



EUROPEAN ASSOCIATION OF
PHARMA BIOTECHNOLOGY

Acronyms and Definitions

A

ADE/AE	Adverse Drug Event/Adverse Event – Any unfavorable and unintended symptom, occurrence or experience that a clinical trial subject experiences during the clinical trial; may or may not be considered related to the study agent.
ADME	Absorption, Distribution, Metabolism and Excretion – Used to describe the Pharmacokinetic process.
ADR	Adverse Drug Reaction – Unwanted or harmful reaction following the administration of a drug or combination of drugs under normal conditions of use and suspected to be related to the drug.
AMC	Advanced Market Commitment (financing tool for vaccine development for developing countries)
ANADA	Abbreviated New Animal Drug Application (see ANDA below).
ANDA	Abbreviated New Drug Application – Shortened version of a New Drug Application (NDA) that may be submitted for approval of a new formulation of an existing drug or investigational drugs that are similar to already approved drugs (used for generic drug products).
API	Active Pharmaceutical Ingredient (or Drug Substance) – 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, becomes an active ingredient of the drug product.
AQL	Acceptable Quality Level.
Autologous Use (GTP)	Means the implantation, transplantation, infusion or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.
AWA	Animal Welfare Act – Codified at 9 CFR Part 2, the USDA regulations for the care and use of animals for research in the US.

B

BA/BE	Bioavailability/Bioequivalence
BIND	Biological Investigational New Drug.
BLA	Biologics License Application

C

Calibration	The demonstration that a particular instrument or device produces results within specified limits by comparison with results produced by a reference or traceable standard over an appropriate range of measurements.
CAPA	Corrective and Preventive Action – a systematic approach to correct, prevent and eliminate the cause of potential nonconforming product and other quality problems. “Corrective” refers to a reaction or an activity meant to correct a nonconformance that has already occurred. “Preventive” refers to an action or activity meant to prevent recurrence of a nonconformance.
CBER	FDA Center for Biologics Evaluation and Research
CDER	FDA Center for Drug Evaluation and Research
CDRH	FDA Center for Devices and Radiological Health
CFR	Code of Federal Regulations – The general and permanent rules published in the U.S. Federal Register (FR) by the Executive Department and agencies of the U.S. federal government.
CMC	The Chemistry, Manufacturing and Controls section of a regulatory submission to FDA.
CRA/CRC	Clinical Research Associate/Clinical Research Coordinator
CRF	In clinical studies, a case report form
CRO	Contract Research Organization
CSR	A Clinical Study Report
CTD	Common Technical document – A standard format for submitting information required for new product applications in the U.S. EU and Japan. The CTD is organized into five modules: M1 – country specific information; M2 – common technical documents summaries; M4Q - Quality; M4S – nonclinical study reports; and M4E – clinical study reports.
CVM	FDA Center for Veterinary Medicine

D

Drug Product/ Drug Substance	The dosage form in the final immediate packaging intended for marketing/the active ingredient of the drug product (API)
Donor (GTP)	Means person, living or dead, who is the source of cells or tissue for an HCT/P

E

EC	The European Commission
EIR	Establishment Inspection Report – the summary of the FDA Investigator/Safety Officer inspection of an establishment.
EPA	The U.S. Environmental Protection Agency
EMA	The European Medicines Agency – Responsible for coordinating the scientific evaluation of the safety, efficacy and quality of human and veterinary drug products that undergo the Centralized Procedure and for arbitration during the Mutual Recognition Procedure.

EU	The European Union
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F

FDA	The U.S. Food and Drug Administration
FFDCA	The Federal Food, Drug and Cosmetic Act of 1938
FOI/FOIA	Freedom of Information/Freedom of Information Act of 1966 – Established the rights of private citizens to obtain information from federal government agencies.
FR	Federal Register – Published daily, Monday through Friday; carries all proposed and finalized regulations and many significant legal notices issued by various federal agencies, as well as presidential proclamations and executive orders.

G

GCP	Good Clinical Practices – the regulations and requirements with which manufacturers, sponsors, clinical investigators, Institutional review Boards and the product must comply while conducting a clinical study.
GCLP	“Good Clinical Laboratory Practice” as discussed in BARQA proposed guideline.
GDP	Good Documentation Practices
GLP	Good Laboratory Practice – Standards for laboratories that conduct safety tests.
GMP	Good Manufacturing Practice – The part of quality assurance that ensures products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use.
GTP	Good Tissue Practice – The regulations and requirements for using Human Cells, Tissues and/or Cellular and Tissue-Based Products (HCT/P)
GXP	Good [Pharmaceutical] Practices – Good Manufacturing, Laboratory, Documentation, Clinical and Tissue Practices – a generic term.

