UNIVERSITÄT BONN

Abkürzungsverzeichnis
List of Abbreviations

für den weiterbildenden Masterstudiengang

„Drug Regulatory Affairs”

Stand: Mai 2021

Short	Cut Complete Name	Additional Information
AADA	Abbreviated Antibiotics Drug Applications	
AAS	Atomabsorptionsspektroskopie	
ABDA	Bundesvereinigung Deutscher Apothekerverbände	
ABDATA	Geschäftsbereich der Apothekenverbände	
ABI	Amtsblatt der Europäischen Gemeinschaft	
ABPI	The Association of the British Pharmaceutical Industry	
ACCSQ	Consultative Committee for Standards and Quality	
ACE	Angiotensin Converting Enzyme	
ACSoMP	Advisory Committee on Safety of Medicinal Products	Beratungskommitte für die WHO
ACTA	Anti Counterfeiting Trade Agreement	Handelsabkommen zum Schutz vor Produktfälschungen
ADBE	absorption, distribution, biotransformation, excretion	
ADEC	Australian Drug Evaluation Committee	
ADI	uthorizat daily intake	
ADM	Administrative Information	
ADME	absorption, distribution, metabolism, excretion	(of a compound)
ADP	Adenosin-Diphosphat	
ADR	Adverse Drug Reaction Noxious/unintended response	
ADRAC	Adverse Drug Reactions Advisory Committee	Unterkommitee von ADEC
ADKA	Arbeitsgemeinschaft Deutscher Krankenhausapotheker	
ADROIT ADRs	Online Information Tracking	
ÄA	Änderungsanzeige	
AE	Adverse Event Untoward medical occurrence	
AECB	acute exacerbation of chronic bronchitis	
AEFI	adverse events following immunization	
AEGIS ADROIT	Electronically Generated Information Service	
AEPAR	Asocación Espanola de Profesionales de Actividades de Registro	
AERS	Adverse Event Reporting System	
AESGP	Assocaiation Européenne des Specialités Pharmaceutiques Grand Public	
AEUV	Vertrag über die Arbeitsweise der Europäischen Union	
AFAR	Association Française des Affaires Réglementaires	
AfLÜ	Amt für Lebensmittelüberwachung	
AFSSAPS	L'Agence Française de Securité Sanitaire de Produits de Santé	Regulatory Authority in France
Ag	Antigen	
AGES	Agentur für Gesundheit und Ernährungssicherheit	Österreichische Zulassungsbehörde
AGF	Alleingeschäftsführer	
AGLMB	Arbeitsgemeinschaft der leitenden Medizinalbeamtinnen und –beamten der Länder	

Short	Cut Complete Name	Additional Information
AHI	Animal Health Institute	
AHP	Analytic Hierarchy Process	
AICRC	Association of Independent Clinical Research Contractors	
AIDS	Acquired Immune Deficiency Syndrome	
AIM	active ingredient manufacturer	
AIMDD	Active Implantable Medical Devices Directive	
AIVR	Accelerated Idioventricular Rhythm	
AkdÄ	Arzneimittelkommission der deutschen Ärzteschaft	
AL	Akzeptanzlimit	
AL	Approvable Letter	(Schweiz)
ALADI	Asociación Latinoamericana de Integración	Latin American Integration Association
ALARP	as low as reasonably practicable	
ALAT	alanine aminotransferase	Synonym: ALT
ALIFAR	Asociación Latinoamericana de Industrias Farmacéuticas Latin American association of the generic industry	
ALT	alanine aminotransferase	Synonym: ALAT
ALV	Arzneiliefervertrag	
AM	Arzneimittel	
AMA	American Medical Association	
AMG	Arzneimittelgesetz	German Drug Law
AMG-AV	Arzneimittelgesetz-Anzeigeverordnung	
AMG-EV AMG-	Einreichungsverordnung	
AMED	Allied and Alternative Medicine	
AMES	Verfahren zur Identifizierung von Mutagenen nach dem Amerikaner Bruce Ames	
AMIS II	Arzneimittel-Informationssystem (BfArM)	
AMK	Arzneimittelkommission der Deutschen Apotheker	
AMM	Autorisation de Mise sur le Marché	
AMNOG	Arzneimittelmarktneuordnungsgesetz	
AMR	Arzneimittelreport	
AMR	Arzneimittelrichtlinie des G-BA	
AMRadV	Verordnung über radioaktive oder mit ionisierenden Strahlen behandelte Arzneimittel	
AMRL	Arzneimittel-Richtlinien des GBA	
AMTS	Arzneimitteltherapiesicherheit	
AMWHV	Arzneimittel-und Wirkstoffherstellungsverordnung	Ersetzt die bisherige PharmBetrV
ANDA	Abbreviated New Drug Application Approval process for generics	(USA)
ANMAT	Administración Nacional de Medicamentos, Alimentos y Tecnologica Médica	Argentinische Zulassungsbehörde National Administration for Medicines, food and Medical Technology
ANOVA	Analysis of Variance	
ANSI	American National Standards Institute	

Short	Cut Complete Name	Additional Information
ANVISA	Agência Nacional de Vigilância Sanitária	Nationale Behörde für Gesundheitsüberwachung in Brasilien (National Health Surveillance Agency)
ANZTPA	Australia New Zealand Therapeutic Products Authority	Gemeinsame Zulassungsbehörde für Australien und Neuseeland
AOK	Allgemeine Ortskrankenkasse	
aP	acellular pertussis	pertussis vaccines
AP	Anstaltspackung	
AP	Alkaline Phosphatase	
ApBetrO	Apothekenbetriebsverordnung	
APC	adenomatous polyposis coli	
APEC	Asia-Pacific Economic Cooperation	
API	Active Pharmaceutical Ingredient	
APNIC	Asia Pacific Network Information Centre	
ApoBetrO	Apothekenbetriebsordnung	
ApoG	Gesetz über das Apothekenwesen	
APR	Annual Product Review	USA
APTT	Activated partial thromboplastin time	
APV	Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik	
AQL	Acceptable Quality Level	Maximum percent defective that can be considered satisfactory as a process average
AQOL	Assessment of Quality of Life	
AR	Assessment Report	
AR	Adverse Reaction	
ARD	Applicant's Response Document	
ARIN	American Registry for Internet Numbers	
ARR	absolute risk rate	
ARTG	Australian Register of Therapeutic Goods	
As	Arsen	
AS	Aminosäure	
ASA	American Society of Anaesthesiology	
ASCO	American Society of Clinical Oncology	
ASEAN	Association of Southeast Asian Nations	
ASI	Arzneimittelschnellinformation	Maßnahme des BfArM bei Risikoverdacht eines Arzneimittels
ASK-Nummer	Arzneimittelklassifikationsnummer des BfArM	
ASMF	Active Substance Master File	
ASMR	Amélioration du Service Médical Rendu	
ASR	Annual Safety Report	
AST	Aspartate Transaminase	
ASTM	American Society for Testing and Materials	
ATC	Acute Toxic Class	
ATC/Vet.	Anatomical Therapeutical Chemical (Code)/Veterinary	
ATC-Code	Anatomisch Therapeutisch Chemischer Code der WHO	
ATMP	Advanced Therapy Medicinal Product	

Short	Cut Complete Name	Additional Information
ATP	Adenosine-triphosphat	
ATP	Federal Act on Therapeutic Products	(Schweiz)
ATS	Application Tracking System	
AUC	Area Under the Curve	
Audit Synonym	Inspection Systematic and documented verification of the implementation of a quality management system or elements of such a system.	External and internal audits.
AVP	Arzneiverordnung in der Praxis	
AVV-RÜB	Allgemeine Verwaltungsvorschrift Rahmen-Überwachung	
AVWG	Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz	
AWB	Anwendungsbeobachtungen	
AWMF	Arbeitsgemeinschaft der wissenschaftlichen Fachgesellschaften	
AZT	Azidothymidin (HIV treatment)	
BAÄK	Bundesausschuss der Ärzte und Krankenkassen	
BÄ	Bioäquivalenz	
BÄK	Bundesärztekammer	
BÄO	Bundesärzteordnung	
BAG	Bundesamt für Gesundheit	(Schweiz)
BAH	Bundesfachverband der Arzneimittelhersteller e.V.	
BAI	Bundesverband der Arzneimittelimporteure	
BAN	British Approved Names	
Banz	Bundesanzeiger	
Batch	Quantity of a product originating from one manufacturing run, assumed to be homogenous	Synomym: Lot
BAZ	Bundesanzeiger	
BB	Bureau of Biologics	jetzt: CBER
BBS	Bulletin Board System	
BCE	beneficial clinical event	
BCG	Bacille Calmette Guérin	
BCG	Bio-Coordination Group	
BCS	Biopharmaceutics Classification System	
BDFA	Bureau of Food and Drug Analysis Taiwan	
BE	Bioequivalence	
BEMA	Benchmarking of European Medicines Agencies	
BER	Base Excision Repair	
BEUC	Bureau Européen des Unions de Consommateurs	European Consumers' Organisation
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte	
BfT	Bundesverband für Tiergesundheit e.V.	
BGA	Bundesgesundheitsamt	Exekutive des BMG bis 1994 (Auflösung in Einzelinstitute)
BGI	Bundesgesundheitsinstitut	

