Acceptance Criteria:
The acceptance criteria are pre-defined and agreed standards, limits or ranges between different parties such as Quality Assurance and Quality Control or Manufacturing and Quality Assurance or suppliers
or
The specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan that are necessary for making a decision to accept or reject a lot or batch of raw material, intermediate, packaging material, or active pharmaceutical ingredient. This term can also be applied to validation.

ACT:
Means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-903, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-394)). All definitions in section 201 of the act shall apply to these regulations.

Action Level:
The action level is a pre-defined and between different parties agreed written level. Once these levels are exceeded, actions must be undertaken. A complete investigation must be carried out and documented accordingly.

Active ingredient:
Any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to effect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

Active Pharmaceutical Ingredient (API):
An API also called Drug Substance (DS) is any physiologically active substance that is intended for use in a Drug Product. An API is also a substance when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished Dosage Form of the Drug.
or
Any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. 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 of humans or other animals. APIs include substances manufactured by processes such as chemical synthesis; fermentation; recombinant DNA or other biotechnology methods; isolation/recovery from natural sources; or any combination of these processes.

Actual Yield:
The quantity that is actually produced at any appropriate phase of manufacture, processing, or packing of a particular API or intermediate.

ADE - Adverse Drug Event
Any adverse event associated with the use of a drug in humans, whether or not considered drug related.

Adulterated Product:
Adulterated Product is a Product or Medical Devices when it contains any filthy, putrid or decomposed Substance. This also applies for a Product or Medical Devices when it was prepared under unsanitary conditions or was not made in accordance with the GMPs. This could be also a Product or Medical Devices which contains an unsafe colour additive, or does not meet the requirements of an official compendium or Product registration.

Analytical methods validation:
The process by which it is established, by laboratory studies, that the performance characteristics of the method meet the requirements for the intended analytical applications.

US Health Agency:
The United States Food and Drug Administration (FDA).

Airlock:
An airlock is called a room or space with two or more doors that is interposed between two or more rooms. This is usually build in between different class of cleanliness, for the purpose of controlling the air flow and pressure differential between those rooms. An airlock is designed for personnel or goods.

PHARMACEUTICAL TERMINOLOGY / DEFINATIONAS

Contact us at: pharmaguidehub@gmail.com

Alert Level:
The alert level is a pre-defined and between different parties agreed written level. This level should be used to predict an action level. Once these levels are exceeded an investigation may not be necessary, but closer attention to the indicator is required.

Approval:
Once a country's regulatory authority (for example, the Food and Drug Administration in the United States) approves a new drug application, the new medicine becomes available for physicians to prescribe. The manufacturing company must continue to submit periodic reports to the regulatory authority, including any cases of adverse reactions and appropriate quality control records. For some medicines, the regulatory authority may require additional studies to evaluate long-term effects.

Aseptic Technique:
Specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by microorganisms.

Aseptic Work Area, Clean Work Environment, Work Area, and Critical Work Area:
For the purposes of this procedure, synonymous with biological safety cabinet (BSC), laminar flow hood, clean bench, or other such clean enclosure.

Archive:
A file or place for the orderly storage and expedient retrieval of raw data, documentation, protocols, samples and interim or final reports.

Artwork:
An artwork could be any printing, text illustration, copy, ornamentation or colouring work on a Product's Packages. This includes also the label, insert, leaflet, carton, shipper, sticker and vignette.

Atypical Result:
An atypical result is a result which could be but must not be outside the pre-defined limit, however the result does not fit to the expectation or the normal distribution of results. These results should be evaluated to predict any trends and to evaluate the significance.

Audit:
An audit is a formal review of the GMP and Quality status of an operation, a facility, a process, a service or system versus the applicable standards and directives.

Auditee:
The Auditee is the organization that is being audited. The Auditee will be responsible for responding in writing to Audit report observations and implementing corrective actions as necessary.

Auditor:
Can be one or more individual(s) who are responsible to support the Audit coordination, the pre-Audit meeting if applicable, the Audit, the final wrap up and Audit report information.

Auditor Lead:
Person assigned by Quality Management who is responsible for assembling the Audit team, Leading the Audit coordination, the pre-Audit meeting if applicable, the Audit, the final wrap up, the Audit report information, writing the Audit report and conducting the follow-up. Typically this is the more senior member of the team.

Authorized Person:
The authorized person in some European countries also called as qualified persons (QP) is the person(s) among key Manufacturing and Quality personnel responsible for GMP compliance and the release of every Batch of final Products.

Batch (Lot):
A Batch sometimes called Lot is defined as an entity, by either time or quantity or both, of a product that is intended to have a uniform character and quality. A batch must be produced within predefined and specified conditions following a defined manufacturing cycle or process.
or
A specific quantity of an intermediate or API intended to have uniform character and quality, within specified limits, and produced according to a single manufacturing order during the same cycle of manufacture. A batch may also mean a specific quantity of material or API processed in one process or

series of processes so that it could be expected to be homogenous.

Calibration:

Calibration is called the process that verifies that under specified conditions, the relationship between values indicated by an instrument or system for measuring, recording, or controlling meets the corresponding known values of a Reference Standard.

or

The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a traceable standard over an appropriate range of measurements

CAPA:

Corrective and Preventive Action, a written plan describing actions to be taken to address an issue, plan must include implementation steps and target dates.

Certificate of Analysis (CoA):

CoA is the listing of testing results found during the analysis of a Sample which was taken by a defined procedure, of a Batch of Drug Product or Drug Substance/Active Pharmaceutical Ingredient, raw material, components etc.

Certificate of GMP Conformance:

The Certificate of GMP Conformance is a signed document demonstrating that the item was made in conformance with GMPs and all applicable procedures.

Chemical Component:

A Chemical Component is defined as any Chemical Substance not mattering if active or inactive, of a defined Quality used in the manufacture of Bulk Materials, Intermediate or Final Product, whether or not it is present in the Finished Product.

Chemistry, Manufacturing and Control Documentation (CMC Documentation):

CMC documentation is the Chemistry, Manufacturing and Control Documentation section of a Drug Substance / Active Pharmaceutical Ingredient (API) or Drug Product registration.

Chemical reaction:

A process that involves a chemical transformation of a starting material or intermediate to form a new compound (e.g., bond formation, oxidation, reduction).

CIP:

Clean In Place is a method of cleaning installed pipe and equipment without having to dismantle or move the pipe and equipment. However, provisions should be made for partial disassembly or for personnel access for purposes of cleaning validation to facilitate inspection and sampling of inner product surfaces for possible residue or contaminates.

Classified Area:

A classified area is called a room, suite or plant which is dedicated to a defined category of activity, where the viable and non-viable particulate levels, airflows, number of air changes and pressure differentials are monitored, checked, and tested to specified limits.

Clean Area (Room):

The clean area is an area with predefined environmental control following the applicable standards of e.g. particulate and microbial contamination. The clean area should be constructed and used reducing the introduction, generation and retention of contaminants within the area.

Cleaning agent:

Any material used to clean process equipment, utensils, and storage vessels. These may include soaps, detergents, surfactants, alkalis, acids, or other materials, such as organic solvents, if the solvent is specifically used for cleaning and is not a solvent used in the next processing step.

Climatic Zone:

The climatic zones into which the world is divided based on the prevailing annual climatic Conditions (ICH stability conditions).

Clinical:

Denotes the symptoms and course of a disease as distinguished from the laboratory findings or anatomical changes.

Clinical investigator:

Experienced clinical researcher who implements a clinical study protocol with patients.

Clinical pharmacologist:
One who has undergone training in basic pharmacology of therapeutic agents in the prevention, treatment and control of disease in man.

Clinical response:
Any response by a patient to therapy. A positive response can be either complete, in which all signs or symptoms of the disease improve or partial, in which at least one half of the signs or symptoms of a disorder improve and no new signs appear.

Clinical trial or clinical study:
Testing in which preventive, diagnostic, or therapeutic agents are given to a human population under controlled conditions to determine the agents' safety and effectiveness. This systematic investigation tests the effects of materials or methods, according to a formal study plan (that is, a protocol), usually in subjects having a particular disease or class of diseases. These trials are conducted to satisfy the regulatory requirements to obtain marketing approval for a new drug or for a new indication for a drug previously approved for marketing. In the United States, must be under an approved investigational new drug application, under the guidance of an Institutional Review Board, and in accordance with the Food and Drug Administration's (FDA) rules on human studies and informed consent of participants. These studies are conducted in three phases: Phase I, Phase II and Phase III.

