



# List of abbreviations

## Medical Affairs international

## Regulatory & Compliance

AGES	Austrian Agency for Health and Food Safety
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (German Federal Institute for Drugs and Medical Devices)
CA	Competent Authority (regulatory body monitoring EU member state compliance)
CAPA	Corrective and Preventive Actions
CDA	Confidential Disclosure Agreement
CFR	Code of Federal Regulations
DIA	Drug Information Association
DGRA	German Society for Regulatory Affairs
eCTD	Electronic Common Technical Document
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GxP	General term for 'Good Practice' quality guidelines (GMP, GCP, GLP, etc.)
ICH	International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
SmPC	Summary of Product Characteristics

## Drug Development & Approval

510(k)	Medical Device Premarket Notification (US FDA)
ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredient
ATMPs	Advanced Therapy Medicinal Products

BLA	Biologic License Application
CAT	Committee for Advanced Therapies
IND	Investigational New Drug
NDA	New Drug Application

## Clinical Research & Trials

ATP	According-to-Protocol
CCI	Committee on Clinical Investigations
CIOMS	Council for International Organizations of Medical Sciences
COL	Clinical Operations Leader
Cochrane	Cochrane Collaboration
CONSORT	Consolidated Standards of Reporting Trials
CRA	Clinical Research Associate
CRO	Contract Research Organization
CSR	Clinical Study Report
CTA	Clinical Trial Application
CTR	Clinical Trial Regulation
DFG	German Research Foundation (Deutsche Forschungsgemeinschaft)
EudraCT	European Clinical Trial Database
IB	Investigator's Brochure
IPRO	Independent Pharmaceutical Research Organization
IRB	Institutional Review Board
IVRS	Interactive Voice Response System
LREC	Local Research Ethics Committee (UK)

NIS	Non-interventional studies
PI	Principal Investigator
RCT	Randomised Controlled Trial

## Pharmacovigilance & Safety

ADR	Adverse Drug Reaction
AE	Adverse Event
DMC	Data Monitoring Committee
DMF	Drug Master File
ICSR	Individual Case Safety Report
MedDRA	Medical Dictionary for Regulatory Activities
PSMF	Pharmacovigilance System Master File
PSP	Patient Support Programme
PSUR	Periodic Safety Update Report
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
RMP	Risk Management Plan

## Pharmacokinetics & Pharmacology

ADME	Absorption, Distribution, Metabolism, Excretion
AUC	Area Under the Curve
C <sub>max</sub>	Maximum Plasma Concentration
CYP	Cytochrome P (enzyme system)
PD	Pharmacodynamics
PK	Pharmacokinetics

$t_{1/2}$	Half-life
Vd	Apparent Volume of Distribution

## Medical & Laboratory Terms

ADD	Acceptable Daily Dose
ADME	Adsorption, Distribution, Metabolisierung, Elimination
ATCC	European Commission
BA	BioavailabilityBCS Biopharmaceutical Classification System
BE	Bioequivalence
CBC	Complete Blood Count
CNS	Central Nervous System
CSF	Cerebrospinal Fluid
CT	Computed Tomography
CrCl	Creatinine Clearance
DDD	Defined Daily Dose
DDL	Dear Doctor Letter
DNA	Deoxyribonucleic Acid
WBC	White Blood Cell

## Regulatory Agencies & Bodies

ACRP	Association of Clinical Research Professionals
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CHMP	Committee for Medicinal Products for Human Use
EMA	European Medicines Agency

FDA Food and Drug Administration (US)

PEI Paul-Ehrlich-Institut

## Medical Affairs Specific

CME Continuing Medical Education

DOL Digital Opinion Leader

DMP Disease-Management-Programm

HCP Healthcare Professional

HEOR Health Economics and Outcomes Research

HTA Health Technology Assessment

IIS Investigator-Initiated Study

KOL Key Opinion Leader

KPI Key Performance Indicator

MIR Medical Information Request

MSL Medical Science Liaison

MSS Market Surveillance Studies

OTC Over-the-Counter

RWD Real World Data

RWE Real World Evidence

SoP Standard Operating Procedure

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