Short	Cut Complete Name	Additional Information
BgVV	Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin	jetzt: BVL
BIO	Biotechnology Industry Association	
BIRA	früher: The British Institute of Regulatory Affairs	jetzt: TOPRA
BKK-BV	Bundesverband der Betriebskrankenkassen	
BkostV-MPG	Medizinprodukte-Gebührenverordnung	
BLA	Biologics Licence Application	
BMA	British Medical Associations	
BMG	Bundesministerium für Gesundheit	
BMI	Bundesministerium des Inneren	
BMJ	British Medical Journal	
BMP	biological medicinal product	
BMU	Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit	
BMWP	Biosimilar Medicinal Products Working Party	Expertenfachgruppe bei der EMA
BNF	British National Formulary	
BOB	Bundesoberbehörde	
BOH	Board of Health	
BOPST	Bundesopiumstelle	Abt. des BfArM
BP	Bündelpackung	
BP	British Pharmacopeia	
BPAD	bipolar affective disorder	
BPC	British Pharmacopoeia Commission	
BPCA	Best Pharmaceuticals for Children Act	US, previsously known as “pediatric exclusivity”
BPD	diastolic blood pressure	
BPG	Best Practice Guide	
BPI	Bundesverband der Pharmazeutischen Industrie	
BPMRG	British Pharmaceutical Market Research Group	
BPS	systolic blood pressure	
BPWP	Blood Product Working Party	Expertenfachgruppe bei der EMA
BrAAP	British Association of Pharmaceutical Physicians	
BS	Benannte Stelle	
BSI	Bundesamt für Sicherheit in der Informationstechnik	Sitz in Bonn
BRAS	Belgian Regulatory Affairs Society	
BSA	Body Surface Area	
BSE	Bovine Spongiforme Encephalopathy	
BSG	Bundessozialgericht	
BTGC	Bio-Technology General Corporation	
BtMAHV	Betäubungsmittel-Außenhandelsverordnung	
BtMBinHV	Betäubungsmittel-Binnenhandelsverordnung	
BtMG	Betäubungsmittelgesetz	
BtMVV	Betäubungsmittel-Verschreibungsverordnung	
BverwG	Bundesverwaltungsgericht	

Short	Cut Complete Name	Additional Information
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit	
BWP	Biologics Working Party	Expertenfachgruppe bei der EMA
C	Kohlenstoff	
CA	Conjoint Analysis	
CA	Competent Authority	(Regulatory body charged with monitoring compliance with national, European Member State, statutes and regulations)
CA	Contract Acceptor	
CABG	Coronary Artery Bypass Graft Surgery	
CAD	Coronary Artery Disease	
CADREAC	The Collaboration Agreement between Drug Regulatory Authorities in European Union Associated Countries	
CADRMP	Canadian Adverse Drug Reaction Monitoring Program	
CAMA	Computer Assisted Marketing Application US	
CANDA	Computer Assisted New Drug Application Electronic Submission in the US	no longer existing
CAP	Community Acquired Pneumonia	
CAP	Centrally authorized product	
CAPA	corrective and preventive actions	
CAPLA	Computer-assisted Product License Application (see PLA)	
CAPLAR	Computer-assisted Product License Agreement Review (FDA)	
CAPRA	Canadian Association of Pharmaceutical Regulatory Affairs	
CARICOM	The Caribbean Community and Common Market	organization of 15 caribbean nations and dependencies
CAS	Chemical Abstracts Service	(American Chemical Society)
CAST	Cardiac Arrhythmia Suppression Trial	(USA)
CAT	Committee for Advanced Therapies	
CAVOD	Clinical Added Value of Orphan Drugs	Working Party
CBCTN	Community Based Clinical Trials Network	
CBE	Changes Being Effected	
CBER	Center for Biologics Evaluation and Research Committee for the evaluation of biologic Products at the FDA	(scientific body)
CBF	cerebral blood flow	
CBI	Confederation of British Industry	
CC	Change Control	
CCD	Canadian Drugs Directorate	
CCDC	Certified Clinical Research Coordinator. See also ACP	
CCDS	Company Core Data Sheet	
CCS	Canadian Cardiovascular Society (scoring system)	

Short	Cut Complete Name	Additional Information
CCS	container closure system	
CCSI	Company Core Safety Information	
Cd	Cadmium	
CD	circular dichronism	
CDA	Clinical Document Architecture	
CDC	Centres for Disease Control (Atlanta, GA)	
CDE	Center for Drug Evaluation technical evaluation	institution for drug registration administration of the Chinese SFDA
CDER	Center for Drug Evaluation and Research Committee for the evaluation of human drugs at the FDA	(scientific body)
CDP	Clinical Data Package	
CDP	Clinical Development Plan	
CDRH	Centre for Drug Evaluation and Research (FDA)	
CDS	Core Data Sheet	
CDSM	Committee on Drug Safety of Medicines	Committee of external experts empowered by MCA (advisory board)
CE	Conformité Européenne	
CE	capillary electrophoresis	
CEC	Commission of the European Committee	
CEEC	Central Eastern European Countries	Geographically assigned
CEN	Comité Européen de Normalisation	European Committee for Standardization
CENELEC	Europäisches Komitee für elektrotechnische Normung	
CEO	Chief Executive Officer	Geschäftsführer, Vorstand
CEP	Certificate of Suitability to the Monographs of the European Pharmacopoeia	
CER	Comparative Effectiveness Research	
CESP	Common European Submission Plattform	
CFC	chlorofluorocarbon	
CFDA	China's FDA	
CFR	Code of Federal Regulations Official Regulatory Announcements in the US	
CG	contract giver	
cGMP	current Good Manufacturing Practices US GMP document 21CFR211	
CHD	Coronary Heart Disease	
ChemG	German Law on Chemicals	Chemikaliengesetz
CHF	congestive heart failure	
CHMP	Committee for Medicinal Products for Human Use	
CHO	Chinese Hamster ovary	
CID	collision-induces dissociation	
CIOMS	Council for International Organisations of Medical Science Postapproval international ADR reporting	UK
CIOMS	Centerwide Oracle Management Information	

Short	Cut Complete Name	Additional Information
	System US (FDA)	
CIS	Commonwealth of Independent States	
Cl	Chlor	
CLIA	Clinical Laboratory Improvements Amendments	
CLL	chronische lymphatische Leukämie	
Cmax	maximale Plasmakonzentration	
CMC	Chemistry, Manufacturing, Control	Term used in the US and corresponds to Modul 3 in the EU
CMDh	Coordination group for Mutual recognition and Decentralized procedure (human)	(CMD h = human; CMD v = veterinary)
CMDv	group Coordination group for Mutual recognition and Decentralized procedure (veterinary)	
CME	continuing medical education	
CMR	Centre for Medicines Research	
CMS	Concerned Member State(s)	Subsequent member states in the MRP
CMV	Cytomegalovirus	
CND	Commission on Narcotic Drugs	Suchtstoffkommission (UN)
CNS	central nervous system	
CNSLD	Chronic Non-Specific Lung Disease	
CO	clinical overview	
COA	certificate of analysis	
COC	Cyclic Olefin Copolymer	
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios	Mexikanische Gesundheitsbehörde (Bundeskommission zum Schutz gegen Gesundheitsrisiken)
COM	Commission (Document)	
COMET	Single Cell Gel Electrophoresis assay	
COMISA	Confédération Mondiale de l'Industrie de la Santé Animale	
COMP	Committee for Orphan Medicinal Products	Located at the EMA
CONEP	National Commission for Ethics in Research	Ethikkommission in Lateinamerika
COPD	Chronic Obstructive Pulmonary Disease	
COS	Certificate of Suitability	
COSTART	Coding Symbols for a Thesaurus of Adverse Reaction Terms	
CP	Centralised Procedure	One of the procedures for market authorization in the EU
CP	Concept Paper	
CPA	Commonwealth of Pharmaceutical Association	
CPI	Consumer price index	
CPM	Centre for Pharmaceutical Medicine	
CPMP	Committee for Proprietary Medicinal Products	siehe auch: CVMP
CPP (CoPP)	Certificate of Pharmaceutical Product	Synonym to FSC (Free Sales Certificate)

Short	Cut Complete Name	Additional Information
CPR	Cardiopulmonary Resusciation	
CPSC	Consumer Product Safety Commission	(USA)
CPV	continuous process verification	
CQA	clinical quality assurance	
CQA	Critical quality attribute	
Cr	Chrom	
CR	Commission Regulation	
CR	Child resistant	siehe auch SF
CR	Clinical Reviewer	
CRA	Clinical Resarch Assistant/Associate	
CRADA	Cooperateive Research and Development Agreement (with NIH)	
CRC	Clinical Resarch Coordinator	See also CCRC
CRD	Common Renewal Date	
CRF	Case Report Form / Record Form Patient forms from clinical studies	
CRF	Code of Federal Regulations	
CRIOC	Centre de Recherche et d'Information des Organisations de Consommateurs	
CRO	Contract Research Organization	
CSDD	Centre for the Study of Drug Development	
C-Section	Cesarian-Section	
CSI	core safety information	
CSM	Committee on Safety of Medicines	Comparable to A-Kommission of BfArM in Germany
CSM	Clinical Study Manager	
CSO	Consumer Safety Officer (FDA)	
cSPC	core Summaries of Products Characteristics	
CSS	Company Sponsored Study	
CSV	Computer Systems Validation	
CT	clinical trial	
CT	Controlled Terms	
CTA	Clincal Trial Application/Authorisation	
CTC	Clinical Trial Certificate Clinical trial licence in the UK	
CTD	Common Technical Document	Single dossier structure for the EU, USA and Japan
CTMP	Clinical Trial on Marketed Product	(UK)
CTN	Clinical Notification Procedure	Australien
CTS	Communication Tracking System (of MRP)/Central Tracking System	
CTWP	Cell Therapy Working Party	Expertenfachgruppe bei der EMA
CTX	Clinical Trial Exemption	Clinical trial licence in the UK and Australia
Cu	Kupfer	
CVM	Centre for Veterinary Medicine	(FDA)
CVMP	Committee for Medicinal Products for Veterinary Use	Committee for the evaluation of animal drugs at the EMA (scientific body)
CYP	Cytochrome P450	
CZ	Climatic zone	

