

COMMON INDUSTRY ACRONYMS & ABBREVIATIONS

[Last updated 24 November 2010]

AADA, Abbreviated Antibiotic Drug Application
AAPS, American Association of Pharmaceutical Scientists
ABPI, Association of the British Pharmaceutical Industry
ACTD, ASEAN Common Technical Dossier (see **ASEAN**)
ADME, Absorption, Distribution, Metabolism and Excretion/Elimination (also **AME**, Absorption, Metabolism, Excretion/Elimination)
AE, adverse event
AERS, Adverse Event Reporting System (US FDA)
Afssaps, French Health Products Safety Agency (Agence Française de Sécurité Sanitaire des Produits de Santé)
ANDA, Abbreviated New Drug Application
API, active pharmaceutical ingredient
AQL, acceptable quality level
ASEAN, Association of Southeast Asian Nations
ASMF, Active Substance Master File
ATMP, Advanced therapy medicinal product
AVEG, AIDS Vaccine Evaluation Group

BfARM, Federal Institute for Drugs and Medical Devices (Bundesinstituts für Arzneimittel und Medizinprodukte)
BIO, Biotechnology Industry Organization (US)
BLA, Biologic License Application (US)
BPC, bulk pharmaceutical chemicals
BPWP, Blood Products Working Party (European Medicines Agency)
BWP, Biotech Working Party (European Medicines Agency)

CA, competent authority
CADREAC, Collaboration Agreement between Drug Regulatory Authorities of European Union Associated Countries (also, **nCADREAC**, new Collaboration Agreement)
CANDA, Computer Assisted New Drug Application
CAPs, Centrally Authorised Products
CAT, Committee for Advanced Therapies (European Medicines Agency)
CAVDRI, Collaboration Agreement between Veterinary Drug Registration Institutions
CBER, Center for Biologics Evaluation and Research (US FDA)
CC, candidate country
CCDS, company core data sheet
CCSI, company core safety information
CDER, Center for Drug Evaluation and Research (US FDA)
CDRH, Center for Devices and Radiological Health (US FDA)
CEE, Central and Eastern Europe
CGLP, Current Good Laboratory Practice
CGMP, Current Good Manufacturing Practice
CHMP, Committee for Medicinal Products for Human Use (European Medicines Agency)
CMC, chemistry, manufacturing, and controls
CMD(h), Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (European Medicines Agency)
CMD(v), Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (European Medicines Agency)

CMS, Concerned member state (EU)
COMP, Committee for Orphan Medicinal Products (European Medicines Agency)
CP, Centralised Procedure (EU)
CPMP, Committee for Proprietary Medicinal Products (European Medicines Agency)
CRF, case report form
CSP, core safety profile
CTA, clinical trial application, **but also:**
CTA, clinical trial authorisation, **and also:**
CTA, clinical trial assay
CTD, Common Technical Document [Dossier*]
*Although 'Dossier' has become commonplace, the correct term is 'Document', **but also:**
CTD, Clinical Trials Directive
CTMS, Clinical Trial Management System
CTX, Clinical Trial Exemption
CVMP, Committee for Medicinal Products for Veterinary Use (European Medicines Agency)

DIA, Drug Information Association
DCP, Decentralised procedure (EU)
DDPS, Detailed Descriptions of Pharmacovigilance System
DES, Data Exchange Standard (EU)
DHPC, Direct Healthcare Professional Communication (formerly 'Dear Doctor Letter')
DLP, data lock point
DMF, drug master file
DP, drug product
DRA, drug regulatory authority
DRF(S), dose range finding (study)
DS, drug substance
DSUR: Drug safety update report

EBE, European Biopharmaceutical Enterprises
EC, European Commission, **but also:** Ethics Committee
ECHAMP, The European Coalition on Homoeopathic and Anthroposophic Medicinal Products
eCTD, electronic Common Technical Document [not Dossier*] *Although 'Dossier' has become commonplace, the correct term is 'Document'
EDC, electronic data capture
EDQM, European Directorate for the Quality of Medicines & HealthCare
EDMF, European drug master file
EEA, European Economic Area
EEC, European Economic Community
EFPIA, European Federation of Pharmaceutical Industries and Associations
EOF, Greece's regulatory agency (Ethnikos Organismos Farmakon – aka National Organization for Medicines)
EMA, European Medicines Agency (formerly European Medicines Evaluation Agency, **EMEA**)
EMEA, see above (as of December 2009, the Agency styles itself 'the European Medicines Agency' or 'the Agency', with the abbreviation 'EMA' being adopted by most media)
EMRC, European Medical Research Councils (a unit of the **ESF**, see below)
EPAR, European Public Assessment Report
EPL, Effective patent life
EPRG, European Pharmacovigilance Research Group
ERB, Ethical review board
ERMS, European Risk Management Strategy
ESF, European Science Foundation

