
GLOSSARY OF TECHNICAL TERMS

“ACCF”	American College of Cardiology Foundation
“acute coronary syndrome”	a set of signs or symptoms due to decreased blood flow in the coronary arteries such that part of the heart muscle is unable to function properly or dies, which often causes severe chest pain or discomfort
“ADCC”	antibody-dependent cell-mediated cytotoxicity, a mechanism of cell-mediated immune defense whereby an effector cell of the immune system actively lyses a target cell
“AE”	adverse event, any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment
“AHA”	American Heart Association
“AMPK”	adenosine monophosphate-activated protein kinase, an enzyme that plays a role in cellular energy homeostasis, largely to activate glucose and fatty acid uptake and oxidation when cellular energy is low
“ANDA”	Abbreviated New Drug Application, an application made in the United States for approval of a generic equivalent to an existing approved drug
“ANDS”	Abbreviated New Drug Submission, a submission filed in Canada for approval of a generic drug
“antibiotics”	a substance, such as penicillin or streptomycin, produced by or derived from certain fungi, bacteria and other microorganisms, or produced by chemical processes that can destroy or inhibit the growth of other microorganisms; widely used in the prevention and treatment of infectious diseases
“anticoagulant”	a class of drugs that work to prevent the coagulation (clotting) of blood and can be used <i>in vivo</i> as a medication for thrombotic disorders or in medical equipment which contact blood, such as test tubes, blood transfusion bags, and renal dialysis equipment
“anti-idiotypic”	an antibody that binds to the antigen-combining site of another antibody either suppressing or enhancing the immune response
“antithrombin III”	a kind of glycoprotein produced by the liver that inactivates several enzymes of the coagulation system

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“API”	active pharmaceutical ingredients, any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug. 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 or function of the body.
“autoimmune diseases”	diseases that arise from an abnormal immune response of the body against substances and tissues normally present in the body
“Baxter Incident”	an incident in 2008, where contamination in the heparin sodium API used in the heparin sodium injections sold by Baxter caused serious acute hypersensitivity reactions in patient
“BBR”	berberine, a compound extracted from several plants including European barberry, goldenseal, goldthread and Oregon grape
“BDL”	bile duct ligation, a surgical method used to induce liver fibrosis
“BE test”	pharmacokinetic testing to determine the similarity of two drugs that share the same desired outcome for patients
“BET”	bromodomain and extraterminal domain, a family of proteins that recognize acetylated chromatin through their bromodomains and help in regulating gene expression
“biosimilar”	a follow-on version of innovator biopharmaceuticals which are separately developed after patents protecting the innovator biopharmaceuticals have expired and have similar quality, safety and efficacy as the innovator biopharmaceuticals
“BLA”	Biologics License Application, a request from FDA for permission to introduce, or deliver for introduction, a biologic product into interstate commerce
“BRD”	Bromodomains, a family of evolutionary conserved protein-interaction modules that play key functions in chromatin organization and regulation of gene transcription
“Breakthrough Therapy Designation”	a process designed by the FDA to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)
“CA125”	Carbohydrate Antigen 125, a protein that in humans is encoded by the MUC16 gene

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“cardiovascular”	pertaining to the heart and blood vessels
“CCR5”	a protein on the surface of white blood cells that is involved in the immune system as it acts as a receptor for chemokines
“CD4”	Cluster of Differentiation 4, a glycoprotein found on the surface of immune cells such as T helper cells
“CD8”	Cluster of Differentiation 8, a transmembrane glycoprotein that serves as a co-receptor for the T-cell receptor
“CDMO”	Contract Development and Manufacturing Organization, a CMO that, in addition to comprehensive drug manufacturing services, also provide process development and other drug development services in connection with its manufacturing services
“CDP scheme”	Centralized Drug Procurement, a scheme under which drugs are procured in large quantities that generates effects of group buying and saves charges and fees in the distribution process, leading to a substantial decrease in drug prices
“Centralized Authorization Procedure”	a market authorization procedure in the EU, which allows the marketing-authorization holder to market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorization
“CGMP”	Current Good Manufacturing Practice, regulations enforced by the FDA on pharmaceutical and biotech firms to ensure that the products produced meet specific requirements for identity, strength, quality and purity
“CHD”	Coronary heart disease, a type of disease that develops when the major blood vessels that supply your heart with blood, oxygen and nutrients (coronary arteries) become damaged or diseased
“chemoimmunotherapy”	chemotherapy combined with immunotherapy
“chemotherapy”	treatment of cancer with chemical substances, chosen based on the type or stage of cancer
“CHF”	a chronic progressive condition that affects the pumping power of heart muscles
“CHO cell”	Chinese hamster ovary cell, an epithelial cell line derived from the ovary of the Chinese hamster, often used in biological and medical research and commercially in the production of therapeutic proteins
“CHP”	Chinese Pharmacopoeia, an official compendium of drugs compiled by the Pharmacopoeia Commission of the Ministry of Health of the PRC