Short	Cut Complete Name	Additional Information
CZE	Capillar zone elctrophorese	
DA	Decision Analysis Modul 12, Unterlagen Herr Jopp	
DAB	Deutsches Arzneibuch	
DAC	Deutscher Arzneimittel Codex	
DAD	Diodenarray-Detector	
DAHTA	Deutsche Agentur für Health Technology Assessment	
DALY	Disability-Adjusted Life Years oder Disease-Adjusted Life Years	
DAMOS	Drug Application Methodology on Optical Storage	Co-operative approach on electronic submission between BfArM and industry
DARE	Datebase of Abstracts of Reviews of Effects	
DAV	Deutscher Apothekerverein	
DAWN	Drug Application Methodology with Optical Storage	
DAZ	Deutsche Apotheker Zeitung	
DCC	deleted in colorectal cancer	
DCP	Decentralised Procedure	Dezentrales Verfahren
DDD	defined daily dose	
DDM	Drug Dossier Manager	
DDPS	Detailed Description of the Pharmacovigilance System	
DDR	Drug Registratioh Department of SFDA	
DDX	Doctor´s and Dentist´s Exemption	
DEA	Drug Enforcement Agency (US)	
DEEC	Drug Evaluation Experts Committee (China)	Constituted of specialists to provice evaluation advice to the Chinese
DEL	Defect evaluation lists	
DEN	Drug Experience Network	
DeNIC	Deutsches Network Information Center	
DER	Drug-Extract-Ratio	
DEREK	Deductive Estimation of Risk from Existing Knowledge	
DES	Data Exchange Standard Specification	
DES	Diethylstilbestrol	synthet. Östrogen
DESI	Drug Efficacy Study Implementation Notice	(FDA, to evaluate drugs in use prior to 1962)
DFG	Deutsche Forschungsgemeinschaft	
DG	Directorate Generale Directorate General of the Commission in Brussels	(e.g. DG III for Pharmaceuticals)
DG ENTR	DG Enterprise and Industry	
DG SANCO	DG Health and Consumer Protection	
DG III	Directorate Generale III	
DGD	Now OGD	formerly CBER`s Division of Generic Drugs
DGPT	Deutsche Gesellschaft für experimentelle und klinische Pharmakologie und Toxikologie	

Short	Cut Complete Name	Additional Information
DG XIII	European Commission Directorate-General XIII	Telecommunications, information market, and exploitation of research
DGPharMed	Deutsche Gesellschaft für Pharmazeutische Medizin	ehemals FÄPI
DHEW	Department of Health, Education and Welfare	now split into Department of Health & Human-Services and Department of Education
DHPC	Direct Healthcare Professional Communication	
DHSS	Department of Health and Social Services	UK
DHT	Dihydrotestosteron	
DIA	Drug Information Association	
DiätV	Diätverordnung	
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information	
DIMDIV	DIMDI-Verordnung	
DIR	Directive	
DITR	Deutsches Informationszentrum für technische Regeln	
DKFZ	Deutsches Krebsforschungszentrum	
DKG	Deutsche Krankenhausgesellschaft	
DLP	Data Lock Point	(s. PSU)
DMC	Date monitoring committee	
DMF	jetzt: ASMF	
DMP	Disease Management Program	
DMS	Document Management System	
DOD	Department of Defense	
DoH	Department of Health	(UK and South Africa)
DP	Drug Product	
DPC-PTR Act.	Drug Price Competition and Patent Term Restoration ACT	1984 (also known as Waxman-Hatobill)
DPhG	Deutsche Pharmazeutische Gesellschaft	
DPI	Dry Powder Inhaler	
DQ	Design Qualification Subset of Validation	
DR	Discipline Review Letter	
DRA	Drug Regulatory Affairs	
DRAM	Drug Regulatory Affairs Manager	
DRG	Diagnosis Related Groups	
DRG	Division of Research Grants	(NIH)
DS	Drug Safety	
DSC	Drug Safety Communication	
DSC	Differential Scanning Calorimetry	
DSEB	Drug Safety and Evaluation Branch	Australien
DSI	Division of Scientific Investigations (FDA)	
DSM	Diagnostic and Statistical Manual	(of the American Psychiatry (Association)
DSMB	Data and Safety Monitoring Board	
DSMC	Data and Safety Monitoring Committee	
DSNP	Development of Standardized Nomenclature Project	FDA
DTA	Differenz(ial)-thermische Analyse	

Short	Cut Complete Name	Additional Information
DTD	Document Type Definition	
DTI	Department of Trade and Industry (UK)	
DTP	Diphtherie-Tetanus-Pertussis-Impfung	
DUNS-Nr	Data Universal Numbering System-Number	
DCVR	Developing Countries´ Vaccine Regulators´ Network	E2B ICH guideline re. Electronic format for exchange of drug safety information
E2B	Standard für elektronische Nebenwirkungsmeldungen an die Behörde	
E2E	ICH guideline reg. pharmacovigilance planning	
EAASM	European Alliance for Access to Safe Medicines	
EAB	Ethical Advisory Board	term used in some nations for groups similar to IRBs and IECs
EAD	early after depolarization	
eAF	electronic application form	
EAMIV	Elektronische Arzneimittelinformations-Verordnung	
EAMS	Earlier Access to Medicines	
EA-Report	environment assessment report	
EATG	European AIDS Treatment Group	
EbD	Ergänzende bilanzierte Diäten	
EBHC	evidence-based health care	
EBM	evidence-based medicine	evidenzbasierte Medizin
EBU	European Blind Union	
EC	European Commission	in documents older than the mid 1980s
EC	Ethics Committee	
EC	European Community	
ECARS	European Computer Assisted Regulatory Submission	
ECG	Electrocardiogram	
ECJ	European Court of Justice	
ECM	Enterprise Content Management System	
ECMA	European Carton Makers Association	
ECOSOC	Economic and Social Council	UNO
ECPHIN	European Community Pharmaceutical Products Information Network	
ECRI	Emergency Care Research Institute	
eCTD	electronic Common Technical Document	
ECU	European Currency Unit	
EDIFACT	Electronic Data Interchange for Administration, Commerce, and Transportation	
EDI	Electronic Data interchange	
EDMF	European Drug Master File	
EDMS	Electronic Document Management System	
EDS	Electronic Data Submission	
EDQM	European Directorate for the Quality of Medicines and HealthCare	Gremium des Europarates mit Sitz in Straßburg
EEA	European Economic Area	

Short	Cut Complete Name	Additional Information
EEC	European Economic Community,	now EU; some regulatory documents still have EEC document numbers
EEG	electroencephalogram	
EFGCP	European Forum on Good Clinical Practice	Evere, Belgium
EFPIA	European Federation of Pharmaceutical Industries' Associations	
EFQM	European Foundation for Quality Management	
EFSA	European Food Safety Authority	Europäische Behörde für Lebensmittelsicherheit
EFTA	European Free Trade Association	Western Europe countries which are not members of the EC
EG	Europäische Gemeinschaft	
EGA	European Generic Medicines Association	
eGK	elektronische Gesundheitskarte	
EGRL	EG-Richtlinie	
EGV	Vertrag zur Gründung der Europäischen Gemeinschaft	
EINECS	European register of old chemicals Europäisches Altstoffverzeichnis	
EIR	Establishment Inspection Report	FDA
EK	Ethikkommission	
ELA	Establishment License Application	FDA
ELINCS	European list of registered chemicals	
ELISA	Enzym-Linked Immunosorbent Assay	Bindungsassay
EMA	European Medicines Agency	vor 11/2009: EMEA
EMCDDA	European Monitoring Centre for Drug and Drug Addiction	WHO
EmLib	Essential Medicines Library	
EMP	siehe EuroPharm	
EMS	Electronic Mail Service	
ENR	Einreichungsnummer	
EOI	Expression of Interest	WHO
EP	European Parliament	
EPAR	European Public Assessment Report	
EPHMRA	European Pharmaceutical Marketing Research Association	
EPI	European Product Index	
EPI	Expanded Programme on Immunization	WHO
EPITT	European Pharmacovigilance Issues Tracking Tool	
EPO	European Patent Office	
EPO	erythropoietin	
EPRG	European Pharmacovigilance Research Group	
EPS	Entwicklungs-Projekte-Steuerungskonferenz	
ERA	Environmental Risk Assessment	
ERG	Electroretonogram	
ESCOP	European Scientific Cooperative for Phytotherapy	
ESG	Electronic Submission Gateway	

Short	Cut Complete Name	Additional Information
ESI	Electrospray Ionization	
ESOP	European Society for Pharmacovigilance	
ESR	Erythrocyte Sedimentation Rate	
ESRA	European Society of Regulatory Affairs	
ESTRI	Electronic Standards for the Transmission of Regulatory Information	
ETF	EMA Task Force	
ETOMEP	European Technical Office for Medicinal Products	EMA
EU	European Union	Cooperation of 26 European Countries
EUDRACT	European Clinical Trials Database	
EUDRANET	European Union Drug Regulatory Authorities Network	(EMA)
EUFEPS	European Federation of Pharmaceutical Sciences	
EuG	Europäisches Gericht,	erste Instanz
EuGH	Europäischer Gerichtshof	
EU-KOM	Europäische Kommission	
EURD	European Union Reference Date and frequency of submission of periodic safety update reports (PSURs)	
EuroPharm	European Pharmacopoeia	
EURS	European Review System	Reviewsystem, das die Behörden bei der Prüfung von e-CTDbasierten Zulassungsdossiers unterstützt
EUSES	European Union System for the Evaluation of Substances	
EVCTM	EudraVigilance Clinical Trial Module	
EVMPD	EudraVigilance Medicinal Products Directory	
EVPM	Earned Value Project Management	
EVPRM	Eudra Vigilance Medicinal Product Report Message	
EVV	Eudra Vigilance Veterinary Module	
EW	Entwicklung	
EWP	Efficacy Working Party	Mittlerweile aufgelöst
EWR	Europäischer Wirtschaftsraum	
F	Fläche	
FÄPI	Fachgesellschaft der Ärzte in der Pharmazeutischen Industrie e.V.	German Association of Physicians in the Pharmaceutical Industry
FAH	Forschungsvereinigung der Arzneimittelhersteller	
FAO	Food and Agriculture Organisation of the United Nations Farmindustria	The Association of the Italian Pharmaceutical Manufacturers FCC Food Chemical Codex (US)
FD	Floppy disk	
FDA	Food and Drug Administration	USA
FDAAA	Food and Drug Administration Amendment Act	