CMO - Contract Manufacturing (CMO)
Organisation A company that carries out the manufacture of marketed or investigational pharmaceutical products for its clients

Complaint (product):
A Complaint by a customer is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a Product (or device) on the market.
or
Means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

Complaint File:
The Complaint File is the documented investigational result including any responses to complainant or authority about a complaint from a released product.

Component:
A Component is any ingredient intended which should be used in the manufacture of a drug product or medical device. This includes those that may not appear in such Drug Product or any Packaging Material containing the Product.
or
means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled material.

Computer System:
A Computer System is defined as a system including the input of data, electronic processing and the output of information. This information can than be used for reporting or automatic control.

Commissioning:
Commissioning can be subdivided into three major activities; installation, operation and performance qualifications. It is a formal, written procedure to the planning, executing and documenting of facility validation. This process may include environmental compliance checks, verification of personnel protection equipment and qualification of containment systems as well as validation of systems related to cGMP regulations.

Component:
Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

Concurrent validation:
A subset of prospective validation in which API batches are released for distribution, based on extensive testing, before completion of process validation. Once data from additional batches produced under replicated conditions show uniformity, the process may be considered validated.

Continuous production:
A process in which a material is continuously produced in a step or series of steps. In a continuous process, the batches of raw materials and the process parameters can be statistically, but not absolutely, correlated to the material produced in a given period of time.

Container/Closure System:
The Container/Closure System is defined as the complete package that holds and protects the Product.

Contamination:
Contamination is defined as the presence of impurities of a chemical or microbiological nature or of foreign matter, into or onto a Material.
or
The introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or API (e.g., occurring during production, sampling, packaging or repackaging, storage or transport).

Containment:
Achieving a level of control over a raw material, intermediate, or API that provides proper protection of these materials from external contamination and cross-contamination.

Contract Research Organisation (CRO)
A company that offers clients pharmaceutical research services, including product development and formulation, clinical trial management, laboratory services, and preparation of regulatory submissions.

Control Number:
Means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished product can be determined.

Controlled study or controlled trial:
Clinical testing in which one group of subjects is used as a standard of comparison to determine the usefulness of a new medical approach. In a controlled study, doctors give the new drug being tested to one group of subjects, called the "treatment group." They give another drug, or no drug, to a second group of people under the same conditions. This group is often called the "control group." Researchers then compare the results of the two groups.

Corrective Actions:
The corrective action is the action necessary to recover the product / process / material / system, affected by the deviation.

Counterfeit Drugs:
Counterfeit Drugs are Drugs which are deliberately and fraudulently mislabelled. The same applies for drugs manufactured deliberately and fraudulently with respect to identity and/or source.

Critical Equipment / Instrumentation:
Critical Equipment / Instrumentation is defined as Equipment / Instrumentation used in a Process that has a direct impact on the Quality, safety, purity or efficacy of Final Product, or are stated as such in Regulatory Dossiers.

Critical Parameters:
Critical Parameters are parameters used in a Process that have a direct impact on the Quality, safety, purity or efficacy of Final Product, or are stated as such in Regulatory Dossiers.

Critical process parameters:
Process parameters that must be controlled within established operating ranges to ensure that the API or intermediate will meet specifications for quality and purity.

Critical process steps:
Process steps that must be controlled within established operating ranges to ensure that the API or intermediate will meet specifications for quality and purity.

Cross-contamination:
A contamination of a material or product with another material or product.

Decontamination:
Under decontamination the action of separating and eliminating contamination is defined. The contaminants

might be of chemical and/or microbiological nature.

Dedicated Rooms or Facility:

Under dedicated rooms or facility a room or suite of rooms or facility are defined with equipment and services used only for the manufacture of one product, or a closely related group of products.

Defect Category Critical:

Examples for a critical defect are problems in plant, systems or materials which affect the Quality, safety, purity or efficacy of products and/or can lead to health threatening conditions in finished pharmaceutical products or materials.

Defect Category Major:

Examples for a major defect are problems in plant, systems or materials which can affect the Quality, safety, purity or efficacy of Products or which lead to non-health threatening conditions in finished Pharmaceutical Products.

Defect Category Minor:

Examples for a minor defect are problems that if they are not corrected, would not cause harm to the Product or patient, but indicate minor breaches to GMP rules.

Degradation Product:

A degradation product is defined as a molecule resulting from a chemical change in the Drug Substance / Active Pharmaceutical Ingredient (API). This might result by the action of e.g. pH, light, temperature or water or by reaction with an Excipient and/or the immediate Container/closure system or if the Drug Substance brought about over time.

Design history file (DHF):

Compilation of records which describes the design history of a finished device.

or

Design history file (DHF) means a compilation of records which describes the design history of a finished device.

Design input:

Physical and performance requirements of a device that are used as a basis for device design.

Design output:

Results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, ist packaging and labeling, and the device master record.

Design review:

Documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

Development report:

A report that summarizes the major stages of API development from early stages through large-scale manufacturing.

Device history record (DHR):

Compilation of records containing the production history of a finished device. Device master record (DMS) means a compilation of records containing the procedures and specifications for a finished device.

Device master record (DMS):

Means a compilation of records containing the procedures and specifications for a finished device.

Design Qualification:

The design qualification should provide documented evidence that the design of e.g. a facility, equipment, services or operation is suitable for the intended purpose. This includes also meeting the Quality and GMP requirements.

Development Report:

The Development Report is defined as a compilation of all documents as well as the supporting documentation for the development of a product from conception to market.

Deviations / Non-conformance:

A Deviation/ Non-conformance is any unplanned event or failure to meet SOPs and/or failure to meet specified limits, which may potentially affect the safety, identity, efficacy, quality, or purity of products or a violation of the cGMP regulations or internal processes and procedures.

Deviation Trending:
Deviations must be trended to detect/predict reoccurrence problems and to monitor the effectiveness of the implementation of the corrective actions. The frequency of the trend analysis and reporting must be at least monthly.

Distribution:
The Distribution is defined as the delivery of an approved finished drug product to authorized sites, wholesalers, distributors or persons which are authorized to deliver drug products to the public.

Documentation:
Documentation is defined as any procedures, instructions, logbooks, records, raw data, manuals, and policies associated with the development, manufacture, testing, marketing and distribution of a medicinal product or devices required demonstrating compliance with GMP standards and any other applicable worldwide regulatory requirements.

Dosage Form:
The dosage form is defined as the product form of the finished product e.g. tablet, capsule, aerosol, pre-filled syringe, elixir and suppository.

Dosage Formulation:
The form in which a drug is produced. Pharmaceutical companies use many methods of drug delivery, including oils, gels, creams and sprays; capsules and tablets; injects; implants; suppositories; and liquids and syrups.

Dosage strength:
Amount of active drug contained in a particular formulation; for example 50, 100, or 500 milligrams.

Double-blind study:
A scientific study in which neither the subject (patients) nor the investigators (treating physicians) know who is receiving the experimental treatment and who is receiving a placebo (a control or "sugar pill").

Drug:
As defined in US CFR Section 201(g)(1) of the Act means (a) articles that are recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; and articles (other than food) intended to affect the structure or any function of the body of humans or other animals.

Drug delivery:
The process by which a formulated drug is administered to the patient. Traditional methods have been orally or by injection. Newer methods include through the skin by application of a transdermial patch, or across the nasal membrane by administration of a specially formulated nasal spray.

Drug interaction:
Modification of the effect of one drug by another in a way that diminishes, negates or enhances the effectiveness or safety of one or both drugs.

Drug Product:
A Drug Product is defined as any product that is offered for sale or distribution and administration to human beings or animals for treatment. Examples for treatment might be but is not limited to preventing and diagnosing disease, for anesthesia, for contraception, and for otherwise altering normal physiological functions.
or
A finished dosage form, for example, a tablet, capsule or solution, that contains an active pharmaceutical ingredient, generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an API but is intended to be used as a placebo.

