

Glossary of Terms

Active Ingredient

The therapeutically active component in a medicine's final formulation that is responsible for its physiological action.

Active Pharmaceutical Ingredient (API)

Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. 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.

Adverse Drug Reaction

A response to a medicine which is noxious and unintended, and which occurs at doses normally used in man. It concerns the response of a patient, in which individual factors may play an important role, and that the phenomenon is noxious (an unexpected therapeutic response, for example, may be a side effect but not an adverse reaction).

Alert Limit

Established criteria giving early warning of potential drift from normal conditions which are not necessarily grounds for definitive corrective action but which require follow-up investigation.

Authorized Person

The person recognized by the regulatory authority as having the necessary basic scientific and technical background and experience as well as the responsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the laws and regulations in force in that place.

Batch

A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous.

Batch Number

A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis, etc.

Batch Records

All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.

Bioavailability

The rate and extent at which the active pharmaceutical ingredient or active moiety is absorbed from a pharmaceutical dosage form and becomes available at the site(s) of action.

Bioequivalence

Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and their bioavailabilities, in terms of peak (C_{max} and T_{max}) and total exposure (area under the curve (AUC)), after administration in the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same.

Chemical Test

Test to identify the chemical content of the product to assess its quality.

Clinical Trial

A planned study in humans designed to investigate or report upon the efficacy/effectiveness and/or safety of a therapeutic good.

Computerised System

A system including the input of data, electronic processing and the output of information to be used either for reporting or automatic control.

Contamination

The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.

Drug or Medicine

Pharmaceutical product, used in or on the human body for the prevention, diagnosis or treatment of disease, or for the modification of physiological function.

Expiry Date

The date given on the individual container (usually on the label) of a product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.

Finished Product

A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling.

Generic Product

Pharmaceutical product, usually intended to be interchangeable with the

innovator product, which is usually manufactured without a licence from the innovator company and marketed after expiry of the patent or other exclusivity rights.

Good Manufacturing Practices (GMP)

That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

Hazard

A factor, an agent or a situation that endangers or poses a potential threat to human health.

Innovator Pharmaceutical Product

Generally the pharmaceutical product which was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality according to requirements at the time of the authorization. When a substance has been available for many years, it may not be possible to identify an innovator pharmaceutical product.

Labelling

Process of identifying a pharmaceutical product including the following information, as appropriate: name; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier.

Manufacture

All operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.

Manufacturer

A person or company who manufactures pharmaceutical products. It produces the product, or engages in any part of the process of producing the product or of bringing the product to its final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the product or of any component of ingredient of the product as part of that process.

Microbiology

A branch of science that refers to microbes of all of types, including bacteria, viruses, rickettsia, protozoa, fungi and prions. Derived words (such as microbiological) have a similar meaning.

Model

A pattern or replica of the same tests or behaviours.

Multisource (generic) Pharmaceutical Product

Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.

New Chemical (or Biological) Entities

Active ingredients that have not previously been authorized for marketing as a drug for use in humans in the country in question.

Pack Size

The size of the products in terms of the quantity contained in the container (e.g. volume in a multi-use container) and/or the number of items in the primary/unit pack (e.g. number of tablets in a bottle).

Pharmaceutical Inspection Co-operation Scheme (PIC/S)

An recognized arrangement between Regulatory Authorities in the field of GMP of medicinal products for human or veterinary use. It aims at harmonizing GMP inspection procedures, training to inspectors, facilitating co-operation and networking between competent authorities and mutual confidence.

Pharmaceutical Product

Any material or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state.

Primary Packaging

Product packaging that is in direct contact with the product, e.g. blister packaging.

Procedures

Description of the operations to be carried out, the precautions to be taken and measures to be applied directly or indirectly related to the manufacture of a medicinal products.

Procurement

The process of purchasing or otherwise acquiring any pharmaceutical product. It means the pre-selection of products and manufacturers through a procedure of qualification and continuous monitoring thereafter.

Product Recall

Product recall is a process of withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because the safety, efficacy and quality of the products could not be assured. The recall might be initiated by the manufacturer, importer, distributor or a

responsible agency.

Production

All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.

Quality Assurance

A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

Quality Control

Quality control covers all measures taken, including the setting of specification, sampling, testing and analytical clearance, to ensure that starting materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.

Quality System

An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

Quarantine

The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their use, rejection or reprocessing.

Registration Certificate

A legal document issued by the competent drug regulatory authority that establishes the registration status of the product.

Risk

The probability of harm or injury. It is most correctly applied to the predicted or actual frequency of occurrence of an adverse event of a drug or other hazard.

Risk Assessment

A systematic process of analysing information to estimate the likelihood of adverse effects that may result from exposure to a specific health hazards.

Risk Communication

The sharing of information about identification and control process of health hazards and decision of action between the decision maker and relevant stakeholders.

Secondary Packaging

Product packaging that is not in direct contact with the product, e.g. carton box packaging.

Shelf-life

The period of time during which a pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.

Side Effect

Any unintended effect of a pharmaceutical product occurring at doses

normally used in man, which is related to the pharmacological properties of the drug.

Specification

A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.

Stability

The ability of a pharmaceutical product to retain its chemical, physical, microbiological and biopharmaceutical properties within specified limits throughout its shelf-life.

Stability Tests

A series of tests designed to obtain information on the stability of a pharmaceutical product in order to define its shelf-life and utilization period under specified packaging and storage conditions.

Stakeholder

Any individual, group, or organization that can affect, be affected by, or perceive itself to be affected by an action or decision. Decision makers might also be stakeholders. Stakeholders can include the patient, healthcare professional, regulatory authority, and industry.

Standard Operating Procedure (SOP)

An authorized written procedure giving instructions for performing operations.

Sterile Product

Product which is free from germs or microorganisms

Supplier

Person or company providing pharmaceutical products on request. Suppliers include distributors, manufacturers or traders.

Tabletting

The process of compacting granules into tablets.

Tender

A procedure for procuring pharmaceutical products which puts a number of suppliers into competition. Purchasing is done on the basis of quotations submitted by the suppliers in response to a public notice.

Transparency

Defining policies and procedures in writing and publishing the written documentation; and giving reasons for decisions to the public.

Trial-run

The testing of a new measure in a fixed period to ascertain if the new measure achieves its intended outcomes before putting the new measure into mass production.

Validation

Action of proving, in accordance with the principles of Good Manufacturing Practice that any procedure, process, equipment, material, activity or system actually leads to the expected results.