Short	Cut Complete Name	Additional Information
FDASIA	FDA Safety andn Innovation Act	
FD&C	Food, Drugs and Cosmetics Act (US)	
FDC	Fixed-dose Combination	
FDLI	The Food and Drug Law Institute	
Fe	Eisen	
F&E	Forschung und Entwicklung	
FEDESA	Fédération Européenne de la Santé Animale	
FEIBA	Factor Eight Inhibitor Bypassing Activity	
FHD	First Human Dose	
FI	Fachinformation	
FICI	Federation of Irish Chemical Industries	
FID	Flammenionisationsdetektor	
FIFARMA	Federación Latinoamericana de La Industria Farmacéutica	Latin American Federation of the Pharmaceutical Industry
FIM	first-in-man	
FIP	Féderation Internationale Pharmaceutique	
FIZ Technik	Fachinformation Technik	
FMEA	Failure Mode Effect Analysis	
FMECA	Failure Mode, Effects and Criticality Analysis	
FO	Forschung	
FOI	Freedom of Information	
FOIA	Freedom of Information Act (USA)	FDA self-obligation to publish information
FPA	Family Planning Association	
FPC	Family Practitioner Committees	
FPC	Federal Partners Collaboration	
FPIF	The Finnish Pharmaceutical Industry Association	
FR	Federal Register	
FRCP	Fellow of the Royal College of Physicians,	sometimes followed by a place name – for example, FRCP (Edin.) – that indicates a university medical school
FSC	Free Sales Certificate	information on product and manufacturer from the country of origin siehe auch CPP
FSCA	Field Safety Corrective Action	Sicherheitsrelevante korrektive Maßnahme im Feld
FSH	Follikel-stimulierendes Hormon	
FT	Freitext	
FTA	fault tree analysis	
FTC	Federal Trade Commission	USA
FTP	File Transfer Protocol	
FVAR	Final Variation Assessment Report	
g	Gramm	
G	Guideline	
GA	Gegenanzeigen	
GABA	Gamma-aminobutyric acid	
GACP	Good Agricultural and Collection Practice	
GALP	Good Automated Laboratory Practice	
GAMP	Good Automated Manufacturing Practice	

Short	Cut Complete Name	Additional Information
GAO	General Accounting Office	U.S. government
GAP	Good Analytical Practices	
GATB	Global Alliance for Tuberculosis	
GATT	General Agreement of Tariffs and Trade	
G-BA/GBA	Gemeinsamer Bundesausschuss	
GC	gas chromatography	
GCC	Gulf Cooperation Council	Kooperationsrat der arabischen Golfstaaten
GCC-DR	Gulf Central Committee for Drug Registration	Behörde zur Förderung der Zusammenarbeit der GCC-Mitglieder im Bereich der AM-Zulassung
GCP	Good Clinical Practice	
GCRP	Good Clinical Research Practice	
G-CSF	granulocyte colony stimulating factor	
GDP	good distribution practice	
GDUFA	Generic Drug User Fee Amendment	
GenTG	Gentechnikgesetz	Gesetz zur Regelung von Fragen der Gentechnik
GEROLIT	Gerontologische Literaturdatenbank des deutschen Zentrums für Altersfragen (DZA)	
Gew.O.	Gewerbeordnung	
GFAP	Glial Fibrillary Acidic Protein	
GfI	Guidance for Industry	
GFP	Gute fachliche Praxis	
GGIMP	Gerência de Inspeção e Control de Medicamentos e Productos	Brasilianische Überwachungsbehörde (General Office of Inspection and Control of Inputs, Drugs, and Products
GGMED	Gerência de Medicamentos	Brasilianische Zulassungsbehörde (General Office of Drug)
GHTF	Global Harmonization Task Force	
GI	Gebrauchsinformation	
GI	Gastrointestinal	
GK	Globale Konzeption	
GKV	Gesetzliche Krankenversicherung	
GKV-SpiV	Spitzenverband der Gesetzlichen Krankenversicherungen	
GKV-WSG	GKV-Wettbewerbsstärkungsgesetz	
GL	Guideline	
GLP	Good Laboratory Practice	
GMA	Global Marketing Authorisation	
GMC	General Medical Council	
GM-CSF	Granulocyte Macrophage Colony Stimulating Factor	
GMDN	Global Medical Device Nomenclature	
GMDS	Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie e.V	
GMG	GKV-Modernisierungsgesetz	
GMO	Genetically Modified Organism	
GMP	Good Manufacturing Practice	

Short	Cut Complete Name	Additional Information
GMSC	General Medical Services Committee	
GNP	Gross National Product	
GÖ	Gesundheitsökonomie	
GOS	Glasgow Outcome Score	
GP	General Practitioner	
GPIA	Generic Pharmaceutical Industry Association	
GPSP	Good Practice Systems and Programs	
GPUE	Groupement de Pharmaciens Européens	
GRP	Good Regulatory Practice	
GSAV	Gesetz für mehr Sicherheit in der Arzneimittelversorgung	
GSG	Gesundheitsstrukturgesetz	
GSL	General Sales List (U.K.)	
GST	Glutathion-S-Transferase	
GTWP	Gene Therapy Working Party	Expertenfachgruppe bei der EMA
GUI	Graphical User Interface	
GÜG	Grundstoff-Überwachungsgesetz	
GUSTO	Global Utilisation of Streptokinase and TPA in the Occlusion of Coronary Arteries	
GVD	gemeinsames Verlängerungsdatum	
GVO	Genetisch veränderter Organismus	(s. GMOS)
GVP	Good Pharmacovigilance Practice	
GWG	Geldwäschegesetz	
HAB	Homöopathisches Arzneibuch	
HACCP	Hazard Analysis of Critical Control Point	
HAI	Health Action International	
HAS	Haute Authorité de Santé French National Authority for Health	
HAZOP	Hazard Operability Analysis	
HBV	Hepatitis B virus	
HC HCQC	Proton-carbon Heteronuclear single Quantum Correlation	
HC HMBC	Proton-carbon Heteronuclear Multiple-bond Correlation	
HC COSY	Proton-carbon Correlated Spectroscopy	
HCV	Hepatitis C Virus	
HCFA	Health Care Financing Administration	(of the HHS)
HDPE	High density polyethylene	
HDL	high-density lipoprotein	
HED	human equivalent dose	
HepB	Hepatitis B	
HEVRA	Heads of European Veterinary Regulatory Authorities for Medicinal Products	
Hg	Quecksilber	
HGB	Handelsgesetzbuch	
Hgb	Hemoglobin	
HH ROESY	Proton-carbon rotating frame Overhauser effect spectroscopy	
HHS	Health and Human Services	
Hib	haemophilus influenza Typ b	

Short	Cut Complete Name	Additional Information
HIMA	Health Industry Manufacturers Association	
HISPP	Healthcare Informatics Standards Planning Panel	
HIV	Human Immunodeficiency Virus	
HL7	Healthcare Linkage version 7	
HMA	Heads of Medicines Agencies	
HMEC	Human Medicines Expert Committee	(Schweiz)
HMG-CoA reductase	3-Hydroxy-3-methylglutaryl-Coenzym-A-Reduktase oder ß-Hydroxy-ß-methylglutaryl-Coenzym-A-Reduktase	
HMO	Health Maintenance Organisation	(US)
HMP	Herbal Medicinal Product	
HMPC	Committee on Herbal Medicinal Products	
HMPWP	Herbal Medicinal Products Working Party	
HNSTD	Highest Non-Severly Toxic Dose	
HOA	Heads of Agencies	
HP	Healthcare Professional	
HPFB	Health Products and Food Branch	kanadische Überwachungsbehörde; s. auch TPD
HPLC	high performance liquid chromatography	
HPV	human papillomavirus	
HR	heart rate	
HRI	Host related impurities	
HRT	Hormone Replacement Therapy	
HS-GC	Headspace-Gas Chromatography	
HSR	Health Services Research	
HTA	Health Technology Assessment	
HTML	Hypertext Mark-up Language	
HTTPS	Hypertext Transfer Protocol Secure	
HVAC	Heating, Ventilation and Air conditioning	Sammelbegriff für Lüftungssysteme
HVD	half value duration	Halbwertzeit
HWG	Heilmittelwerbegesetz	
HWI	Harnwegsinfektion	
IANA	Internet Assigned Numbers Authority	
IARC	International Agency for Research on Cancer, Lyon	
IAS	International Accounting Standards	
IB	Investigator’s Brochure	
IBD	International Birth Date	
IBS	International biometric society	Internationale biometrische Gesellschaft
IBS-DR	Deutsche Region der Internationalen Biometrischen Gesellschaft	
IC	Informed Consent	
IC	Ion Chromatography	
ICD	International Classification of Diseases	
ICD-O	International Classification of Diseases for Oncology	
ICDRA	International Conference of Drug Regulatory Authorities	

Short	Cut Complete Name	Additional Information
ICER	Incremental cost-effectiveness ratio	
ICF	Internationale Klassifikation der Funktionsfähigkeit, Behinderung und Gesundheit	
ICH	International Conference on the Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)	
ICP-AES	Inductively coupled plasma – atomic emission spectroscopy	
ICP-MS	Inductively coupled plasma – mass spectroscopy	
ICP-OES	Inductive Coupled Plasma Optical Emission Spectroscopy	
ICPM	International Clinical Project Manager	
ICSR	Individual Case Safety Report	
ICTH	International Committee on Thrombosis and Haemostases	
IDE	Investigational Device Exemption	FDA
IDL	Import Drug License	
IDMA	Indian Drug Manufacturers' Association	
IDMC	Independent Data Monitoring Committee	
IDMP	Identification of Medicinal Product	
IDP	Import Drug Permission	
IDR	Idiosyncratic drug reaction	
IEC	Independent ethics committee	See also EAB, IRB, NRB
IEF	Isoelectric focusing	
IFA	Informationsstelle für Arzneimittel GmbH	
IFAH	International Federation of Animal Health	Sitz in Brüssel
IFAPP	International Federation of Association of Pharmaceutical Physicians	
IFG	Informationsfreiheitsgesetz	
IFPMA	International Federation of Pharmaceutical Manufacturers Association	
IfSG	Infektionsschutzgesetz	
IG	The Office of the Inspector General	HHS
IGPA	International Generic Pharmaceutical Alliance	
IHE	Swedish Institute for Health Economics	
IHTA	International Health Technology Assessment	
IIT	investigator initiated study	
IKS	Interkantonale Kontrollstelle für Heilmittel	Schweiz (jetzt: Swissmedic)
ILSI	International Life Science Institute	Sitz in Washington D.C.
IMAP	International Medical Advisory Panel	
IMCT	International Multicenter Clinical Trial	
IMMED	International Marketed Medicines Database	
IMP	investigational medicinal product	
IMPACT	International Medicinal Products Anti-Counterfeiting Task Force	Netzwerkaus zahlreichen Interessenverbänden, Organisationen und staatlichen bzw. internationalen Behörden
IMPD	Investigational Medicinal Product Dossier	
INAHTA	International Health Technology Assessment	