ESRA, European Society of Regulatory Affairs
EU, European Union
EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EUREC, European Network of Research Ethics Committees
EVM, European Vaccine Manufacturers
EVPM, EudraVigilance post-authorisation module
EWG, Expert Working Group
EWP, Efficacy Working Party (European Medicines Agency)

Farmindustria, the Association of Italian Pharmaceutical Manufacturers
FDA, the Food and Drug Administration (the US regulatory authority)
FDAAA, FDA Amendments Act
FIH, first-in-human (aka **FIM**, first-in-man; and **FTIM**, first-time-in-human)
FPIF, The Finnish Pharmaceutical Industry Association
FrP, The French Pharmacopoeia (Pharmacopée Française, aka **PF**)
FU, Farmacopea Ufficiale, the Italian Pharmacopoeia

GCP, Good Clinical Practice
GDP, Good Distribution Practice
GLP, Good Laboratory Practice
GMP, Good Manufacturing Practice, **but also: GMP**, Good Management Practice
GPMS, Good Postmarketing Surveillance Practice (Japan)
GPP, Good Paediatric Practice
GpvP, Good Pharmacovigilance Practice
GRB, Global Regulatory Board
GSP, Good Statistics Practice
GTWP, Gene Therapy Working Party
GxP, general term for Good Practice quality guidelines and regulations, where *x* is the symbol for the variable descriptor

HDE, Humanitarian Device Exemption
HHS, US Department of Health and Human Services
HMA, Heads of Medicines Agencies (EU)
HMPC, Committee on Herbal Medicinal Products (European Medicines Agency)
HTA, Health Technology Assessment
HTS, high-throughput screening

IB, Investigator's Brochure
IC, informed consent
ICDRA, International Conference of Drug Regulatory Authorities
ICH, International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICSR, Individual Case Safety Report
IDE, Investigational Device Exemption
IDR, Idiosyncratic Drug Reaction
IEC, Independent Ethics Committee
IFAH, International Federation for Animal Health
IFPMA, International Federation of Pharmaceutical Manufacturers and Associations
IGZ, the Netherlands Healthcare Inspectorate
IMB, Irish Medicines Board
IMDA, Irish Medical Device Association
IMP(D), investigational medicinal product (dossier)

INADA, investigational new animal drug application
IND(A), investigational new drug (application)
INDC, Investigational New Drug Committee
INFARMED, Instituto Nacional da Farmacia e do Medicamento (Portugal's regulatory agency)
INN, International Approved Names for Pharmacopoeial Substances
IPU, Irish Pharmaceutical Union
IQM, Integrated Quality Management
IRB, institutional review board (aka Independent Ethics Committee (**IEC**) or Ethical Review Board (**ERB**))
IRC, Institutes Review Committee
IRD, International Registration Document
ISE, Integrated Summary of Efficacy
ISO, International Standards Organisation
ITT, intent-to-treat
IVD, *in vitro* device; **but also** *in vitro* diagnostics
IWP, Immunologicals Working Party (European Medicines Agency)

JPMA, Japan Pharmaceutical Manufacturers Association

LAT, Light Authoring Tool (EU)

MA, marketing authorisation
MAA, marketing authorisation application
MAH, marketing authorisation holder
MABEL, minimal anticipated biological effect level
MDD, Medical Device Directive
MDR, Medical Device Reporting
MDV, Medical Device Vigilance
MedDevs, Guidances outlining the requirements of the Medical Devices Directive
MedDRA, Medical Dictionary for Regulatory Activities
MHRA, Medicines and Healthcare products Regulatory Agency (UK's regulatory body)
MLD, minimal lethal dose
MRA, Mutual Recognition Agreement
MRI, mutual recognition information
MRD, multiple rising dose
MRFG, Mutual Recognition Facilitation Group (European Medicines Agency)
MRP, Mutual Recognition Procedure (EU)
MS, Member state/s (EU), **but also**:
MS, Mass spectrometry
MTD, maximum tolerated dose
MUMS, Minor use in minor species

NADA, New Animal Drug Application (US)

NAS, new active substance (preferred to NCE or NME)

NB, Notified Body (EU)

NBE, new biological entity

NCA, national competent authority

NCE, new chemical entity

NDA, new drug application (US)

NDS, new drug submission (Canada)

NeeS, Non eCTD electronic submission

NICE, National Institute for Health and Clinical Excellence (formerly without the 'for Health',

hence the acronym)

NIH, National Institutes of Health

NME, new molecular entity

NOEL, no observable effect level

NOAEL, no observable adverse effect level

NSA, National Security Agency (US)