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“CKD”	Chronic Kidney Disease, a slowly progressive (months to years) decline in the kidneys’ ability to filter metabolic waste products from the blood
“CLD”	cell line development
“CMC”	Chemistry and Manufacturing Control, chemistry, manufacturing and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CSO”	contract sales organization, a company that provide a series of services and solutions related to pharmaceutical marketing and sales activities under contracts with pharmaceutical or biotech companies
“CVD”	cardiovascular disease, a class of diseases that involve the heart or blood vessels
“depolymerisation”	the process of converting a polymer into a monomer or a mixture of monomers
“DM”	diabetes mellitus, a disorder in which blood sugar (glucose) levels are abnormally high because the body does not produce enough insulin to meet its needs
“DMF”	drug master files, submissions to FDA used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products
“DTRPAP”	a synthetic peptide derived from Human MUC1, which corresponds to amino acid
“DVT”	deep vein thrombosis, which occurs when a blood clot forms in one or more of the deep veins in human body, usually in legs
“E. coli”	a kind of bacteria normally live in the intestines of healthy people and animals
“endotoxin”	a type of pyrogen and a component of the exterior cell wall of Gram-negative bacteria
“enoxaparin” or “enoxaparin sodium”	an anticoagulant medication used to treat and prevent DVT and pulmonary embolism including during pregnancy and following certain types of surgery
“enzymolysis”	decomposition catalyzed by an enzyme

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“EP standards”	European Pharmacopoeia standards, a catalog which lists all the reference standards officially valid for uses prescribed in the European Pharmacopoeia monographs, promulgated by EDQM
“EudraVigilance”	a system for managing and analyzing information on suspected adverse reactions to medicines which have been authorized or being studied in clinical trials in the EEA, which is operated by EMA
“factor IIa”	an enzyme formed in shed blood that converts fibrinogen into fibrin by hydrolyzing peptides of L-arginine
“factor Xa”	activated factor X, an enzyme of the coagulation cascade which is synthesized in the liver and requires vitamin K for its synthesis
“Fast Track Designation”	a designation by FDA of an investigational drug for expedited review to facilitate development of drugs which treat a serious or life-threatening condition and fill an unmet medical need
“Fc γ ”	a tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system. This property allows antibodies to activate the immune system
“fibrin”	a fibrous, non-globular protein involved in the clotting of blood, which is formed by the action of the protease thrombin on fibrinogen which causes it to polymerize
“fibrosis”	the formation of excess fibrous connective tissue in an organ or tissue in a reparative or reactive process
“first-in-class drug”	a drug with a new and unique mechanism for treating a medical condition
“generic drug”	a drug that is no longer under patent protection, which may be produced by any manufacturer which follows good manufacturing protocols
“glycoprotein”	proteins having covalently bound carbohydrate, which play a part in important cellular functions like cell-cell recognition, immune functions, and pathogen identification. Glycoproteins have a close association with serious human diseases like cancer, rheumatoid arthritis, and immunodeficiency diseases
“glycosaminoglycan”	a family of high sulfated, complex, polydisperse linear polysaccharides that display a variety of important biological roles
“Grade A”	a level of cleanroom cleanliness under which the maximum amount of 5 μm particles per cubic meter at rest is 20
“Grade B”	a level of cleanroom cleanliness under which the maximum amount of 5 μm particles per cubic meter at rest is 29

