Bioprocess Glossary

Term	Definition
Bioinformatics	the science of using computer technology to gather, store, analyze and merge biological data
Biologics	a wide range of medicinal products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins created by biological processes
Biopharmaceuticals	ethical pharmaceutical drugs that are derived through bioprocessing
Bioprocessing	any process that uses complete living cells or their components (e.g., bacteria, enzymes, chloroplasts) to obtain desired products
Bioreactor	a closed system used for bioprocessing (flask, roller bottle, tank, vessel, or other container), which supports the growth of cells, mammalian or bacterial, in a culture medium.
Bulk Drug Substance (BDS)	pharmaceutical product derived by through bioprocessing or chemical synthesis, in bulk form, for later dispensing, formulation or compounding, and filling in a pharmaceutical finishing facility.
Cell Culture	the complex process by which cells are grown under controlled conditions.
Cell Lines	a permanently established cell culture that will proliferate indefinitely given appropriate fresh medium and space
Centrifugation	a process that involves the use of the centrifugal force for the separation of mixtures, used in industry and in laboratory settings
Centrifuge	an Instrument used for Centrifugation
Chromatography	collective term for a set of laboratory techniques for the separation of mixtures.
Cleanroom	an environment, typically used in manufacturing or scientific research that has a low level of environmental pollutants such as dust, airborne microbes, aerosol particles and chemical vapors.
Compound Libraries	the collections of compounds that provide a variety of chemically diverse structures that can be used to identify structure types that have affinity with pharmacological targets.
Contract Manufacturing Organization (CMO)	a firm that manufactures components or products for another "hiring" firm. It is a form of outsourcing. The practice of utilizing contract manufacturing relies on the manufacturer's ability to drive down the cost of production through economies of scale. It also allows the hiring company to obtain the needed components or products without needing to own and operate a factory.
Cytotoxic	term that refers to a compound that results in a variety of cell fates. The cells may undergo necrosis, in which they lose membrane integrity and die rapidly as a result of cell lysis. The cells can stop actively growing and dividing (a decrease in cell viability), or the cells can activate a genetic program of controlled cell death (apoptosis).
Cytotoxicity	the quality of being toxic to cells.
Diafiltration	See TFF.

DNA (Deoxyribonucleic Acid)	the molecular basis for genes; every inherited characteristic has its origin somewhere in the code of the organism's complement of DNA
Downstream Processing	the recovery and purification of biosynthetic products, particularly pharmaceuticals, from natural sources such as animal or plant tissue or fermentation broth, including the recycling of salvageable components and the proper treatment and disposal of waste. It is an essential step in the manufacture of pharmaceuticals such as antibiotics, hormones (e.g. insulin and human growth hormone), antibodies (e.g. infliximab and abciximab) and vaccines; antibodies and enzymes used in diagnostics; industrial enzymes; and natural fragrance and flavor compounds. Downstream processing is usually considered a specialized field in biochemical engineering.
Drug Manufacturing	the process of industrial-scale synthesis of pharmaceutical drugs by pharmaceutical companies
Elastomer	defined as the migration of electrically charged proteins, colloids, molecules, or other particles when dissolved or suspended in an electrolyte through which an electric current is passed. The most important use of electrophoresis is in the analysis of blood proteins and study bacteria and viruses
European Medicines Evaluation Agency (EMEA)	European agency for the evaluation of medicinal products
FDA Approval	approved by the Food and Drug Administration (FDA) for sale in the United States
FDA Compliance	conforming to a rule, such as a specification, policy, standard or law stated by U.S. FDA
Fermentation	he biochemical synthesis of organic compounds by microorganisms. It is the process of growing microorganisms within an enclosed tank (fermenter) under controlled conditions of aeration, agitation, temperature, and pH. The different types organisms used as a basis for fermentation are: bacteria (E. coli), yeasts, molds, Chinese Hamster Ovary (CHO) cells, kidney cells and vaccines to viruses.
Filtration	a mechanical or physical operation which is used for the separation of solids from fluids (liquids or gases) by interposing a medium through which only the fluid can pass.
Final Bulk Product	as the final drug product after chemical or biological processing and purification, ready for concentration, drying, and filling into containers prior to dispensing and final filling.
Finished Product	he medicinal product that has undergone all stages of production, including packaging in its final container. The specifications for release of the finished product must comply with the FDA regulations.
Flow Cytometry	analysis of biological material by detection of light-absorbing or fluorescing properties of cells or subcellular fractions (i.e., chromosomes) passing in a narrow stream through a laser beam. An absorbance or fluorescence profile of the sample is produced. Automated sorting devices, used to fractionate samples, sort successive droplets of the analyzed stream into different fractions depending on the fluorescence emitted by each droplet.