NSAIDs, nonsteroidal anti-inflammatory drugs

NTA, Notice to Applicants (EC)

OCP, The Office of Combination Products (US FDA)

ODA, Orphan Drugs Act (US)

OTC, over-the-counter

OMCL, Official Medicines Control Laboratories (part of **EDQM**)

OOPD, Office of Orphan Products Development (US FDA)

ORA, Office of Regulatory Affairs (US FDA)

PAB, Pharmaceutical Affairs Bureau (Japan)

PAL, Pharmaceutical Affairs Law (Japan)

PAT, Process analytical technology

PCWP, Patients' and Consumers' Working Party

PD, pharmacodynamics

PDCO, Paediatric Committee (European Medicines Agency)

PDMA, Prescription Drug Marketing Act (US)

PDUFA, Prescription Drug User Fee Act (US)

PECA, Protocol to the Europe Agreement on Conformity Assessment and Acceptance of industrial products

PEI, Paul-Ehrlich-Institut, a division of Germany's Federal Ministry of Health

PERF, Pan European Regulatory Forum

PgWP, Pharmacogenics Working Party

Ph Eur, European Pharmacopoeia

PhRMA, The Pharmaceutical Research and Manufacturers of America

PhVWP, Pharmacovigilance Working Party (European Medicines Agency)

PI, principal investigator

PIC, Pharmaceutical Inspection Convention (EU)

PICS, Pharmaceutical Inspection Cooperation Scheme (EU)

PIL, patient information leaflet

PIM, Product Information Management (European Medicines Agency)

PIP, Paediatric investigation plan

PK, pharmacokinetics

PL, Package leaflet

PLA, Product License Application (for biologics) (US)

PMDA, Japan's regulatory agency, the Pharmaceutical and Medical Devices Agency (within the Ministry of Health, Labor and Welfare, **MHLW**)

P-RMS, PSUR Reference Member State (also see **PSUR**)

PMS, postmarketing surveillance

PPI, patient package insert (US)

PRS, PIM Review System (EU)

PSUR, periodic safety update report

PUMA, Paediatric-use marketing authorisation

PV, pharmacovigilance

QA, quality assurance
QALY, quality-adjusted life year
QbD, quality by design
QC, quality control
QOL, quality of life
QP, Qualified Person
QPPV, Qualified Person for Pharmacovigilance
QRD, Quality Review of Documents [template]
QWP, Quality Working Party (European Medicines Agency)

RA, Regulatory affairs
RADAR, Risk Assessment of Drugs Analysis and Response
RAPS, Regulatory Affairs Professionals Society (US)
REMS, risk evaluation and mitigation strategy
RiskMAP, risk minimisation action plan
RLD, Reference Listed Drug (US)
RMP, risk management plan, **BUT ALSO:**
RMP, Reference Medicinal Product (RMP)
RMS, Reference Member State (Europe)
RSI, Reference Safety Information/Request for Supplementary Information
RTF, Refusal-to-file (US)

S+T, sampling and testing
SAE, serious adverse event
SAG, Scientific Advisory Group
SAP, scientific advice procedure
SAR, serious adverse reaction
SAWP, Scientific Advice Working Party
SFDA, (China's) State Food and Drug Administration **but also:**
SFDA, Saudi Food & Drug Authority
SmPC, Summary of Product Characteristics (aka **SPC**)
SMF, Site Master File
SMO, Site Management Organisation
SNDA, supplemental new drug application (US)
SOCRA, Society of Clinical Research Associates (US-based)
SOP, standard operating procedure
SPC, Summary of Product Characteristics (European Medicines Agency), **but also:**
SPC, supplementary protection certificate (EU)
SPL, Structured Product Labeling (US)
SUD, sudden unexpected death
SUPAC, Scale Up and Post-Approval Changes
SUSAR, Suspected Unexpected Serious Adverse Reaction
SWP, Safety Working Party

TCM, Traditional Chinese medicine
TDD, transdermal drug delivery
TE, therapeutic equivalence
TGA, Therapeutic Goods Administration (Australia's regulatory agency)
TIGes, Telematic Implementation Group—electronic submissions
TIND, Treatment IND (see **IND**)
TK, toxicokinetics
TOPRA, The Organisation for Professionals in Regulatory Affairs

TSE, Transmissible spongiform encephalopathy

USP, United States Pharmacopoeia

VAERS, Vaccine Adverse Event Reporting System (US)

VICH, International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products

VMRFG, Veterinary Mutual Recognition Facilitation Group

VHP, Voluntary Harmonisation Procedure

VWP, Vaccine Working Party

WHO, World Health Organisation