

## GLOSSARY – Acronyms, Abbreviations, & Initials

**Note:** This glossary of acronyms, abbreviations, and initials is intended to assist users of and the volunteer community associated with the *United States Pharmacopeia*. For a more general acronym resource, users may wish to consult [www.acronymfinder.com](http://www.acronymfinder.com). An acronym finder gleaned from MEDLINE can be found at [lethargy.swmed.edu/argh/ARGH.asp](http://lethargy.swmed.edu/argh/ARGH.asp). Medical abbreviations, a medical dictionary, and ICD-9 codes can be found at <http://www.medilexicon.com/>.

**802 (monograph):** monograph prepared under section 802(b)(1)(a) of the Food, Drug, & Cosmetic Act

**AA:** Alcoholics Anonymous

**AAAS:** American Association for the Advancement of Science

**AABB:** American Association of Blood Banks

**AACN:** American Association of Critical Care Nurses

**AACP:** American Association of Colleges of Pharmacy

**AACR:** American Association for Cancer Research

**AADA:** Abbreviated Antibiotic Drug Application (Food & Drug Administration) (used primarily for generics)

**AAFP:** American Academy of Family Practice

**AAI:** American Academy of Immunologists

**AAMC:** Association of American Medical Colleges

**AAMI:** Age-Associated Memory Impairment

**AAMI:** Association for the Advancement of Medical Instrumentation

**AAP:** American Association of Pathologists

**AAPCC:** American Association of Poison Control Centers

**AAPP:** American Academy of Pharmaceutical Physicians

**AAPS:** American Association of Pharmaceutical Scientists

**AARP:** American Association of Retired Persons

**AATB:** American Association of Tissue Banks

**AAV:** Adeno-associated Virus

**ABC:** ATP-Binding Cassette

**ABPI:** Association of the British Pharmaceutical Industry

**AC:** Added for Clarity

**ACCP:** American College of Clinical Pharmacology

**ACDM:** Association of Clinical Data Management (U.K.)

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Please send suggested additions to Stefan Schuber, PhD, Director of Scientific Reports at USP: [sps@usp.org](mailto:sps@usp.org)

## GLOSSARY – Acronyms, Abbreviations, & Initials

**ACE:** Antiotensin I Converting Enzyme

**ACGME:** Accredited Council for Graduate Medical Education

**ACIL:** A national trade association representing independent, commercial scientific, and engineering firms (formerly the American Council of Independent Laboratories)

**ACIP:** Advisory Committee on Immunization Practices, Immunization Practices Advisory Committee

**ACPE:** Accreditation Council for Pharmacy Education

**ACPU:** Association of Clinical Pharmacology Units

**ACRA:** Associate Commissioner for Regulatory Affairs (Food & Drug Administration)

**ACRP:** Association of Clinical Research Professionals, formerly Associates in Clinical Pharmacology (ACP)

**ACRPI:** Changed its name to Institute of Clinical Research (U.K.)

**ACS:** American Chemical Society

**ACTG:** AIDS Clinical Trials Group (NIAID)

**ACTH:** Adrenocorticotropin

**ACTU:** AIDS Clinical Trials Unit (National Institutes of Health)

**AD:** Alzheimer's Disease

**ADA:** Amino Deaminase

**ADA:** American Dental Association

**ADaM:** Analysis Dataset Model (CDISC)

**ADAMHA:** Alcohol, Drug Abuse, and Mental Health Administration (no longer exists)

**ADCC:** Antibody-Dependent Cell-Mediated Cytotoxicity

**ADE:** Adverse Drug Event; Adverse Drug Effect

**ADH:** Antidiuretic Hormone

**ADHD:** Attention Deficit Hyperactivity Disorder

**ADI:** Acceptable Daily Intake (National Academy of Science)

**ADME:** Absorption, Distribution, Metabolism, and Excretion (Used to Describe Pharmacokinetic Processes)

**ADMET:** Absorption, Distribution, Metabolism, Excretion, and Toxicology

**ADR:** Adverse Drug Reaction; Adverse Drug Effect

**ADRS:** Adverse Drug Reactions

**ADS:** Automated Directives System (USAID)

**AE:** Adverse Event; Adverse Experience

**AEGIS:** ADROIT Electronically Generated Information Service (a subscription service that provides subscribing organizations with access to

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adverse drug reaction data from the Medicines Control Agency's ADROIT) (Adverse Drug Reaction On-line Information Tracking) database

**AER:** Aerosols (USUSP Expert Committee designation)

**AERS:** Adverse Event Reporting System (Food & Drug Administration)

**AES:** Auger Electron Spectrometry

**AF:** Argentine Pharmacopeia

**AFCR:** See *AFMR*

**AFMR:** American Federation for Medical Research, formerly the American Federation for Clinical Research (AFCR)

**AHA:** American Heart Association

**AHA:** American Hospital Association

**AHCPR:** Agency for Health Care Policy Research (National Institutes of Health)

**AHFS:** American Hospital Formulary System

**AHP:** American Herbal Pharmacopeia

**AHPA:** American Herbal Products Association

**AHQA:** American Healthcare Quality Association

**AHRQ:** Agency for Healthcare Research and Quality

**AI:** Adequate Intake

**AICRC:** Association of Independent Clinical Research Contractors (U.K.)

**AIDS:** Acquired Immune Deficiency Syndrome (see also SIDA and HIV)

**AIM:** Active Ingredient Manufacturer

**ALCOA:** Attributable, Legible, Contemporaneous, Original, Accurate (dimensions of data quality)

**AMA:** American Medical Association

**AMA-DE:** AMA Drug Evaluations

**AMB:** Analytical Microbiology (USP Expert Committee designation)

**AMC:** Antibody-Mediated Cytotoxicity

**AMCP:** Academy of Managed Care Pharmacy

**AmFAR:** American Foundation for AIDS Research

**AMG:** Arzneimittelgesetz (German Drug Law)

**AMI:** Acute Myocardial Infarction

**AMRS:** Ancillary Materials Reference Standards

**AMWA:** American Medical Writers Association

**ANA:** American Nurses Association

**ANADA:** Abbreviated New Animal Drug Application

**ANCC:** American Nurses Credentialing Center

## GLOSSARY – Acronyms, Abbreviations, & Initials

**ANDA:** Abbreviated New Drug Application (for a generic drug)

**ANMAT:** Argentine National Agency for Medicines, Food, and Technology

**ANOVA:** Analysis of Variance (statistics)

**ANPR:** Advance Notice of Public Rulemaking

**ANSI:** American National Standards Institute

**AOAC:** Association of Official Analytical Chemists

**APB:** Association Pharmaceutique Belge (Belgium)

**APC:** Antigen-Presenting Cell

**APCI:** Atmospheric Pressure Chemical Ionization (Mass Spectrometry)

**APhA:** American Pharmacists Association

**APHA:** American Public Health Association

**API:** Active Pharmaceutical Ingredient

**AR:** Accounts Receivable

**ARB:** Angiotensin II Receptor Blocker (Antagonist)

**ARCS:** Association of Regulatory & Clinical Scientists (Australia)

**ARENA:** Applied Research Ethics National Association

**ARO:** Academic Research Organization

**AS:** Administrative Services

**AS:** Authentic Substance

**ASA:** American Statistical Association

**ASCO:** American Society for Clinical Oncology

**ASL:** Approved Supplier List

**ASAP:** Administrative Systems Automation Project (Food & Drug Administration)

**ASCII:** American Standard Code for Information Interchange (computer files)

**ASCPT:** American Society for Clinical Pharmacology and Therapeutics

**ASCP:** American Society for Clinical Oncology

**ASCP:** American Society of Consultant Pharmacists

**ASHP:** American Society of Health-System Pharmacists

**ASM:** American Society for Microbiology

**ASO:** Administrative Service Organizations

**ASQ:** American Society for Quality, formerly American Society for Quality Control

**ASTM:** American Society for Testing and Materials

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**ATCC:** American Type Culture Collection

**ATF:** (Bureau of) Alcohol, Tobacco, and Firearms

**ATP:** Analytical Testing Plan

**AU:** Absorbance Unit

**AUC:** Area under the Curve (statistics)

**AZT:** Zidovudine (HIV treatment)

**B&B:** Biologicals and Biotechnological (ingredients and products)

**BAM:** Bacteriological Analytical Manual (FDA)

**BAN:** British Approved Names (see USP Dictionary)

**B/BT:** Biologicals and Biotechnological (ingredients)

**BARQA:** British Association of Research Quality Assurance

**BBP:** Blood and Blood Products (USP Expert Committee designation)

**BBT:** Biologics and Biotechnological Ingredients

**BCE:** Beneficial Clinical Event

**BDPA:** Bureau of Drug Policy and Administration (China)

**BET:** Bacterial Endotoxin Test

**BEUC:** European Bureau of Consumer Unions

**BfArM:** Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices, Germany)

**BGA:** Bundesgesundheitsamt (Federal health office; former German public health agency)

**BGVV:** Bundesinstitut für gesundheitlichen Verbraucherschutz and Veterinärmedizin (Federal Institute for Health Protection of Consumers and Veterinary Medicine, Germany)