Drug Regulatory Affairs (DRA):
The Drug Regulatory Affairs department is the group being responsible for interaction with the regulatory authorities in the registration of Drug Substance / Active Pharmaceutical Ingredient (APIs) and Drug Products.

Efficacy:
Measure of the therapeutic effectiveness of a drug.

Electropolishing:

The electrochemical method of removing metal (usually stainless steel) from a surface. More specifically, it is the anodic dissolution of metal in the presence of an electrolyte and an imposed current potential. This process creates a continuous film of chromium rich oxide on the affected surface. The resulting film provides the following benefits:

1. It provides an excellent passive barrier between the body of the material (i.e. internal or external pipe wall) and the contained fluid, orexternal environment, enhancing corrosion resistance.
2. Provides for improved cleanability and sterilization aspects.
3. Allows for improved quality control by exposing defects in welds andbase material.
4. Avoids the surface tension caused when mechanical polishing is used.

Eligibility criteria:
Key facts about a person's health that make a patient right, or not right, for a certain research study. Examples of these facts include: a person's age, what symptoms of the illness he or she has, results of certain laboratory tests, a person's overall health, and past treatments. Both the "must-have" and the "can't-have" check lists help doctors get clear research results about whom a new drug will help, not help, or harm.

European Medicines Evaluation Agency (EMEA):
The EU licensing authority for pharmaceutical products

Enantiomers:
Compounds with the same molecular formula as the API, which differ in the spatial arrangement of atoms within the molecule and are non-superimposable mirror images.

Ethical drug:
A drug that primarily sold only through physicians and pharmacists, rather through direct selling to customers. Sometimes referred to as a "prescription-only" drug.

European Medicines Evaluation Agency (EMEA):
The EMEA is an agency, which was created for having a centralized licensing of medicinal Products. This includes administering applications for mutual recognition of medicinal products for the European Union member states.

Establish:
Define, document (in writing or electronically), and implement.

Evaluation of Training:
Any attempt to obtain information (feedback) on the effectiveness of a training program and to assess the value of the training in the light of that information.

Evidential Material Coordinator:
A representative of the company who is assigned responsibility for fulfilling evidential material requests made by the Inspector/Investigator as is conveyed them, typically by a Inspection Runner.

Evidential Material List:
A list used for tracking evidential material submitted to the Inspector/Investigator for review. The list is updated concurrently with material submission. At the completion of the Inspection, the list is printed (if it has been managed electronically), reviewed and filed in the Inspection File.

Excipient:
An Excipient is defined as any chemical component other than the Drug Substance / active Pharmaceutical Ingredient (API) in a Dosage Form / Drug product. Examples for excipients are e.g. binders, fillers diluents, disintegrants, lubricants, flavours, colours, and sweeteners.

Expected yield:
The quantity of API or intermediate or the percentage of theoretical yield anticipated at any appropriate phase of production based on data from process development or process validation.

Expiry Date or Expiration Date:
Expiry Date or Expiration Date is defined as the shelf life of products and therefore the date beyond which the product should not longer be used.
or

The date (usually placed on the containers/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 alter which it should not be used.

Extraneous substance:

An impurity arising from any source extraneous to the manufacturing process.

Export Certificates:

An export certificate is issued by foreign governments to firms. These certificates are applicable for products that are approved or manufactured in one country and exported to another country.

External Audits:

External Audits are defined as audits conducted by external agencies, both government and client companies

Facilities:

Facilities are commonly defined in GMP environment as room, suite or plant used for the Manufacture of Products.

FDA:

Food and Drug Administration. The FDA is the heath agency of the United States.

FDA Form 481:

The FDA Form 481 is the official FDA Form which must filled out by an FDA Investigator to officially request the collecting of a sample at a site.

FDA Form 482:

The FDA Form 482 is the official FDA notice of Inspection. This document gives the FDA the authority to enter and inspect per Section 704 of the FD&C Act.

FDA Form 483:

The FDA Form 482 is the official FDA inspectional observation sheet. This document is issued at the end of the inspection by the FDA and lists all significant objectionable findings noted during an inspection.

FDA (Field) Investigator:

FDA Investigator is the Inspector / Auditor from the FDA conducting inspections to enforce the Food, Drug and Cosmetic Act.

Field Alert:

The Flied Alert is a notification to the US FDA of a potential or actual problem with a marketed drug product or device, e.g. OOS within the shelf life during ongoing stability studies a for marketed drug product.

Fiber:

Any particulate contaminant with a length at least three times greater than its width.

Finished device:

Device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Finished Product:

Finished Product is defined as a final product that went trough all stages of manufacturing, including packaging, and is in its final, labelled primary and secondary packaging. These may be Drug Substances / Active Pharmaceutical Ingredients (API) APIs or Drug Products.

Final Intermediate:

The final Intermediate is defined as the final synthesis starting material for the process step, which produces the Drug Substance / Active Pharmaceutical Ingredient (API).

Functional Specifications:

Functional Specifications are commonly understood as the specifications that define functions, standards and permitted tolerances of systems or parts of systems e.g. components such as equipment. Functional Specifications will therefore define the operating capabilities of the equipment.

Gang-printed labeling:

Labeling derived from a sheet of material on which more than one item of labeling is printed.

Generic Drug Product:

A generic drug product is an off patent drug product with the same strength and dosage but other brand as the drug product. Not all components must be necessarily identical.

or

A broad term for chemically equivalent drugs that are available from multiple manufacturers. Commonly used to refer to products, other than then innovator's, that are sold under the universal chemical name for the drug.

GMP (cGMP):

"Current" Good Manufacturing Practice as put forth in various guidelines through the combined efforts of the FDA, U.S. Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER) and Center for Veterinary Medicine (CVM). These guidelines, without providing specific methodology, identify the expectations of the FDA in regard to the design, construction and operation of facilities intended for the manufacturing, processing, packing or holding of API's.

GMP Document:

A GMP documents can be any written record associated with the manufacture and control or distribution of the Drug Substance / Active Pharmaceutical Ingredient (API) or drug product.

GMP Training:

GMP training is defined as a documented and assessed GMP training that can be both, general GMP/Quality as well as job specific.

GMP / Quality Training Assessment:

A GMP/Quality training assessment assesses formally the training. This assessment should track on the one hand the training requirements of the personnel and on the other hand should record the attendance and successful fulfilment and understanding of the training course content.

Good Clinical Practice (GCP):

The Good Clinical Practice (GCP) is applicable for clinical trials and should assure that generated data, results and conclusions are accurate and credible. GLP includes but is not limited to the design, conduct, performance, monitoring, auditing, recording and analyzing of clinical trials.

or

An international ethical and scientific quality standard for the design, conduct and record of research involving humans. The principles of GCP are outlined in EU Directive 2005/28/EC

Good Laboratory Practice (GLP):

The Good Laboratory Practices are predefined, common criteria, which should be addressed as a basis for validating results and conclusions generated in pre-clinical laboratory studies. GLP defines a recognized standard for the management of laboratory studies and results that gives transparent and comprehensible evidence of what has been done.

Good Manufacturing Practice (GMP):

The Good Manufacturing Practice (GMP) or the current Good Manufacturing Practices (cGMP) are the minimum criteria and expectations to be met to assure that a drug meets the requirements of the regulations as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess. The GMPs are applicable for e.g. methods, facilities and controls, the manufacture, processing, testing, packaging or holding of a drug.

Grit:

In reference to the polishing of stainless steel pipe:

Grit is one method of determining or specifying a degree of smoothness or surface roughness required. Initially a desired smoothness for the inside or outside of pipe was specified in polish numbers such as #4 or #7. However, this system of specifying surface roughness provided for too broad a range of roughness. Grit numbers have essentially replaced polish numbers in an effort at providing more specific requirements.

For example: a #4 polish could vary from an 80 grit to a 150 grit finish; a #7 polish could vary from a 180 grit to a 320 grit finish. The industry is now adopting an even more specific method of determining surface roughness. The surface is specified in micro inches or microns and measured with a profilometer. The surface roughness is measured or specified as either of two arithmetic derivations: Rq – root mean square or Ra – arithmetic mean. In utilizing a quantitative measuring technique, all of the variables inherent in polishing are eliminated. An end user can now specify a specific surface roughness. For example by specifying 25 m in Ra for a surface roughness the vendor now has to determine the best way to achieve that very specific finish requirement.

