

GLOSSARY OF TECHNICAL TERMS

This glossary of technical terms contains explanations of certain technical terms used in this document. As such, these terms and their meanings may not correspond to standard industry meanings or usage of these terms.

“ADC”	antibody-drug conjugates, a drug composed of an antibody linked to a cytotoxic drug via a chemical linker to treat cancer
“Ancillary” or “AMP”	auxiliary medicinal products used for the needs for clinical trials, but not as an investigational medicinal product
“biospecimen”	a sample of biological material, such as blood, tissue, saliva, DNA, or urine, from living organisms, collected for medical research, diagnostics, or drug development, to understand diseases, develop personalized medicine and treatments
“CAGR”	compound annual growth rate, a measurement used to determine the annual growth rate of an investment or market size over a specified period of time longer than one year
“CAPA”	a corrective and preventive action, a systematic approach to eliminating causes of non-conformities or other undesirable situations to prevent their recurrence
“CAR-T”	an immunotherapy that genetically that modifies a patient’s own T-cells to recognize and treat cancers
“CDMO”	a contract development and manufacturing organization, which is a company that serves pharmaceutical companies on a contract basis to provide services from drug development through drug manufacturing
“CGT”	cell and gene therapy, an advanced medical treatment that modify a patient’s own cells or introduce new cells or genes to correct genetic defects, reprogram cellular function, or fight diseases like cancers
“Clinical Depot”	a specialized, highly regulated storage and distribution center for clinical trial materials, acting as a central hub for investigational drugs, supplies and samples

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“CRO”	a contract research organization, which is a company that services pharmaceutical companies on a contract basis to manage all or part of their clinical trials and drug development
“DFP”	direct-from-patient services, which involve collecting biological samples for central labs and unused investigational medicinal product or supplies from patients in clinical trials to go back to the site, pharmacy, or depot
“DTP”	direct-to-patient services, which involve delivering medications, including IMPs and ancillaries to the patient themselves, a nurse, or caregiver
“EPS”	expanded polystyrene, a rigid, closed cell, thermoplastic foam material produced from solid beads of polystyrene
“GAMP5”	Good Automated Manufacturing Practice, Version 5, which is an internationally recognized standard providing guidelines for the validation of automated systems used in pharmaceutical manufacturing and clinical operations
“GDP”	Good Distribution Practice, a set of quality system ensuring pharmaceutical products maintain their quality, integrity, and safety throughout the entire supply chain, from raw materials to the patient, covering storage, transport, and handling to prevent counterfeiting, contamination, or deterioration through strict guidelines on temperature control, traceability, and personnel training
“GMP”	good manufacturing practices, which include measures for both production and quality control and general measures to ensure that processes necessary for production and testing are clearly defined, validated, reviewed, and documented, and that the personnel, premises and materials are suitable for the production of pharmaceuticals and biologicals
“GSP”	Good Supply Practice, a set of quality management standards specifically for the commercial distribution and warehousing of pharmaceutical products to ensure quality during circulation

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“GxP”	Good Practice, a general term for quality guidelines and regulations (such as GMP, GDP, and GSP) used to ensure product safety and quality throughout the pharmaceutical lifecycle
“IMP”	an investigational medicinal product, which is being tested or used as a reference in clinical trials
“IND”	an investigational new drug application, which is a request for authorization from the competent authority to administer an investigational drug or biological product to humans
“IoT”	Internet of Things, a network of physical objects embedded with sensors and software to connect and exchange data for real-time monitoring and tracking
“IVD”	in vitro diagnostics, which are tests done on blood or tissue samples to detect diseases or other conditions, and can be used to monitor a person’s overall health to help cure, treat, or prevent diseases
“R&D”	research and development
“microservices”	an architectural and organizational approach to software development where software is composed of small independent services that communicate using APIs, and these services are owned by small, self-sufficient teams
“MRCT”	multiregional clinical trial, a single clinical study run in multiple countries or regions under one protocol
“mRNA”	messenger RNA, a type of single-stranded RNA involved in protein synthesis
“NMPA”	National Medical Products Administration, the Chinese agency responsible for drug supervision and administration
“PCM”	phase change materials, which are substances that absorb and release thermal energy as they change from solid to liquid or liquid to solid at a specific temperature
“SITE”	a clinical trial site, usually being a hospital, research center, or medical facility, where the clinical trial activities are conducted

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“SOP”	Standard Operating Procedure, a set of step-by-step instructions compiled by an organization to help workers carry out complex routine operations
“TMS”	Transportation Management System, a logistics platform that helps businesses plan, execute, and optimize the physical movement of goods
“VIP”	vacuum insulated panel, a form of thermal insulation consisting of a gas-tight enclosure surrounding a rigid core, from which the air has been evacuated
“W/m·K” or “Watts per meter-Kelvin”	a unit of thermal conductivity that measures how well a material conducts heat
“WHO”	World Health Organization
“WMS”	Warehouse Management System, a software application designed to optimize warehouse functionality and distribution center management