



Abkürzungsverzeichnis List of Abbreviations

für den weiterbildenden Studiengang

„Master of Drug Regulatory Affairs“

Stand: Februar 2016

| Short | 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 | Beratungskomitee für die WHO |
| ACTA | Anti Counterfeiting Trade Agreement | Handelsabkommen zum Schutz vor Produktfälschungen |
| ADBE | absorption, distribution, biotransformation, excretion | |
| ADEC | Australian Drug Evaluation Committee | |
| ADI | acceptable 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 | Unterkomitee von ADEC |
| ADKA | Arbeitsgemeinschaft Deutscher Krankenhausapotheker | |
| ADROIT ADRs | Online Information Tracking | |
| ÄA | Änderungsanzeige | |
| AE | Adverse Event Unfavorable medical occurrence | |
| AECB | acute exacerbation of chronic bronchitis | |
| AEFI | adverse events following immunization | |
| AEGIS ADROIT | Electronically Generated Information Service | |
| AEPAR | Asociación Española de Profesionales de Actividades de Registro | |
| AERS | Adverse Event Reporting System | |
| AESGP | Association Européenne des Spécialités 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 Sécurité Sanitaire de Produits de Santé | Regulatory Authority in France |
| Ag | Antigen | |
| AGES | Agentur für Gesundheit und Ernährungssicherheit | Österreichische Zulassungsbehörde |
| AGF | Alleingeschäftsführer | |

| Short | Cut Complete Name | Additional Information |
|--------------|---|--|
| AGLMB | Arbeitsgemeinschaft der leitenden Medizinalbeamtinnen und –beamten der Länder | |
| 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 Ärzteschaft | |
| AMM | Autorisation de Mise sur le Marché | |
| AMNOG | Arzneimittelneuordnungsgesetz | |
| 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 Tecnológica Médica | Argentinische Zulassungsbehörde National |

| Short | Cut Complete Name | Additional Information |
|--------------|---|---|
| | | Administration for Medicines, food and Medical Technology |
| ANOVA | Analysis of Variance | |
| ANSI | American National Standards Institute | |
| 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 | |
| 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 | |
| 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 | |

| Short | Complete Name | Additional Information |
|---------------|--|----------------------------------|
| | Code der WHO | |
| ATMP | Advanced Therapy Medicinal Product | |
| 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 | Synonym: 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 |

| Short | Cut Complete Name | Additional Information |
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| | | (Auflösung in Einzelinstitute) |
| BGI | Bundesgesundheitsinstitut | |
| 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 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 | |
| BPACA | Best Pharmaceuticals for Children Act | US, previously 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 | |

| Short | Complete Name | Additional Information |
|--------------|---|--|
| BtMG | Betäubungsmittelgesetz | |
| BtMVV | Betäubungsmittel- Verschreibungsverordnung | |
| BverwG | Bundesverwaltungsgericht | |
| 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 authorised 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 of 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 | |

| Short | Cut Complete Name | Additional Information |
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| | also ACP | |
| CCDS | Company Core Data Sheet | |
| CCS | Canadian Cardiovascular Society (scoring system) | |
| CCS | container closure system | |
| CCSI | Company Core Safety Information | |
| Cd | Cadmium | |
| CD | circular dichroism | |
| 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 | |

| Short | Complete Name | Additional Information |
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| CID | collision-induces dissociation | |
| CIOMS | Council for International Organisations of Medical Science Postapproval international ADR reporting | UK |
| CIOMS | Centerwide Oracle Management Information System US (FDA) | |
| CIS | Commonwealth of Independent States | |
| Cl | Chlor | |
| CLIA | Clinical Laboratory Improvements Amendments | |
| CLL | chronische lymphatische Leukämie | |
| C _{max} | maximale Plasmakonzentration | |
| CMC | Chemistry, Manufacturing, Control | Term used in the US and corresponds to Modul 3 in the EU |
| CMDh group | 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 (Bundeskommision 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 | |

| Short | Complete Name | Additional Information |
|--------------|---|--|
| 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) |
| CPR | Cardiopulmonary Resuscitation | |
| 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 Research Assistant/Associate | |
| CRADA | Cooperative Research and Development Agreement (with NIH) | |
| CRC | Clinical Research 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 | Clinical 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 | |

| Short | Complete Name | Additional Information |
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| 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 | |
| CZE | Capillar zone electrophoresis | |
| 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 | Database 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 Registration 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 provide 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 | |

| Short | Cut Complete Name | Additional Information |
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| 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 | |
| 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) | |

| Short | Cut Complete Name | Additional Information |
|--------------|--|---|
| 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 | |
| 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 | |
| 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|--|---|
| 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 | |
| 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- | |

| Short | Complete Name | Additional Information |
|--------------|---|--|
| | Steuerungskonferenz | |
| ERA | Environmental Risk Assessment | |
| ERG | Electroretinogram | |
| ES COP | European Scientific Cooperative for Phytotherapy | |
| ESG | Electronic Submission Gateway | |
| 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 | The Association of the Italian |