Short	Cut Complete Name	Additional Information
	Database	
INCB	International Narcotics Control Board	(UNO) (Internationaler Suchtstoffkontrollrat
IND	Investigational New Drug Application	
INN	International Non-proprietary Name	
INTDIS	WHO database of side-effects	
INTERNIC	The Internet´s Network Information Centre	
IPA	International Pharmaceutical Abstracts	
IPC	In-Process-Control	
IPK	Inprozesskontrolle	
IPM	International Project Manager	
IPPF	International Planned Parenthood Federation	
IPRO	Independent Pharmaceutical Research Organization.	See also CRO.
IPS	Industrial Pharmacists Section	
IPV	Inactivated Poliomyelitis Vaccination/Virus	
IPTS	Institute for Prospective Technological Studies	
IQ	Installation Qualification	
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen	
Ir	Iridium	
IR	Infrarotspektroskopie	
IR	Information Request Letter	USA
IRB	Institutional Review Board	
IRD	International Registration Document	
IRDAC	Industrial Research and Development Advisory Committee	
IRF	International Reviewer Forum	
ISE	Integrated Summary on Efficacy	Part of the NDA for FDA (Efficacy)
ISO	International Standards Organization	
ISOC	Internet Society	
ISS	Integrated Summary on Safety	Part of the NDA for FDA (Safety)
IT	Information Technology	
IT	Index Terms	
ITCVDR	International Technical Consultation on Veterinary Drug Registration	
ITT	Intention to treat	Analyse-Technik, bei der die Patienten nach ihrer ursprünglichen Gruppenzuteilung analysiert werden, unabhängig davon, ob sie die zugeordnete (intendierte) Therapieform vollständig, partiell oder gar nicht erhalten haben
IUB	International Union of Biochemistry Enzyme Nomenclature	
IUD	intrauterine device	
IUPAC	International Union of Pure and Aplied Chemistry a In Vitro Diagnostics	
IVD	In-vitro-Diagnostikum	

Short	Cut Complete Name	Additional Information
IVDMDD	In Vitro Diagnostics Medical Devices Directive	
IVF	In Vitro Fertilization	
IVF/ET	In Vitro Fertilization/Embryo Transfer	
IVR	Interactive Voice Responding	
JAMA	Journal of the American Medical Association	
JAN	Japanese approved names	
JAPIC	Japan Pharmaceutical Information Center	
JCAH	Joint Commission for the Accreditation of Hospitals	
JCAHO	Joint Commission of Accreditation of Health Care Organizations	
JCPAC	Japanese Central Pharmaceutical Affairs Council	
JCPT	Journal of Clinical Pharmacology and Therapeutics	
JCRDD	Journal of Clinical Research and Drug Development	
JCRP	Journal of Clinical Research and Pharmacoepidemiology	
JDI	Joint Declaration of Intent	
JEFA	Joint FAO/WHO Expert Committee on Food Additives	
JGMP	Japanese GMP	
JP	Japanese Phamacopeia	
JPMA	Japan Pharmaceutical Manufacturers Association	
JRC	European Commission Joint Research Centre	
KALP	Kalenderpackung	
KBE	keimbildende Einheiten	
KBV	Kassenärztliche Bundesvereinigung	
KK	Krankenkasse	
KFDA	Korea Food and Drug Administration	
KFEB	Committee for Clinical Pharmacology and Ethics	
KM	Knowledge Management	
KMU	Kleine und mittlere Unternehmen	
KPT	Kern Projekt Team	
KS	Kaposi’s sarcoma	
KV	Kassenärztliche Vereinigung	
kwV	keine weitere Verlängerung	
KZBV	Kassenzahnärztliche Bundesvereinigung	
LACNIC	Latin American and Carribean Internet Adresses Registry	
LAG	Länderausschuss	Gentechnik
LAL-Test	Limulus Amoebocyte Lysate Test Pyrogenic endotoxins in injectable preparations	
LAS	Labor-Automationssystem	
LAS	Lymphadenopathy Syndrome	(= AIDS)
LAT	Light Authorig Tool	
LB	deutsche Landesbehörde	
LBBB	Left Bundle Branch Block	

Short	Cut Complete Name	Additional Information
LC	Liquid chromatography	
LCM	Life-cycle-management	
LDH	Laktatdehydronegase	
LDL	low-density lipoprotein	
LEEM	Les Entreprises du Médicament	Französischer Verband der Medikamentenhersteller
LFGB	Lebensmittel-und Futtermittelgesetzbuch	
LH	Luteinisierendes Hormon	
LIGA	life gained table	
LIMS	Laboratory Information Management System	
LM	Lösemittel	
LMBG	Lebensmittel-und Bedarfsgegenständegesetz	
LMR	Lebensmittelrecht	
LMKV	Lebensmittel-Kennzeichnungsverordnung	
LOC	Locally Operating Company	
LOD	Limit of Detection	Nachweisgrenze
LOCF	Last Observation Carried Forward	
LOEL	Lowest Observed Effect Level	
LOINC	Logical Observation Identifier Names and Codes	
LoOI	List of Outstanding issues	Day 180 (CP)
LoQ	limit of quantification	
LoQ	List of Questions	Day 120 (CP)
Lot	franz; Synonym: Batch	
LPLV	Last Patient Last Visit	
LSL	Lower Specification Limit	
LVZ	Lager-und Versandzentren	
MA	Marketing Authorisation	
MAA	Marketing Authorisation Application	
MAB	monoclonal antibody	
MABEL	minimally anticipated biological effect level	
MAH	Marketing Authorisation Holder	
MAIL	Medicines Act Information Letter	(U.K.)
MAL	Medicines Act Leaflet	(U.K.)
MALDI	Matrix assisted laser desorption/ionization	
MANSEV	Marketing Authorisation by Network Submission and Evaluation	
MAO	Monoamine Oxidase	
MAPP	Manual of Policies and Procedures	Regulatory procedures manual issued by the FDA
MCA	früher: Medicines Control Agency (UK);	jetzt: MHRA
MCASE	Multiple Computer Automated Structure Evaluation	
MCC	Medicines Control Council	Südafrikan. Zulassungsbehörde
MCH	Mean Corpuscular Hemoglobin	
MCHC	Mean Corpuscular Hemoglobin Concentration	
MCM	multi-component mixture	
MCRC	Medical and Clinical Research Consultants	(UK)
MCV	Mean Corpuscular Volume	
MD	Multiple dose	
MDA	Medical Devices Agency (UK)	

Short	Cut Complete Name	Additional Information
MDCG	Medical Device Coordination Group	
MDD	Medical Device Directives (EU)	
MDI	Metered Dose Inhaler; Manic Depressive Illness	
MDK	Medizinischer Dienst der Krankenkassen	
MDN	Message Disposition Notification	
MDS	Medizinischer Dienst der Spitzenverbände	
MDS	Master Data Sheet	
MDV	Medical Device Vigilance	
MEB	Medicines Evaluation Board	(Netherlands)
MECU	Million ECU	
MEDDEV	MEDical DEVices	
MedDRA	Medical Dictionary for Drug Regulatory Activities	Result of ICH M1
MEDLARS	Medical Literature Analysis and Retrieval System	
Medsafe	Neuseeländische Zulassungsbehörde	
MEFA	The Association of the Danish Pharmaceutical Industry	
MEGRA	Mitteleuropäische Gesellschaft für Regulatorische Angelegenheiten e.V.	
MEMO	Medicines Evaluation and Monitoring Organisation	
MENA	Middle East & North Africa	(Nahost und Nordafrika)
MEP	Member of the European Parliament	
MERCOSUR	Mercado Común del Sur	Gemeinsamer Markt Südamerikas
MERS	Multiagency Electronic Regulatory Submission	
MeSH	Medical Subject Headings	
Mg	Milligram	
MGMT	Methylguaninemethyltransferase	
MGV	maximale prozentuale Gesamtverunreinigung	
MHRA	Medicines and Healthcare products Regulatory Agency	(UK)
MHLW	Ministry of Health, Labour and Welfare	(Japan)
MIC	Minimum Inhibitory Concentration	
MIHWAF	Ministry of Healthcare, Welfare and Family	Korea
MIMS	Monthly Index of Medical Specialities	
MIST	Mexico, Indonesia, South Korea and Turkey	
ml	milliliter	
mm	millimeter	
MMR	Maser-Mumps-Röteln-Schutzimpfung	
MMV	Medicines for Malaria Venture	
Mn	Mangan	
MNA	µ-Agonist + NA-Reuptake-Inhibitor: Analgetika mit doppeltem Wirkprinzip	
Mo	Molybdän	
MOH	Ministry of Health China	
MOU	Memorandum of Understanding	between FDA and a regulatory agency in another country that allows mutual recognition of