**BHP:** British Herbal Pharmacopeia

**BID:** Two Times per Day

**BIND:** Biological Investigational New Drug

**BIO:** Biotechnology Industry Organization

**BIRA:** British Institute of Regulatory Affairs

**BLA:** Biologics License Application (Food & Drug Administration)

**BMI:** Body Mass Index

**BMS:** Building Management System

**BNA:** Bioavailability and Nutrient Absorption (USUSP Expert Committee designation)

**BNT:** Biotechnology and Natural Therapeutics and Diagnostics (USUSP Expert Committee designation)

**BOM:** Bill of Materials

**BoT:** Board of Trustees

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**BP:** British Pharmacopeia

**BPC:** Biopharmaceutics (USUSP Expert Committee designation)

**BPI:** Bundesverband der Pharmazeutischen Industrie EV (Germany)

**BQL:** Below Quantifiable Limit

**BrAPP:** British Association of Pharmaceutical Physicians

**BRCA2:** Gene [Implicated in Breast Cancer]

**BSA:** Body Surface Area

**BSE:** Bovine Spongiform Encephalopathy

**BST:** Biostatistics (USP Expert Committee designation)

**BUD:** Beyond-Use Date

**BVC:** British Veterinary Codex

**C & S:** Culture and Sensitivity

**C of A:** Certificate of Analysis

**CA:** Chemical Abstracts

**CA:** Competent Authority (regulatory body charged with monitoring compliance with European Union member state national statutes and regulations)

**CA:** Complex Actives (Division of USP Council of Experts)

**CA:** Cooperative Agreement

**CAB:** Change Advisory Board

**CABG:** Coronary Artery Bypass Graft

**CAD:** Coronary Artery Disease

**CADD:** Computer-Assisted Drug Design

**cAMP:** Cyclic Adenosine Monophosphate, Cyclic Adenosine-3'5'-Monophosphate

**CANDA:** Computer Assisted New Drug Application

**CAPA:** Corrective and Preventive Actions

**CAPLA:** Computer Assisted Product License Application

**CAPRA:** Canadian Association of Pharmaceutical Regulatory Affairs

**CAPS:** Center for the Advancement of Patient Safety

**CARES:** Customer Advantage Renewal Enrollment System

**CAS:** Chemical Abstracts Service

**CBD:** Corporate Business Development (Department of USP)

**CBER:** Center for Biologics Evaluation and Research (Food & Drug Administration)

**CBC:** Complete Blood Count

**CBO:** Chief Business Officer

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**CCB:** Calcium Channel Blockers

**CCD:** Charge-Coupled Device

**CCHIT:** Certification Commission for Healthcare Information Technology

**CCI:** Committee on Clinical Investigations

**CCPPRB:** Comité Consultative pour la Protection des Personnes dans les Recherches Biomédicales (France)

**CCRA:** Certified Clinical Research Associate

**CCRC:** Certified Clinical Research Coordinator

**CDC:** Centers for Disease Control and Prevention

**CDER:** Center for Drug Evaluation and Research (Food & Drug Administration)

**CDISC:** Clinical Data Interchange Standards Consortium (formerly a DIA special interest group called the Clinical Data Interchange Standards Committee)

**CDM:** Clinical Data Management

**cDNA:** Complementary DNA

**CDR:** Complete Drug Reference

**CDRH:** Center for Devices and Radiological Health (Food & Drug Administration)

**CDS:** Controlled Drug Substance

**CE:** Continuing Education

**CEA:** Carcinoembryonic Antigen

**CEN:** Comité Européen de Normalisation (European Committee for Standardization)

**CEO:** Chief Executive Officer

**CEO/EVP:** Chief Executive Officer and Executive Vice President

**CEU:** Continuing Education Unit

**CF:** Consent Form

**CF:** Cystic Fibrosis

**CFAO:** Chief Financial and Administrative Officer

**CFC:** Chlorofluorocarbons

**CFG:** Cross-Functional Group

**CFH:** Connecting for Health

**CHN:** Carbon, Hydrogen, Nitrogen

**CHP:** Chemical Hygiene Plan

**CFR:** *Code of Federal Regulations* (usually cited by title and part; for example: Title 21, Part 211 is shown as 21 CFR 211)

**CFSAN:** Center of Food Safety and Applied Nutrition

**CFTR:** Cystic Fibrosis Transmembrane Regulator

**CFU:** Colony-Forming Unit

**CGE:** Capillary Gel Electrophoresis

**cGMP:** Current Good Manufacturing Practices

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**cGMP:** Cyclic Guanosine-3'5'-Monophosphate

**CHI:** Consolidated Health Initiative (eGov)

**CHO:** Chinese Hamster Ovary

**CHPA:** Consumer Healthcare Products Association

**CHR:** Committee on Human Research

**CI:** Confidence Interval

**CIB:** Clinical Investigator's Brochure

**CID:** CTFA Cosmetic Ingredient Dictionary

**CIEF:** Capillary Isoelectric Focusing

**CIMS:** Chemical Ionization Mass Spectroscopy

**CIOMS:** Council for International Organisations of Medical Sciences

**CIP:** Certified IRB Professional

**CIP:** Clean-in-Place

**CIPIH:** Commission on Intellectual Property Rights, Innovation, and Public Health (WHO)

**CIR:** Cosmetic Ingredient Review

**CIS:** Chemical Information Sheet

**CIS:** Commonwealth of Independent States

**CITAC:** Co-Operation on International Traceability in Analytical Chemistry

**CKD:** Chronic Kidney Disease

**CL:** Compulsory Licensing

**CLAS:** Clinical Ligand Assay Society

**CLIA:** Clinical Laboratory Improvements Amendments

**CLO:** Chief Legal Officer

**Cmax:** Concentration Maximum (used in pharmacokinetics and bioequivalence to indicate maximum plasma concentration for a drug)

**CMC:** Chemistry, Manufacturing, and Controls

**CME:** Continuing Medical Education

**CMI:** Cell-Mediated Immunity

**CML:** Chronic Myeloid Leukemia

**CMMS:** Computerized Maintenance Management Systems

**CMS:** Centers for Medicare & Medicaid Services

**CMV:** Cytomegalovirus

**CNS:** Central Nervous System

**CoA:** Certificate of Analysis

**CoC:** Council of the Convention

**CoE:** Council of Experts

**CoE EC:** Council of Experts Expert Committee

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**COMIS:** Center Office Management Information System

**CONSORT:** Consolidated Standards of Reporting Trials

**COO:** Chief Operating Officer

**COP:** CDISC Operating Process/Procedure

**COPD:** Chronic Obstructive Pulmonary Disease

**CoR:** Committee of Revision (former name for Council of Experts)

**CoS:** Certificate of Suitability

**COSTART:** Coding Symbols for a Thesaurus of Adverse Reaction Terms –  
*See also MedDRA*

**COX:** Cyclooxygenase

**CP:** Comparability Protocol

**CP:** Compliance Program

**CPC:** Council on Pharmacy and Chemistry

**CPC:** Critical Process Control

**CPDC:** Corporate Planning, Development, & Communications

**CPH:** Chinese Pharmacopeia Commission

**CPHS:** Committee for the Protection of Human Subjects

**CpK:** Process Capability Index

**CPLM:** Crosspolarizing Light Microscopy

**CPMP:** Committee for Proprietary Medicine Products (EU)

**CPOE:** Computerized Prescriber Order Entry

**CPP:** Critical Process Parameter

**CPPDE:** Calcium Pyrophosphate Deposition Disease

**CPSC:** Consumer Product Safety Commission (U.S.)

**CRA:** Clinical Research Association (see also CCRA)

**CRADA:** Cooperative Research and Development Agreement (with National Institutes of Health)

**CRB:** Case Record Book

**CRB:** Central Review Board

**CRB:** Change Review Board

**CRC:** Clinical Research Coordinator –  
*see also CCRC, SC, SSC*

**CRF:** Case Report Form (sometimes case record form)

**CRM:** Certified Reference Material (See NIST Special Publication 260-136)

**CRM:** Customer Relationship Management

**CRN:** Council for Responsible Nutrition

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**CRO:** Contract Research Organization  
(see also IPRO)

