ACRONYMS

TERM	COUNTRY	DEFINITION
AADA	Int	Abbreviated Antibiotic Drug Application
AAPS	US	American Association of Pharmaceutical Scientists
ABC	US	American Botanical Council
ABPI	UK	Association of British Pharmaceutical Industries
ACSI	US	American Customer Satisfaction Index
ADME	Int	Absorption, Distribution, Metabolism, and Excretion
ADR	Int	Adverse Drug Reaction
AF	Int	Application Form
AFI	IT	Associazione Farmaceutici Industria
AFSSPS	FR	Agence Francaise de Securite Sanitaire des Produits de Sante
AIC	IT	Autorizzazione Immissione in Commercio
AICQ	IT	Associazione Italiana per la Qualità
AICRC	UK	Association of Independent Clinical Research Contractors
AIFA	IT	Agenzia Italiana del Farmaco
AMG	DE	Arzneimittelgesetz (German Drug Law)
ANDA	US	Abbreviated New Drug Application
ANDS	Int	Abbreviated New Drug Submission
AO	IT	Azienda Ospedaliera
API	Int	Active Pharmaceutical Ingredients
ASL	IT	Azienda Sanitaria Locale
AR	Int	Assessment Report
ASMF	Int	Active Substance Master Files
BAPP	UK	British Association of Pharmaceutical Physicians
BfArM	DE	Bundesinstitut für Arzneimittel und Medizinprodukte (German: Federal Institute for Drugs and Medical Devices

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BLA	Int	Biologics License Application
BP	UK	British Pharmacopoeia
BPD	Int	Biocidal Products Directive
BPL	IT	Buona Pratica Laboratorio
BSE	Int	Bovine Spongiform Encephalopathy
CAPRA	CND	Canadian Association of Pharmaceutical Regulatory Affairs
CAT	Int	Committee for Advanced Therapies
CAS Number	Int	Chemical Abstracts Service Number
CBER	US	Center for Biologics Evaluation and Research
CDC	US	Centers for Disease Control
CDER	US	Center for Drug Evaluation and Research
CDRH	US	Center for Devices and Radiological Health
CE	IT	Consiglio Europeo
CEN	Int	Comité Européen de Normalisation
CEP	Int	Certificate European Pharmacopoeia
CES	IT	Comitato Economico e Sociale
CHMP	Int	Committee for Medicinal Products for Human Use
CIOMS	Int	Council for International Organizations of Medical Sciences
CIPE	IT	Comitato Interministeriale per la Programmazione Economica
CLP regulation	Int	Classification, Labelling and Packaging Regulation
CLV	IT	Certificato di Libera Vendita
CMC	US	Chemistry, Manufacturing, and Controls
CMD(h)	Int	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
CMD(v)	Int	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

ACRONYMS

CMS	Int	Concerned Member State
CND	IT	Classificazione Nazionale dei Dispositivi Medici
COLIPA	Int	Comité de Liaison des Associations Européennes de LIndustrie de la Parfumerie, des Produits Cosmetiques et de Toilette
COMP	Int	Committee for Orphan Medicine Product
COPR	Int	Control of Pesticides Regulations
CoS	Int	Certificate of Suitability
CP	Int	Centralized Procedure
CPP	IT	Certificato di Prodotto Farmaceutico
CRC	Int	Clinical Research Coordinator
CRO	Int	Contract Research Organisation
CSD	UK	Committee on Safety of Medicines
CSR	Int	Clinical Study Report
CSS	IT	Consiglio Superiore di Sanità
CTD	Int	Common Technical Dossier
CTC	UK	Clinical Trial Certificate
CTS	IT	Commissione Tecnico Scientifica
CTX	UK	Clinical Trial Exemption
CUF	IT	Commissione Unica del Farmaco
CVMP	Int	Committee for Medicinal Products for Veterinary Use
DCP	Int	Decentralised Procedure
DD	Int	Due Diligence
DDD	Int	Dear Doctor Letter
DDD	Int	Define Daily Dose/ Dose Define Die
DdL	IT	Disegno di Legge
DL	IT	Decreto Legge

