

Acronyms

510(k)	FDA clearance category based on demonstration of substantial equivalence to a pre-existing device
AADA	Abbreviated Antibiotic Drug App1ic (FDA) (used primarily for generics)
AAPS	American Association of Pharmaceutical Scientists
Ab	Antibody
ACB	Association of Clinical Biochemists
ACE	Adverse Clinical Event
ACT	Applied Clinical Trials
ADA	American Diabetes Association
ADE	Adverse Drug Event
ADME	Absorption, Distribution, Metabolism and Excretion
ADR	Adverse Drug Reaction
AE	Adverse Experience
AERS	Adverse Events Reporting System
AFP	Alpha Feto Protein
Ag	Antigen
AHI	Animal Health Institute
AIDS	Acquired Immune Deficiency Syndrome
AIM	Active Ingredient Manufacture
Alb	Albumin
ALP	Alkaline Phosphatase
ANA	Anti-nuclear Antibodies
ANCA	Anti-neutrophill Cytoplasmic Antibodies
ANDA	Abbreviated New Drug Application
ANSI	American National Standards Institute
AOAC	Association of Official Analytical Chemists
API	Active Pharmaceutical Ingredient
APTT	Activated partial thromoplastin time
ARPI	Association of the British Pharmaceutical Industry
ASCII	American Standard Code for Information Interchange
ASQC	American Society for Quality Control
AST	L-aspartate aminotransferase
AT III	Antithrombin III
BACPAC	Bulk Active Post-Approval Changes
B-ALP	Bone Alkaline Phosphatase
BAP	Bone-specific Alkaline Phosphatase
BDA	The British Diabetic Association
BDPA	Bureau of Drug Policy and Administration (China)
B-HCG	Beta Subunit of Human Chorionic Gonadotrophin
BIMO	Bioresearch Monitoring System
BIVDA	British In Vitro Diagnostics Association
BLA	Biologics License Application (FDA)
BMD	Bone Mineral Density
BMJ	British Medical Journal
BPC	Bulk Pharmaceutical Chemical
BRMS	Biologics Regulatory Management System
BSA	Bovine serum albumin
BSE	Bovine Spongiform Encephalopathy
CA	Competent Authority
CABS	Conformity Assessment Bodies
CANDA	Computer Assisted New Drug Application
CAPRA	Canadian Association of Pharmaceutical Regulatory Affairs
CARS	Compliance Achievement Reporting System

CAS	Chemical Abstracts Service
CBER	Centre for Biologics Evaluation and Research (FDA)
CDC	Centres for Disease Control and Prevention (FDA)
CDER	Centre for Drug Evaluation and Research (FDA)
CDER	Centre for Drug Evaluation and Research
CDM	Clinical Data Management
CDRH	Centre for Devices and Radiological Health (FDA)
CDRN	Centre for Devices and Radiological Health (FDA)
CEA	Carcino embryonic antigen
CEN	Comite Européen de Normalisation (Européen Standards Body)
CENELEC	European Standards Body for electrical standards
CFR	Code of Federal Regulations
CFSAN FDA	Centre for Food Safety and Applied Nutrition
CGMP	Current Good Manufacturing Practices
cGMP	Current Good Manufacturing Practice
cGMPRs	Current Good Manufacturing Practice Regulations
CIA	Chemiluminoimmunoassay
CIB	Clinical Investigator Brochure
CIN	Cervical intraepithelial neoplasia
CJD	Creutzfeldt-Jakob Disease
CK	Creatine Kinase
CK-BB	Creatine kinase-BB isoform
CK-MB	Creatine kinase-MB isoform
CK-MM	Creatine kinase-MM isoform
CK-MMC	Creatine kinase-MMC isoform
CLIA	Clinical Laboratory Improvement Act 1988
CMC	Chemistry, Manufacturing and Controls
CMCCC	Chemistry and Manufacturing Controls Coordinating Committee (CDER)
CMV	Cytomegalovirus
COMSTAT	Compliance Status Information System
CPMP	Committee for Proprietary Medicinal Products
CPSC	Consumer Product Safety Commission
CR0	Contract Research Organization
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreement (with NIH)
CRF	Case Report Form
CRP	C Reactive Protein
CRS	Contamination Response System
CSF	Cerebrospinal Fluid
CSM	Committee on Safety of Medicines (UK)
CSO	Consumer Safety Officer (FDA)
CSU	Catheter Specimen of Urine
CTC	Clinical Trial Certificate (UK)
CTM	Clinical Trials Materials
CTS	Common Technical Specification of the IVD Directive
CTx	C-Telopeptide "Crosslaps"
CTX	Clinical Trial Exemption (UK)
CV	Coefficient of Variation
CVM	Centre for Veterinary Medicine (FDA)
CVM FDA	Centre for Veterinary Medicine
CVP	Central Venous Pressure
DCCT	Diabetes Control and Complications Trial
DEA	Drug Enforcement Administration (U.S.)
DESI	Drug Efficacy Study Implementation notice (FDA, to evaluate drugs in use before 1962)

