cycle | The process of a computerized system from proposing user requirements to termination of use includes the stages of design, standard setting, programming, testing, installation, operation, maintenance and other stages. |
| C | Concurrent Process Validation | The validation performed in the commercial production process verifies that the quality of the batch of products meets all the requirements specified in the validation plan, but the product is released to the market without completing all the process and quality evaluations. |
| C | Consignee | anyone who received, purchased, or used the product being recalled. |
| C | Contained Area | An area constructed and operated in such a manner (and equipped with appropriate air handling and filtration) so as to prevent contamination of the external environment by biological agents from within the area. |
| C | 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. |
| C | Containment | The action of confining a biological agent or other entity within a defined space. Primary containment: A system of containment which prevents the escape of a biological agent into the immediate working environment. It involves the use of closed containers or safety biological cabinets along with secure operating procedures. Secondary containment: A system of containment which prevents the escape of a biological agent into the external environment or into other working areas. It involves the use of rooms with specially designed air handling, the existence of airlocks and/or sterilisers for the exit of materials and secure operating procedures. In many cases it may add to the effectiveness of primary containment. |
| C | Contamination | Adverse impacts of impurities with chemical or microbiological properties or foreign matters, into starting materials, intermediate, bulk, or finished products during production, sampling, packaging or repackaging, storage or transport. |
| C | Continual Improvement | Recurring activity to increase the ability to fulfil requirements. |
| C | Continuous Process Verification | An alternative approach to process validation in which manufacturing process performance is continuously monitored and evaluated. |
| C | CMO | Contract Manufacturing Organization (or Contract Manufacturer). A manufacturer performing some aspect of manufacturing on behalf of the original manufacturer. |
| C | 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. |
| C | Controlled Area | An area constructed and operated in such a manner that some attempt is made to control the introduction of potential contamination (an air supply approximating to grade D may be appropriate), and the consequences of accidental release of living organisms. The level of control exercised should reflect the nature of the organism employed in the process. At a minimum, the area should be maintained at a pressure negative to the immediate external environment and allow for the efficient removal of small quantities of airborne contaminants. |
| C | CPP | Critical Process Parameter – process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to assure the process produces the desired product quality. |
| C | CQA | Critical Quality Attribute – a physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to assure the desired product quality. |
| C | Cross-Contamination | Contamination of raw materials and excipients (starting materials) or of a product with another material or product. |
| D | Data Audit Trail | It is a series of records of events related to computer operating systems, applications, and user operations to help trace from original data to related records, reports or events, or trace back from records, reports, and events to original data. |
| D | Data Integrity | The accuracy and reliability of the data, used to describe that all stored data values are in an objective and true state. |
| D | Decision Maker(s) | Person(s) with the competence and authority to make appropriate and timely quality risk management decisions. |
| D | Design Qualification | Various verifications and documentation to confirm that the design plan of facilities, systems and equipment meets the expected goals. |
| D | 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. |
| D | Detectability | The ability to discover or determine the existence, presence, or fact of a hazard. |
| D | 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. |
| D | Deviation | Departure from an approved instruction or established standard. |
| D | Digital Signature | an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified. |
| D | Discontinued Drug Product | Approved products that have never been marketed, have been discontinued from marketing, are for military use, are for export only, or have had their approvals withdrawn for reasons other than safety or efficacy after being discontinued from marketing. |
| D | Distribution | A series of operations to send the product from manufacturer to the distributor or customer, including loading, transportation, and etc. |
| D | Documentation | The documentation in the Provisions includes specifications, master manufacturing documents, operation procedures, records, reports, and etc. |
| D | Dosage Form | A dosage form is the physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable. |
| D | Drug Product | A finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo. |
| D | Drug Substance (Bulk Material) | The material which is subsequently formulated with excipients to produce the drug product. It can be composed of the desired product, product-related substances, and product- and process-related impurities. It may also contain excipients including other components such as buffers. |