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D.Lgs.	IT	Decreto Legislativo
D.M.	IT	Decreto Ministeriale
DM	IT	Dispositivo Medico
DMF	Int	Drug Master File
DPI	IT	Dispositivi per la Protezione Individuale
DRG	Int	Diagnosis Related Groups
DDPS		Detailed Description Pharmacovigilance System
ECHA	Int	European Chemical Agency
ECM	IT	Educazione Continua in Medicina
eCTD	Int	electronic Common Technical Dossier
EDQM	Int	European Directorate for the Quality of Medicines & HealthCare
EEA	Int	European Economic Area
EFPIA	Int	European Federation of the Pharmaceutical Industries and Associations
EFQM	Int	European Foundation for Quality Management
EFSA	Int	European Food Safety Authority
EFTA	Int	European Free Trade Association
EGA	Int	European Generic medicines Association
EINECS	Int	European Inventory of Existing Commercial Chemical Substances
EMA	Int	European Medicine Agency
EOQ	Int	European Organization for Quality
EPAR	Int	European Public Assessment Report
EPO	Int	European Patent Organisation
ESTRI	Int	Electronic Standards for the Transmission of Regulatory Information
ETOMEP	Int	European Technical Office for Medicinal Products

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EUCOMED	Int	European Confederation of Medical Devices Association
EUDRA	Int	European Union Drug Regulatory Authorities
EVCTM	Int	EudraVigilance Clinical Trial Module
EVDAS	Int	EudraVigilance Data warehouse Analysis System
FANS	IT	Farmaci Anti-infiammatori non Steroidei
FDA	US	Food and Drug Administration
FMEA	Int	Failure Mode and Effects Analysis
FSC	Int	Free Sale Certificate
FU	IT	Farmacopea Ufficiale
GCP	Int	Good Clinical Practice
GDP	Int	Good Distribution Practice
GHS	Int	Globally Harmonised System
GHTS	Int	Global Harmonisation Task Force
GLP	Int	Good Laboratory Practice
GMDN	Int	Global Medical Device Nomenclature
GMP	Int	Good Manufacturing Practice
GPvP	Int	Good Pharmacovigilance Practise
GVP	Int	Good Vigilance Practises
GU	IT	Gazzetta Ufficiale
HACCP	Int	Hazard Analysis Critical Control Point
HMA	Int	Heads of Medicines Agency
HMPC	Int	Committee on Herbal Medicinal Products
HPFB	Int	Health Products and Food Branch
HPLC	Int	High-performance liquid chromatography
HSE	UK	Healthy Survey for England

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ICDRA	Int	International Conference of Drug Regulatory Authorities
ICH	Int	International Conference on Harmonisation
ICSR	Int	Individual Case Safety Report
IDE	US	Investigational Device Exemption
IFPMA	Int	International Federation of Pharmaceutical Manufacturers & Associations
IfU	Int	Istruction for Use
INCI	Int	International Nomenclature of Cosmetic Ingredients
IND	US	Investigational New Drug Application
IRD	Int	Initial Receipt Dates
ISBN	Int	International Standard Book Number
ISO	Int	International Organization for Standardization
ISPRA	IT	Istituto Superiore per la Protezione e la Ricerca Ambientale
ISS	IT	Istituto Superiore di Sanità
ISTAT	IT	Istituto Nazionale di Statistica
IUCLID	Int	International Uniform Chemical Information Database
IUPAC	Int	International Union of Pure and Applied Chemistry
IVD	Int	In Vivo Diagnostic
JPMA	Int	Japan Pharmaceutical Manufacturers Association
LARN	IT	Livelli di Assunzione giornalieri Raccomandati di energia e Nutrienti
LoA	Int	Letter of Access
MA	Int	Marketing Authorization
MAA	Int	Marketing Authorization Application
MAH	Int	Marketing Authorization Holder
MBTC	Int	Management Board Telematics Committee