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“Grade C”	a level of cleanroom cleanliness under which the maximum amount of 5µm particles per cubic meter at rest is 2,900
“Grade D”	a level of cleanroom cleanliness under which the maximum amount of 5µm particles per cubic meter at rest is 29,000
“GxP”	general abbreviation for the “good practice” quality guidelines and regulations. The “x” stands for various specific fields, including “M” for “Manufacturing,” “C” for “Clinical,” “D” for “Distribution,” “E” for “Engineering,” and “L” for “Laboratory,” etc.
“HAMA”	human anti-mouse antibodies, an antibody found in humans which reacts to immunoglobins found in mice
“HAP”	hospital-acquired pneumonia, a lung infection that develops in people who have been hospitalized, typically after about 2 days or more of hospitalization
“heparanase”	an enzyme that acts both at the cell-surface and within the extracellular matrix to degrade polymeric heparan sulfate molecules into shorter chain length
“heparin”	an anticoagulant used to decrease the clotting ability of the blood and help prevent harmful clots from forming in blood vessels, including heparin sodium and heparin calcium
“heparin sodium”	the sodium salt form of heparin
“HDL”	high-density lipoprotein, one of the major groups of lipoproteins, which are complex particles composed of multiple proteins which transport all fat molecules (lipids) around the body within the water outside cells
“hypercholesterolemia”	the presence of high levels of cholesterol in the blood
“IC”	immune complex, a molecule formed from the integral binding of an antibody to a soluble antigen
“ICH”	International Council for harmonization of Technical Requirements for Pharmaceuticals for Human Use
“idiotype”	the molecular structure and conformation of an antibody that confers its antigenic specificity
“IFN- γ”	a dimerized soluble cytokine that is the only member of the type II class of interferons
“IgG1”	one type of the most common class of antibody, Immunoglobulin G, which includes IgG1, IgG2, IgG3 and IgG4
“immunology”	a branch of biology that covers the study of immune systems in all organisms
“immunotherapy”	the treatment of disease by activating or suppressing the immune system

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“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“injectable finished dose”	pharmaceutical drug products that can be injected into human body in the form in which they are marketed for use, with a specific mixture of active ingredients and inactive components
“IQVIA database”	a database for pharmaceutical sales and marketing operated by IQVIA, a public company incorporated in the U.S. and listed on NYSE
“IRB”	a committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical
“IU”	international unit, an internationally accepted amount of a substance
“K-M analysis”	Kaplan-Meier analysis, a non-parametric statistic used to estimate the survival function from lifetime data
“LDL-c”	low-density lipoprotein cholesterol, the amount of cholesterol which is estimated to be contained with low-density lipoprotein particles, using a formula on average
“LMWH”	low molecular weight heparin, a class of antithrombotic agents with relatively more anti-Xa activity, greater bioavailability at low doses, longer half-life, and more predictable anticoagulant response when administered in fixed doses, compared with unfractionated heparin
“LPS”	lipopolysaccharide is an integral component of the <i>P. aeruginosa</i> cell envelope
“lymphocyte”	white blood cells that are also one of the body’s main types of immune cells
“mAb”	monoclonal antibody, which is an antibody generated by identical immune cells that are all clones of the same parent cell
“MACE”	major adverse cardiac events, a composite endpoint frequently used in cardiovascular research, comparable to the composite endpoint all-cause mortality
“mega”	a unit prefix in metric system of units denoting a factor of one million

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“methotrexate”	a chemotherapy agent and immune system suppressant used to treat cancer, autoimmune diseases, ectopic pregnancy, and for medical abortions
“MRCT”	multi-regional clinical trial
“meropenem”	a broad-spectrum antibiotic used to treat a variety of bacterial infections
“MRSA”	methicillin-resistant <i>S. aureus</i> , a type of staph bacteria that has become resistant to the effects of many common antibiotics
“MSC”	mesenchymal stem cells, multipotent stromal cells that can differentiate into a variety of cell types
“MSSA”	methicillin-sensitive <i>S. aureus</i> , a type of staph bacteria that is not resistant to certain antibiotics
“MUC1”	a membrane-associated glycoprotein detected in most epithelial tissues and is highly expressed in the pancreas and breast
“NASH”	non-alcoholic steatohepatitis, the liver inflammation and damage caused by a buildup of fat in the liver
“NDA”	New Drug Application, the vehicle in the United States through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing
“NFLD” or “NAFLD”	non-alcoholic fatty liver disease, a very common disorder and refers to a group of conditions where there is accumulation of excess fat in the liver of people who drink little or no alcohol
“NRDL”	China’s National Reimbursement Drug List
“oncology”	the study and treatment of tumors
“orphan drug”	a pharmaceutical agent that has been developed specifically to treat a rare medical condition
“Orphan Drug Designation”	a designation to medicines developed for rare condition
“OS”	overall survival, the length of time from either the date of diagnosis or the start of treatment for a disease, such as cancer, that patients diagnosed with the disease are still alive.
“OSCS”	oversulfated chondroitin sulfate, a contaminant in heparin associated with adverse clinical events