Short	Cut Complete Name	Additional Information
		inspections
MP	medicinal product	Deutsch: Arzneimittel (nicht Medizinprodukt !!)
MPA	Medical Products Agency	Schwedische Zulassungsbehörde
MPAV	Verordnung zur Regelung der Abgabe von Medizinprodukten	
MPBetreibV	Medizinprodukte-Betreiberverordnung	
MPG	Medizinproduktegesetz	
MPGVwV	Allgemeine Verwaltungsvorschrift zur Durchführung des MPG	
MPS	Medizinisch-pharmazeutische Studiengesellschaft	
MPSV	Medizinprodukte-Sicherheitsplanverordnung	
MPV	Medizinprodukteverordnung	
MPVerschrV	Verordnung über die Verschreibungspflicht von Medizinprodukten	
MPVertrV	Verordnung über Vertriebswege für Medizinprodukte	
Mr	Relative molecular mass	
MR	Mutual Recognition	
MRA	Mutual Recognition Agreement	
MRA	Medical Research Associate	
MRC	Medical Research Council (U.K.)	
MRFG	Mutual Recognition Facilitation Group	
MRI	Magnetic Resonance Imaging	
MRL	maximum residue limit	
MRP	Mutual Recognition Procedure	One of the procedures for marketing authorization in the EU
MRSD	maximum recommended starting dose	
MRT	Magnet-Resonanz-Tomographie	
MRT	Mean residence time	Mittlere Verweilzeit
MS	Member State(s)	Countries organized in the EU
MS	mass spectrometry	
MTC	mixed treatment comparison	
MTD	maximum tolerated dose	
MTPT	Methylphenyltetrahydropyridine	
MUMS	Minor Use and Minor Species	
MVI	Malaria Vaccine Initiative	
N	Stickstoff	
n.d.	not detected	
NA	Norepinephrine	
NA	New Approach/Neuer Ansatz	
NADA	New Animal Drug Application	
NAF	Notice of Adverse Findings	(FDA post-audit letter)
NAFTA	North American Free Trade Agreement	
NAI	no action indicated	(most favourable FDA post-inspection classification)
NAP	nationally authorised product	MRP/DCP
NAS	New Active Substance	
NAS-NRC	National Academy of Sciences – National	

Short	Cut Complete Name	Additional Information
	Research Council	
NAT	National	
NATRIK	National Reporting and Investigation Centre	UK
NBE	new biological entity	
NB-MED	Empfehlungspapiere, welche vom Europäischen Erfahrungsaustausch der Benannten Stellen im Bereich Medizinprodukte (NB-MED), an dem auch Vertreter der Herstellerverbände und EG-Kommission teilnehmen, verabschiedet wurden	
NCA	National Competent Authority	
NCE	New Chemical Entity	
NCHS	National Centre for Health Statistics (in CDC)	
NCHSR	National Center for Health Services Research (and Health Care Technology Assessment)	(USA)
NCI	National Cancer Institute (NIH)	
NCO	Non-clinical Overview	
NCPIE	National Council on Patient Information and Education	(Washington, DC)
NCR	no carbon required	
NCRP	Northwest Clinical Research Professionals	Portland, OR
NCVIA	National Childhood Vaccine Injury Act (1986)	
NDA	New Drug Approval/Application	
NDAB	National Drug Advisory Board	
NDS	New Drug Submission	(Kanada)
NDS	new drug study	(Canada's new drug application)
NECSI	New England Complex Systems Institute	
NEDO	National Economic Development Office	
NEFARMA	The Dutch Association of the Innovative Pharmaceutical Industry	
NEI	National Eye Institute (NIH)	
NEM	Nahrungsergänzungsmittel	
NemV	Nahrungsergänzungsmittelverordnung	
NF	national formulary	
NfG	Note for Guidance	
NG	Nachweisgrenze	
NGO	Non-Governmental Organisation	
NHI	National Health Insurance (Japan)	
NHLBI	National Heart, Lung and Blood Institute	NIH
NHS	National Health Service (UK)	
NHW	National Health and Welfare Department	Canada
Ni	Nickel	
NIAID	National Institute of Allergies and Infectious Diseases	USA)
NICE	National Institute for Health and Clinical Excellence	
NICHD	National Institute of Child Health and Human Development	NIH
NIDA	National Institute on Drug Abuse	
NIFDE	National Institute of Food and Drug Safety Evaluation	Korean Technical Evaluation Institute

Short	Cut Complete Name	Additional Information
NIH	National Institutes of Health (USA)	
nih	not invented here	
NIMP	Non-Investigational Medicinal Product	
NINDS	National Institute of Neurological Disorders & Stroke (NIH)	
NIP	National Institute of Pharmacy	
NIR	Nah-Infrarot	
NIS	Nichtinterventionelle Studie	
NIT	non-interventional trial	
NITR	National Institute of Toxicological Research	Korea
NJW	Neue Juristische Wochenschrift	
nK	neue Konzeption	
NMDA	N-Methyl-D-aspartate	
NME	New Molecular Entity	
NMR	nuclear magnetic resonance	
NMT	not more than that	
NNH	number needed to harm	
NNT	number needed to treat	
NOAEL	non-observed adverse effect level	höchste toxische Dosis, die nichts zeigt
NOC	Notice of Compliance	Canada, India
NOEC	No Observed Effect Concentration	
NOEL	no observed effect level	
NRB	Non-institutional Review Board,	also known as an independent review board. See also EAB, IEC, IRB
NRC	Nuclear Regulatory Commission	
NRF	Neues Rezept Formularium	
NRG	Name Review Group	
NSAID	non-steroidal anti-inflammatory drug	
NtA	Notice to Applicants	
NTP	National Toxicology Program	
NUB	Neue Untersuchungs- und Behandlungs-methoden	
NUIS	Non-Urgent Information System	
NUMA	New Use marketing authorization	
NvWZ	Neue Zeitschrift für Verwaltungsrecht	
NW	Nebenwirkungen	
NwG	Notification with grounds	
NYHA	New York Heart Association (scoring system)	
NZ	New Zealand	
NZL	Nachzulassung	
NZLB	Nachzulassungsbescheid	
OAI	Official Action Indicated	(serious FDA post-inspection classification)
OC	Operationscharakteristik	
OC	Oral Contraceptive	
OCABR	Official control authority batch release	
OCI	Office of Criminal Investigation	
OCLC	Online Computer Library Center	
OD	optical disk	

Short	Cut Complete Name	Additional Information
ODE	Office of Drug Evaluation	(CDER now has five such offices: ODE I, II, III, IV, and V.)
ODE	Orphan Drug Exclusivity	Generics USA
OE	oral explanation	
OECD	Organisation for Economic Co-operation and Development	(Organisation für wirtschaftliche Zusammenarbeit und Entwicklung) franz.: OCDE (organisation de coopération et de devéloppement économiques)
OFT	Office of Fair Trading	
OGD	Office of Generic Drugs	(CDER, formerly DGB)
OGE	Office of Government Ethics	(formerly part of Office of Personnel Management, separate executive branch in 1989)
OHE	Office of Health Economics (U.K.)	
OHIM	Office for Harmonisation in the Internal Market (Warenzeichen)	
OHRP	Office for Human Research Protection	USA
OIE	International Office of Epizootics	Internationales Tierseuchenamt
OJC	Office Journal of the EU-C Series (Information)	
OJEC	Official Journal of the European Community	
OJL	Office Journal of the EU-L Series (Legislation)	
OLAF	European Anti-Fraud Office	
OLG	Oberlandesgericht	
OMB	Office of Management and Budget (USA)	
OMCL	Official Medicines Control Laboratories	
OMICS	Sammelbegriff für Spezialdisziplinen aus dem Bereich der Biotechnologie mit der Endsilbe „-omics“	
OML	overall migration limit	
OMOP	Observational Medical Outcomes Partnership	
OMP	Orphan Medicinal Product	
OOS	out of specification	
OP	Originalpackung	
OPPI	Organisation of Pharmaceutical Producers of India	
OPRR	Office of Protection from Research Risks	NIH
OPS	Operationsschlüssel nach Paragraph 301 SGB V	
OQ	Operational Qualification	
ORA	Office of Regulatory Affairs	
ORD	Optische Rotationsdispersion	
Os	Osmium	
OSPAR	Oslo-Paris-Konvention	
OSHA	Occupational Safety Health Administration	USA
OTA	Office of Technology Assessment	USA; Congress abolished, fall 1995
OTC	over-the-counter, apothekenpflichtig	non-prescription medicines
OVG	Oberverwaltungsgericht	

Short	Cut Complete Name	Additional Information
OwiG	Ordnungswidrigkeitengesetz	German Law on Misdemeanors
P-i	parallel-imported	
PA	Proprietory Association	
PAD	Pharmacologically Active Dose	
PAES	Post Authorisation Efficacy Studies	
PAF	platelet activating factor	
PAG	Post uthorization guidance (EMA)	
PAGB	Proprietary Association of Great Britain	
PAHO	Pan-American Health Organisation	
PAI	pre-approval inspection	
PAP	Programmablaufplan	
PALC	Pre-Accession Linguistic Checking	
PANDRH	Pan American Network for Drug Regulatory Harmonization	
PAR	Public Assessment Report, pain relief	
PARNUTS	Foods for Particular Nutritional Use	
PASS	Post Authorisation Safety Study	
PAT	process analytical technology	
PatG	Patentgesetz	
Pb	Blei	
PBS	Pharmaceutical Benefit Scheme (AUS)	
PBL	Packungsbeilage	
PBM	pharmacy benefit management	
PCA	patient controlled analgesia	
PCC	Poison Control Centre	
PCP	Pneumocystis Carnii Pneumonia	
PCR	Polymerase-Kettenreaktion (engl. polymerase chain reaction)	
PCR	Preclinical Reviewer	
PCV	packed cell volume	
PCWP	Patients' and Consumers' Working Party	EMA Human Scientific Committees Working Party with Patients' and Consumers' Organisations
Pd	Palladium	
PD	pharmacodynamics	
PDCO	Paediatric Committee	
PDE	permitted daily exposure	
pdf	portable document format	
PDG	Pharmacopeial Discussion Group	
PDQ	Physicians' Data Query (NCI-sponsored cancer trial registry)	
PDR	Physician Desk Reference	
PDUFA	Prescription Drug User Fee Act US act for faster review of drug applications	
PDVE	PIM DES Validation Engine	Siehe auch PIM und DES
PE	Polyethylene	
PEAKPID	peak pain intensity difference	
PEC	Predicted Environmental Concentration	
PEFRAS	Pan-European Federation of Regulatory Affairs Societies	