H

HTA	Health Technology Assessment
HCT/P (GTP)	Human cells, tissues or cellular or tissue-based products – articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient.
Homologous (GTP)	The repair, reconstruction, replacement or supplementation of a recipient’s cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor
HPB	Health Protection Branch – The Canadian equivalent of the U.S. FDA

I

IACUC	Institutional Animal Care and Use Committee – Required by US law (9 CFR Part 2) for all institutions using laboratory animals for research or instructional purposes to oversee and evaluate all aspects of the institution’s animal care and use program.
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IC/ICD	Informed Consent/Informed Consent Document – The process by which a subject voluntarily confirms his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed Consent is documented by means of a written, signed and dated form.
ICH	International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use - A joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs. Participants include the US, EU and Japan; observers include Australia and Canada.
IDE	Investigational Device Exemption – Allows companies to sell and use a limited number of devices for investigational purposes and clinical studies.
IEC	Independent Ethics Committee – An independent body (a review board of a committee, institutional, regional, national or supranational) constituted of medical/scientific professionals and nonmedical/nonscientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of subjects involved in a clinical trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities and the methods and materials to be used in obtaining and documenting informed consent of the trial subjects.
INAD/ INADA	Investigational New Animal Drug/Investigational New Animal Drug Application
IND/INDA	Investigational New Drug//Investigational New Drug Application
IRB	Institutional (Independent) Review Board – required by GCP standards, a committee that reviews and approves clinical trial protocols/conduct, through prior and periodic review to ensure subject risks are minimized, selection is equitable, informed consent is properly conducted, adequate monitoring is provided, confidentiality is protected and safeguards are available to protect the rights and welfare of vulnerable subjects.
IVD	In Vitro Device/In Vitro Diagnostic
IVP	Investigational Veterinary Product

M

MHW	Ministry of Health and Welfare – Japan’s equivalent to the FDA
MIC/MBC	Minimum Inhibitory Concentration/Minimum Bactericidal Concentration
MHRA	Medicines and Healthcare Products Regulatory Agency

N

NADA	New Animal Drug Application – An application requesting FDA approval to market a new drug for animal use in interstate commerce.
NCE/NME	New chemical Entity/New Molecular Entity
NDA	New Drug Application – An application requesting FDA approval to market a new drug for human use in interstate commerce
NICE	National Institute for Health and Clinical Excellence

O

OECD	Organization for Economic Cooperation and Development – An international organization of developed countries that accept the principles of representative democracy and a free market economy to: support sustainable economic growth; boost employment; raise living standards; maintain financial stability; assist other countries' economic development; and contribute to growth in world trade.
OEM	Original Equipment Manufacturer
OTC	Over the counter – drugs available without prescription

P

PD	Pharmacodynamics – the study of the effects of the drug on the body and the mechanisms by which it acts (what the drug does to the patient.)
PI	Principle Investigator
PK	Pharmacokinetics – Study of the processes of absorption, distribution, metabolism and excretion (ADME) of chemicals and medicines.
PLA	Product License Application

Q

QA	Quality Assurance – those planned and systematic actions established to ensure that tests are performed and data generated are documented and reported in compliance with applicable regulatory requirements.
QAU	Quality Assurance Unit – group within an organization charged with carrying out the Quality Assurance duties.
QC	Quality Control – the operational techniques and activities undertaken within the QA system to verify that quality requirements have been fulfilled.
Quality Audit	A documented, independent inspection and review of an establishment's activities related to core regulatory requirements. The purpose of the quality audit is to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review.
QMS	Quality Management System – Formalized business practices that define management responsibilities for organizational structure, processes, procedures and resources needed to fulfill product/service requirements, customer satisfaction and continual improvement.
Qualification	Action of proving and documenting 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 validation

R

Recovery (GTP)	Obtaining from a human donor cells or tissues that are intended for use in human implantation, transplantation, infusion or transfer
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S

SAE	Serious Adverse Event – Any undesirable experience associated with the use of a healthcare product in a patient where the outcome is death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly or requires intervention to prevent permanent impairment or damage.
SOP	Standard Operating Procedure – Detailed, written instructions to achieve uniformity of the performance of a specific function.

T

TK	Toxicokinetics – A subfield of toxicology that studies how toxins are absorbed by, metabolized by and eliminated from the bodies of living organisms.
Transfer (GTP)	The placement of human reproductive cells or tissues into a human recipient
TTP	Time to progression

U

UAE	Unexpected Adverse Event – An AE whose nature or severity is not described in the Investigator’s Brochure (for an approved product) or in the package insert (for an approved product).
USDA	United States Department of Agriculture

V

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.
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled
VICH	International Cooperation of Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products