Food and Drug Administration (FDA)	an agency of the United States Department of Health and Human Services. The FDA is one of the United States federal executive departments, responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics.
Gene	a natural unit of hereditary material that is the physical basis for the transmission of the characteristics of living organisms from one generation to another.
Gene Expression	defined as the process by which a gene's coded information is converted into the structures present and operating in the cell. Expressed genes include those that are transcribed into mRNA and then translated into protein and those that are transcribed into RNA but not translated into protein.
Gene Family	a set of several similar genes, formed by duplication of a single original gene, and generally with similar biochemical functions.
Gene Sequencing	the determination of the sequence of bases in a DNA strand
Gene Therapy	the insertion of genes into an individual's cell and biological tissues to treat disease, such as cancer where deleterious mutant alleles are replaced with functional ones. Although the technology is still in its infancy, it has been used with some success. Scientific breakthroughs continue to move gene therapy toward mainstream medicine.
Generic Drugs	drugs produced and marketed under its chemical or "generic" name (e.g. acetaminophen) as opposed to "Tylenol", a brand name for the former produced by Johnson & Johnson. A generic drug can be sold only after a proprietary drug goes off patent
Generic Pharmaceutical	a drug which is produced and distributed without patent protection. The generic drug may still have a patent on the formulation but not on the active ingredient.
GMP Facility	a production facility or a clinical trial materials pilot plant for the manufacture of pharmaceutical products. It includes the manufacturing space, the storage warehouse for raw and finished product, and support lab areas. A GMP facility operates under the guidelines established by the CFR (Code of Federal Regulations) Title 21, Parts 225 (Current Good Manufacturing for Medicated Feeds - Subpart B), and Part 226
Good Manufacturing Practice (GMP)	part of a quality system covering the manufacture and testing of active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices. GMPs are guidelines that outline the aspects of production and testing that can impact the quality of a product. Many countries have legislated that pharmaceutical and medical device companies must follow GMP procedures
IBC (Intermediate Bulk Container)	(also known as a carboy) a container used for transport and storage of fluids and bulk materials. The construction of the IBC container and the materials used are chosen depending on the application, i.e. there are various types available in the market: plastic composite IBC Container, steel IBC Container and stainless steel IBC Container.