Surface roughness conversion chart

Micro Inch in.	Micron m	Grit #	Polish #
35	0.89	150	4
25	0.64	180	7
20	0.51	240	7
11	0.28	320	7

HVAC:

Acronym that stands for "heating, ventilating, and air conditioning"

Hygiene:

Practices associated with ensuring good health and cleanliness. Assurance of cleanliness and sanitation in environmentally controlled areas or clean rooms for the manufacture of sterile drug products.

International Committee on Harmonisation (ICH):

The international body responsible for harmonising worldwide regulatory requirements for pharmaceuticals

Identified impurity:

An impurity for which a structural characterization has been achieved.

Inactive ingredient:

Any component other than an "active ingredient".

Indications:

Treatments that a drug will address. Approved indications are those that government regulators have accepted based on clinical testing. Only these indications may be marketed and offered for sale to the public, although physicians may prescribe drugs for unapproved indications according to their professional judgment.

Informed consent:

The process by which patients learn about and document their understanding of the purpose and procedures of a clinical trial and their agreement to participate in that trial.

Investigational Medicinal Product:

The dosage form to be tested in a clinical trial, along with any placebo or comparator products

Impurity:

Any component of an API that is not the entity defined as the API

Impurity profile:

A description of the identified and unidentified impurities present in an API.

Immediate Action:

An immediate action is the action taken at the time of an occurrence to:
Make the process / product / system / material safe and secure, and/or
Contain effects of event, and / or
Prevent further deterioration and / or
Correct the event.

Incident (minor deviation):

An incident is defined as an unplanned event or deviation from SOP that if occurs probably does not have

potentially impact on the safety, quality, purity, identity or efficacy of the API, drug product, medical device or material.

Inspection:

The process undertaken by an Inspector/Investigator to review the company facilities and/or systems.

Inspection Coordinator:

A representative of the company, typically the QA Manager, assigned responsibility for preparing for the inspection, escorting the Inspector/Investigator and facilitating the inspection while the Inspector/Investigator is on the company premises.

Inspection File:

A compilation of documents pertaining to the inspection. This may include, but is not limited to forms and letters from inspecting parties, inspection report, inspection notes, Evidential Materials List, evidential material or reference to location, list of assigned corrective actions, meeting minutes, sample submission forms, and other inspection supported and related materials.

Inspection Report:

A document issued by the Inspector/Investigator that describes the scope of the inspection and any observations resulting from the inspection.

Inspection Runner:

:

A representative of the company that accompanies the Inspector/Investigator, Inspector/Investigator Coordinator, and Scribe while touring the facilities. The runner will convey requests and any other needed actions to the Evidential Material Coordinator.

Inspection Scribe:

:A representative of the company assigned responsibility for taking detailed notes during an Inspection.
Inspection Team:
Company personnel that are directly involved in the inspection. Typically this is the Inspection Coordinator, Scribe, Runner, Subject Matter Experts, Evidential Material Coordinator, Department Managers from the areas that were inspected, and the Head of Regulatory Affairs.

Investigation:

An investigation is the systematic process by which an incident is examined to determine:

- The immediate cause, conditions or situation
- The root cause
- The overall impact on API, drug product, medical device or material
- The need for any action required to prevent reoccurrence

The investigation of the root cause should be understood and documented normally after 30 working days.

Impurity Profile:

An impurity profile is defined as the description of the identified and unidentified impurities present.

In-Process Control (IPC):

In-Process Control are commonly understood as checks being performed during a Production process for the purpose of monitoring and if necessary, to adjust the process to assure that the Product conforms to its specifications. They are usually part of the registration file.
or
Testing and activities performed during production to monitor and, if necessary, adjust the process.

In-Process Materials:

In-Process Materials are defined as materials which are only partly manufactured and will undergo further operations before it becomes a final product.

or
Any material manufactured, blended, or derived by chemical reaction that is produced for, and used in, the preparation of an API.

Installation Qualification (IQ):

The Installation Qualification (IQ) is defined as the performed and documented operations to ensure that facilities, utilities, equipment and systems are installed as designed and specified.
or
Establishing confidence that process equipment and ancillary systems are capable of consistently operating within established limits and tolerances.

Institutional Review Board (IRB):

A group of doctors, science experts, clergy and others in the US who review and approve the performance of each clinical study at their institution. Each hospital doing the research must have a review board. This board makes sure that the study protects patient safety in light of the potential benefit that it may bring. IRB is the term used in the United States, but the committee is more frequently referred to as an "ethics committee" in other markets.

Instrumentation:

Instrumentations are devices and linkages used to control, measure, calibrate, record or alarm a process, equipment or service function.

Intermediate:

A material produced during steps in the synthesis of an API that must undergo further molecular change or processing before it becomes an API.

ISO:

International Standards Organization

Investigational New Drug (IND) application:

The document that a sponsor (usually a drug company) must submit to the FDA before beginning testing of a new drug on humans. This IND application contains the plans for the clinical for the clinical studies and gives a complete picture of the drug, including its structural formula, animal test results, and manufacturing information. The IND application contains information resulting from several years of research and testing.

In vitro:

Latin phrase meaning "in glass". It refers to a process, test or procedure in which something is measured, observed or produced outside a living organism after extraction from the organism. In vitro studies are carried out in animals or humans.

In vivo:

Latin phrase meaning "in the body". Referring to a biological process or experiment occurring or carried out in the living organism. In vivo studies are carried in animals or humans.

Label:

A label is defined as the product identifier including patient instructions that are placed on the primary container.

Labeling:

Labeling is defined as the process when a label is put on a product.
or
Printed materials that accompany a prescription drug when shipped in interstate commerce.

Laboratory Scale:

A Laboratory scale is a small batch size production of drug product or drug substance / Active pharmaceutical ingredient (API) under laboratory conditions.

Ligand:

An agent with a strong affinity to a metal ion.

License (Product License):

The license is the registration containing the regulatory requirements for a product, such as Market Application Authorization (MAA) or New Drug Application (NDA).

Lifecycle:

The term Lifecycle is commonly used in relationship to the entire lifetime of a product or process. This may

start from design, development, realization, validation, production, change control, process improvements and re-validation until the product or process ends.

Limit of Detection:

The term limit of detection is used for the lowest level of analyte that can be detected using a specific method under the required conditions.

Limit of Quantitation:

The term limit of quantitation is used for the lowest concentration of analyte in a sample that may be determined with acceptable accuracy and precision when the required method is applied.

Line Clearance:

The term line clearance is used for the documented act of conducting any necessary removal of products and materials from a manufacturing line to prepare the line for the next production (packaging).

Line Segregation:

The term line segregation describes the usage of a physical separation of lines, usually done with a physical wall or barrier (packaging).

Load Configuration:

The term load configuration is the pre-defined, documented description of the exact configuration of material or product when entering a lyophilizer or sterilizer (e.g. autoclave).

Long Term Stability:

The term long term stability describes a stability evaluation of the physical, chemical, biological and microbiological characteristics of a material or product. The long term stability should cover the expected duration of the shelf life that is claimed in the submission and will appear on the Labeling of the product.

Lot:

Please refer to batch.

or

A batch, or a specific identified portion of a batch having uniform character and quality within specified limits. For an API produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that ensures its having uniform character and quality within specified limits.

Lot Number (control number, or batch number):

Please refer to batch number.

or

Any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of an API or other material can be determined.

Maintenance:

The term maintenance is used for a system describing on how to maintain good working order facility, utility, equipment or instruments for their intended use. Maintenance is categorized in planned or preventative maintenance or breakdown maintenance or repair.

Management with executive responsibility:

Senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer´ s quality policy and quality system.

Manufacture, processing, packing, or holding:

All operations used to manufacture an API to include packaging and labeling operations, testing, and quality control of an API.

Manufacture:

The term manufacture also often referenced as manufacturing describes the complete cycle of manufacture of drug substance / Active Pharmaceutical Ingredient (API) or drug product from start of material purchasing till dispatch for sale or supply purchase of final rug substance / Active Pharmaceutical Ingredient (API) or drug product.

Manufacturer:

The manufacturer is the producer of the drug substance / Active Pharmaceutical Ingredient (API) or drug product.

Market:

The term market describes wholesalers or distributors outside the manufacturing site, governmental

organisations, pharmacists, hospitals, doctors, patients and or external organisations to which the sites distributes the product.