**CRP:** C-Reactive Protein

**CRT:** Complaint Response Team

**CRX:** Compounding Pharmacy (USP  
Expert Committee designation)

**CSA:** Comprehensive Drug Abuse  
Prevention and Control Act of 1970

**CSF:** Cerebrospinal Fluid

**CSF:** Colony-Stimulating Unit

**CSDD:** Center for the Study of Drug  
Development

**CSF:** Collaborative Standards Forum  
(CDISC)

**CSM:** Committee on Safety of  
Medicines (U.K.)

**CSO:** Chief Scientific Officer

**CSO:** Consumer Safety Officer (Food &  
Drug Administration)

**CSP:** Compounded Sterile Presentation

**CSR:** Clinical Study Report

**CSU:** Clinical Supply Unit

**CSU:** Continued Suitability for Use

**CT:** Clinical Trial

**CT:** Computerized Tomography

**CTC:** Clinical Trial Certificate  
(U.K.)

**CTD:** Common Technical Document

**CTEP:** Clinical Therapeutics Evaluation  
Program (NCI)

**CTL:** Contract Testing Laboratory

**CTM:** Clinical Trials Materials

**CTX:** Clinical Trial Exemption (MCA)

**CV:** Cardiovascular

**CV:** Curriculum Vitae

**CVM:** Center for Veterinary Medicine  
(Food & Drug Administration)

**CX:** Correction(s)

**CXR:** Chest X-ray

**CYP:** Cytochrome P450 Enzymes

**CZE:** Capillary Zone Electrophoresis

**DALY:** Disability-adjusted Life Year

**DAWN:** Drug Abuse Warning Network

**DB:** Double-Blind

**DBU:** Dried before Use

**DCA:** DC Amperometric Detection

**DCGI:** Drugs Controller General of India  
(equivalent to FDA)

**DCS:** Distributed Control System

**DD:** Department of Drugs (Swedish  
regulatory agency)

**DDIR:** Division of Drug Information  
Resources

## GLOSSARY – Acronyms, Abbreviations, & Initials

**DDMAC:** Division of Drug Marketing, Advertising, and Communications

**DEA:** Drug Enforcement Administration (U.S.)

**DEN:** Drug Experience Network

**DES:** Data Encryption Standard

**DES:** Division of Epidemiology and Surveillance

**DESI:** Drug Efficacy Study Implementation Notice (Food & Drug Administration, to evaluate drugs in use before 1962)

**DGPharMed:** Deutsche Gesellschaft für Pharmazeutische Medizin (German Society of Pharmaceutical Medicine), formerly FÄPI

**DHEW:** Department of Health, Education, and Welfare (U.S., now split into DHHS and Department of Education)

**DHHS:** Department of Health and Human Services (U.S.)

**DHTML:** Dynamic HTML

**DIA:** Drug Information Association

**DIC:** Drug Information Center

**DICOM:** Digital Imaging and Communications in Medicine

**DL:** Designated Liaison

**DLT:** Dose-Limiting Toxicity

**DMB:** Data Management Biomedical (France)

**DMET:** Division of Medication Errors and Technical Support

**DMF:** Drug Master File

**DMSO:** Dimethyl Sulfoxide

**DMT:** Dimethyltryptamine

**DNA:** Deoxynucleic Acid

**DoC:** Department of Commerce (U.S.)

**DoD:** Department of Defense (U.S.)

**DOE:** Design of Experiment

**DPC-PTR Act:** Drug Price Competition and Patent Term Restoration Act of 1984 (also Waxman–Hatch or Hatch–Waxman bill)

**DPPC:** Dipalmitoylphosphatidylcholine

**DPSV:** Differential Pulse Stripping Voltametry

**DRA:** Drug Regulatory Agency

**DRG:** Diagnosis-Related Groups

**DS:** Dietary Supplement

**DSB:** Dietary Supplements—Botanicals (USP Expert Committee designation)

**DSC:** Differential Scanning Calorimetry

**DSD:** Department of Standards Development

**DSHEA:** Dietary Supplement Health and Education Act (1994)

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**DSI:** Division of Scientific Investigations  
(Food & Drug Administration)

**DSI:** Dietary Supplements—Information  
(USP Expert Committee designation)

**DSM:** Diagnostic and Statistical Manual  
(of the American Psychiatric  
Association)

**DSMB:** Data and Safety Monitoring  
Board

**DSN:** Dietary Supplements—Non-  
Botanicals (USP Expert Committee  
designation)

**DSNP:** Development of Standardized  
Nomenclature Project (Food & Drug  
Administration)

**DTA:** Differential Thermal Analysis

**DTC:** Direct-to-Consumer (drug  
advertising)

**DTD:** Document Type Definition (XML)

**DTP:** Diphtheria, Tetanus, and  
Pertussis

**DTS:** Document Tracking System

**DUE:** Drug Utilization Evaluation

**DUR:** Drug Utilization Review

**Dv 50:** Volume Median Diameter (of  
Aerosols)

**DVA:** Department of Veterans Affairs

**DVT:** Deep Venous Thrombosis

**E3C:** European CDISC Coordinating  
Committee

**EAB:** Ethical Advisory Board (*Applied  
Clinical Trials*)

**EAB:** Ethical advisory board

**EC:** Expert Committee, Executive  
Committee

**EC:** Ethics Committee

**EC:** European Commission (in  
documents older than the mid-1980s,  
EC may mean European Community)

**ECF:** Equipment Change Form

**ECG:** Electrocardiogram

**ECG:** European CDISC Group

**ECJ:** European Court of Justice

**ECOG:** Eastern Cooperative Oncology  
Group (U.S.)

**ECPPIN:** European Community  
Pharmaceutical Products Information  
Network

**eCRF:** Electronic Case Report Form

**ED<sub>50</sub>:** 50% Effective Dose

**EDC:** Electronic Data  
Capture/Collection

**EDI:** Electronic Data Interchange

**EDQM:** European Directorate for the  
Quality of Medicines

**EDTA:** Ethylenediaminetetraacetic Acid

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**EEC:** European Economic Community (now EU; some regulatory documents still have EEC document numbers)

**EEG:** Electroencephalogram

**EEO:** Equal Employment Opportunity

**EFGCP:** European Forum for Good Clinical Practice

**EFPIA:** European Federation of Pharmaceutical Industries and Associations

**EFTA:** European Free Trade Association

**EGF:** Epidermal Growth Factor

**EGFR:** Epidermal Growth Factor Receptor (sometimes seen as HER1)

**EIR:** Establishment Inspection Report (Food & Drug Administration)

**ELA:** Establishment License Application (Food & Drug Administration)

**ELISA:** Enzyme-Linked Immunosorbent Assay

**ELN:** Electronic Laboratory Notebook

**EMC:** Excipient Monograph Content<sup>†</sup> (USP Expert Committee designation)

**EMA:** European Agency for the Evaluation of Medicinal Products

**EMLA:** Eutectic Mixture of Local Anesthetic

**EMS:** Electronic Mail Service

**EMS:** Emergency Medical Service

**EMWA:** European Medical Writers Association

**EORTC:** European Organization for the Research and Treatment of Cancer

**EP:** European Parliament

**EP:** European Pharmacopeia

**EPA:** U.S. Environmental Protection Agency

**EPAR:** European Public Assessment Report

**EPL:** Effective Patent Life

**EPMA:** Electron Probe Microanalysis

**EPO:** European Patent Office

**EPRG:** European Pharmacovigilance Research Group

**ER:** Essential Requirements (EMA)

**ER/ES:** Electronic Record/Electronic Signature

**ERH:** Equilibrium Relative Humidity

**ERP:** Enterprise Resource Planning

**ES:** Executive Secretariat, ISD

**ESCA:** Electron Spectroscopy Chemical Analysis

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<sup>†</sup>The Expert Committee has been renamed. The old name, Excipients—Substances and Characterization (ESC) has been changed to Excipient Monograph Content (EMC).

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**ESRA:** European Society of Regulatory Affairs

**ESC:** Excipients—Substances and Characterization]

**ESCOPE:** European Scientific Cooperative on Phytotherapy

**ESI-MS:** Electrospray-Ionization Mass Spectrometry

**ESRD:** End-stage Renal Disease

**ESTRI:** Electronic Standards for the Transfer of Regulatory Information (ICH)

**ETM:** Excipients—Test Methods (USP Expert Committee designation)

**ETT:** Exercise Tolerance Test

**EU:** European Union

**EUDRA:** European Union Drug Regulatory Authorities  
European Union clinical trials database

**EVP:** Executive Vice President

**EWG:** Expert Working Group

**EC:** Expert Committee

**F-lot:** (Of Reference Standards) First Lot

**Fab, Fc, Fv:** Antibody Fragments

**FAC:** Food Advisory Committee (CFSAN)

**FACA:** Federal Advisory Committee Act 1972

**FACS:** Fluorescence-Activated Cell Sorter

**FAQ:** Frequently Asked Questions

**FARBRAS:** Brazilian Pharmacopeia

**Farindustria:** The Association of Italian Pharmaceutical Manufacturers

**FAX:** Facsimile

**FBS:** Fetal Bovine Serum

**FCC:** Federal Communications Commission

**FCC:** *Food Chemicals Codex*

**FD&C Act:** Food, Drug, and Cosmetic Act (U.S.)

**FDA:** Food and Drug Administration (U.S.)

**FDA-SRS:** Spontaneous Reporting System of the Food and Drug Administration

**FDAMA:** Food & Drug Administration Modernization Act

**FDC:** Fixed-Dose Combination (e.g., of Anti-tuberculosis Drugs)

**FDCA:** Food, Drug, & Cosmetic Act

**FDLI:** Food and Drug Law Institute

**FDP:** Fibrinogen Degradation Products

**FEBRAFARMA:** Brazilian Federation of the Pharmaceutical Industry

**FEF:** Forced Expiratory Flow

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**FEUM:** Mexican Pharmacopeia