| E | Electronic Data | Also known as data message, it refers to information generated, sent, received or stored by electronic, optical, magnetic or similar means. |
| E | Electronic Record | any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. |
| E | Electronic Signature | The data contained in electronic data in electronic form and attached to identify the identity of the signatory and indicate that the signatory approves the content. |
| E | Excipient | The auxiliary materials used in the preparation of biological products, such as adjuvants, stabilizers, excipients, etc. |
| E | Expiry Date (or Expiration Date) | The date placed on the container/labels of an API designating the time during which the API is expected to remain within established shelf life specifications if stored under defined conditions, and after which it should not be used. |
| F | Fiber | any particulate contaminant with a length at least three times greater than its width. |
| F | Finished Product | A medicinal product which has undergone all stages of production, including packaging in its final container. |
| G | GQMS | Global Quality Management System. QMS is a management system to direct and control an organization with regard to quality |
| H | Handwritten Signature | the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark. |
| I | Primary Packaging | is that constituent of the packaging that is in direct contact with the drug substance or drug product, and includes any appropriate label. |
| I | In Operation State | The “in operation” state is the condition where the production equipment is functioning in the defined operating mode and the specified number of personnel is present. |
| I | Inactivation | Reduction of virus infectivity caused by chemical or physical modification. |
| I | Inactive Ingredient | any component other than an active ingredient. |
| I | Infrastructure | A series of hardware and basic software, such as network software and operating system, that provide a platform for application programs to realize their functions. |
| I | Installation Qualification (IQ) | Establishing confidence that process equipment and ancillary systems are compliant with appropriate codes and approved design intentions, and that manufacturer's recommendations are suitably considered |
| I | Intermediate Product | Partly processed product which must undergo further manufacturing steps before it becomes a bulk product. |
| I | Isolator | device or system equipped with air clean devices of Grade B (ISO 5) or better cleanliness, and which can completely isolate internal environment from external environment (e.g. clean room where it is located and operation personnel). |
| K | Knowledge Management | Systematic approach to acquiring, analysing, storing, and disseminating information related to products, manufacturing processes and components. |
| M | MAH | Marketing Authorisation Holder |
| M | Manufacture | All operations of purchase of materials and products, Production, Quality Control, release, storage, distribution of medicinal products and the related controls. |
| M | Manufacturer | Referred to as manufacturer of drugs, unless specified otherwise in the Provisions. |
| M | Manufacturing Scale Production | Manufacture at the scale typically encountered in a facility intended for product production for marketing. |
| M | Market Withdrawal | a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the authority agency or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. |
| M | 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. |
| M | Master Cell Bank (MCB) | An aliquot of a single pool of cells which generally has been prepared from the selected cell clone under defined conditions, dispensed into multiple containers and stored under defined conditions. The MCB is used to derive all working cell banks. The testing performed on a new MCB (from a previous initial cell clone, MCB or WCB) should be the same as for the MCB unless justified. |
| M | Materials | Raw materials and excipients packaging materials, and etc. For example, the raw materials for chemical drug preparations are referred to as active pharmaceutical ingredients (APIs); those for biological products are referred to as raw ingredients; those for traditional Chinese medicine preparations are referred to as Chinese crude drugs, prepared slices of Chinese crude drugs and outsourced traditional Chinese medicine extracts; and the raw materials for the APIs are referred to any substances used in the manufacture of APIs excluding packaging materials. |
| M | Monoclonal Antibodies (Mab) | Homogenous antibody population obtained from a single clone of lymphocytes or by recombinant technology and which bind to a single epitope. |
| N | New Drug Application (NDA) | When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet authority agency's requirements for marketing approval, the sponsor submits to authority agency a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States. For internal tracking purposes, all NDA's are assigned an NDA number. |
| O | Open System | an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system. |
| O | Operational Qualification (OQ) | Documented verification that a system operates according to written and pre-approved specifications throughout all specified operating ranges. |
| O | OOS | Out of Specification. All events that the testing results fail to meet the regulatory standards or acceptance criteria established by the manufacturer. |
| O | Outsourced Activities | Activities conducted by a contract acceptor under a written agreement with a contract giver. |
| O | OOT | Out of Trend. A time dependent result which falls outside a prediction interval or fails a statistical process control criterion. |