Market withdrawal:

The removal or correction of a distributed product, which involves a minor violation which would not be subject to any legal action by the health authorities or which involves no violation (e.g. stock rotation practices).

Marketing Authorization Application (MAA):

The Marketing Authorization Application is the registration file submitted to the relevant national authorities of EU member states or the EMEA (European Medicines Evaluation Agency) as part of an application to market a new product in the European Union.

Master Manufacturing Record:

The Master Manufacturing Record is the comprehensive document describing the full manufacturing process for the manufacture of a drug substance or drug product. The process starts with the starting materials, their quantities, to be used, together with a description of the manufacturing operations including details of the In Process Controls (IPC).

Master Validation Plan:

Please refer to Validation Master Plan

Material:

The term material is used for either raw materials, intermediates or packaging components used in the manufacture of drug substance / Active Pharmaceutical Ingredients (API) and drug products.

Medical Device:

FDA, Federal Food, Drug, and Cosmetic Act, 21:
http://www.fda.gov/cdrh/devadvice/312.html#link_2
European Definition: DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007, which amended the COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993

Method:

A method is a designed way of performing a process, a check-up or a test which must be normally validated under GMP conditions.

Medicines & Healthcare Products Regulatory Agency (MHRA):

The UK licensing authority for pharmaceutical products and medical devices

Mother liquor:

The residual saturated liquid that remains after crystallization. A mother liquor may contain unrecovered or unreacted starting materials, intermediates, the API and/or impurities

Mock Recall:

A mock recall is called a simulation of a recall inside a site or company.
The intend is to verify the effectiveness of the internal steps in the recall procedure except the notification of any regulatory agency.

Monitor:

The term monitoring is frequently used in the context of carrying out repeated measurements or observations of one or more characteristics of a product, process or environment. Monitoring, continuous or intermittent is used to assure that the above mentioned processes are performed as intended.

New Drug Application (NDA):

The New Drug Application is the company's registration file sent to the FDA for the marketing of a new drug product in the United States.
or
A formal application to the FDA for approval to market a new drug product. When the investigational phase of a drug is completed, the manufacturer gathers together the results of all studies and submits them to the FDA in a New Drug Application. This application is reviewed in detail by a team of reviewers. The purpose of the NDA is to determine whether the drug meets the statutory standards for safety, effectiveness, labeling and manufacturing.

New Chemical Entity (NCE):

The New Chemical Entity is a new Drug Substance / Active Pharmaceutical Ingredient (API), which has not been previously registered in a business region.
or
The designated therapeutic moiety (API) in a dosage form that has not been approved for marketing in the United States (also referred to as a new chemical entity or new drug substance). It may be a complex, simple ester, or salt of a previously approved API.

Nonconformity:
Nonfulfillment of a specified requirement.

Non-fiber-releasing filter:
Any filter which, after any appropriate treatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered. All filters composed of asbestos are deemed to be fiber-releasing filters.

Non-viable Particulate:
A non-viable particulate is any type of particle, which is not living microorganisms.

Official Standards:
Official Standards are commonly reference Standards, which had been provided by a Compendial body, the WHO organization or another certified body.

Operational Qualification (OQ):
Operational Qualification is the documented verification after the Installation Qualification that a System or sub-system performs as intended.
or
Operational Qualification (OQ) is the documented verification that the identified system or subsystem performs as intended throughout all operating ranges of pressure and temperature.

Out of Specification Results (OOS):
An OOS is a result that fall outside the predefined specifications or acceptance criteria.

Over-the-counter drug (OTC):
Any drug that can be bought without a prescription. Distribution of nonprescription drugs is unrestricted, and may be sold , for example, in grocery stores and pharmacies.

Packaging Integrity:

The packaging integrity is the assurance that the designed packaging component fulfils the predefined requirements in protecting the product during transportation, storage and handling during the products full self life.

Packaging:
Packaging is called the process of assembling the Final Product. This act may include but is not limited to filling, capping, labelling, cartoning and packing.

Packaging Components:
The term packaging components or packaging material is used for delivery devices, primary packaging Components, secondary packaging components or any other packaging components.

Packing Material:
The term Packing Material is used for the non-product contact materials used to hold, protect and ship the primary container.

Passivation:
A process in which a diluted nitric acid solution is used to remove discoloration from weld areas as well as dissolve and flush out all iron particulates and residue. These deposits may be the result of being improperly cleaned and stored at the mill, the fab shop or the site. In the case of piping systems the process involves circulating the heated nitric acid solution for a period of time followed by a thorough flushing with potable or purified water. A test is then done to determine if free iron can be detected. When the test determines that the system is clear of any contaminants potable or purified water is flushed through the system until the pH and conductivity/resistivity of the effluent water samples are the same as that of the influent.

Percentage of theoretical yield:
The ratio of the actual yield (at any appropriate phase of the manufacture, processing, or packing of a

particular drug product) to the theoretical yield (at the same phase), stated as a percentage.

Performance Qualification (PQ):

The performance qualification is the documented evidence that an operation consistently operates in its predefined acceptance criteria.

or

Performance Qualification (PQ) provides documented evidence that the integrated system or process is capable of consistently producing the intended product in a high quality and safe manner.

Personal Training File:

The personal training file contains the relevant employee's documentation on the qualifications, experience, and training/assessment of an individual.

Personal Training Plan:

The personal training plan is an employee specific plan addressing an individual's GMP and technical training needs.

Pest Control Program:

The Pest Control Program is a documented program which should be applied at any warehouse, storage or manufacturing facilities to monitor the presence of rodents, pests, birds and insects with the goal to eliminate the vermin.

Pharmaceutical:

Referring to pharmacy or medical drugs; any therapeutic product used in medicine. A pharmaceutical is a drug derived from organic or inorganic chemicals and used to treat a wide range of medical conditions.

Pharmaceutical Waste:

Pharmaceutical Waste is the waste which is generated during the manufacture of Drug Substance / Active Pharmaceutical Ingredient or a Pharmaceutical Product.

Pharmaceutical Research and Manufacturers of America (PhRMA):

Formerly known as PMA, this is a nonprofit scientific and professional organization of more than 100 firms that discover, develop and produce prescription drugs and biological products in the United States. The Association's members produce most of the prescription drugs used in the United States and about half of the free world's supply of prescription drugs.

Pharmacodynamics:

The study of drug action primarily in terms of drug structure, site of action, and the biochemical and physiological consequences of the action. pharmacoeconomics: Studies focusing on the total impact of the product or services on the health system. Pharmacoeconomics relies upon several economic methodologies, including cost-benefit, cost-effectiveness and cost-utility analysis.

Pharmacokinetics:

The study of how the body handles a drug, with particular emphasis on the time required for absorption, duration of action, distribution through the body and method of excretion. pharmacology: The science that deals with the study of drugs in all aspects, including drugs' mechanisms of action.

Phase I clinical trials:

Small studies involving healthy volunteers to assess drug tolerability (safety), metabolism, structure-activity relationships, and mechanism of action in humans.

Phase II clinical trials:

Tests designed to determine, under controlled conditions, whether or not a drug has therapeutic benefit (efficacy) with individuals having the target disease (patients) and document eventual short-term side effects (adverse reactions) and risks associated with the drug.

Phase III clinical trials:

Larger studies to gain confirmatory efficacy and safety data in a broad base of patients. The compound is given to patients according to a protocol that reflects the way the compound is expected to used when it is on the market. These expanded studies generally include hundreds of site locations and involve thousands of patients.

Phase IIIb clinical trials:

Trials that come after the new drug application is filed, but before the product is approved for marketing. The goal of these studies is to provide additional data for marketing support and the ultimate product

launch, including conducting country-specific studies to support local needs.

Phase IV human testing or post-marketing surveillance:

Tests conducted after marketing to obtain additional data regarding product safety and efficacy over the life of a drug. The pharmaceutical is on the market and generating revenue during this period.

Physical manipulation:

A process other than a chemical reaction that may change the purity or the physical properties of the material, including but not limited to crystallization, recrystallization, gel filtration, chromatography, milling, drying, or blending.

Pilot scale:

The manufacture of an API on a reduced scale by processes representative of and simulating those to be applied on a larger commercial manufacturing scale.