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MCA	UK	Medicines Control Agency
MD	Int	Medical Device
MDMA	US	Medical Device Manufacturers Association
MdS – MinSal	IT	Ministero della Salute
MedDRA	Int	Medical Dictionary for Drug Regulatory Affairs
MHRA	UK	Medicines and Healthcare Products Regulatory Agency
MIUR	IT	Ministero dell'Istruzione, dell'Università e della Ricerca
MND	SGP	Ministry of National Development
MRP	Int	Mutual Recognition Procedure
NAS	IT	Nucleo Antisofisticazione e Sanità
NAS	Int	New Active Substance
NB	Int	Notified Body
NBF	IT	Norme di Buona Fabbricazione
NCA	UK	National Competent Authority
NCI	US	National Cancer Institute
NCNPR	Int	National Center Natural Products Research
NDA	US	New Drug Application
NDS	Int	New Drug Submission
NIH	Int	National Institutes of Health
NOIS	IT	Nulla Osta Igienico Sanitario
NPA	UK	National Pharmaceutical Association
OD	Int	Orphan Drug
NSAID	Int	Nonsteroidal Anti-inflammatory Drug
OGD	US	Office of Generic Drugs
OGM	IT	Organismo Geneticamente Modificato

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OMCL	Int	Official Medicines Control Laboratories
OMS	IT	Organizzazione Mondiale della Sanità
OTC	Int	Over the Counter
PAT	Int	Process Analytical Technology
PDCO	Int	Pediatric Committee
PHT	IT	Prontuario ospedale-territorio
PhVWP	Int	Pharmacovigilance Working Party
PICS	FR	Programmes Internationaux de Coopération Scientifique
PICS	Int	Pharmaceutical Inspection Cooperation Scheme
PIL	Int	Product Information Label
PIM	Int	Product Information Management
PIP	Int	Pediatric Investigation Plan
PMA	US	Pre-market Authorization for approval of class III devices
PMC	IT	Presidio Medico Chirurgico
PMI	IT	Piccole e Medie Imprese
PRR	Int	Proportional Reporting Ratio
PRAC		Pharmacovigilance Risk Assessement Committee
PSMF	Int	Pharmacovigilance Sistem Master File
PSUR	Int	Product Safety Update Report
PVAR	Int	Preliminary Variation Assesment Report
RMS	Int	Reference Member State
QA	Int	Quality Assurance
QC	Int	Quality Control
QOS	Int	Quality Overall Summary
QP	Int	Qualified Person

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QPPV	Int	Qualified Person Pharmacovigilance
QRD	Int	Quality Review of Documents
RAEE	IT	Rifiuti di Apparecchiature Elettriche ed Elettroniche
RAPEX	Int	Rapid Exchange about Safety Product
RAPS	Int	Regulatory Affairs Professionals Society
RCP	IT	Riassunto delle Caratteristiche del Prodotto
RDA	Int	Recommended Daily Allowance
REACH	Int	Registration, Evaluation, Authorisation and Restriction of Chemicals
R&D	Int	Research and Development
RMP	Int	Risk Management Plan
RPSGB	UK	Royal Pharmaceutical Society of Great Britain
SAE	Int	Serious Adverse Event
SAG	Int	Scientific Advisory Group
SCI	IT	Società Chimica Italiana
SDRs	Int	Signals Disproportionate Reporting
SMF	Int	Site Master File
SME	Int	Small and Medium-sized Enterprise
SOP	US	Standard Operating Procedure
SOP	IT	Senza Obbligo di Prescrizione
SIAF	IT	Sistema Informatico Anagrafe Fondi
SIAR	IT	Società Italiana Attività Regolatorie
SPC	Int	Summary of Product Characteristics
SSN	IT	Servizio Sanitario Nazionale
SUSAR	Int	Suspected, Unexpected, Serious Adverse Reaction
THR	Int	Traditional Herbal Registration

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THRMS	Int	Traditional Herbal Medicines Registration Scheme
TNG	Int	Technical Note for Guidance
ToC	Int	Table of Contents
TOPRA	Int	The Association for Regulatory Affairs Professionals
TRACS	US	Transit Rail Advisory Committee for Safety
TSE0	Int	Transmissible Spongiform Encephalopathy
USAN	US	United States Adopted Names
USP	US	United States Pharmacopeia
USR	Int	Urgent Safety Restriction
VAMF	Int	Vaccine Antigen Master File
WHO	Int	World Health Organisation