GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain technical terms used in this document in connection with us and our business. These may not correspond to standard industry definitions and may not be comparable to similar terms adopted by other companies.

"ADC"	antibody-drug conjugate, a class of targeted biopharmaceutical that combines the target specificity of a monoclonal antibody with the cytotoxicity of a small-molecule drug through a chemical linker, enabling selective delivery of the cytotoxic payload to tumor cells
"antibody"	a protective protein produced by the immune system in response to a foreign substance, or a therapeutic molecule engineered to bind specifically to a target antigen for the treatment or prevention of disease
"bioconjugate"	a molecule formed by the covalent attachment of a biomolecule, such as an antibody or protein, to another chemical entity, including a drug, toxin, label or polymer, to create a therapeutic or diagnostic agent
"bioreactor"	a vessel or system designed to support a biologically active environment for the cultivation of cells, microorganisms, or tissues under controlled conditions, used in biologics manufacturing for upstream production
"biosimilar"	a biologic product that is highly similar to and has no clinically meaningful differences from an existing approved reference biologic product in terms of quality, safety and efficacy
"bispecific antibody"	an engineered antibody or antibody fragment capable of simultaneously binding two different antigens or two distinct epitopes on the same antigen, enabling novel mechanisms of action
"BLA"	biologics license application
"CAGR"	compound annual growth rate, the mean annual growth rate of an investment or business metric over a specified period of time longer than one year, assuming steady growth compounded each year
"CAPA"	corrective action and preventive action, a systematic approach within a quality management system to investigate non-conformances, identify root causes, implement corrective measures for existing issues and preventive measures to avoid recurrence

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"CDMO"	contract development and manufacturing organization, a service provider that offers integrated drug development and manufacturing services to pharmaceutical and biotechnology companies on a contract basis across the product lifecycle
"cell line"	a defined population of cells derived from a single progenitor cell that can be stably maintained in culture and used for the consistent production of recombinant proteins or other biologics
"cell line development"	the process of engineering, selecting and characterizing a host cell line to stably express a target recombinant protein at commercially viable levels with appropriate quality attributes
"chromatography"	a separation technique used in downstream processing to purify target biomolecules from complex mixtures based on differential partitioning between a stationary phase and a mobile phase, including affinity, ion-exchange and size-exclusion chromatography
"CMC"	chemistry, manufacturing and controls, the body of information that defines the identity, strength, quality, purity and potency of a drug product, and describes the manufacturing process, specifications and control strategies submitted to regulatory authorities
"CMO"	contract manufacturing organization, a service provider that offers drug manufacturing services to pharmaceutical and biotechnology companies on a contract basis
"conjugation"	the chemical process of covalently linking a cytotoxic drug payload to an antibody or other targeting moiety, typically via a linker, to produce an antibody-drug conjugate or other bioconjugate
"CPP"	critical process parameter, a process parameter whose variability has an impact on a critical quality attribute and therefore must be monitored and controlled to ensure the process produces the desired product quality
"CPV"	continued process verification, the ongoing monitoring and evaluation of a manufacturing process during commercial production to ensure it remains in a state of control, as required under ICH and GMP guidelines

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"CQA"	critical quality attribute, a physical, chemical, biological or microbiological property or characteristic that must be within an appropriate limit, range or distribution to ensure the desired product quality
"deviation"	a departure from an approved instruction, procedure, specification or established standard within a quality management system, which must be documented, investigated and resolved in accordance with applicable GMP requirements
"DoE"	design of experiments, a structured statistical methodology used in process development to systematically evaluate the relationships between multiple input factors and output responses, enabling efficient process characterization and optimization
"downstream processing"	the series of unit operations in biologics manufacturing that follow the bioreactor production step, including product recovery, purification by chromatography, viral inactivation and removal, concentration, and formulation, to isolate and purify the target molecule to required specifications
"DP"	drug product, a finished dosage form, such as a vial, prefilled syringe or lyophilized cake, that contains the drug substance formulated with excipients and is ready for administration to patients
"DS"	drug substance, the active pharmaceutical ingredient or bulk purified biologic material prior to formulation into the final drug product
"EMA"	European Medicines Agency, the regulatory agency of the European Union responsible for the scientific evaluation, supervision and safety monitoring of medicines for human and veterinary use
"EU QP"	European Union Qualified Person, a professional certified under EU legislation who is responsible for certifying that each batch of medicinal product has been manufactured and tested in compliance with EU GMP requirements before its release to the market

