Glossary

Definitions

ALCOA - attributable, legible, contemporaneous, original and accurate.

ALCOA+ has four additions: Complete, Consistent, Enduring and Available

Abbreviated New Drug Application (ANDA): An Abbreviated New Drug Application is an application for a U.S. generic drug approval for an existing licensed medication or approved drug. The ANDA is submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, which provides for the review and ultimate approval of a generic drug product.

Antibody: An antibody is a large, Y-shaped protein used by the immune system to identify and neutralize foreign objects such as pathogenic bacteria and viruses known as antigen.

Antigen: An antigen is any a substance from the environment, such as chemicals, bacteria, viruses, or pollen that causes the immune system to produce antibodies against it.

Biologics: A biologic drug is a product that is produced from living organisms or contain components of living organisms. Biologic drugs include a wide variety of products derived from human, animal, or microorganisms by using biotechnology.

Cancer: A term for diseases in which abnormal cells divide without control and can invade nearby tissues.

Carcinogen: A carcinogen is a substance, organism or agent capable of causing cancer.

Cell line: Cells of a single type (human, animal, or plant) that have been adapted to grow continuously in the laboratory and are used in research.

Chromatography: Chromatography is the physical process of separating or analyzing complex mixtures. Chromatography is used in industrial processes to purify materials, test trace amounts of contaminants, isolate chiral compounds and quality control test products.

DNA-encoded chemical libraries (DEL): It is a technology for the synthesis and screening at scale of collections of small molecule compounds. The aim of DEL technology is to accelerate the drug discovery process and in particular early phase discovery activities such as target validation and hit identification.

DEREK Nexus™: A statistical-based software platform used in toxicity prediction.

Drug metabolism: Biotransformation of pharmaceutical substances in the body so that they can be eliminated more easily.

Electronic Laboratory Notebook (ELN): A computer program designed to replace paper laboratory notebooks. They are used by scientists and technicians to document research, experiments, and procedures performed in a laboratory.

ELISA (Enzyme-Linked Immunosorbent Assay): It is a commonly used laboratory test to detect antibodies in the blood. An antibody is a protein produced by the body's immune system when it detects harmful substances, called antigens.

GEMBA walks: Gemba walks denote the action of managers going to see the actual process, understand the work, ask questions, and learn.

Globally Harmonized System (GHS): GHS defines and classifies the hazards of chemical products and communicates health and safety information on labels. It ensures information on the hazardous properties of chemicals are properly communicated to enhance the protection of human health and the environment during the handling, transport and use of chemicals.

High-throughput screening (HTS): A drug discovery process that allows automated testing of large numbers of chemical and/or biological compounds for a specific biological target.

HTS methods are extensively used in the pharmaceutical industry, leveraging automation to quickly test the biological or biochemical activity of a large number of molecules, usually drugs. They accelerate target analysis, as large-scale compound libraries can quickly be screened in a cost-effective way.

Highly potent active pharmaceutical ingredients (HPAPIs): They are pharmacologically active substances that exhibit biological activity at extremely low concentrations.

In Vivo: In vivo refers to research or work is done with or within an entire, living organism.

In Vitro: In vitro refers to a medical study or experiment which is done in the laboratory within the confines of a test tube or laboratory dish.

Insilico tools: In biology and other experimental sciences, it means experimentation performed by computer.

Knockout mice: They are genetically modified organism and have a gene that is depleted or silenced to cause a loss of gene function.

Kaizen: a Japanese business philosophy of continuous improvement of working practices.

Large molecule: Large molecules are therapeutic proteins. They are also known as biologics.

m-RNA: In molecular biology, messenger ribonucleic acid is a single-stranded molecule of RNA that corresponds to the genetic sequence of a gene, and is read by a ribosome in the process of synthesizing a protein.

Mammalian: Relating to mammals.

Monoclonal Antibodies (mAb): These are produced in labs and engineered to bind specific targets such as antigens located on cancer cells.

Mutagen: A mutagen causes change in the DNA of a cell (mutation), which may harm cells and cause certain diseases, such as cancer.