| O | OOE | Out of Expectation. Event that the testing result meet specifications, but is outside the expected variability of the analytical procedure. |
| P | Packaging | All operations, including filling and labeling, which a bulk product has to undergo in order to become a finished product. Aseptic filling, filling of products for terminal sterilization, and etc., are not regarded as packaging. |
| P | Packaging Materials | Any materials employed in the packaging of a drug, including immediate packaging materials, container in direct contact with drugs, and printed packaging materials, but excluding any outer packaging materials used for transportation or shipment. |
| P | 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. |
| P | Performance Qualification  (PQ) | Commissioning, verification and documentation to confirm that the installed and connected facilities, systems and equipment can operate effectively and stably (with good reproducibility) in accordance with the approved production methods and technical requirements of the products. |
| P | Pharmaceutical Quality System (PQS) | Management system to direct and control a pharmaceutical company with regard to quality. |
| P | PQR | Product Quality Review – regular periodic review of API or drug products with the objective to verify process consistency, to highlight any trends and to identify product and process improvements |
| P | Process Validation | Validation activities to prove that the process can run effectively and stably within the range of the set parameters and produce the verification activities that meet the predetermined quality standards and quality characteristics of drugs. |
| P | Product Lifecycle | All phases in the life of the product from the initial development through marketing until the product's discontinuation. |
| P | Product Realisation | Achievement of a product with the quality attributes appropriate to meet the needs of patients, health care professionals, and regulatory authorities (including compliance with marketing authorisation) and internal customers requirements. |
| P | 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. |
| P | Product-Related Impurities | Molecular variants of the desired product (e.g., precursors, certain degradation products arising during manufacture and/or storage) which do not have properties comparable to those of the desired product with respect to activity, efficacy, and safety. |
| P | Product-Related Substances | Molecular variants of the desired product formed during manufacture and/or storage which are active and have no deleterious effect on the safety and efficacy of the drug product. These variants possess properties comparable to the desired product and are not considered impurities. |
| Q | QRM | Quality Risk Management |
| Q | QSSC | Quality System Steering Council, including Head of Site/Function/Operation Unit/Business Unit, Quality Head of Site/Function/Operation Unit/Business Unit, Corporate Quality Head, Corporate Head. |
| Q | Qualification | A series of actions proving that the premises, facilities and equipment work correctly and actually lead to the expected results. |
| Q | Quality | The degree to which a set of inherent properties of a product, system or process fulfills requirements (see ICH Q6a definition specifically for "quality" of drug substance and drug (medicinal) products.). |
| Q | Quality Assurance (QA) | The sum total of the organised arrangements made with the object of ensuring that all APIs are of the quality required for their intended use and that quality systems are maintained. |
| Q | Quality Attribute | A molecular or product characteristic that is selected for its ability to help indicate the quality of the product. Collectively, the quality attributes define identity, purity, potency and stability of the product, and safety with respect to adventitious agents. Specifications measure a selected subset of the quality attributes. |
| Q | Quality by Design (QbD) | A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. |
| Q | Quality Control (QC) | Checking or testing that specifications are met. |
| Q | Quality Manual | Document specifying the quality management system of an organisation. |
| Q | Quality Objectives | A means to translate the quality policy and strategies into measurable activities. |
| Q | Quality Planning | Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives. |
| Q | Quality Policy | Overall intentions and direction of an organisation related to quality as formally expressed by senior management. |
| Q | 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. |
| R | Raw Material | A general term used to denote starting materials, reagents, and solvents intended for use in the production of intermediates or APIs. |
| R | Reagent | A substance other than a starting material, intermediate, or solvent that is used in the manufacture of a new drug substance. |
| R | Real Time Release Testing (RTRT) | The ability to evaluate and ensure the quality of in-process and/or final product based on process data, which typically include a valid combination of measured material attributes and process controls. |
| R | Reconciliation | A comparison, making due allowance for normal variation, between the amount of product or materials theoretically produced or used, and actually produced or used plus loss collected. |
| R | Release | The operation to make decisions, such as approval to use, distribution into the market, or others, by evaluating the quality of a batch of material or product. |