Immune Response	a bodily defense reaction that recognizes an invading substance (an antigen: such as a virus or fungus or bacteria or transplanted organ) and produces antibodies (humoral response) or particular types of cytotoxic lymphoid cells (cell-mediated response) specific against that antigen.
Immunoglobulin (Ig)	also known as Antibodies, are gamma globulin proteins that are found in blood or other bodily fluids of vertebrates, and are used by the immune system to identify and neutralize foreign objects, such as bacteria and viruses. They are typically made of basic structural units—each with two large heavy chains and two small light chains—to form, for example, monomers with one unit, dimers with two units or pentamers with five units. Antibodies are produced by a kind of white blood cell called a plasma cell. Five different antibody isotypes are known in mammals, which perform different roles, and help direct the appropriate immune response for each different type of foreign object they encounter.
Impurity	the substances inside a confined amount of liquid, gas, or solid, which differ from the chemical composition of the material or compound. Impurities are either naturally occurring or added during synthesis of a chemical or commercial product. During production, impurities may be purposely, accidentally, inevitably, or incidentally added into the substance.
In-vitro	Latin: within the glass) is a procedure performed not in a living organism but in a controlled environment, such as in a test tube or Petri dish.
In-vivo	(Latin for "within the living") is experimentation using a whole, living organism as opposed to a partial or dead organism, or an in vitro controlled environment. Animal testing and clinical trials are two forms of in vivo research. In vivo testing is often employed over in vitro because it is better suited for observing the overall effects of an experiment on a living subject.
Life Science	the study of living things. The life sciences comprise all fields of science that involve the scientific study of living organisms, like plants, animals, and human beings.
Lipids	a broad group of naturally occurring molecules which includes fats, waxes, sterols, fat-soluble vitamins (such as vitamins A, D, E and K), monoglycerides, diglycerides, phospholipids, and others. The main biological functions of lipids include energy storage, as structural components of cell membranes, and as important signaling molecules.
Mab (Monoclonal Antibody)	antibodies derived from a single source or clone of cells that recognize only one type of antigen. They are produced from hybridomas formed by the hybridization of two cells: a single antibody-producing cell and a cell that can be grown indefinitely in culture. Monoclonal antibodies have found markets in diagnostic kits and show potential for use in drugs and industrial purification processes.
Manufacturing Process (Biotechnology)	all manufacturing and storage steps in the creation of the finished product from the weighing of components through the storing, packaging, and labeling of the finished product, including, but not limited to, the following: Mixing, granulating, milling, molding, formulating, lyophilizing, tableting, encapsulating, coating, sterilizing, and filling

Medical devices	medical Device refers to any health care product that does not achieve its principal intended purposes by chemical action in or on the body or by being metabolized. The term "devices" also includes components, parts, or accessories of medical devices, diagnostic aids such as reagents, antibiotic sensitivity disks, and test kits for in vitro diagnosis of diseases and other conditions.
Microbial Barrier	prevents the migration of microbial contaminants. The tests used with microbiological barrier systems include air sampling, surface sampling, filter and air incinerator testing, and gas-tightness testing. Microbiological barrier systems can be classified according to purpose, size, and degree of containment. Sterilization and decontamination agents are used with barrier systems for initial or terminal treatment, for the treatment of supplies and equipment moved in or out of the system, and for the maintenance of its microbiological state during use (eg, sterile barrier. Paper strip on aqg)
Pharmaceutical Development	the design of a quality product and its manufacturing process to consistently deliver the intended performance of the product. The information and knowledge gained from pharmaceutical development studies and manufacturing experience provide scientific understanding to support the establishment of the design space, specifications, and manufacturing controls.
Phase I Clinical Trials	the first stage of testing in human subjects. Normally, a small (20-100) group of healthy volunteers will be selected. This phase includes trials designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a drug. These trials are often conducted in an inpatient clinic, where the subject can be observed by full-time staff. The subject who receives the drug is usually observed until several half-lives of the drug have passed. Phase I trials also normally include dose-ranging, also called dose escalation, studies so that the appropriate dose for therapeutic use can be found.
Phase II Clinical Trials	performed on larger groups (20-300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients. Phase II studies are sometimes divided into Phase IIA and Phase IIB. Phase IIA is specifically designed to assess dosing requirements (how much drug should be given). Phase IIB is specifically designed to study efficacy (how well the drug works at the prescribed dose(s)).
Phase III Clinical Trials	randomized controlled multicenter trials on large patient groups (300–3,000 or more depending upon the disease/medical condition studied) and are aimed at being the definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment. Because of their size and comparatively long duration, Phase III trials are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for chronic medical conditions.
Phase IV Clinical Trials	the safety surveillance (pharmacovigilance) and ongoing technical support of a drug after it receives permission to be sold. Phase IV studies may be required by regulatory authorities or may be undertaken by the sponsoring company for competitive (finding a new market for the drug) or other reasons (for example, the drug may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women, who are unlikely to subject themselves to trials). The safety surveillance is