Placebo:

Inactive agent without therapeutic value used in controlled studies to determine the efficacy of the potential therapeutic agent against which it is being compared. The placebo is made to look exactly like the therapeutic agent.

PIC:

Pharmaceutical Inspection Convention

Placebo:

The Placebo is an inactive clinical supply containing all excipients but no Drug Substance / Active Pharmaceutical Ingredient.

Polishing (sanitary stainless steel piping):

The process of resolving the roughness of the outside and/or the inside wall of stainless steel pipe by one of two methods:

1. grit polishing – a manual method of using an abrasive pad (sandpaper) with varying, specified degrees of fineness to achieve a specified degree of smoothness.
2. electropolish – an electrochemical method of removing metal from a surface.

Polymorphism:

The occurrence of different crystalline forms of the same API.

Potential impurity:

An impurity that, from theoretical considerations, may arise from or during manufacture. It may or may not actually appear in the API.

Preclinical Research:

Group of studies that test a drug on animals and other nonhuman test systems. This testing is conducted to gain more data about the pharmaceutical's efficacy and safety before tests on humans can begin.

Pre-Approval Inspection (PAI):

A Pre-Approval Inspection is an inspection performed by a government regulatory agency such as the FDA in response to an NDA (New Drug Application) or equivalent submission whose objective is to assess the applicant's attributes against the GMPs and filed documents before final approval of the submitted dossier.

Preventative Action:

The preventive action is the action taken to address the root cause of the deviation and prevent reoccurrence of the event.

Preventive Maintenance:

The Preventive Maintenance describes all scheduled work done on a routine, predefined basis to maintain facilities, equipment, utilities and devices in good status in order reliably performance.

Primary (primacy) Reference Standards:

A primary reference standard is an official substance whose characteristics and potency are warranted by a certified body.

or

A particular portion, lot or batch of an API or intermediate that has been shown by an extensive set of analytical tests to be of the highest purity. This standard may be purchased from a recognized source or

may be prepared by independent synthesis or by further purification of existing production material.

Primary Container:

The primary container is the container containing the product.

Printed packaging components:

Printed packaging components are e.g. labels, leaflets, inserts, cartons, etc.

Procedure:

A procedure is a clear and precise documented description of an activity including the methods to be employed and responsibilities. This might be in may cases a Standard Operating Procedure (SOP).

Process Control

The process control are the installed controls helping to manage a process and limiting process variations by observation, analysis, interpretation and action.

Process Validation:

The process validation is the documented evidence that a process will consistently produce a product meeting its predefined acceptance criteria and quality attributes with a high degree of assurance.

or

Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics.

Process Performance Qualification:

Establishing confidence that the process is effective and reproducible.

Product Performance Qualification:

Establishing confidence through appropriate testing that the finished product produced by a specified process meets all release requirements for functionality and safety.

Prophylactic Treatment:

Preventative treatment or precautions to avoid disease; treatment intended to preserve health and prevent the spread of disease.

Proprietary Medicines:

Over the counter (nonprescription) medicines sold under a trademark and advertised to the general public.

Production Scale:

The production scale is the scale of a proposed commercial process for the commercial production of Drug Substance / Active Pharmaceutical Ingredient or Drug Product.

Prospective Validation:

A prospective validation is a validation, which must be completed before a process is used, or before a Product is released to the market.

or

Establishing documented evidence that a system does what it purports to do prior to the commercial distribution of a new API or an existing API made by a new or modified process.

Protocol:

A protocol is a reviewed and approved document that clearly indicates the objectives, experimental steps, test parameters and the acceptance criteria to perform a study in a GMP environment.

or

Written documentation establishing strict and detailed guidelines and requirements for the proper execution of an activity designed to verify the proper installation or operation of a specific component, segment or system of a new or existing facility.

Purification Procedure:

A process, such as crystallization, distillation, or chromatography, intended to improve the purity of an API or intermediate.

Qualification:

The term Qualification allocates certain limits or restrictions to attributes of equipment, utilities or processes related to its performance. The qualification normally includes Design Qualification (DQ), Installation Qualification (IQ) and Operation Qualification (OQ). Finally, the measurement of those attributes in those ranges for those functions is done in the Performance Qualification (PQ).

or

The action of proving that any equipment or process works correctly and consistently and produces the

expected results. Qualification is part of, but not limited to, a validation process, i.e., installation qualification (1Q), operation qualification (OQ), and performance qualification (PQ).

Qualification Protocol:

A Qualification Protocol (QP) is a written plan or procedure stating in sufficient detail how qualification will be achieved. Included are specific qualification requirements for each equipment item, each system requirement, and product requirement. Each protocol should stipulate test parameters as well as decision points on what constitutes acceptable test results. The written protocols should be based on the associated qualification procedures and should be step-by-step instructions to be used in the field to qualify equipment, instruments, materials, systems and subsystems, and should include data sheets to record critical data.

Qualified:

The term qualified is used in the content of verification of being capable of providing the required performance, used in reference to personnel, utilities, and equipment.

Qualified Person EC Directive 75/319:

The qualified person (QP) is the person(s) among key Manufacturing and Quality personnel responsible for GMP compliance and the release of every Batch of final Products.

or

A person who meets educational and experience requirements detailed in EU Directive 2001/83/EC. All holders of Manufacturer's Authorisations in the EU must have at least one QP permanently and continuously available. QP release is required for each batch of product sold or used in a clinical trial in the EU.

Qualified Supplier:

A qualified supplier is often defined as an approved supplier which did undergo a program of comparative testing that has demonstrated the ability to consistently supply a material of an acceptable quality level and has demonstrated the reliability of their test results.

Quality:

The term Quality is used in the GMP environment as the totality of features and characteristics of a product or service that bears on its ability to satisfy stated or implied needs including the conformance to requirements to specifications.

Quality Audit:

Is a systematic, independent examination of a manufacturer´s quality system that is performed at whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

Quality Assurance:

The Quality Assurance ensures that Product Quality, safety, purity and efficacy is known and effectively controlled.

or

The sum total of the organized activities performed with the intent to ensure that all APIs are of the quality required for their intended use.

Quality Assurance Unit:

The Quality Assurance Unit sets policies, procedures and specifications, audits, reviews, assesses and training including continuous evaluation of the adequacy and effectiveness of the overall quality program, including corrective and preventive measures (CAPA) which are initiated where necessary.

Quality Control:

The term Quality Control is used as part of GMP, which is concerned with assessing and measuring specific quality attributes.

Quality Control Unit:

The Quality Control Unit is the function in the Quality Unit that is responsible for the ongoing control of product and environment quality. Therefore the Quality Control Unit (QC) has the overall responsibility for acceptance or rejection of e.g.:

1. Raw materials
2. Drug Substance /API

3. Packaging components
4. In-Process Controls (IPC)
5. Labelling and Inspection
6. Assurance that supporting systems are being controlled and monitored
7. Drug Product / finished dosage forms.

or

Any person or organizational element designated by the firm to be responsible for the duties relating to quality control.

Quality Records:

A Quality Records in the GMP environment is any official written and retained raw data records that cover any part of the overall Production and Storage process of a Product.

Quality policy:

The overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

Quality System:

Organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quality Unit:

The term Quality Unit is often used for all encompassing roles and responsibilities of the Quality Assurance and Quality Control units.

Quarantine:

The term quarantine is used to describe a special status of Materials, Intermediates or Products that are isolated or otherwise withheld from use, pending a decision on their release, rejection, or reprocessing.

or

The status of materials isolated physically or by other effective means pending a decision on their subsequent use.

Ra (CLA):

Arithmetic mean roughness value. The arithmetical average of all absolute distances of the roughness profile R from the center line within the measuring length lm.

Rq (RMS):

root mean square roughness value. (An alternative to Ra.) The RMS value of a profile calculated over a single sampling length, but can be expressed as the mean result of 5 consecutive sampling lengths.

Random Sample:

A random sample is defined a unit taken from a larger population of such units.In a simple random sample each unit has an equal chance of being included.

Range for critical process parameter:

The range for each process parameter generally developed on laboratory-, pilot-, or plant-scale batches that encompasses values that are capable of producing intermediates and APIs having acceptable quality attributes.