**FEV<sub>1</sub>:** Forced Expiratory Volume in 1 Second

**FFDCA:** Federal Food, Drug, & Cosmetic Act

**FFPM:** Fellow of the Faculty of Pharmaceutical Medicine (U.K.)

**FGFR:** Fibroblast Growth Factor Receptor

**FID:** Flame Ionization Detector

**FIFRA:** Federal Insecticide, Fungicide, and Rodenticide Act

**FIP:** Fédération Internationale Pharmaceutique

**FOI:** Freedom of Information

**FOIA:** Freedom of Information Act

**FOP:** Fiber-Optic Probe

**FR:** Federal Records Center (Suitland)

**FR:** *Federal Register*

**FRC:** Functional Residual Capacity

**FRCP:** Fellow of the Royal College of Physicians, sometimes followed by a place name—for example, FRCP (Edin.)—that indicates a university medical school

**FSH:** Follicle-Stimulating Hormone

**FSIS:** Food Safety and Inspection Service

**FT-IR:** Fourier Transform–Infrared Spectrometry

**FTC:** Federal Trade Commission (U.S.)

**FTE:** Full-Time Equivalent

**FTP:** File Transfer Protocol

**FWA:** Federal-Wide Assurance

**FY:** Fiscal Year

**GAI:** Global Assistance Initiatives

**GAMP:** Good Automated Manufacturing Practices

**GAO:** General Accounting Office (U.S. government)

**GATT:** General Agreement of Tariffs and Trade

**GBP:** Good Business Practices

**Gbps:** Gigabits or Billions of Bits per Second (data transmission)

**GC:** Gas Chromatography

**GCL:** General Counsel and Legal Affairs

**GCP:** Good Clinical Practice

**GCRP:** Good Clinical Research Practice

**GCT:** Gene Therapy, Cell Therapy, and Tissue Engineering (USP Expert Committee designation)

**GDP:** Good Distribution Practices

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**GFR:** Glomerular Filtration Rate

**GI:** Gastrointestinal

**G6PD:** Glucose 6-Phosphate  
Dehydrogenase

**GLP:** Good Laboratory Practice

**GM-CSF:** Granulocyte–Macrophage  
Colony-Stimulate Factor

**GMP:** Good Manufacturing Practice

**GP:** General Practitioner; General  
Practice (U.K.)

**GPhA:** Generic Pharmaceutical  
Association

**GPMS:** Good Postmarketing  
Surveillance Practice (Japan)

**GPR:** General Policies and  
Requirements (Division)

**GPRA:** Government Performance and  
Results Act

**GRAS:** Generally Regarded as Safe  
(FDA)

**GRASE:** Generally Recognized as Safe  
and Effective

**GRP:** Good Review Practice

**GTB:** General Toxicity and  
Biocompatibility (USP Expert Committee  
designation)

**GTRS:** Genetic Testing and DNA  
Standards

**GVHD:** Graft Versus Host Disease

**GXP:** Good [Pharmaceutical] Practice

**HAACP:** Hazard Analysis and Critical  
Control Point (inspection technique)

**HAI:** Health Action International

**HC:** Hydrocarbons

**HC:** Hycrocortisone

**HCFA:** Health Care Financing  
Administration; now renamed The  
Centers for Medicare & Medicaid  
Services

**HCFC:** Hydrochlorofluorocarbons

**HCP:** Home-Care Pharmaceuticals

**HDL:** High-Density Lipoprotein

**HEPA:** High-Efficiency Particle  
Accumulator

**HETP:** Height Equivalent to a  
Theoretical Plate

**HEX:** Human Experimentation  
Committee

**HFA:** Hydrofluoroalkane (such as HFA  
134a used in pressurized metered-dose  
inhalers)

**HFC:** Hydrofluorocarbons

**HHS:** Department of Health and Human  
Services (U.S., also called DHHS)

**Hib:** *Haemophilus influenzae* type b

**HIC:** Hydrophobic-Interaction  
Chromatography

## GLOSSARY – Acronyms, Abbreviations, & Initials

**HIMA:** Health Industry Manufacturers Association

**HIMSS:** Health Information and Management Systems Society

**HIPPA:** Health Insurance Portability and Accountability Act

**HIV:** Human Immunodeficiency Virus

**HL7:** Health Level 7 [a not-for-profit ANSI-accredited standards-developing organization (SDO)]

**HLA:** Human Leukocyte Antigen

**HLB:** Hydrophile–Lipophile Balance

**HMO:** Health Maintenance Organization

**HPAEC-PAD:** High-Performance Anion-Exchange Chromatography–Pulsed Amphoteric Detection

**HPB:** Health Protection Branch, Laboratory Centre for Disease Control (Canada)

**HPBCD:** Hydroxypropyl-Beta-Cyclodextrin; also **HP $\beta$ CD** Hydroxypropyl- $\beta$ -Cyclodextrin

**HPLC:** High-Performance Liquid Chromatography

**HPLC ESI MS:** High-Performance Liquid Chromatography Electrospray Ionization Mass Spectrometry

**HR:** Human Resources

**HRG:** Health Research Group

**HRRC:** Human Research Review Committee

**HRSA:** Health Research Services Administration

**HSA:** Human Serum Albumin

**HSRC:** Human Subjects Review Committee

**HSV:** Herpes Simplex Virus

**HTML:** Hypertext Markup Language

**HTS:** High-Throughput Screening

**HTTP:** Hypertext Transfer Protocol

**HVAC:** Heating, Ventilation, and Air Conditioning

**HX:** History

**I3C:** India CDISC Coordinating Committee

**IA:** Infrastructure Administrator

**IA:** Integrated Amperometry

**IA:** International Affairs

**IAB:** Industry Advisory Board (for CDISC)

**IACP:** International Academy of Compounding Pharmacists

**IAPO:** International Alliance of Patient Organizations

**IARC:** International Agency for Research on Cancer

**IB:** Investigator's Brochure

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Please send suggested additions to Stefan Schuber, PhD, Director of Scientific Reports at USP: [sps@usp.org](mailto:sps@usp.org)

## GLOSSARY – Acronyms, Abbreviations, & Initials

**IC:** Informed Consent

**ICD:** Informed Consent Document

**ICD9:** International Classification of Diseases, 9<sup>th</sup> revision – *see also MedDRA*

**ICDRA:** International Conference of Drug Regulatory Authorities (WHO)

**ICG:** India CDISC Group

**ICH:** International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

**ICMCM:** International Conference & Exhibition of the Modernization of Chinese Medicine & Health Products (exhibition and conference organized by MCMIA and TDC, qv)

**ICN:** International Council of Nurses

**ICP:** Inductively Coupled Plasma

**ICP–AES:** Inductively Coupled Plasma–Atomic Emission Spectroscopy (cf. <730> *Plasma Spectrochemistry* and <231> Heavy Metals)

**ICP–OES:** Inductively Coupled Plasma–Optical Emission Spectroscopy

**ICPEMC:** International Commission for Protection against Mutagens and Carcinogens

**ICR:** Institute of Clinical Research (formerly ACRPI, Association for Clinical Research in the Pharmaceutical Industry, U.K.)

**ICSR:** Individual Case Safety Report

**ICTH:** International Committee on Thrombosis and Haemostases

**ID:** Infrastructure Director

**IDE:** Investigational Device Exemption

**IDR:** Idiosyncratic Drug Reaction

**IDSMB:** Independent Data Safety Monitoring Board

**IEC:** Ion-Exchange Chromatography

**IEC:** Independent Ethics Committee

**IEF:** Isoelectric Focusing

**IEEE:** Institute of Electrical and Electronic Engineers

**IFAPP:** International Federation of Associations of Pharmaceutical Physicians

**IFPMA:** International Federation of Pharmaceutical Manufacturers' Associations

**IG:** Inspector General (HHS)

**IGPA:** International Generic Pharmaceutical Alliance

**IGT:** Impaired Glucose Tolerance

**IHD:** Ischemic Heart Disease

**IHS:** Indian Health Service

**IKS:** Interkantonale Kontrollstelle für Heilmittel (Switzerland)

**IL:** Interleukin [e.g., IL-1, IL-6]

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Please send suggested additions to Stefan Schubert, PhD, Director of Scientific Reports at USP: [sps@usp.org](mailto:sps@usp.org)