	designed to detect any rare or long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase I-III clinical trials. Also known as Post Marketing Surveillance Trial
Polypropylene	(PP) is a thermoplastic polymer, made by the chemical industry and used in a wide variety of applications, including packaging, textiles (e.g. ropes, thermal underwear and carpets), stationery, plastic parts and reusable containers of various types, laboratory equipment, loudspeakers, automotive components, and polymer banknotes. An addition polymer made from the monomer propylene, it is rugged and unusually resistant to many chemical solvents, bases and acids.
Process Monitoring	the collection of information on the use of inputs, the progress of activities, and the way these are carried out. Process monitoring looks at why and how things have happened; it looks at relevance, effectiveness and the efficiency of processes. It involves stakeholders and beneficiaries in planning, in deciding what is to be monitored, and in developing and recording monitoring processes.
Process Validation	establishing, through documented evidence, a high degree of assurance that a specific process will consistently produce a product that meets its predetermined specifications and quality characteristics.
Process Validation Protocol	a documented plan for testing a pharmaceutical product and process to confirm that the production process used to manufacture the product performs as intended. This includes a review of process variables and operational limitations as well as providing the sampling plan under actual use conditions.
Production	the production of the drugs or chemicals in a pharmaceutical preparation that exert an effect pharmacologically. This includes all operations involved in the preparation of an API (Active Pharmaceutical Ingredient), from receipt of materials, through processing and packaging, to its completion as a finished API.
Purification	the removal of impurities of concern.
QA (Quality Assurance) Group	the group who interprets the GMP regulations and guidelines. The responsibilities of the QA group includes: perform pharmaceutical QA oversight (auditing, analytical data and document review/approval, and regulatory compliance), perform investigations and initiate corrective action, host and facilitate client/agency audits, possess excellent time m
QA and QC (Quality Assurance and Quality Control)	the various process management procedures employed to preserve and enhance the quality of products or services. It is a system of procedures, checks, audits, and corrective actions used to ensure that fieldwork and laboratory analysis during the drug investigation and must meet established standards.
QC (Quality Control)	a process by which entities review the quality of all factors involved in production. Quality control emphasizes testing of products to uncover defects, and reporting to management who make the decision to allow or deny the release, whereas quality assurance attempts to improve and stabilize production, and associated processes, to avoid, or at least minimize, issues that led to the defects in the first place.

QC (Quality Control) Group	the group who enforces the GMP regulations. Lead the laboratories towards attainment of FDA accreditation and maintain compliance on an ongoing basis to all relevant standards. QC group will manage all aspects of raw material, bulk and finished product/stability analytical testing in the relevant laboratories (chemistry and microbiology), manage all aspects of packaging components and testing, and the QC Inspection of filling & packaging lines, implement and monitor initiatives to improve efficiency and effectiveness in the Quality Control services and delivery.
Qualification	action of providing that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation. It is the entire process by which products are obtained from manufacturers or distributors, examined and tested, and then identified as a qualified products list.
Quality Assurance (QA)	a program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.
Reagent	a "substance or compound that is added to a system in order to bring about a chemical reaction or is added to see if a reaction occurs". Such a reaction is used to confirm the presence of another substance.
Recombinant Antibody	A Recombinant Antibody is defined as an antibody produced by genetic engineering. Recombinant antibody has significant advantages compared with the conventional antibody and there for its use becoming more popular today
Resistance (Filter)	the pressure drop across a filter at a stated flow and under given conditions
Reverse Osmosis	the reversal of osmosis to purify water. In osmosis, water diffuses through a semi permeable membrane from a region of higher concentration (such as pure fresh water) into one of lower concentration (such as a solution of water and salt). The flow of water can be reversed with an opposing pressure that exceeds osmotic pressure. With RO, water is forced out of the lower concentrated solution (such as the salt solution), leaving the solute (impurities) behind.
RNA	Ribonucleic Acid (RNA) is a biologically important type of molecule that consists of a long chain of nucleotide units.
Scale-up	to take a biopharmaceutical manufacturing process from the laboratory scale to a scale at which it is commercially feasible. It is to increase the size of something whilst maintaining proportion or to change a process in order to allow for greater quantities.
Solubility	the property of a solid, liquid, or gaseous chemical substance called solute to dissolve in a liquid solvent to form a homogeneous solution of the solute in the solvent.
Spectrophotometry	process in which light of known intensity and wavelength is passed through a solution and used to estimate the levels of substances dissolved in that solution. Different materials absorb light of specific wavelength and the more of that substance present, the more light of that wavelength will be absorbed. If we measure the amount of light of a particular wavelength which passes through the substance, we can calculate the amount absorbed and therefore estimate the levels of the material absorbing the light.
Sterile Engineering Design (Fermentation)	is the application of techniques to prevent contamination of a fermentation process by undesirable organisms.