NGS: Next generation sequencing is a sequencing technology used to determine the order of nucleotides in entire genomes or targeted regions of DNA or RNA,

Nanoparticle drug delivery systems are engineered technologies that use nanoparticles for the targeted delivery and controlled release of therapeutic agents.

qPCR (quantitative PCR) allows monitoring of amplification of any double-stranded DNA sequence

Oligonucleotides: Oligonucleotides are short DNA or RNA molecules that have a wide range of applications in genetic testing, research, and forensics. Commonly made in the laboratory these small bits of nucleic acids are vital for artificial gene synthesis, polymerase chain reaction (PCR), DNA sequencing, molecular cloning and as molecular probes.

Orthotopic tumor model: These involve the seeding of tumor cell lines or patient-derived cell xenografts into animal models

Pharmacology: Pharmacology is the study of how a drug affects a biological system and how the body responds to the drug.

Pharmacokinetics: The branch of pharmacology concerned with the movement of drugs within the body.

Research Informatics: Combination of Bioinformatics and Cheminformatics capabilities.

RT-PCR: The reverse transcription–polymerase chain reaction (RT PCR) is a nuclear-derived method for detecting the presence of specific genetic material in any pathogen, including a virus.

SOC is treatment that is accepted by medical authorities as a suitable treatment for a certain type of disease and that is widely used by healthcare professionals.

SQDECC – an acronym representing the six elements of operational excellence: safety, quality, delivery, engagement, compliance and cost.

Spheroids tumor model: These are simple, widely used multicellular 3D models that form due to the tendency of adherent cells to aggregate. They can be generated from a broad range of cell types such as embryos, liver and neural cells.

Target validation: Target validation is the first step in discovering a new drug. The process involves the application of a range of techniques that aim to demonstrate that drug effects on the target can provide a therapeutic benefit with an acceptable safety window.

T-cells: T cells are part of the immune system and develop from stem cells in the bone marrow. They help protect the body from infection and may help fight cancer.

Toxicology: Used to characterize the toxicity profile of a drug by identifying its impact on organ structure and / or functionality. This includes assessment of the severity and reversibility of toxicity, as well as dose ranges and their relationship to exposure.

Tumor: An abnormal mass of tissue that forms when cells grow and divide more than they should or do not die when they should. Tumors may be benign (not cancer) or malignant (cancer)

Vaccine: Vaccine is preparation that reduce risks of getting a disease by stimulating the body's immune response against diseases

Abbreviations

Active Pharmaceutical Ingredient (API): Any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

Contract Research Organization (CRO): These organizations provide support to a range of industrial sectors engaged in discovery research and development of large and small molecules.

CLM: Complete List of Materials

DS: Drug Substance

Good Clinical Practice (GCP): GCP is an international quality standard for conducting clinical trials that in some countries is provided by ICH, an international body that defines a set of standards, which governments can then transpose into regulations for clinical trials involving human subjects.

Good Laboratory Practice (GLP): Set of rules and criteria for a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, reported and archived.

HPLC: High Performance Liquid Chromatography (HPLC) is a form of column chromatography that pumps a sample mixture or analyte in a solvent (known as the mobile phase) at high pressure through a column with chromatographic packing material (stationary phase).

ICH Guidelines: ICH Guidelines were created by The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH aims to provide uniform standards for technical requirements for pharmaceuticals for human use.

ICMR: The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world.

National Accreditation Board for Testing and Calibration Laboratories (NABL): It is a constituent board of quality council of India. The objective of NABL is to provide third party assessment of the quality and technical competence of testing and calibration laboratories. Government of India has authorized NABL as the accreditation body for Testing and Calibration Laboratories.

National GLP Compliance Monitoring Authority (NGCMA): Industries/test/ facilities/laboratories dealing with above chemicals and looking for approval from regulatory authorities before marketing them, may apply to the National GLP Compliance Monitoring Authority for obtaining GLP Certification. It is voluntary by nature.

NDA: New Drug Application (NDA) is the vehicle in the United States through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing.

ORABS: Open Rigid Access Barrier System

pH: Hydrogen ion concentration

United States Food and Drug Administration (US FDA or FDA): Federal agency of the United States Department of Health and Human Services. FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.