**Active Pharmaceutical Ingredient (API)** can be defined as 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 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 body.

**Actual yield** means the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular probiotic product.

**Airlock** is an enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for use either by people or for goods and/or equipment.

**Assorted pack** means a package containing two or more individual packages of different/dissimilar probiotic products.

**Authorized person** is the person recognized by the national regulatory authority as having the responsibility for ensuring that each batch of finished product has been manufactured, tested or approved for release in compliance with the laws and regulations in force in that country.

**Batch number, lot number, or control number** means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, labeling, and/or holding of a batch or lot of probiotic product can be determined.

**Batch or lot** means a specific quantity of a probiotic product that is uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture.

**Batch records** means 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.
**Best before** means the date which signifies the end of the period under any stated storage conditions during which the product shall remain fully marketable and shall retain specific qualities for which specified expressed claims have been made. Beyond that date, the product may still be perfectly safe to consume or its quality may have diminished.

**Bulk pack** means a commodity of food packed in bulk for storage, transportation or selling to an intermediary to enable such intermediary for further processing or selling, distributing or delivering such commodity of food in smaller quantities, for sale to the consumer.

**Bulk products** represent any product that has completed all processing stages up to, but not including final packaging.

**Cell bank system** is a system whereby successive batches of a product are manufactured by culture in cells derived from the same master cell bank.

**Cell culture** refers to the result from the *in vitro* growth of cells isolated from multicellular organisms.

**Classification** is the arranging of organisms into taxonomic groups (taxa) on the basis of similarities or relationships.

**Clean area** is an area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants within the area.

**Consignment (Delivery)** is the quantity of a pharmaceutical(s) probiotic product, made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include materials belonging to more than one batch.

**Contact surface** means any surface that contacts a component or probiotic product, and those surfaces from which drainage onto the component or probiotic product, or onto surfaces that contact the component or probiotic product, occurs during the normal course of operations. Examples of contact surfaces include containers, utensils, tables, contact surfaces of equipment, and packaging.
Contamination is the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.

Cross contamination is contamination of a starting material, intermediate product or finished product with another starting material or product during production.

Culture media is any liquid or solid preparation made specifically for the growth, storage, or transport of microorganisms or other types of cells.

Date of manufacture means the date on which the probiotic product becomes the product as described.

Date of packaging means the date on which the probiotic product is placed in the immediate container in which it will be ultimately sold.

Finished product is a finished dosage form that has undergone all stages of manufacture including packaging in its final container and labeling.

Function claims are health claims that describe the physiological effects of probiotic products or product constituents on normal functions or biological activities of the body associated with health or performance.

Health claim means any representation in labeling or advertisement that states, suggests, or implies that a relationship exists between consumption of a probiotic product or product constituent and a person’s health.

Identification refers to the process of determining that a new isolate belongs to one of the established named taxa.

In process control includes checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment and equipment may also be regarded as a part of the in process control.
In process material means any material that is fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way for use in the manufacture of a probiotic product.

Industrial Pack means a packaged commodity purchased from the manufacturer/packer for further processing by the business operator/industrial consumer in order to make a finished product to be used by the end consumer.

Ingredient means any substance that is used in the manufacture of a probiotic formulation and that is intended to be present in the finished batch of the probiotic product.

Institutional Pack means a packaged commodity purchased from the manufacturer/packed for an institutional consumer for its own use or redistribution, but not for retail sale.

Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed graphic, perforated, stamped or impressed or securely affixed to the container, cover, lid or crown of any probiotic product package.

Labeling includes any written, printed or graphic matter that is present on the label accompanying the probiotic product.

Lot number or Code number or Batch number means the number either in numericals or alphabets or in combination thereof, representing the lot number or code number or batch number, being preceded by the words Lot No or Lot or Code number or Code or Batch No or Batch or any other distinguishing prefix by which the food can be traced in manufacture and identified in distribution.

Manufacture means all operations of purchase of materials and products, production, quality control (QC), release, storage and distribution of pharmaceutical probiotic products, and the related controls.

Manufacturer is generally a company that carries out operations such as production, packaging, repackaging, labeling and relabeling of probiotics.
**Master cell bank** is a culture of fully characterized cells distributed into containers in a single operation, processed together in such a manner as to ensure uniformity and stored in such a manner as to ensure stability. A master cell bank is usually stored at -70°C or lower.

**Master Formula** is a document or set of documents specifying the starting materials with their quantities and the packaging materials, together with the description of the procedures and precautions required to produce a specified quantity of a finished product as well as processing instructions, including the in process controls.

**Master record** is a document or set of documents that serve as a basis for the batch documentation (blank batch record).