Sterile Fluid-Path Packaging	the system of protective port covers and/or packaging designed to be used to ensure sterility of the portion of the device intended for contact with fluids.
Sterilisation Compatibility	the ability of the packaging material to both withstand the intended sterilization process and to allow attainment of the required conditions for sterilization within the final pack. Most commonly used sterilization methods are: ethylene oxide (EtO), gamma, electron-beam, steam (under controlled conditions), and plasma/hydrogen peroxide
Tamper-Evident Closure	lids for plastic and glass bottles used in the packaging and pharmaceutical industries. The closures are positioned mechanically and a seal needs to be broken in order to open them
Temperature Controlled Transportation	maintaining the temperature during transportation. Temperature controlled transportation is still one of the most challenging issues within the pharmaceutical supply chain. With regulatory requirements currently under review and expected to change, the need for up-to-date cold chain logistic solutions will be paramount.
Tissue Culture	growing mammalian cells in the laboratory in a tissue culture medium (in vitro). For example, this allows researchers to determine the effects of various chemicals on mammalian cells without experimenting directly on live animals or man
Toxicity	the degree to which a substance can damage an organism. Toxicity can refer to the effect on a whole organism, such as an animal, bacterium, or plant, as well as the effect on a substructure of the organism, such as a cell (cytotoxicity) or an organ (organotoxicity), such as the liver (hepatotoxicity).
Traceability	the completeness of the information about every step in a process chain. It is a prerequisite for trustworthy records, apart from data security. Traceability is the part of the laboratory data system audit trail that holds the evidence of who did what to a record and when.
U.S.P. (United States Pharmacopeia)	The official pharmacopeia of the United States, published dually with the National Formulary as the USP-NF. The United States Pharmacopeial Convention (usually also called the USP) is the nonprofit organization that owns the trademark and copyright to the USP-NF and publishes it every year. Prescription and over–the–counter medicines and other health care products sold in the United States are required to follow the standards in the USP-NF.
Ultrafiltration	Ultrafiltration (UF) is a type of filtration. Industries such as chemical and pharmaceutical manufacturing, food and beverage processing, and waste water treatment, employ ultrafiltration in order to recycle flow or add value to later products. UF's main attraction is its ability to purify, separate, and concentrate target macromolecules in continuous systems. UF does this by pressurizing the solution flow. The solvent and other dissolved components that pass through the membrane are known as permeate. The components that do not pass through are known as retentate. See TFF.
Upstream Processing	the first step in which biomolecules are grown, usually by bacterial or mammalian cell lines, in bioreactors. When they reach the desired density (for batch and fed batch cultures) they are harvested and moved to the downstream section of the bioprocess.

Vaccine	a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe or its toxins.
Validation	a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria.
Validation Protocol	a written plan describing the process to be validated, including production equipment and how validation will be conducted. A Validation Protocol is necessary to define the specific items and activities that will constitute a cleaning validation study.
Viral Clearance	the removal of viral contamination using specialized membranes (mostly proteins) or chromatography. In order to ensure that therapeutic drugs derived from certain sources are fully rid of any viral contamination, these protein solutions undergo viral clearance to inactivate or remove viral materials.