Short	Cut Complete Name	Additional Information
PEI	Paul-Ehrlich-Institut	Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, Deutschland
PEM	Prescription Event Monitoring (UK)	
PER scheme	Pharmaceutical Evaluation Report Scheme for mutual recognition of evaluation reports	
PERI	Pharmaceutical Education & Research Institute	
PET	positron emission tomography	
PET	Polyethylene Terephthalate	
PfSchG	Pflanzenschutzgesetz	
PFT	pulmonary function tests	
PGP	pretty good privacy	Verschlüsselungssoftware
PHA	preliminary hazard analysis	
PharmBetr.V	Pharmazeutische Betrieb-Verordnung	wurde durch die AMWHV ersetzt
PHI	Private Health Insurance	
Ph.Eur.	European Pharmacopoeia	
Ph. Helv.	Pharmacopoeia Helvetica Arzneibuch der Schweiz	
PhRMA	Pharmaceutical Research and Manufacturers of America	
PHS	Public Health Service	
Ph.U.	Pharmazeutischer Unternehmer	auch: PU
PhV	Pharmakovigilanz	
PhVWP	Pharmacovigilance Working Party	
PI	principle investigator	
PI	parallel Import/Importeur	
PI	package insert	
PI	Produktinformation (FI + GI)	
PI	Product Information (SPC, PIL, labeling)	
PIA	Pre-Approval Inspections (USA)	
PIC	Pharmaceutical Inspection Convention	
PICO	Hilfsschema für die Formulierung einer klinischen Frage zur Wirkung von Interventionen: ***p**atient, **i**ntervention, Vergleichsintervention (**c**omparison), Zielgrösse (**o**utcome)*	relevant bei der Nutzenbewertung von AM
PIC Site Master File	Explanatory notes for industry on the preparation of a Site Master File	guidelines for GMP
PIC-S	PIC-Scheme	
PID	pain intensity difference	
PID	pelvic inflammatory disease	
PIF	products information form	
PIL = PL	patient information leaflet	
PIM	Product Information Management	
PIP	Paediatric Investigation Plan	
PK	pharmacokinetics	
PK	Produktkonferenz	
PKV	Private Krankenversicherung	
PL	package leaflet	Packungsbeilage

Short	Cut Complete Name	Additional Information
PL(PI)	Product License for Parallel Imports	
PLA	Product Licence Application (biological in the US)	
PLATO	Plättchenhemmung und Patienten-Outcomes (PLATO) Studie	
PLUS	Product Licence User System	
PMA	Pharmaceutical Manufacturers Association	now PhRMA
PMA	Premarket approval application	FDA
PMDA	Pharmaceuticals and Medical Device Evaluation Center	japan. Zulassungsbehörde
PMF	Plant Master File (US); Plasma Master File(EU)	
PMQR	Pre-Migration Quality Review	
PMS	post-marketing surveillance	
PMS	Paul-Martin-Stiftung	
PNEC	predicted no effect concentration	
PNR	Pharmazeutischer Unternehmer-Nummer des BfArM	
PoC	Proof of Concept	
POM	prescription only medicines	
PP	Polypropylene	
PPA	potential problem analysis	Modul 12, Unterlagen Herr Jopp
PPB	plasma products biotechnology	
PPI	producer price index	
PPI	proton pump inhibitor	
PPI	patient package insert	
PPID	peak pain intensity difference	
PPO	Preferred Provider Organization; Policy and Procedure Order	
PPP	Pregnancy Prevention Program	
PPPA	Poison Prevention Packaging Act	
PPRS	Pharmaceutical Price Regulation Scheme	UK
PPSB	Prothrombinkonzentrat	Blutprodukt, in dem bestimmte Vitamin-K-abhängige Gerinnungsfaktoren konzentriert sind
PPSR	Proposed Pediatric Study Request	
PQ	performance qualification	
PQR	product quality review	
PR	Public Relations	
PR	pain relief	
PRAC	Pharmacovigilance Risk Assessment Committee	
PREA	Pediatric Research Equity Act	USA
PRIMR	Public Responsibility in Medicine and Research	(Boston, MA)
P-RMS	PSUR Reference Member State	
PRS	PIM Review System	
PSC	Pharmaceutical Committee	Unterkommitee von ADEC
PSD	Particle size distribution	
PSMF	Pharmacovigilance System Master File	
PSP	Paediatric Study Plan	

Short	Cut Complete Name	Additional Information
PSRPH	Potential Serious Risk to Public Health	
PSU/PSUR	Periodic Safety Update Report	
Pt	Platin	
PTA	Percutaneous Transluminal Angioplasty	
PTB	Physikalisch-Technische Bundesanstalt	
ptc	points to consider	
PTCA	Percutaneous Transluminal Coronary Angioplasty	
PTE	Patent Term Extension	
PTF	Peak Trough Flukt.	
PTH	Parathormon	
PTL	Product Team Leader EMA Product Team	
PTM	Products Team Member EMA Product Team	
PTP	Previously Treated Patients	
PTS	proficiency testing study	
PU	Pharmazeutischer Unternehmer	auch: Ph.U.
PUD	peptic ulcer disease	
PUMA	Paediatric Use Marketing Authorisation	
PUP	previously untreated patients	
PV	Pharmacovigilance	
PVA	Polyvinyl Alcohol	
PVAR	Preliminary Variation and Assessment Report	
PVC	Polyvinyl Chloride	
PVP	polyvinylpyrollidone	
PZ	Pharmazeutische Zeitung	
PZN	Pharmazentralnummer	
PZU	Postzustellungsurkunde	
QA	Quality Assurance	
QALY	Quality Adjusted Life Year	qualitätsadjustiertes Lebensjahr
QOS	Quality Overall Summary	
QALY	quality-adjusted life year	
QAU	Quality Assurance Unit	
QbD	Quality by Design	
QBR	question-based review	
QC	quality control	concerned with sampling, specifications, testing and documentation and release procedures
QCO	Quality Control Organization	
QM	Quality Management	
QM	Maximum Quantity	Max. allowed monomeric residue in plastic compnents
QMS	Quality Management System	
QL / QOL	quality of life	
QP	Qualified Person	
QPPV	Qualified Person for Pharmacovigilance	
QR	Quality Reviewer	
QRD	Quality Review of Documents	
QS	Qualitätssicherung	
QT-interval	QT-Zeit	(gesamte intraventrikuläre Erregungsdauer)

Short	Cut Complete Name	Additional Information
QTPP	Quality Target Product Profile	
QWP	Quality Working Party	
R & D	Research and Development	Forschung und Entwicklung
R&TD	Research and Technological Development	
RA	Rheumatoid Arthritis	
RAD-AR	Risk-Benefit Assessment of Drugs-Analysis and Response	
RAM	Regulatory Affairs Manager	
RAPS	Regulatory Affairs Professionals Society	
RAS	rapid alert system	
RBC	red blood cell	rotes Blutkörperchen
RCP	Royal College of Physicians (London, UK)	
RCT	randomized clinical trial	
RDA	recommended daily allowances	
RDE	remote data entry	
RDP	Regulatory Data Protection	
RDRC	Radioactive Drug Research Committee	
REA	relative effectiveness assessment	
REACh	Registration, Evaluation and Authorisation of Chemicals	
Reg.	Regulation	
Reg. Nr.	Registrierungsnummer	
REMS	Risk Evaluation and mitigation strategy	
RFD	request for designation	
Rh	Rhodium	
RHA	Regional Health Authorities	
RIA	Radioimmunpräzipitation	
RiliBÄK	Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen rINN recommended International Nonproprietary Name	
RINGs	Regulatory Intelligence Network Groups	
RKI	Robert-Koch-Institut	
RL	Regulatory Letter	(FDA post-audit letter)
RL	Richtlinie	
RMP	Risk Management Plan	
RMS	Reference Member State, Member state which issued the first marketing authorization in the EU	(base of a MRP)
rm TD	rechnerische mittlere Tagesdosis	
RPM	Regulatory Project Manager (USA)	
RPS	Regulated Product Submission	
RQ	Risk quotient	
RQA	Research Quality Assurance	
RRR	Relative Risk Reduction	
RSA	Risikostrukturausgleich	Modul 11
RSI	Request for Supplementary Information	
RTF	refuse/refusal to file	Ablehnender Bescheid der FDA
RTR	real-time release	
RTRT	real-time release testing	

Short	Cut Complete Name	Additional Information
Rx	prescription only medicines	Verschreibungspflichtiges Medikament
SA	scientific advice	
SA	situation appraisal	Modul 12, Unterlagen Herr Jopp
SAA	Standard-Arbeits-Anweisung	
SADC	Southern African Development Community	
SADR	serious adverse drug reaction	
SAE	serious adverse event	
SAG	Scientific Advisory Group EMA	
SAMM	Guidelines for Company Sponsored Safety Assessment of Marketed Medicines	(UK)
SAR	structure activity relationship	
SAS	statistical analysis system	
SAWP	Scientific Advice Working Party	
SBA	Summary Basis of Approval	USA, now: New Drug Approval Package
SBD	Summary Basis of Decision Kanada	
SC	Study Coordinator. See also CCRC, CRC.	
SCI	spinal cord injury	
SCM	Suppy Change Management	
SCT	Society for Clinical Trials	
SD	source data / source document	
SD	single dose	
SD	standard deviation	
SDH	Sorbitol Dehydrogenase	
SDAT	Senile Dementia of the Alzheimer's Type	
SDO	Standard Development Organization	
SDV	Source Data Verification	
SE	standard error	
S/E-Pre	Safety and efficacy, pre-authorisation	
SEA	Single European Act of 1987	
SEC	Stock Exchange Commission	
SEC	Size-exclusion chromatography	
SEDAMM	Submissions Electronique de Dossiers d'France de Mise sur le Marche	
SEER	Surveillance, Epidemiology, and End Results (Registry of NCI)	
SESAR	Suspected Expected Serious Adverse Reaction	
SEQ	Safety, Efficacy, Quality	
SF	safety factor	
SF	Senior friendly	Siehe auch CR
SFC	Supercritical fluid chromatography	
SFDA	State Food and Drug Administration	Chin. Zulassungsbehörde
SGB	Sozialgesetzbuch	
SGB V	Sozialgesetzbuch, Fünftes Buch	
SGML	Standard Generalised Mark-up Language	
SH	Subject Heading	
SHR		
SI	Système International d'Unités	
SIAMED	Model System for Computer-assisted Drug	WHO