| Short | Cut Complete Name | Additional Information |
|--------------|---|---|
| | United Nations Farindustria | Pharmaceutical Manufacturers FCC Food Chemical Codex (US) |
| FD | Floppy disk | |
| FDA | Food and Drug Administration | USA |
| FDAAA | Food and Drug Administration Amendment Act | |
| 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 | Fédération 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|--|--|
| 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 | |
| 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 | |

| Short | Complete Name | Additional Information |
|--------------|--|--------------------------------|
| 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 | |
| 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 | |
| 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 Autorité 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 | |

| Short | Cut Complete Name | Additional Information |
|-------------------|---|---|
| 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 | |
| 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 β -Hydroxy- β -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 | Halbwertszeit |
| HWG | Heilmittelwerbeengesetz | |
| 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 | |

| Short | Complete Name | Additional Information |
|--------------|---|-------------------------------|
| 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 | |
| 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 | |

| Short | Complete Name | Additional Information |
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| IMCT | International Multicenter Clinical Trial | |
| IMMED | International Marketed Medicines Database | |
| IMP | investigational medicinal product | |
| IMPACT | International Medicinal Products Anti-Counterfeiting Task Force | Netzwerk aus zahlreichen Interessenverbänden, Organisationen und staatlichen bzw. internationalen Behörden |
| IMPD | Investigational Medicinal Product Dossier | |
| INAHTA | International Health Technology Assessment 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 Gruppeneinteilung analysiert |

| Short | Cut Complete Name | Additional Information |
|--------------|--|---|
| | | 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 Applied Chemistry a In Vitro Diagnostics | |
| IVD | In-vitro-Diagnostikum | |
| 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|--|--|
| 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 | |
| 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 Bedarfsgegenstände-gesetz | |
| 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 | |

| Short | Complete Name | Additional Information |
|--------------|--|--|
| 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) | |
| 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) |

| Short | Cut Complete Name | Additional Information |
|------------|---|--|
| 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 inspections |
| MP | medicinal product | Deutsch: Arzneimittel (<u>nicht</u> 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|--|--|
| 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 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|---|---|
| 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 | |
| NICHHD | 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 |
| 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|---|--|
| NUB | Neue Untersuchungs- und Behandlungsmethoden | |
| 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 | |
| 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 développement 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|---|------------------------------------|
| | 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 | |
| OwiG | Ordnungswidrigkeitengesetz | German Law on Misdemeanors |
| P-i | parallel-imported | |
| PA | Proprietary Association | |
| PAD | Pharmacologically Active Dose | |
| PAES | Post Authorisation Efficacy Studies | |
| PAF | platelet activating factor | |
| PAG | Post authorisation 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|--|---|
| 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 | |
| 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 | |

| Short | Cut Complete Name | Additional Information |
|----------------------|--|---|
| 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: <i>patient, intervention, Vergleichsintervention (comparison), Zielgrösse (outcome)</i> | 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 |
| 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|--|--|
| 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 | Unterkomitee von ADEC |
| PSD | Particle size distribution | |
| PSMF | Pharmacovigilance System Master File | |
| PSP | Paediatric Study Plan | |
| 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 | polyvinylpyrrolidone | |
| PZ | Pharmazeutische Zeitung | |
| PZN | Pharmazentralnummer | |
| PZU | Postzustellungsurkunde | |

| Short | Cut Complete Name | Additional Information |
|--------------|---|---|
| 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) |
| 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|--|--------------------------------------|
| RiliBÄK | Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen rINN recommended International Nonproprietary Name | |
| 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 | |
| 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 | Supply 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|---|--|
| 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 Registration | WHO |
| 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 |

| Short | Cut Complete Name | Additional Information |
|------------------|--|---|
| 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 Points of Contact EDQM | |
| 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 Impfkommision | (des Robert-Koch-Instituts (RKI)) |
| 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 _{1/2} | 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|--|--|
| 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 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 | |

| Short | Cut Complete Name | Additional Information |
|--------------|---|--|
| 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 | Ultraviolett-spektroskopie | |
| 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 | |
| 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 | vesiculärer stomatis virus | |
| VU | Verunreinigung | |
| vWF | von Willebrand Faktor | |
| VwGO | Verwaltungsgerichtsordnung | |
| VWP | Vaccine Working Party Experten-fachgruppe bei der EMA | |
| VwV | Verwaltungsvorschrift | (German Administrative Procedure) |
| VwVfG | Verwaltungsverfahrensgesetz | |
| WBC | white blood cell | |
| WCO | World Customs Organization | Internationale Organisation mit |

| Short | Cut Complete Name | Additional Information |
|--------------|--|--|
| | | 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 Agencies (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 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 | |

| Short | Complete Name | Additional Information |
|--------------|--|-------------------------------|
| | Sicherheitstechnik | |
| Zn | Zink | |
| ZKA | Zollkriminalamt | |
| ZKBS | Zentrale Kommission für Biologische Sicherheit | (D) |
| ZQ | Zentralstelle für Qualitätssicherung | |
| Zul. Nr. | Zulassungsnummer | |
| ZZuV | Zusatzstoff-Zulassungsverordnung | |