## GLOSSARY – Acronyms, Abbreviations, & Initials

**ILAC:** International Laboratory Accreditation Cooperation

**IM:** Intramuscular

**IMP:** Investigational Materials Plan

**INAD:** Investigational New Animal Drug

**IND:** Investigational New Drug, Investigational New Drug Application (Food & Drug Administration)

**INDA:** Investigational New Drug Application

**INDC:** Investigational New Drug Committee

**INN:** International Nonproprietary Name

**IOM:** Institute of Medicine (National Academy of Science, U.S.)

**IP:** Information Programs

**IP:** Intellectual Property

**IPA:** International Pharmaceutical Abstracts

**IPCS:** International Program for Chemical Safety

**IPEC:** International Pharmaceutical Excipients Council

**I-PHP-CFG:** International Public Health Program Cross-Functional Group

**IPRA:** International Product Registration Document

**IPRG:** Interdisciplinary Pharmacogenomics Review Group (FDA)

**IPRO:** Independent Pharmaceutical Research Organization – *see also CRO*

**IQ:** Installation Qualification

**IR:** Infrared

**IRA:** Interim Revision Announcements

**IRB:** Institutional Review Board; Independent Review Board

**IRC:** Institutes Review Committee

**IRD:** International Registration Document

**IRS:** Identical, Related, or Similar

**IS:** Information Sciences

**ISCB:** International Society for Clinical Biostatistics

**ISD:** Information and Standards Development (Now Known as DSD, Department of Standards Development)

**ISDN:** Integrated Services Digital Network

**ISMP:** Institute for Safe Medication Practices

**ISO:** International Organization for Standardization

**ISP:** Internet Service Provider

**ISPE:** International Society for Pharmacoepidemiology

## GLOSSARY – Acronyms, Abbreviations, & Initials

**ISPOR:** International Society for Pharmacoeconomics & Outcomes Research

**ISQA:** Information Systems Quality Assurance

**ISS:** Ion-Scattering Spectroscopy

**IT:** Information Technology

**IT:** Intrathecal

**ITSC:** Information Technology Service Center

**IU:** International Units

**IUPAC:** International Union of Pure and Applied Chemistry

**IVD:** In Vitro Diagnostics

**IVP:** Ingredient Verification Program (USP)

**IVR:** Interactive Voice Response (telephone technology)

**IVRS:** Interactive Voice Response System

**IWG:** Interdepartmental Working Group

**J3C:** Japan CDISC Coordinating Committee

**JAN:** Japanese Accepted Names (see USP Dictionary)

**JCAH:** Joint Commission for the Accreditation of Hospitals

**JCAHO:** Joint Commission on Accreditation of Healthcare Organizations, Hospitals

**JCG:** Japan CDISC Group

**JMA:** Japan Medical Association

**JP:** Japanese Pharmacopeia

**JPMA:** Japan Pharmaceutical Manufacturers Association

**kb:** Kilobase

**Kbps:** Kilobits or Thousands of Bits per Second (data transmission)

**KF:** Karl Fisher

**KSA:** Knowledge, Skills, & Abilities

**LA:** Laser Ablation

**LA-ICP:** Laser Ablation–Inductively Coupled Plasma (sometimes seen as LA-ICP-MS); MS = Mass Spectrometry

**LAB:** Laboratory Data Model (CDISC)

**LAN:** Local Area Network

**LC:** Liquid Chromatography

**LC–MS:** Liquid Chromatography–Mass Spectrometry

**LD:** Lethal Dose

**LD<sub>50</sub>:** Lethal Dose (for 50% of the population tested)

**LDC:** Least-developed countries

**LDL:** Low-Density Lipoprotein

**LH:** Luteinizing Hormone

## GLOSSARY – Acronyms, Abbreviations, & Initials

**LHRH:** Lutinizing Hormone–Releasing Hormone

**LIBS:** Laser-Induced Breakdown Spectroscopy

**LIF:** Swedish Pharmaceutical Industry Association

**LIMS:** Laboratory Information Management Systems

**LIR:** Laboratory Investigation Report

**LKP:** Leiter der klinischen Prüfung

**LLOQ:** Lower Limit of Quantification

**LOA:** Letter of Agreement

**LOAEL:** Lowest Observed Adverse Effect Level

**LOCF:** Last Observation Carried Forward

**LOD:** Loss on Drying

**LOI:** Loss on Ignition

**LOQ:** Limit of Quantitation

**LR:** Light-Resistant

**PREC:** Local Research Ethics Committee (U.K.)

**LSD:** Lysergic Acid Diethylamide

**LTE:** Less Than Effective

**M&S:** Marketing and Sales

**MA:** Marketing Authorization

**MAA:** Marketing Application (EU)

**MAb:** Monoclonal Antibody

**MAC:** Monograph Acquisition Campaign

**MALDI-TOF MS:** Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry

**MAP:** Manager, Administrative Programs

**MAOIs:** Monoamine Oxidase Inhibitors

**MaRS:** Monographs and Reference Standards Database

**MBC:** Minimum Bactericidal Concentration

**Mbps:** Millions of Bits per Second (data transmission)

**MC:** Marketing and Communications

**MCA:** Medicines Control Agency (U.K.)

**MCH:** Mean Corpuscular Hemoglobin

**MCHC:** Mean Corpuscular Hemoglobin Concentration

**MCI:** Mild Cognitive Impairment

**MCM:** Manager, Conferences and Meetings

**MCMIA:** Modernized Chinese Medicine International Association

**MCV:** Mean Corpuscular Volume

**MD:** Manufacturing Documentation

**MDI:** Metered-Dose Inhaler

## GLOSSARY – Acronyms, Abbreviations, & Initials

**MDR:** Medical Device Reporting

**MDR:** Multidrug Resistant (e.g., Tuberculosis)

**MedDRA:** Medical Dictionary for Regulatory Activities (new global standard medical terminology designed to supersede other terminologies used in the medical product development process, including COSTART, ICD9, and others)

**MEDLARS:** Medical Literature Analysis and Retrieval System

**MEFA:** Association of the Danish Pharmaceutical Industry

**MEP:** Member of the European Parliament

**MER:** Medication Errors Reporting

**MG:** Management Group

**MG:** [Medicare] Model Guidelines

**MGEC:** Model Guidelines Expert Committee (See MMA)

**MHC:** Major Histocompatibility Complex

**MHLW:** Ministry of Health, Labor, and Welfare (Japan)

**MHW:** Ministry of Health and Welfare (Japan's equivalent to the FDA)

**MI:** Myocardial Infarction

**MIAME:** Minimum Information about a Microarray Experiment (standard for microarray data)

**MIC:** Minimum Inhibitory Concentration

**MKT:** Marketing and Sales Department

**MKT:** Mean Kinetic Temperature

**MLR:** Master Labeling Record

**MLV:** Multilamellar Vesicles

**MMA:** Medicare Prescription Drug, Improvement, and Modernization Act (2003) (Named USP to develop Model Guidelines)

**MMCP:** Manager, Meeting and Conference Planning

**MMX:** MEDMARx Development Group

**MOA:** Method of Action

**MOH:** Ministry of Health (U.K., Canada, others)

**MOPH:** Ministry of Public Health

**MOU:** Memorandum of Understanding (an MOU between Food & Drug Administration and a regulatory agency in another country allows mutual recognition of inspections)

**MPM:** Monograph Procurement Manager

**MPR:** Master Packaging Record

**MR:** Medical Representative (Japan)

**MRA:** Medical Research Associate

**MRB:** Material Review Board

**MREC:** Multicentre Research Ethics Committee (U.K.)

## GLOSSARY – Acronyms, Abbreviations, & Initials

**MRI:** Magnetic Resonance Imaging

**mRNA:** Messenger RNA

**MRSD:** Maximum Recommended Starting Dose (for a clinical trial in humans)

**MRSD:** Monograph and Reference Development [Laboratory] at USP

**MRS EC:** Monographs and Reference Standards Executive Committee (USP)

**MS:** Mass Spectrometry

**MS:** Multiple Sclerosis

**MSC:** Medical Service Corps

**MSDS:** Material Safety Data Sheet

**MSPPA:** Model State Pharmacy Practice Act

**MSS:** Master Specification Sheet

**MTD:** Maximum Tolerated Dose (that does not produce unacceptable toxicity)

**MVP:** Master Validation Plan

**MW:** Molecular Weight

**NABP:** National Association of Boards of Pharmacy

**NABR:** National Association for Biomedical Research

**NACDS:** National Association of Chain Drug Stores

**NADA:** New Animal Drug Application

**NADPH:** Nicotinamide-Adenine-Dinucleotide Phosphate

**NAF:** Notice of Adverse Findings (Food and Drug Administration Postaudit Letter)

**NAFLEX:** North American Pharmacist's Licensure Exam

**NAFTA:** North American Free Trade Agreement

**NAHC:** National Advisory Health Council

**NAI:** No Action Indicated (Most Favorable Food & Drug Administration Post-inspection Classification)

**NARD:** National Association of Retail Druggists

**NAS:** National Academy of Sciences

**NAS:** New Active Substance (U.K.)

**NAS-NRC:** National Academy of Sciences-National Research Council (U.S.)

**NBAC:** National Bioethics Advisory Commission (U.S.)

**NCA&E:** Noncomplex Actives and Excipients (Division of USP Council of Experts)

**NCCAM:** National Center for Complementary and Alternative Medicine (formerly Office of Alternative Medicine, National Institutes of Health)