**Master seed lot** is a culture of a micro-organism distributed from a single bulk into containers in a single operation in such a manner to ensure uniformity, prevent contamination and to ensure stability. A master seed lot in liquid form is usually stored at or below -70°C. A freeze dried master seed lot is stored at a temperature known to ensure stability.

**Multipiece package** means a package containing two or more individually packaged or labeled pieces of the same commodity of identical quantity, intended for retail either in individual pieces or packages as a whole.

**Nomenclature** is the assignment of names to the taxonomic groups according to rules.

**Packaging** includes all operations including filling and labeling, that a bulk product has to undergo in order to become a finished product.

**Packaging material** is any material, including printed material, employed in the packaging of probiotic product, but excluding any outer packaging used for transportation and shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

**Physical plant** means all or any part of a building or facility used for or in connection with manufacturing, packaging, labeling, or holding a probiotic product.
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*Prepackaged or Pre-packed food* means product, which is placed in a package of any nature, in such a manner that the contents cannot be changed without tampering it and which is ready for sale to the consumer.

*Principal display panel* in relation to a package means that part of total surface area of a label, which is intended or is likely to be displayed, and presented or shown to a customer under normal and customary conditions of display, sale or purchase of the commodity contained in the package.

*Production* includes all operations involved in the preparation of a probiotic product, from receipt of materials, through processing, packaging and repackaging, labeling and relabeling, to completion of the finished product.

*Qualification* means action of proving that any premises, systems and items of equipment work correctly and actually leads to expected results. The meaning of the word “validation” is sometimes extended to incorporate the concept of qualification.

*Quality assurance (QA)* refers to the processes and procedures that systematically monitor different aspects of a service, process or facility to detect, correct and ensure that quality standards are being met.

*Quality control (QC)* means a planned and systematic operation or procedure for ensuring the quality of a probiotic product.

*Quality control personnel* mean any person, persons, or group, within or outside of your organization, who you designate to be responsible for your quality control operation.

*Quality unit* is an organizational unit independent of production which fulfils both quality assurance and quality control responsibilities. This can be in the form of separate QA and QC units or a single individual or groups, depending upon the size and structure of the organization.

*Quarantine* is the status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a design is awaited on their release, rejection or reprocessing.
Reprocessing means using, in the manufacture of a probiotic product, clean, uncontaminated components or probiotics that have been previously removed from manufacturing and that have been made suitable for use in the manufacture of a probiotic product.

Reserve sample means a representative sample of product that is held for a designated period of time.

Retail pack or Retail unit means the smallest unit of probiotic product packaged individually that can be sold to the ultimate consumer.

Sanitize means to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer [4].

Seed lot system is a system according to which successive batches of a product are derived from the same master seed lot at a given passage level.

Self contained area is premise which provides complete and total separation of all aspects of an operation including personnel and equipment movement, with well established procedures, controls and monitoring. This includes physical barriers as well as separate air handling systems, but does not necessarily imply into distinct and separate buildings.

Species means collection of strains that have many features in common and that differs in a significant way from all other species.

Specifications are 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.

Standard operating procedure (SOP) is an authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g. equipment operation, maintenance and cleaning; validation; cleaning of
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premises; and environmental control; sampling and inspection). Certain SOPs may be used to supplement product–specific master and batch production documentation.

**Starting material** is any substance of a defined quantity used in the production of a probiotic product but excluding packaging materials.

**Strain** means the product of a succession of cultures derived from an initial single colony.

**Therapeutic claims** are claims that would bring a probiotic product into the definition of a drug or a natural health product (drug claims). These are claims about the diagnosis, treatment, mitigation or prevention of a disease, disorder abnormal physical state or its symptoms in humans, restoring or correcting organic functions in humans, and modifying organic functions in humans. Products that carry such claims are considered to be represented for “therapeutic use”.

**Use – by date** or **Recommended last consumption date** or **Expiry date** means the date which signifies the end of the estimated period under any stated storage conditions, after which product may not remain safe and the food shall not be consumed.

**Validation** is action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results.

**Water activity** (wa) is a measure of the free moisture in a component or probiotic product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

**Wholesale package** means

1. A number of retail packages, where such first mentioned package is intended for sale, distribution or delivery to an intermediary and is not intended for sale direct to a single consumer;
2. Packages containing two or more retail packs which is not intended to be sold as such to consumer but only after opening and individually as retail packs;
c) A commodity of probiotic product sold to an intermediary in bulk to enable such intermediary to sell, distribute or deliver such commodity of probiotic product to the consumer in smaller quantities.

**Working cell bank** is a culture of cells derived from the master cell bank and intended for use in the preparation of production cell cultures. The working cell bank is usually stored at -70°C.

**Working seed lot** is a culture of a micro-organism derived from the master seed lot and intended for use in production. Working seed lots are distributed into containers and stored as described above for master seed lots.