Raw Data:

Raw data in the GMP environment can be defined as any work sheets, records, memoranda, notes or exact copies thereof, that are the result of original observations and activities of a study, or a process, and are necessary for the reconstruction and evaluation of the report of that study or process. Raw data includes e.g. photographs, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments where applicable.

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Raw Material:
Any ingredient intended for use in the production of APIs. These may include starting materials, process aids, solvents, and reagents. reagent: A substance, other than a starting material or solvent, that is used in the manufacture of an API or intermediate.

Reanalysis:
Reanalysis is the repetition of some or all conducted analytical testing. This is different than Retesting or a Resample.

Recovery:
Any treatment of materials by a process intended to make them suitable for further use.

Recall:
The product recall is basically the removal of one or more batches of product from the market, thought or known to be in violation of one or more laws or rules in that country with full knowledge of one or more regulatory agencies.

Reconciliation:
The term reconciliation is used to for performing a comparison between the amount of product or materials theoretically produced or used and the amount actually produced or used.

Reference Standard:
A reference standard is defined as any chemical substance or mixture, or analytical standard, or material other than a test substance that is used for the purposes of establishing a basis for comparison with the test substance for known chemical or biological measurement.

Regulatory Authority:
The Regulatory Authority (Regulatory Body) is a legislatively empowered organization, group, or individual charged with evaluating the compliance profile of a site and/or product as measured against applicable standards.

Regulatory Compliance:
The term Regulatory Compliance is used for the system within the organization administered by the Quality Assurance Unit to ensure adherence to the applicable Regulatory Requirements.

Regulatory Requirements:
The term Regulatory Requirements is often used for mandates and standards enforced by a government-appointed agency designed to protect the public interest by assuring identity, potency, Quality, purity, safety and efficacy of drugs, devices and components entering into the market place.

Regulatory Specifications:
For Pharmacopoeia articles, the specifications in the current edition of the pharmacopoeias are those legally recognized and are used by the agencies when determining compliance with the Regulations or the defined limits within which physical, chemical, biological and microbiological test results for a Drug Substance / API (Active Pharmaceutical Ingredient) or a Drug Product should fall when determined by the Regulatory methodology.

Release Specification:
The release specifications are the specifications which must be met to release a Product. This might be a combination of physical, chemical, biological and microbiological test requirements that determine that a

final product is suitable for release.

Remanufacturer:

Person or institution who processes, conditions, renovates, repackages, restores, or does any other act to a finished product that significantly changes the product performance or safety specifications, or intended use.

Repeating a chemical reaction:

Adding fresh reagents or solvents to unreacted or base material and repeating a chemical reaction from its beginning. This excludes those situations where a chemical reaction is continued or extended in the same vessel with the addition of more solvent, to ensure completion of a reaction or increase the yield and/or purity of the API (e.g., continuation of a hydrogenation step).

Representative Sample:

A representative sample is defined as a sample that is based on rational criteria such as random sampling, and is intended to assure that the sample is representative of the sampled material.

or

A sample that consists of a number of units that are drawn based on rational criteria such as random sampling and intended to assure that the sample accurately portrays the material being sampled.

Reprocessing:

The treatment of all or a part of a batch of product from a defined stage of production with the original process so that it's quality may be rendered acceptable by one or more additional operations.

ICH Q7A defines reprocessing as is introducing an intermediate or Drug Substance…back into the process and repeating appropriate chemical or physical manipulation steps (e.g., distillation, filtration, chromatography or milling) that are part of the established manufacturing process.

or

Introducing an intermediate or API that does not conform to standards or specifications, back into the process and repeating one or more steps that are part of the established manufacturing process (e.g., recrystallization using the same solvent).

Resample:

A resample is an additional sample taken from the batch of material Resample should only been taken if the original sample used for testing is deemed not representative of the batch or the original sample has been compromised in some manner.

Reserve Sample:

A reserve sample also called retained sample is a sample being representative of the batch from which it was taken and which is stored over a pre-determined period of time to perform testing if needed against established specifications.

Retesting:

Retesting is defined as the conduct of repeating an analytical procedure on a different portion of the same sample.

Retest Date:

The retest date of a material is the date when material must be tested again to assure that the material still meets all specification.

or

The date when the Product (API) should be re-examined to ensure that it is still suitable for use.

Retest Period:

The retest period is the timeframe during which the Drug Substance / Active Pharmaceutical Ingredient (API) can be considered to remain within the predefined specification and therefore, acceptable for use.

or

The period of time during which the API can be considered to remain within specifications, and therefore acceptable for use in the manufacture of a given drug product, provided that it has been stored under defined conditions. After this period, the API should be retested for compliance with specifications before use.

Retrospective concurrent drug use evaluation:

One of three forms of evaluation of prescribing patterns to specifically determine the appropriateness of drug therapy. Retrospective drug use evaluation is conducted after the therapy has been completed. There

are two other forms of drug use evaluation: concurrent (during the course of drug therapy) and prospective (before or at the time of despensing).

Retrospective Process Validation:

A Retrospective Process Validation is a validation of a process which is already in use based upon accumulated historical data's conformance to predetermined acceptance criteria.

or

Establishing documented evidence that a system does what it purports to do based on a review and analysis of historic information. It is normally conducted on an API already being commercially distributed and is based on accumulated production, testing, and control data.

Retrospective Qualification:

A Retrospective Qualification is qualification of a system already in use based upon accumulated historical data's conformance to predetermined acceptance criteria.

Returned Goods:

Any returned finished packaged drug product not associated to a complaint or a recall.

Revalidation Process:

The term Revalidation Process is used for the description of a repeated validation to provide assurance that changes in the Process or Process environment, whether introduced intentionally or unintentionally do not adversely affect process characteristics and process quality of a validated process.

Reworking / Rework:

The treatment of all or part of a batch of material of unacceptable quality using an approved process other than that used to produce the original.

ICH Q7A defines reworking as subjecting an intermediate or Drug Substance (DS=API) that does not conform to standards or specifications to one or more processing steps that are different from the established manufacturing process to obtain [material of] acceptable quality (e.g., re-crystallizing with a different solvent).

or

US GMPs for APIs: Subjecting an intermediate or API that does not conform to standards or specifications, to one or more processing steps that are different from the established manufacturing process (e.g., recrystallizing with a different solvent).

Risk-benefit ratio:

Relation between the risks and benefits of a given treatment or procedure. Institutional review boards located where the study is to take place determine whether the risks in a study are reasonable with respect to the potential benefits. The patient also decides if it is reasonable, in light of the risk-benefit ratio, to take part in the study.

Rx:

An abbreviation of the Latin word "recipere" which means "to take". The symbol is used at the beginning of a medical prescription

Sampling:

Sampling commonly describes the process of taking samples/units of finished material, In-process Material, Raw Material or Components for assessment.

Sampling Plan:

A sampling plan describes the details of the planed sampling activity e.g. the number of units or quantity of Material that must be collected and the manner in which it is to be collected.

Sanitation:

The term sanitisation in the GMP environment is defined as the hygienic control on production processes as well as personnel, premises, equipment and material handling. This will reduce e.g. the bio-burden to a defined level.

Scale-up:

The term scale up is often used to describe the increase of a batch size during development of a Drug Substance or Drug Product.

Segregation:

The tem segregation describes the physical separation of Product or equipment.

Self Inspection:
The term Self Inspection is used for the scheduled internal Audits to check for compliance with cGMP, ISO requirements or other relevant requirements.

Semi Finished Product:
The definition semi-finished product stands for product that has not completed the full production steps, such as tablets waiting blistering, or filled vials waiting labelling.

Shelf Life:
The Shelf Life, which is used to establish the Expiry Date of each
Batch is the timeframe at which a drug product is expected to stay within its predefined specification.

Shelf Life Specification:
The predefined combination of physical, chemical, biological and microbiological test Requirements that a drug product must meet during its shelf life or a drug substance up to its retest.

Shipping:
The term shipping is used in the GMP environment for the transport of any pharmaceutical product or ingredient in accordance with the GMP regulations

Side effect:
Secondary and usually adverse effect, as from a drug or other treatment. For example, nausea is a side effect of some anticancer drugs.

Single-blind study:
A study in which one party (either the patient or investigator) is unaware of what medication the patient is taking.

Site:
A site is called any facility where GMP operations for Drug Product or Drug substance, a testing, a research or distribution are conducted.