**NCCLS:** National Committee for Clinical Laboratory Standards

## GLOSSARY – Acronyms, Abbreviations, & Initials

**NCC MERP:** National Coordinating Council for Medication Error Reporting and Prevention

**NCCTG:** North Central Cancer Treatment Group (U.S.)

**NCDM:** Nordic Clinical Data Management Association

**NCE:** New Chemical Entity

**NCHGR:** National Center for Human Genome Research (National Institutes of Health)

**NCHS:** National Center for Health Statistics (in Center for Disease Control)

**NCI:** National Cancer Institute (National Institutes of Health)

**NCPA:** National Community Pharmacists Association

**NCPDP:** National Council for Prescription Drug Programs

**NCPIE:** National Council on Patient Information and Education (Washington, DC)

**NCQA:** National Committee for Quality Assurance

**NCR:** No Carbon [paper] Required

**NCRR:** National Center for Research Resources (National Institutes of Health)

**NCS:** Not Clinically Significant

**NCSPA:** National Council of State Pharmacy Association Executives

**NCTC:** National Collection of Type Cultures (London, U.K.)

**NCTR:** National Center for Toxicological Research

**NCVIA:** National Childhood Vaccine Injury Act (1986)

**NDA:** New Drug Application (Food & Drug Administration)

**NDC:** National Drug Code

**NDE:** New Drug Evaluation

**NDS:** New Drug Study

**NDS:** New Drug Submission (Canada's equivalent of a new drug application)

**NEFARMA:** Dutch Association of the Innovative Pharmaceutical Industry

**NEI:** National Eye Institute (National Institutes of Health)

**NEJM:** *New England Journal of Medicine*

**NF:** National Formulary

**NF- $\kappa$ B:** Nuclear factor- $\kappa$ B

**NGO:** Nongovernmental Organization

**NHI:** National Health Insurance (Japan)

**NHLBI:** National Heart, Lung, and Blood Institute (National Institutes of Health)

**NHPD:** Natural Health Products Directorate (Canada)

**NHS:** National Health Service (U.K.)

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## GLOSSARY – Acronyms, Abbreviations, & Initials

**NHLBI:** National Heart, Lung, and Blood Institute (National Institutes of Health)

**NHW:** National Health and Welfare Department (Canada's equivalent of DHHS)

**NIA:** National Institute on Aging (National Institutes of Health)

**NIAAA:** National Institute on Alcohol Abuse and Alcoholism (National Institutes of Health)

**NIAID:** National Institute of Allergies and Infectious Diseases (National Institutes of Health)

**NIAMS:** National Institute of Arthritis and Musculoskeletal and Skin Diseases (National Institutes of Health)

**NICHD:** National Institute of Child Health and Human Development (National Institutes of Health)

**NICPB:** National Institute for the Control of Pharmaceutical and Biological Products (China)

**NIDA:** National Institute on Drug Abuse (National Institutes of Health)

**NIDCD:** National Institute on Deafness and Other Communication Disorders (National Institutes of Health)

**NIDDK:** National Institute of Diabetes and Digestive and Kidney Diseases (National Institutes of Health)

**NIDDKD:** National Institute of Diabetes and Digestive and Kidney Diseases

**NIDR:** National Institute of Dental Research (National Institutes of Health)

**NIEHS:** National Institute of Environmental Health Sciences (National Institutes of Health)

**NIGMS:** National Institute of General Medical Sciences (National Institutes of Health)

**NIH:** National Institutes of Health (DHHS)

**NIMH:** National Institute of Mental Health (National Institutes of Health)

**NINDS:** National Institute of Neurological Disorders & Stroke (National Institutes of Health)

**NINR:** National Institute of Nursing Research (National Institutes of Health)

**NIR:** Near-Infrared Spectrometry

**NIRB:** Noninstitutional Review Board

**NIRVoG:** Near-IR Validation Working Group

**NISPC:** National Institute for Standards in Pharmacist Credentialing

**NIST:** National Institute of Standards and Technology

**NK:** Natural Killer Cells

**NK- $\kappa$ B:** Nuclear Factor  $\kappa$ B

**NL:** Nomenclature and Labeling (USP Expert Committee designation)

**NLEA:** Nutrition Labeling and Education Act (1990)

## GLOSSARY – Acronyms, Abbreviations, & Initials

**NLM:** National Library of Medicine  
(National Institutes of Health)

**NMBA:** Neuromuscular Blocking Agent

**NMDR:** National Marrow Donor Registry

**NME:** New Molecular Entity

**NMR:** Nuclear Magnetic Resonance  
(spectroscopy)

**NNRTI:** Nonnucleoside Reverse  
Transcriptase Inhibitor

**NO:** Nitric Oxide

**NOA:** Notice of Availability

**NOAEL:** No Observed Adverse Effect  
Level

**NOEL:** No Observable Effect Level  
(dose of an experimental drug given  
preclinically that does not product an  
observable toxicity)

**NOOH:** Notice of Opportunity for  
Hearing (first step in FDA procedure to  
remove a drug from the market against  
a manufacturer's desires)