| R | Representative Sample | If a sampling program ensures that the samples taken are proportionally representative of different parts of the same batch or different attributes of non-uniform sample totality, this sample taken is a representative sample. |
| R | Reprocessing | Subjecting all or part of a batch of intermediate, bulk or finished products that fails to meet the specifications to a previous step of the same manufacturing process in order to meet the predetermined specifications. |
| R | Return | Actions of sending back drugs to the manufacturer. |
| R | Reworking | Subjecting all or part of a batch of intermediate or bulk product which fails to meet the specifications to an alternate manufacturing process in order to meet the predetermined specifications. |
| R | Risk Acceptance | The decision to accept risk . |
| R | Risk Analysis | The estimation of the risk associated with the identified hazards. |
| R | 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. |
| R | Risk Communication | The sharing of information about risk and risk management between the decision maker and other stakeholders. |
| R | Risk Control | Actions implementing risk management decisions. |
| R | 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. |
| R | Risk Identification | The systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description. |
| R | Risk Management | The systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating and reviewing risk. |
| R | Risk Reduction | Actions taken to lessen the probability of occurrence of harm and the severity of that harm. |
| R | Risk Review | Review or monitoring of output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk. |
| S | Secondary Packaging | outer packaging material or container that is not and will not be in direct contact with the dosage form. |
| S | Sample | It refers to one or a group of materials or products that are taken from a batch and provide information about the batch. |
| S | Senior Management | Personnel on the top level of the manufacturer to command and control it, and have the power and responsibility to allocate resources. |
| S | Shelf Life (also Referred to as Expiration Dating Period) | The time period during which a drug product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label. |
| S | Simulated Products | Products that are very similar to the verified product in physical and chemical properties. In many cases, the placebo has similar physical and chemical characteristics to the product and can be used as a simulated product. |
| S | Solvent | An inorganic or an organic liquid used as a vehicle for the preparation of solutions or suspensions in the synthesis of a new drug substance or the manufacture of a new drug product. |
| S | Specification | A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a drug substance, drug product or materials at other stages of its manufacture should conform to be considered acceptable for its intended use. “Conformance to specification” means that the drug substance and drug product, when tested according to the listed analytical procedures, will meet the acceptance criteria. Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities as conditions of approval. |
| S | 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. |
| S | Standard Operating Procedure (SOP) | An authorized written procedures giving instructions for performing operations not necessarily specific to a given product or material (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premisesand environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation. |
| S | State of Control | A condition in which the set of controls consistently provides assurance of continued process performance and product quality. |
| S | Sterility | Sterility is the absence of living organisms. The conditions of the sterility test are given in the European Pharmacopoeia. |
| S | Strength | (i) The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis), and/or (ii) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard). |
| S | Supplier | A party providing materials, equipment, instruments, reagents or services, such as manufacturer, distributor, etc. |
| T | Theoretical Yield | the quantity that would be produced at any appropriate phase of manufacture, processing, or packing of a particular drug product, based upon the quantity of components to be used, in the absence of any loss or error in actual production. |
| T | Trend | A statistical term referring to the direction or rate of change of a variable(s). |
| U | Unidirectional Airflow | Air flow in the same direction, at sufficient rate in a stable and uniform manner. Unidirectional air flow can continuously clear the particles in critical operation zones. |
| U | User Requirement Specification | Refers to the requirements and expectations of the user for the plant, facility, equipment or other systems. |
| V | Validation | A series of actions of proving that any operation procedure (or method), manufacturing process or system actually leads to the expected results. |
| V | Virus Removal/Inactivation | The process of removing or inactivating the virus from the product to ensure a safe process. |
| W | WCB (Working Cell Bank) | The Working Cell Bank is prepared from aliquots of a homogeneous suspension of cells obtained from culturing the MCB under defined culture conditions. |
| W | Worst Condition | Within (or beyond) the standard operating procedures, one or a series of conditions consisting of the upper and lower limits of the process parameters and related factors. When compared with ideal conditions, the worst conditions maximize the probability of product or production process failure. Such conditions do not necessarily lead to product or production process failure. |

**END of Document.**