Site Master File:
A site master file is the comprehensive documentation describing the facilities, utilities, computer systems, organizational structure and manufacturing processes at a site.

Site Quality Manual:
A Site Quality Manual is the documentation of the Quality Systems in place at a Site.

Site Training Plan:
The site training plan documents the overall training program to be performed in a certain time period (annually) within the site.

Site Validation Master Plan:
The site validation master plan describes the assessment of the validation for the sites facilities, utilities, computer systems and manufacturing processes.

Solvent:
Any liquid used as a vehicle for the preparation of solutions or suspensions in the synthesis of an API or intermediate.

Specifications:
The term specification is used for the predefined written, chemical, physical, biological and environmental characteristics for testing a product or system. This includes but is not limited to starting materials, packaging materials, intermediate, bulk, drug substance or drug product.

Stability:
The term stability is used for the ability of a drug product or drug substance to stay in there chemical, physical, microbiological and biopharmaceutical specified limits during its whole shelf life.

Stability Program:
The stability program is a planned and documented program assessing the stability profile of materials and products to establish their retest periods or shelf life and storage directions.

Stability Testing:
Stability testing is the testing used to provide evidence on how the Quality of a API or Drug Product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light.

Standard Operating / Operation Procedure (SOP):

A SOP is an authorized and approved written procedure giving instructions to perform standard operations.

Starting Material:

A material used in the synthesis of an API, which is incorporated as an element into the structure of an intermediate and/or of the API. Starting materials are normally commercially available and of defined chemical and physical properties and structure.

Statistical Control:

Process for which the observed values are scattered about a mean value in such a way as to imply that the origin of the variations is entirely random with no assignable causes of variation and no runs or trends.

Statistical Process Control:

Statistical Process Controls are statistically based techniques, e.g. for measuring and trending for the assessment and control including special cause variation in a system or process.

Status:

The term status in the GMP environment is commonly used for an assessment of the condition of equipment, materials or processes.

Status Label:

A status label is a designation, physically or electronically indicating the acceptability for use, further processing or distribution of any material, product, or equipment such as quarantined, approved, rejected, restricted use, etc.

Sterile Product:

Products that have been processed to ensure that there is absence of living organisms.

Stock Recovery:

The removal or correction of a product that has not been marketed or has not left the direct control of the site.

Strength:

The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis) and/or, 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).

Atudy Arm:

Patients in clinical trials are assigne to one part or segment of a study – a study "arm". One arm receives a different treatment from another.

Sub-Contractor:

A supplier, vendor or consultant used by contractor of the company.

Supplier Audit:

A Supplier Audit is a formal quality review of a supplier of goods or services for a company.

Subject Matter Expert (SME):

A company employee who has demonstrated competency and mastery in a particular process or function. These individuals are called upon to answer question or provide detailed explanation of processes pertinent to their area of expertise during an inspection.

System Qualification:

System Qualification (SQ) consists of the IQ/OQ documentation pertaining to all equipment, instruments, materials and subsystems within a specific system or unit operation, generally identified by a single Piping & Instrument Flow Diagram (P&ID)

Target Level:

The term target level is commonly used in specifications to define the formulated value.

Technical Agreement, Technical Quality Agreement, TQA:

A technical agreement sometimes also called quality agreement or quality technical agreement is a contract agreement which states the manufacturing and quality control provisions as well as the GMP provisions required. The rules should be stated as part of this Agreement (e.g. immediate information about changes in production or manufacturing failures).

Technical Training:

In the GMP environment the technical training is any kind of training relevant to technical operations and maintenance in order to acquire and develop technical knowledge and skills to perform a certain task.

Theoretical yield:
The quantity that would be produced at any appropriate phase of manufacture, processing, or packing of a particular API or intermediate, based upon the quantity of components to be used, in the absence of any loss or error in actual production.

Therapeutic category:
Group of drugs intended to treat or cure a particular disease or related diseases. Several of these categories are antibiotics (drugs that prevent, inhibit or destroy microorganisms), cardiovascular (drugs that treat diseases of the heart and blood vessels), hypnotics (drugs that induce sleep), and nonsteroidal anti-inflammatory drugs or NSAIDs (drugs used to treat pain, fever and swelling).

Third Party Manufacturing:
The term Third Party Manufacturing is used for outside contract manufacturers, testing laboratories or packagers.

Toxic Impurity:
A toxic impurity is any impurity having significant undesirable biological activity

Toxicology:
Scientific discipline concerning the identification and effects of poisons and the treatment of poisoned individual.

Toxicology safety and testing:
Group of tests to determine the potential risk of a compound to man and the environment. These studies involve the use of animals, tissue cultures and other test systems to examine dose level, frequency of administration, and duration on the dose-response pattern of the compound and its toxic side effects. Most toxicology and safety testing is conducted before its human introduction.

TRx:
A measure of total prescriptions (new and refills) issued in a given time period.

Training - Formal:
The systematic development of knowledge, skills and attitudes required by an individual to perform adequately a given task or job, through courses that may be presented externally or internally.

Training On-the-job:

The Training- On-the-job is the development of knowledge, skills and attitudes through training in the workplace. Training methods may include verbal instruction, physical demonstration, including group discussion, simulation, case studies and surveys.

Training Master Plan:
The training master plan is a document describing a general as well as the mid and long term program that is designed to address employee training in regard to quality, compliance, technical and organizational objectives.

Transportation:
The movement of Material or Product by any conveyance between a point of origin to the point of designation

Unidentified Impurity:
An unidentified impurity is defined as an Impurity that is identified solely by qualitative analytical properties, e.g. chromatographic retention time.

Unplanned Maintenance:
Unplanned Maintenance is any maintenance, which must be conducted on short notice because of an occ0orence, also known as breakdown maintenance or repair.

User Requierment Specification (URS):
The user specifications are the specifications written down in a document describing in detail the requirements of the customer (user) with which the e.g. product, materials, process or computer system must confirm

Validation:
The term validation is used to demonstrate with written evidence that the item under consideration, e.g. process does what it purports to do. Validation includes but is not limited to: equipment, computer systems, production processes, cleaning procedures, facilities, utilities as well as analytical methods.

or

The procedure for establishing documented evidence that a specific system or facility is constructed and operates according to a predetermined set of specifications and guidelines.

Validation Master Plan:

The Validation Master Plan is a summary plan which communicates management's expectations and commitments to be followed for the sites validation program including the responsibilities and is therefore a key document at a site. It describes the program to be conducted to get the items in question in a validated manner. The plan lists all of the validation activities to be completed, as well as the schedule for their completion.

Validation protocol:

A written plan stating how validation will be conducted while identifying specific acceptance criteria. For example, the protocol for a typical manufacturing process identifies processing equipment, critical process parameters/operating ranges, product characteristics, sampling and test data to be collected, number of validation runs, and acceptable test results.

Validation or Qualification Plan:

A validation or qualification plan is a written plan stating how the particular Validation/Qualification will be conducted. This includes but is not limited to the individual tests to execute and the key and critical operating variables, equipment, number of repetitions as well as the acceptance criteria.

Validation or Qualification Report:

The Validation or Qualification Report concludes summaries and approves the relating result of the Qualification/Validation activities and data with respect to the protocol requirements and acceptance criteria.

Verification:

The term verification is broadly used in the GMP environment describe the act of reviewing, inspecting, testing, checking, auditing or otherwise establishing and documenting whether or not items, processes, services or documents conform to specified requirements.

Viable Contamination:

The term viable contamination is used when a product or a device is contaminated with any sort of living organisms

World Health Organisation (WHO):

A specialized agency of the United Nations that acts as a coordinating authority on international public health.

Worst Case:

Worst case is term commonly used to describe set of conditions encompassing upper and lower processing limits and circumstances posing the greatest chance of process or product failure, compared with ideal conditions.

Work or Inspection Instruction:

Those documents used to convey, to the work place, the requirements of the purchaser and how the specified quality is to be achieved.

Warehouse:

The warehouse for pharmaceutical products in a GMP environment is a registered facility of an authorized distributor operated in compliance to all applicable GMPs.

Working standard:

An API, intermediate or other substance of established quality and purity, as shown by comparison to a primary reference standard, used as a reference for routine laboratory analysis