Short	Cut Complete Name	Additional Information
	Registration	
SIAR	Società Italiana Attività Registrativa	
SICA	Sistema de la Integración Centroamericana	Zentralamerikanisches Integrationssystem
SIDA	The Spanish (syndrome inmunodeficiencia adquirida), Italian and French abbreviation for AIDS: see AIDS.	
SKNR	Strukturnummer	Vierstellige Nummer
SL-List	List of Pharmaceutical Specialities	(Schweiz)
SM	Selbstmedikation	(s.OTC)
SMART	Submission Management and Review Tracking	(FDA)
SMDA	Safe Medical Devices Act	(1990)
SME	Significant Medical Event	
SME	small and medium enterprises	
SMEC	Swissmedic Medicines Expert Committees	(Schweiz)
SMF	Site Master File	
SML	specific migration limit	
SMOP	summary of opinion	
SmPC	Summary of Product Characteristics	
SNIP	Syndicat National de l'Industrie Pharmaceutique	(France)
SAOD	Scientific Advice and Orphan Drugs Sector EMA	
SOMED	Datenbank der Sozialmedizin	
SOP	Standard Operating Procedure	
SPA	Special Protocol Assessment	binding advice in US
SPC	Supplementary Protection Certificate	Extension of the period of patent protection in the EU
SPC (SmPC)	Summary of Product Characteristics	Corresponds to the German Fachinformation
Spec	Specification	
SPID	sum of pain intensity difference	
SPIDt	sum of pain intensity difference over time	
SPOC	Single Point of Contact EDQM	
SPOR	**S**ubstance, **P**roduct, **O**rganisation, **R**eferential	
SPS	Summary of Pharmacovigilance System	
SRA	Scientific Research Associates	
SRS	Sleep Research Society	
SSC	Sunset Clause	
SSI	Structured Substance Information	
SSL	secure sockets layer	
SSM	skin surface microscopy	
SSRA	Swedish Society of Regulatory Affairs	
SST	System Suitability Test	(Systemeignungstest)
STD	sexually transmitted disease	
STD	Severely Toxic Dose	
STE	Surrogate Threshold Effect	
StGB	Strafgesetzbuch	
STIKO	Ständige Impfkommission	(des Robert-Koch-Instituts (RKI))

Short	Cut Complete Name	Additional Information
STP	sewage treatment plant	
STR	Scientific Technical and Regulatory	
STS	standard toxicity study	
STT	short term tests	
SUD	Sudden Unexpected Death	
SUPAC	Scale-up and Post Approval Changes	
SUSAR	Suspected Unexpected Serious Adverse Reaction	
SVR	sustained virologic response	dauerhaftes virologisches Ansprechen
SWEDIS	A computer system used by the Swedish MPA	
SWISSMEDIC	Swiss Agency for Therapeutic Products	Schweizerisches Heilmittelinstitut
SWP	Safety Working Party	
t ½	half life time	
TAM	Tierarzneimittel	
TCM	Traditionelle Chinesische Medizin Traditional Chinese Medicine	
TCP	Transmission Control Protocol Protokoll in der Informationstechnik	
TDAR	T-cell Dependent Antibody Response	
TDI	Total Daily Intake	
TE	Therapeutice Equivalence	
TEP	Tissue Engineered Products	
TF	Tabular Formats	
TGA	Therapeutic Goods Authority	Regulatory authority in Australia
TGD	Technical Guidance Document	
TIGes	Telematics Implememtation Group	
THMP	Traditional Herbal Medicinal Product	
TIND	Treatment IND	See also IND.
TIVA	totale intravenöse Anaesthesie	
TK	toxicokinetics	
TKM	toxicokinetic measurements	
TLC	Thin Layer Chromatography	
tmax	Zeitpunkt der maximalen Plasmakonzentration	
TMF	Trial Master File	
T (O)	Plasma concentration at time zero	
TOC	Total Organic Carbon Gesamter organischer Kohlenstoff	
TOC	Table of Contents	
TOPRA	The Organisation for Pharmaceutical Regulatory Affairs	
TOTPAR	total pain relief	
TPA	tissue plasminogen activator	
TPD	Therapeutic Products Directorate	Büro innerhalb der kanadischen HPFB, zuständig für die Arzneimittelzulassung
TPM	third party manufacturer	
TQM	Total Quality Management	
TRGS	technische Regeln für Gefahrstoffe zur	

Short	Cut Complete Name	Additional Information
	Gefahrstoffverordnung	
TRIPS	Trade-Related Aspects of Intellectual Property Rights	
TSC	Telematics Steering Committee	
TSD	target standard deviation	(Zielstandardabweichung)
TSH	Thyroidea-stimulierendes Hormon	
TTC	Treshold of Toxicological Concern	
TUR	traditional use registration	
UAW	Unerwünschte Arzneimittelwirkung	
UDP-	Uridine 5'-diphospho-	Siehe: UGT
UDS	unplanmäßige DANN-Synthese	
UE	Unerwünschtes Ereignis	
UGT	UDP-Glucuronosyltransferase	Siehe: UDP
UKCCR	UK Coordinating Committee on Cancer Research	
UM	Unverkäufliches Muster	
UMC	Uppsala Monitoring Center	
UMDNS	Universal Medical Device Nomenclature System	
UMLS	Unified Medical Language System	
UNESCO	United Nations Educational, Scientific and Cultural Organisation	
UNAIDS	Gemeinsames Programm der Vereinten Nationen für HIV/Aids	
UNDCP	United Nations Drug Control Programme	
UNII	Unique Ingredient Identifiers	
UNODC	United Nations Office on Drugs and Crime	
URL	Uniform Resource Locator	
USAN USP	Dictionary of US Adopted Names and International Drug Names	
USC	United States Code	(book of laws)
USDA	United States Department of Agriculture	
USL	upper specification limit	
USP	United States Pharmacopeia	Amerikanisches Arzneibuch
USP	unique selling position	Marketing term
USPTO	US Patent & Trademark Office	
USR	Urgent Safety Restriction	
UT	Uncontrolled Terms	
UTI	urinary tract infection	
UTN	Universal Trial Number	
UV	Ultraviolettspektroskopie	
V	Vanadium	
VA	Verlängerungsantrag	
VA	Veterans Administration	(officially, United States Department of Veterans Affairs)
VAI	Voluntary Action Indicated	(FDA post-audit inspection classification)
VAMF	Vaccine Antigen Master File	
VAS	Visual analogue scale	
VAR	Variation Assessment Report	
VB	Verlängerungsbescheid	

Short	Cut Complete Name	Additional Information
VCJD	Variant Creutzfeldt-Jakob Disease	
VEDDRA	Veterinary Dictionary for Drug Related Affairs	
vfa	Verband forschender Arzneimittelhersteller	
VHP	Voluntary Harmonisation Procedure	
VICH	Veterinary International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Veterinary Use	
VMEC	Veterinary Medicines Expert Committee	(Schweiz)
VMP	Veterinary Medicinal Product	
VMRF	Veterinary Mutual Recognition Facilitation Group	
VO	Verordnung	
VOI analysis	value of information analysis	
VohA	Verordnung über homöopathische Arzneimittel	
VPN	virtual private network	
VRS	verbal rating scale	
vs	versus	
VSV	vesciculärer stomatis virus	
VU	Verunreinigung	
vWF	von Willebrand Faktor	
VwGO	Verwaltungsgerichtsordnung	
VWP	Vaccine Working Party Expertenfachgruppe bei der EMA	
VwV	Verwaltungsvorschrift	(German Administrative Procedure)
VwVfG	Verwaltungsverfahrensgesetz	
WBC	white blood cell	
WCO	World Customs Organization	Internationale Organisation mit Sitz in Brüssel (Belgien), die sich darauf spezialisiert hat, die Zollformalitäten zwischen den internationalen Handelspartnern zu vereinfachen.
WE	Wareneingang	
WEU	well-established use	
WGEO	Working Group of Enforcement Officers by Heads of Medicines Agensies (HMA)	
WGQM	Working Group QM	
WHA	World Health Assembly	
WHO	World Health Organization (Weltgesundheitsorganisation)	
WHOART	World Health Organization Adverse Reaction Terminology	
WHO-ECDD	Expert Committee on Drug Dependence	UN: Sachverständigen-ausschuss
WI	Working Instructions	
WIDO	Wissenschaftliches Institut der Ortskrankenkassen	
WIPO	World Intellectual Property Organization	Teilorganisation der UN
WL	Warning Letter	(most serious FDA post-audit

Short	Cut Complete Name	Additional Information
		letter, demands immediate action within 15 days)
WMA	World Medical Association	Weltärztebund
WOCP	Worldwide Organization for Collaborations in the Pharmaceutical Industry	
wP	whole-cell pertussis	pertussis vaccines
WP	Working Party	
WS	Worksharing	
WSMI	World Self Medication Industry	
WSP	Worksharing Project	
WTO	World Trade Organization	
WVFR	Water Vapor Transmission Rate	
WW	Wechselwirkungen	
WWW	World Wide Web	
XCOMP	Eudra Vigilance External Compliance	Eudra Vigilance External Compliance (XCOMP) Testing Environment
(X)EVMPD	(Extended) Eudra Vigilance Medicinal Product Dictionary	
(X)EVPRM	(Extended) Eudra Vigilance Medicinal Product Report Message	
XML	Extensible Markup Language	
XPA	Xeroderma pigmentosum group A	
ZEBET	Zentrale Erfassungs-und Bewertungsstelle für Ersatz-und Ergänzungsmethoden zum Tierversuch	
ZLG	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten	
ZLS	Zentralstelle der Länder für Sicherheitstechnik	
Zn	Zink	
ZKA	Zollkriminalamt	
ZKBS	Zentrale Kommission für Biologische Sicherheit	(D)
ZQ	Zentralstelle für Qualitätssicherung	
Zul. Nr.	Zulassungsnummer	
ZZulV	Zusatzstoff-Zulassungsverordnung	