**NOR:** Normal Operating Range

**NORD:** National Organization for Rare  
Diseases

**NOS:** Not Otherwise Specified

**NPCC:** National Patient Counseling  
Competition

**NPN:** Nonprotein Nitrogen Compounds

**NPRM:** Notice of Proposed Rulemaking

**NPV:** Negative Predictive Value (e.g., of  
a diagnostic test)

**NQF:** National Quality Forum

**NRB:** Noninstitutional Review Board  
(also known as an independent review  
board)

**NRC:** National Research Council

**NRC:** Nuclear Regulatory Committee

**NRTI:** Nucleoside Reverse  
Transcriptase Inhibitor

**NSAIDs:** Nonsteroidal Anti-  
Inflammatory Drugs

**NSCLC:** Non-Small Cell Lung  
Carcinoma

**NSF:** National Science Foundation

**NSR:** Nonsignificant Risk

**NTG:** Network Technologies Group

**NTP:** National Toxicology Program

**NTRM™:** NIST Traceable Reference  
Material (See NIST Special Publication  
260-136)

**OAI:** Official Action Indicated (serious  
Food & Drug Administration post-  
inspection classification)

**OAM:** See *NCCAM*

**OASH:** Office of the Assistant  
Secretary for Health

**OB-GYN:** Obstetrics-Gynecology

## GLOSSARY – Acronyms, Abbreviations, & Initials

**OBRA:** Omnibus Budget Reconciliation Act

**OCP:** Office of Combination Products (FDA)

**OCR:** Optical Character Recognition

**OCT:** Organic Cation Transporters

**ODAC:** Oncologic Drugs Advisory Committee (U.S.)

**OD:** Right Eye

**ODE:** Office of Drug Evaluation (CDER now has five such offices: ODE I, II, III, IV, and V)

**ODM:** Operational Data Model [CDIS]

**ODS:** Office of Drug Safety (FDA)

**OEB:** Office of Epidemiology and Biostatistics (CDER)

**OEM:** Original Equipment Manufacturer

**OES:** Optical Emission Spectroscopy/Spectrometry

**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)

**OHA:** Office of Health Affairs

**OHRP:** Office for Human Research Protections

**OIG:** Office of the Inspector General

**OINDP:** Orally Inhaled and Nasal Drug Products

**OIVD:** Office of in Vitro Diagnostics Device Evaluation and Safety

**OJC:** *Office Journal of the European Union-C Series* (Information)

**OJEC:** *Official Journal of the European Communities*

**OJL:** Office Journal of the European Union-L Series (Legislation)

**OLE:** Object Linking and Embedding (Microsoft communication protocol)

**OMA:** *Official Methods of Analysis* (published by AOAC)

**OMB:** Office of Management and Budget (U.S.)

**OMCL:** Official Medicines Control Laboratories

**OOS:** Out of Specification

**OOS:** Out of Stock

**OOS:** Out of Service

**OPC:** OLE (q.v.) for Process Control

**OPR:** Office of Public Relations

**OPRR:** Office for Protection from Research Risks (predecessor to OHRP)

**OQ:** Operational Qualification

**OR:** Odds Ratio

**ORD:** Optical Rotatory Dispersion

## GLOSSARY – Acronyms, Abbreviations, & Initials

**OS:** Left Eye

**OSHA:** Occupational Safety and Health Administration (U.S.)

**OTA:** Office of Technology Assessment (U. S.; abolished by Congress, Fall 1995)

**OTC:** Over-the-Counter (refers to nonprescription drugs)

**OU:** Both eyes

**OVI:** Organic Volatile Impurities

**P4P:** Pay for Performance

**P&T:** Pharmacy and Therapeutics Committee

**PA:** Pulsed Amperometric

**PAB:** Pharmaceutical Affairs Bureau (Japan)

**PAD:** Pharmacologically Active Dose

**PAD:** Premature Atrial Depolarizations

**PAHO:** Pan American Health Organization

**PAR:** Postapproval Research

**PAR:** Proven Acceptable Range

**PAT:** Process Analytical Technology

**PAHO:** Pan American Health Organization

**PAM:** Pesticide Analytical Manual (FDA)

**PANDRH:** Pan American Network for Drug Regulatory Harmonization

**PAR:** Postapproval Research

**PAR:** Proven Acceptable Range

**PBM:** Pharmacy Benefits Management (or Manager)

**PBPC:** Peripheral Blood Progenitor Cell

**PBS:** Phosphate Buffered Saline

**PC:** Personal Computer

**PC:** Principal Component

**PC:** Protocol Amendment—Change (COMIS term)

**PCA:** Patient-Controlled Analgesia

**PCA:** Principal-Component Analysis

**PCAB:** Pharmacy Compounding Accreditation Board

**PCC:** Poison Control Center

**PCCF:** Pharmacist Care Claim Form

**PCP:** Phencyclidine

**PCP:** *Pneumocystis carinii* Pneumonia

**PCR:** Polymerase Chain Reaction

**PCS:** Photon correlation spectroscopy

**PCS:** Process Control System

**PD:** Pharmacodynamics

**PDA:** Parenteral Drug Association

**PDA:** Personal Digital Assistant (Palm Pilot, for example)

## GLOSSARY – Acronyms, Abbreviations, & Initials

<b>PDA:</b> Photodiode Array (Detector)	PMA, Pharmaceutical Manufacturers Association)
<b>PDEL:</b> Patient Drug Education Leaflet	<b>PHS:</b> Public Health Service (U.S.)
<b>PDF:</b> Pharmaceutical Dosage Forms (USP Expert Committee designation)	<b>PHSA:</b> Public Health Service Act
<b>PDE:</b> Permissible Daily Exposure	<b>PI:</b> Package Insert (approved product labeling)
<b>PDF:</b> Portable Document Format	<b>PI:</b> Parallel Imports
<b>PDG:</b> Pharmacopeial Discussion Group	<b>PI:</b> Principal Investigator
<b>PDQ:</b> Physicians' Data Query (NCI-sponsored cancer trial registry)	<b>PK:</b> Pharmacokinetics
<b>PDR:</b> <i>Physicians' Desk Reference</i>	<b>PKI:</b> Public Key Infrastructure
<b>PDUFA:</b> Prescription Drug User Fee Act (1992, U.S.)	<b>PL:</b> Primary Liaison
<b>PE:</b> Pulmonary embolism	<b>PLA:</b> Product License Application (Food & Drug Administration)
<b>PEG:</b> Poly(ethylene glycol)	<b>PLC:</b> Programmable Logic Controller
<b>PEL:</b> Permissible Exposure Limit	<b>PLGA:</b> Poly(lactide-co-glycolide)
<b>PEM:</b> Prescription Event Monitoring	<b>PLS:</b> Partial Least Squares
<b>PERI:</b> Pharmaceutical Education & Research Institute	<b>PMA:</b> Pre-Market Approval Application (Food & Drug Administration)
<b>PET:</b> Positron Emission Tomography	<b>pMDI:</b> Pressurized Metered-Dose Inhaler
<b>PF:</b> Pharmacopeial Forum	<b>PMS:</b> Postmarketing Surveillance
<b>PFT:</b> Pulmonary Function Tests	<b>PN:</b> Parenteral Nutrition
<b>P-gp:</b> P-Glycoprotein	<b>PN:</b> Protocol Amendment—New Protocol (or Pending Review) (COMIS term)
<b>PGDB:</b> Prevention Guidelines Database	<b>P/NP:</b> Prescription/Nonprescription Stakeholders' Forum
<b>PhRMA:</b> Pharmaceutical Research and Manufacturers of America (formerly	

## GLOSSARY – Acronyms, Abbreviations, & Initials

**PO:** Per Os (by mouth)

**PO:** Purchase Order

**POC:** Point of Contact

**POMR:** Problem-Oriented Medical Record

**PPA:** Poison Prevention Act

**PPA:** Professional and Public Affairs Department

**PPAC:** Pharmacy Practice Activity Classification

**PPC:** Parenteral Products—Compounding and Preparation (USP Expert Committee designation)

**PPI:** Patient Package Insert

**PPI:** Parenteral Products—Industrial (USP Expert Committee designation)

**PPM:** Parts per Million

**PPO:** Policy and Procedure Order

**PPO:** Preferred Provider Organization

**PPPA:** Poison Prevention Packaging Act (1970)

**PPR:** Production Packaging Record

**PPV:** Positive Predictive Value (e.g., of a diagnostic test)

**PQ:** Performance Qualification

**PQRI:** Product Quality Research Institute

**PR:** Partial Response; Pulse Rate; Public Relations

**PRIM&R:** Public Responsibility in Medicine and Research (Boston, MA)

**PRN:** Practitioner Reporting Network

**PROG:** Peer-Review Oversight Group (National Institutes of Health)

**PRN:** As Needed

**PRS:** Procedural Reference Standards

**PSD:** Packaging, Storage, and Distribution (USP Expert Committee designation)

**PSD:** Particle-Size Distribution

**PSI:** Patient Safety Indicators

**PSUR:** Periodic Safety Update Report

**PSVT:** Paroxysmal Supraventricular Tachycardia

**PTC:** Points to Consider

**PTH:** Parathyroid Hormone

**PTT:** Partial Thromboplastin Time

**PUD:** Peptic Ulcer Disease

**PVD:** Premature Ventricular Depolarization

**PVP:** Polyvinylpyrrolidone

**PVT:** Performance Verification Testing

**PVT:** Programmable Vaporization Temperature

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Please send suggested additions to Stefan Schuber, PhD, Director of Scientific Reports at USP: [sps@usp.org](mailto:sps@usp.org)

## GLOSSARY – Acronyms, Abbreviations, & Initials

**PW:** Pharmaceutical Waters (USP Expert Committee designation)

**PWG:** Pharmacopeial Working Group (AF, FARBRAS, FEUM, & USP)

**Q1:** ICH Guidelines Having to Do with Stability

**Q2:** ICH Guidelines Having to Do with Analytical Validation

**Q3:** ICH Guidelines Having to Do with Impurities

**Q6A:** ICH Guidelines Having to Do with Setting Specifications for Chemical Drug Substances and Products

**Q6B:** ICH Guidelines Having to Do with Setting Specifications for Biological Drug Substances and Products

**QA:** Quality Assurance

**QALY:** Quality-adjusted Life Year

**QAU:** Quality Assurance Unit

**QC:** Quality Control

**QCD:** Quality Control Documentation

**QCGs:** Quality Communication Groups

**QD:** Once Daily

**QID:** Four Times a Day

**QL:** Quality of Life

**QM:** Quality Manual

**QOD:** Every Other Day

**QOL:** Quality of Life

**QR:** Quality Review

**R-list:** Index of All Proposed Revisions for a Particular Number of PF (along with items proposed for inclusion in an Interim Revision Announcement)

**R&D:** Research and Development

**RA:** Rheumatoid Arthritis

**RADAR:** Risk Assessment of Drugs-Analysis and Response

**RAPS:** Regulatory Affairs Professionals Society

**RBRVS:** Resource-Based Relative Value Scale

**RCA:** Replication-Competent Adenovirus

**RCA:** Root-Cause Analysis

**RCR:** Replication-Competent Retrovirus

**RCRIM:** Regulated Clinical Research and Information Management (HL7)

**RCT:** Randomized Clinical Trial

**RCV:** Replication-Competent Virus

**RDA:** Recommended Daily Allowance

**RDE:** Remote Data Entry

**RDL:** Research and Development Laboratory

**RDL ERT:** Research and Development Laboratory Emergency Response Team

**rDNA:** Recombinant DNA

## GLOSSARY – Acronyms, Abbreviations, & Initials

**RDRC:** Radioactive Drug Research Committee

**REB:** Research Ethics Board (Canada)

**RfD:** Reference Dose (EPA)

**RFID:** Radio-Frequency Identification

**RFLP:** Restriction Fragment Length Polymorphism

**RFP:** Request for Proposals

**RGAs:** Return Goods Authorization

**RIA:** Radioimmunoassay

**RIM:** Reference Information Model (HL7)

**RKI:** Robert-Koch-Institut, Bundesinstitut für Infektionskrankheiten und nicht-übertragbare Krankheiten (Federal Institute for Infection and Noncommunicable Diseases, Germany)