DEXA	Dual Energy X-Ray Absorptiometry.
DHA	Dehydroepiandrosterone
DHF	Device History file (FDA)
DHHS	Department of Health and Human Services
DIA	Drug Information Association
DMF	Drug Master File
DMR	Device Master Record (FDA)
DNA	Deoxyribonucleic Acid
DOA	Drugs of Abuse
DPYR	Deoxypyridinoline
DQRS	Drug Quality Reporting System
DRG	Division of Research Grants (NIH); Diagnosis Related Groups
DRLS	Drug Registration and Listing System
DS	Drug Substance
DSHEA	Dietary Supplement Health and Education Act
DSI	Division of Scientific Investigations (FDA)
DTC	Direct-to-Consumer (drug advertising)
DTD	Document Type Definition (for electronic interchange)
DVT	Deep Venous Thrombosis
EA	Environmental Assessment
EC	European Community
EDMA	European Diagnostics Manufacturing Association
EDMS	Electronic Data Management System
EDR	Electronic Document Room
EDTA	Ethylene Diamine Tetra Acetic Acid (anti-coagulant)
EEA	European Economic Area
EEC	European Economic Community
EGA	European Generics Association
EIA	Enzymoimmunoassay
EIP	Emerging Infection Program
EIR	Establishment Inspection Report
ELA	Establishment License Application (FDA)
ELISA	Enzyme Linked Immunosorbent Assay
EMI	European Agency for the Evaluation of Medicinal Products
EMU	Early Morning Urine
EOP1	End-of-phase 1
EOP2	End-of-phase 2
EP	European Pharmacopoeia
EPA	Environment Protection Agency
ERS	Economic Research Service
ESR	Erythrocyte Sedimentation Rate
ESRA	European Society of Regulatory Affairs
ET	Endotracheal Tube
EU	European Union
FACTS	Field Accomplishment and Compliance Tracking System
FAI	Free Androgen Index
FAO	United Nations Food and Agricultural Organisation
FAS	Foreign Agriculture Service
FBC	Full Blood Count
FD&C Act	Federal Food Drug and Cosmetic Act
FDA	Food and Drug Administration
FDAMA	Food and Drugs Administration Modernisation Act of 1997
FDPs	Fibrin Degradation Products
FIA	Fluoroimmunoassay

FIS	Field Information System
FLQ	Fluroquinolone
FOI	Freedom of Information
FOIA	Freedom of Information Act
FPG	Fasting Plasma Glucose
FPL	Final Printed Label
FPLA	Fair Packaging and Labelling Act
FR	Federal Register
FSH	Follicle Stimulating Hormone
FSI	National Food Safety Initiative
FSIS	Food Safety Inspection Service
FTC	Federal Trade Commission
FTE	Full Time Equivalents
FY	Fiscal Year
GATT	General Agreement on Tariffs and Trade
GCP	Good Clinical Practice
GFR	Glomerular Filtration Rate
GGT	Gamma Glutamyl Transpeptidase
GH	Growth Hormone
GHb	Glycated Haemoglobin
GHRH	Growth Hormone Releasing Hormone
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GMP	Good Manufacturing Practice
GnRH	Gonadotrophin Releasing Hormone
GP's	General Practitioners
GPRA	Government Performance and Results Act of 1993
GRAS	Generally Recognized as Safe
GRASE	Generally Recognized as Safe and Effective
GRP	Good Review Practice
HACCP	Hazard Analysis Critical Control Points
Hb	Haemoglobin
HbA	Adult Haemoglobin
HbA1c	Haemoglobin A1c
HDE	Humanitarian Device Exemption
HDL	High Density Lipoprotein
HIV	Human Immunodeficiency Virus
HPB	Health Protection Bureau (Canada)
HPLC	High Performance Liquid Chromatography
HRT	Hormone Replacement Therapy
HTML -	Hypertext Mark-up Language
HUD	Human Use Device
HVS	High Vaginal Swab
IB	Investigator Brochure
IC	Informed Consent
ICH	International Conference on Harmonisation
ID	Identification
IDDM	Insulin-Dependent Diabetes Mellitus
IDE	Investigational Device Exemption (FDA)
IEMA	Immunoenzymomatic Assay
IFMA	Immunofluorimetric Assay
IFPMA	International Federation of Pharmaceutical Manufacturers Association
IFU	Instructions for use
IGH1	Insulin Like Growth Hormone 1