"FDA"	the U.S. Food and Drug Administration, the federal agency of the United States Department of Health and Human Services responsible for protecting public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products and medical devices
"FFS"	fee-for-service, a commercial model under which a CDMO charges customers based on the specific services performed, materials consumed and resources utilized for a given project, as opposed to fixed-price or risk-sharing arrangements
"fill-finish"	the aseptic process of filling a sterile drug product into its final primary container, such as a vial, syringe or cartridge, and completing the sealing, labeling and packaging operations in a controlled environment
"formulation"	the composition and process by which a drug substance is combined with excipients to produce a stable, safe and efficacious drug product suitable for its intended route of administration
"fusion protein"	a recombinant protein created by genetically fusing two or more genes or gene fragments that originally coded for separate proteins, designed to combine functional domains with distinct therapeutic properties
"GMP"	good manufacturing practice, a system of regulations, codes and guidelines governing the production of pharmaceutical, biologic and medical device products to ensure they are consistently produced and controlled according to quality standards
"ICH"	the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, which brings together regulatory authorities and the pharmaceutical industry to develop harmonized scientific and technical guidelines for drug development and registration
"IND"	investigational new drug application, a regulatory submission filed with a competent authority, such as the FDA or NMPA, seeking authorization to administer an investigational drug to human subjects in clinical trials

"linker"	a chemical moiety used in antibody-drug conjugates to covalently attach the cytotoxic payload to the antibody, designed to be stable in circulation while releasing the payload upon internalization into target cells
"lyophilization"	freeze-drying, a low-temperature dehydration process in which a drug product is frozen and then subjected to a vacuum to remove water by sublimation, commonly used to enhance the stability and shelf-life of biologic drug products
"media"	the nutrient solution used in cell culture to support the growth, metabolism and productivity of cells in a bioreactor; includes base media and supplemental feeds
"modality"	a classification of therapeutic agents based on their molecular format and mechanism of action, including monoclonal antibodies, bispecific antibodies, antibody-drug conjugates, fusion proteins and recombinant proteins
"molecular type"	the structural and functional category of a therapeutic molecule, such as monoclonal antibodies, bispecific antibodies, ADCs, fusion proteins, enzymes and peptides
"multispecific antibody"	an engineered antibody capable of binding to three or more different antigens or epitopes simultaneously, designed to achieve novel mechanisms of action beyond those of monospecific and bispecific antibodies
"NDA"	new drug application, a comprehensive regulatory submission to the FDA seeking approval to market a new drug in the United States, containing data from preclinical and clinical studies together with CMC information
"NMPA"	National Medical Products Administration, the regulatory authority of the People's Republic of China responsible for the supervision and approval of drugs, medical devices and cosmetics, including GMP inspections and marketing authorization
"PAI"	pre-approval inspection, a critical evaluation conducted by regulatory agencies, such as the FDA, to ensure that a manufacturing site can produce a drug product according to the required standards before it is approved for market release

"payload"	the cytotoxic drug molecule attached to an antibody via a linker in an antibody-drug conjugate, designed to be released inside target cells to induce cell death
"PPQ"	process performance qualification, the stage of process validation in which the manufacturing process as designed and qualified is evaluated to confirm that it is capable of reproducible commercial manufacturing that consistently meets all predefined acceptance criteria
"process characterization"	the systematic study of a manufacturing process to identify and understand the relationships between process parameters and product quality attributes, establishing proven acceptable ranges and supporting the definition of a control strategy
"process development"	the systematic design, optimization and scale-up of a manufacturing process for a biologic product, encompassing cell line development, upstream and downstream process development, formulation and analytical development
"process validation"	the collection and evaluation of data from the process design stage through commercial production to establish scientific evidence that a process is capable of consistently delivering a product meeting its predetermined quality attributes
"QA"	quality assurance, the systematic activities and functions within a quality management system that ensure processes are adequate for a product to meet quality requirements, focused on preventing defects through process oversight
"QbD"	quality by design, a systematic approach to pharmaceutical development that begins with predefined objectives and emphasizes product and process understanding, process control and risk management throughout the product lifecycle
"QC"	quality control, the laboratory testing and operational activities performed to verify that materials, intermediates and finished products conform to established specifications and quality standards

"recombinant protein"	a protein produced by genetically engineered host cells into which the gene encoding the target protein has been introduced, enabling the large-scale production of therapeutic proteins that are otherwise difficult to isolate from natural sources
"resin"	the solid-phase chromatographic medium used in downstream processing to selectively capture or separate target biomolecules from process impurities, including Protein A resins for antibody purification and ion-exchange resins for polishing steps
"stainless-steel bioreactor"	a fixed, reusable bioreactor constructed of stainless steel, designed for large-scale commercial manufacturing of biologics, offering high durability, scalability to 6,000 L and above, and established cleaning and sterilization protocols
"viral clearance"	a set of dedicated unit operations, such as low-pH inactivation, solvent/detergent treatment and nanofiltration, designed to remove or inactivate potential viral contaminants during the downstream processing of biologic products, as required by ICH and regulatory guidelines