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“p”	P-value, the probability of obtaining test results at least as extreme as the results actually observed during the statistical hypothesis test, assuming that the null hypothesis is correct
“P. aeruginosa”	opportunistic pathogens that frequently cause hospital-acquired infections, particularly in ventilator patients, burn patients, and patients with chronic debility
“PAI”	FDA pre-approval inspection, which is performed to contribute to FDA’s assurance that a manufacturing establishment named in a drug application is capable of manufacturing a drug, and that submitted data are accurate and complete
“pancreatin”	a combination of digestive enzymes (proteins), which are normally produced by the pancreas and are important for digesting fats, proteins, and sugars
“PARP”	poly (ADP-ribose) polymerase, a family of proteins involved in numerous cellular processes, mostly involving DNA replication and transcriptional regulation, which plays an essential role in cell survival in response to DNA damage
“PCI”	percutaneous coronary intervention, a non-surgical procedure used to treat narrowing of the coronary arteries of the heart
“PCSK9”	proprotein convertase subtilisin/kexin type 9, an enzyme encoded by the PCSK9 gene in humans on chromosome 1
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages. The normal function of PD-1 is to turn off the T cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of a T cell attaches to certain proteins on the surface of a normal cell or a cancer cell, the T cell turns off its ability to kill the cell
“pDNA”	a small, circular, double-stranded DNA molecule that is distinct from a cell’s chromosomal DNA
“PFS”	progression-free survival, the length of time during and after the treatment of a disease that a patient lives with the disease but it does not get worse

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“pharmacovigilance”	the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem
“PK”	pharmacokinetics, a branch of pharmacology dedicated to determine the fate of substances administered to a living organism
“poly (I:C)”	polyinosinic:polycytidylic acid, an immunostimulant used in the form of its sodium salt to simulate viral infections
“poly ICLC”	a synthetic complex of carboxymethylcellulose, polyinosinic-polycytidylic acid, and poly-L-lysine double-stranded RNA
“polymerization”	a process of reacting monomer molecules together in a chemical reaction to form polymer chains or three-dimensional networks
“polysaccharide”	long chains of carbohydrate molecules
“PSC”	primary sclerosing cholangitis, inflammation with progressive scarring and narrowing of the bile ducts in and outside the liver
“pulmonary embolism”	the blocking of an artery of the lung by a collection of solid material brought through the bloodstream, usually a blood clot or rarely other material
“puromycin”	an antibiotic protein synthesis inhibitor which causes premature chain termination during translation
“QCE”	quality consistency evaluation, a process conducted by NMPA to evaluate quality consistency of composition and clinical efficacy between the generic drug and originator drug
“RCT”	reverse cholesterol transport, a multi-step process resulting in the net movement of cholesterol from peripheral tissues back to the liver first via entering the lymphatic system, then the bloodstream
“R&D”	research and development
“RegIII α ”	regenerating islet-derived protein 3 alpha, also known as PAP, a protein encoded by the REG3A gene
“SAE”	serious adverse event, any untoward medical occurrence in a patient during clinical trials that results in death, is life-

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	threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect
“S. aureus alpha-toxin”	the major cytotoxic agent released by bacterium <i>S. aureus</i> and first identified member of the pore forming beta-barrel toxin family
“SOC”	standard of care, treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
“standard heparin”	as used in the section entitled “Industry Overview” has the same meaning as heparin
“STEMI”	ST-elevation myocardial infarction, a type of heart attack during which one of the heart’s major arteries is blocked
“T cell”	a type of lymphocyte which develops in the thymus gland and plays a central role in the immune response
“TEAE”	treatment emergent adverse event, undesirable events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment
“thrombosis”	formation of a blood clot inside a blood vessel, obstructing the flow of blood through the circulatory system
“TTCP”	time to clinical progression, the length of time from the date of diagnosis or the start of treatment for a disease until the disease starts to get worse or spread to other parts of the body.
“UDCA”	ursodexycolic acid, one of the secondary bile acids, which are metabolic byproducts of intestinal bacteria
“USP”	United States Pharmacopeia, a pharmacopeia for the United States published annually by the United States Pharmacopeial Convention
“VAP”	ventilator associated pneumonia, a type of lung infection that occurs in people who are on mechanical ventilation breathing machines in hospitals
“virtual biotech companies”	early-stage biotech companies that have few or no tangible assets and employees, with intellectual properties as their primary assets, and outsource most of their operations to third-party contractors, such as CRO and CDMO.
“VTE”	venous thromboembolism, a blood clot that starts in a vein