IGT	Impaired Glucose Tolerance
IHD	Ischaemic Heart Disease
IM	Infectious Mononucleosis
IM	Intramuscular
INAD	Investigational New Animal Drug
INADA	Investigational New Animal Drug Application
IND	Investigational New Drug
INDA	Investigational New Drug Application
INDC	Investigational New Drug Committee
IOM	Institute of Medicine
IPRO	Independent Pharmaceutical Research Organization
IQ	Installation Qualification
IRB	Institutional Review Board
IRMA	Immunoradiometric Assay
IRP	International Reference Preparation
IS	International Standard
ISO	International Standards Organisation
ISRA	Individual Safety Reports
IT	Information Technology
ITP	Immune Thrombocytopenic Purpura
IU	International Unit
IV	Intravenous
IVD	In Vitro Device; In Vitro Diagnostics
JP	Japanese Pharmacopoeia
JPMA	Japan Pharmaceutical Manufacturers Association
Km	Michaelis-Menten Constant
LAN	Local Area Network
LD	Lethal Dose in X% of animals
LDL	Low Density Lipoprotein
LFT's	Liver function tests
LH	Luteinizing Hormone
LIS	Laboratory Information System
LV	Leucovorin
MA	Marketing Authorization
Mab	Molecular Antibody
MATS	Management assignment Tracking System
MBR	Manufacturing batch records
MCA	Medicines Control Agency (UK)
MDA	Medical Devices Agency (UK)
MED	Minimum Effective Dose
MHW	Ministry of Health and Welfare (Japan's equivalent to the FDA)
MI	Myocardial Infarction
MOU	Memorandum of Understanding
MRA	Mutual Recognition Agreement
MRC	Medical Research Council
MSU	Midstream Urine
MTD	Maximum Tolerated Dose
NADA	New Animal Drug Application
NADPH	Nicotinamide Adenine Dinucleotide Phosphate
NAF	Notice of Adverse Findings
NAI	No Action indicated (most favourable FDA post inspection classification)
NAM	National Agency for Medicines (Finland)
NARMS	National Antimicrobial Resistance Monitoring System
NAS	New Active Substance

NB	Notified Body
NCE	New Chemical Entity
NCI	National Cancer Institute
NCIE	Notice of Claimed Investigational Exemptions
NCTR FDA	National Centre for Toxicological Research
NDA	New Drug Application
NDE	New Drug Evaluation
NDE/MIS	New Drug Evaluation Management Information Service
NDEP	National Diabetes Education Programme
NDS	New Drug Submission (Canada's equivalent to NDA)
NF	National Formulary
NHS	National Health Service
NIAID	National Institute of Allergy and Infectious Diseases
NIBSC	National Institute of Biological Standards and Controls
NIDA	National Institute on Drug Abuse (NIB)
NIDDM	Non-Insulin Dependent Diabetes Mellitus
NIEHS	National Institute for Environmental Health Sciences
NIH	National Institutes of Health (DHHS)
NIMH	National Institute of Mental Health (NIB)
NLEA	National Labelling and Education Act
NME	New Molecular Entity
NPA	Nasopharyngeal Aspirate
NPR	National Partnership for Reinventing Government
NRC	National Research Council
NRC	Nuclear Regulatory Commission
NSAD	Nonsteroidal Anti-Inflammatory Drug
NSB	Non-specific Binding
NTP	National Toxicology Programme
NTx	N-Telopeptide
NVPO	National Vaccine Programme Office
OASIS	Operational and Administrative System for Import Support
OBRR	Office of Blood Research and Review
OEM	Original Equipment Manufacturer (subcontractor)
OGD	Office of Generic Drugs
OGTT	Oral Glucose Tolerance Test
ONDC	Office of New Drug Chemistry (CDER)
OPA	Office of Premarket Approvals
OPS	Office of Pharmaceutical Science (CDER)
OQ	Operational Qualification
ORA	Office of Regulatory Affairs
ORA FDA	Office of Regulatory Affairs
ORISE	Oak Ridge Institute for Science and Education
OSHA	Occupational Safety and Health Administration
OTC	Over the Counter
OTR	Office of Testing and Research (CDER)
Pab	Polyclonal Antibody
PAI	Pre-Approval Inspection
PAITS	Pre-Approval Inspection Tracking System
PALA	N-(phosphonacetyl)-L-aspartic acid
PAP	Prostatic Acid Phosphatase
PAS FDA	Public Affairs Specialist
PBG	Porphobilinogen
PC	Personal Computer
PCB	Post Coital Bleeding

PCC	Poison Control Centre
PCV	Packed Cell Volume
PD	Pharmacodynamics
PDP	Product Development Protocol
PDR	Physicians' Desk Reference
PDUFA	Prescription Drug User Fee Act of 1992
PhEMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Services
PK	Pharmacokinetics
PLAP	Product License Application
PLAP	Placental Alkaline Phosphatase
PLC	Pharmaceutical Inspection Convention
PMA	Pre-market Approval
PMA.	Pharmaceutical Manufacturer's Association
Po	Oral
PoC	Point-of-Care
POCT	Point-of-Care Testing
PODS	Project Oriented Data System
POL	Physicians Office Laboratory
PQRI	Product Quality Research Initiative
PR	Partial Response
PSA	Prostatic Specific Antigen
PT	Prothrombin Time
PTH	Parathyroid Hormone
PYR	Pyridinoline
QA	Quality Assurance
QAU	Quality Assurance Unit
QC	Quality Control
Qd	Once Daily
QS	As Much as is Sufficient
QSIT	Quality System Inspection Technique (FDA)
QSR	Quality System Regulations (FDA)
R&D	Research and Development
RA	Regulatory Affairs
RA	Rheumatoid Arthritis
RAPS	Regulatory Affairs Professionals Society
RCHSA	Radiation Control for Health and Safety Act
REGO	Reinventing Government Initiative
RhD	Rhesus D Antigen
RIA	Radioimmunoassay
RIMS	Regulatory Information Management Staff
RNA	Ribonucleic Acid
RRL	Rapid Response Laboratory
RSV	Respiratory Syncytial Virus
RT	Room Temperature
RVIS	Residue Violation Information System
SAB	Science Advisory Board
SAE	Serious Adverse Event
SAE	Serious Adverse Experience
SAMHSA	Substance Abuse and Mental Health Services Administration
SBA	Summary Basis of Approval
SD	Standard Deviation
SE	Salmonella Enteritidis
SERMS	Selective Oestrogen Receptor Modulators

SGML	Standard Generalized Mark-up Language (IT)
SHBG	Sex Hormone Binding Globulin
SLE	Systemic Lupus Erthematosis
SMART	Submission Management and Review Tracking (FDA)
SMBG	Self Monitoring of Blood Glucose
SNDA	Supplemental New Drug Application
SOP	Standard Operating procedure
STARS	Submission Tracking and Review System
SWOG	Southwest Oncology Group
t'A	Half-Life
TAH	Total Abdominal Hysterectomy
TAT	Turn Around Time
TB	Tuberculosis
TLA	Total Laboratory Automation
TMs	Test Methods
TOP	Termination Of Pregnancy
TRIMS	Tissue Residue Information System
TSH	Thyroid Stimulating hormone
U&E	Urea and Electrolyte
UGDP	University Group Diabetes Programme
UK	United Kingdom
UKPDS	UK Prospective Diabetes Study
UL	Underwriters Laboratory
ULN	Upper Limit of Normal
USDA	United States Department of Agriculture
USP	United States Pharmacopoeia-National Formulary
USPDI	United States Pharmacopoeia-Drug information
VAERS	Vaccine Adverse Event Reporting System
VFD	Veterinary Feed Directive
VLDL	Very Low Density Lipoprotein
VMA	Vaninyl Mandelic Acid
WFI	Water for Injection
WHO	World Health Organisation
WL	Warning Letter
WTO	World Trade Organisation