**RL:** Regulatory Letter (Food & Drug Administration post-audit letter)

**RLD:** Reference Listed Drug

**RM:** Reference Material (Cf. NIST Special Publication 260-136)

**RMI:** Radiopharmaceuticals and Medical Imaging (USP Expert Committee designation)

**RNA:** Ribonucleic Acid

**ROI:** Residue on Ignition

**R&R:** Repeatability and Reproducibility

**RRC:** Registration & Regulatory Compliance

**RRF:** Relative Response Factor

**RRS:** Reagent Reference Standards

**RRT:** Relative Retention Time

**RS:** Reference Standard

**RS-485:** Communications Protocol (used, e.g. in BMS, q.v.)

**RSC:** Reference Standard Committee (USP Expert Committee designation)

**RSCEP:** Reference Standard Committee Evaluation Package

**RSD:** Relative Standard Deviation

**RSE:** Reference Standards Evaluation

**RSO:** Reference Standards Operations

**RSP:** Reference Standards Production

**RSP CFG:** Reference Standards and Publications Cross-Functional Group (USP)

**RTECS:** Registry of Toxic Effects of Chemical Substances

**RTF:** The decision by FDA to refuse to file an application

**RTI:** Reverse Transcriptase Inhibitor

**RT-PCR:** Real-Time Polymerase Chain Reaction

**RTS:** Revision Tracking System

**RV:** Residual Volume

## GLOSSARY – Acronyms, Abbreviations, & Initials

<b>Rx:</b> Prescription	<b>SCT:</b> Society for Clinical Trials
<b>S&amp;M:</b> Sales and Marketing	<b>SD:</b> Standard Deviation
<b>S&amp;MC:</b> Sales and Marketing Communications	<b>SDA:</b> State Drug Administration (China)
<b>SAE:</b> Serious Adverse Event	<b>SDM:</b> Submission Data Model (CDISC)
<b>SAL:</b> Sterility Assurance Level	<b>SDO:</b> Standards Development Organization
<b>SALMOUS:</b> Standards for Articles Legally Marketed Outside the US	<b>SDS:</b> Submissions Data Standard
<b>SAMHSA:</b> Substance Abuse and Mental Health Services Administration	<b>SDS:</b> Submission Domain Standards (CDISC)
<b>SAR:</b> Structure–Activity Relationship	<b>SDS–PAGE:</b> Sodium Dodecyl Sulfate–Polyacrylamide Gel Electrophoresis
<b>SAS:</b> Statistical Analysis System (commonly used statistical analysis package)	<b>SE:</b> Standard Error (statistics)
<b>SAT:</b> Safety Action Team	<b>SEA:</b> Single European Act of 1987
<b>SATCM:</b> State Administration of Traditional Chinese Medicine (China)	<b>SEC:</b> Size-Exclusion Chromatography
<b>SBA:</b> Summary Basis of Approval	<b>SEER:</b> Surveillance, Epidemiology, and End Results (program of the National Cancer Institute that collects and publishes cancer incidence and survival data)
<b>SC:</b> Study Coordinator – <i>see also</i> CRC, CCRC, SSC	<b>SF:</b> Safety Factor
<b>SC:</b> Subcutaneous	<b>SFC:</b> Supercritical Fluid Chromatography
<b>SCDM:</b> Society for Clinical Data Management (U.S.)	<b>SGML:</b> Standard Generalized Markup Language
<b>SCNT:</b> Somatic-Cell Nuclear Transfer (i.e., Therapeutic Cloning)	<b>SHQM:</b> Semihemiquinquennial Meeting
<b>SCSI:</b> Small Computer Systems Interface	<b>SI:</b> Supplemental Information
<b>sCT:</b> Salmon Calcitonin	<b>SI:</b> Système International d'Unités

## GLOSSARY – Acronyms, Abbreviations, & Initials

**SIAC:** Special Interest Area Community (DIA)

**SIADS:** Syndrome of Inappropriate Antidiuretic Secretion

**SIDS:** Sudden Infant Death Syndrome

**SIG:** Special Interest Group (HL7)

**SIMS:** Secondary Ion Mass Spectrometry

**SKU:** Stock-Keeping Unit

**SL:** Secondary Liaison

**SLA:** Service Level Agreement

**SLE:** Systematic Lupus Erythematosus

**SMART:** Submission Management and Review Tracking (Food & Drug Administration)

**SME:** Significant Medical Event

**SMG:** Senior Management Group (USP)

**SMO:** Site Management Organization

**SmPC:** Summary of Product Characteristics

**SMU:** Safe Medication Use (USP Expert Committee designation)

**SNDA:** Supplemental New Drug Application

**SNIP:** Syndicat National de l'Industrie Pharmaceutique (France)

**SNOMED:** Systematized Nomenclature of Medicine (a dictionary)

**SNRI:** Serotonin–Norepinephrine Reuptake Inhibitor

**SO:** Standards Operations

**SOCRA:** Society of Clinical Research Associates

**SOP:** Standard Operating Procedure

**SPAC:** State Pharmaceutical Administration of China

**SPC:** Statistical Process Control

**SPM:** Society of Pharmaceutical Medicine (U.K.)

**SQA:** Society of Quality Assurance

**SQAP:** Systems Quality Assurance Plan

**SQC:** Statistical Quality Control

**SRM<sup>®</sup>:** NIST Standard Reference Material (See NIST Special Publication 260-136)

**SRS:** Spontaneous Reporting System

**SSC:** Study Site Coordinator – *see also* CRC, CCRC, SC

**SSCT:** Swedish Society for Clinical Trials

**SSFA:** Società di Scienze Farmacologiche Applicate (Italy)

**SSRI:** Selective Serotonin Reuptake Inhibitor

**SSSR:** Scientific Staff Second Reader; scientific liaison responsible for

## GLOSSARY – Acronyms, Abbreviations, & Initials

reviewing draft monographs or general chapters

**STF:** Study Tagging File

**STT:** Short-Term Tests

**SUAE:** Serious Unexpected Adverse Event

**SUD:** Sudden Unexpected Death

**SUV:** Small Unilamellar Vesicles

**SVP COO:** Senior Vice President and Chief Operating Officer

**SVP SGC:** Senior Vice President, Secretary, and General Counsel

**SWOG:** Southwest Oncology Group

**SX:** Symptoms

**Sys Admin:** System Administrator, Applications Development

**T<sub>4</sub>:** Thyroxine

**T<sub>a</sub>:** Triiodothyronine

**TB:** Tuberculosis

**TC:** Technical Committee (HL7)

**TCC:** Technical Coordinating Committee (TDISC)

**TCD:** Thermal Conductivity Detector

**TCID<sub>50</sub>:** Tissue Culture Infectious Dose, 50%

**TCM:** Traditional Chinese Medicine

**TCP/IP:** Transmission Control Protocol/Internet Protocol

**TDC:** Trade Development Council (Hong Kong)

**TDI:** Tolerable Daily Intake (WHO)

**TDM:** Therapeutic Decision Making (Expert Committee)

**TEA:** Time and Extent Application (cf. 21 *CFR* 330.14)

**TESS:** Treatment Emergent Signs and Symptoms

**TGA:** Thermogravimetric analysis

**TGF:** Transforming Growth Factor [e.g., TGF- $\alpha$ ]

**TIA:** Transient Ischemic Attacks

**TID:** Three Times a Day

**TIND:** Treatment IND – *See Also IND*

**TK:** Toxicokinetics

**TLC:** Thin-Layer Chromatography

**TLV:** Threshold Limit Values

**T<sub>max</sub>:** Time after Dosing When C<sub>max</sub> Occurs

**TMO:** Trial Management Organization

**TNF- $\alpha$ :** Tumor-Necrosis Factor- $\alpha$

**TOC:** Total Organic Carbon

**TOF MS:** Time-of-Flight Mass Spectrometry

## GLOSSARY – Acronyms, Abbreviations, & Initials

<b>TPC:</b> Total Process Control	<b>USCA:</b> U.S. Code Annotated
<b>TPN:</b> Total Parenteral Nutrition	<b>USDA:</b> Department of Agriculture (U.S.)
<b>TQM:</b> Total Quality Management	<b>USP:</b> United States Pharmacopeia
<b>TRIPs:</b> Trade-related Aspects of Intellectual Property Rights	<b>USP DI:</b> U.S. Pharmacopeia Dispensing Information
<b>TSE:</b> Transmissible Spongiform Encephalopathy	<b>USP-DQI:</b> USP Drug Quality and Information Program
<b>TSH:</b> Thyroid Stimulating Hormone	<b>USP-IV:</b> U.S. Pharmacopeia's Ingredient Verification Program
<b>TV:</b> Tidal Volume	<b>USP-NF:</b> U.S. Pharmacopeia–National Formulary
<b>TWEA:</b> Trading with the Enemy Act	<b>VA:</b> Veterans Administration (officially, United States Department of Veteran Affairs)
<b>TXN:</b> Transcription	<b>VAERS:</b> Vaccine Adverse Event Reporting System
<b>UA:</b> Urinalysis	<b>VAI:</b> Voluntary Action Indicated (Food & Drug Administration postaudit inspection classification)
<b>UHF:</b> Ultrahigh Frequency	<b>VC:</b> Vital Capacity
<b>UKCCR:</b> United Kingdom Coordinating Committee on Cancer Research	<b>VEGFR:</b> Vascular Endothelial Growth Factor
<b>ULOQ:</b> Upper Limit of Quantification	<b>VET:</b> Veterinary Drugs (USP Expert Committee designation)
<b>UND:</b> Undried	<b>VGDS:</b> Voluntary Genomic Data Submission
<b>UNESCO:</b> United Nations Education Science and Cultural Organization	<b>VMP:</b> Validation Master Plan
<b>UNPA:</b> Utah Natural Products Alliance	<b>VNTR:</b> Variable Number of Tandem Repeats
<b>URL:</b> Uniform Resource Locator (address of a Web site)	
<b>USAID:</b> US Agency for International Development	
<b>USAN:</b> United States Adopted Names	
<b>USC:</b> United States Code (book of laws)	

## GLOSSARY – Acronyms, Abbreviations, & Initials

**VOA:** Volunteer and Organizational Affairs [Department]

**XRPD:** X-Ray Powder Diffraction

**VP:** Vice President

**VPN:** Virtual Private Network

**v/v:** Percent Volume in Volume

**VVI:** Vaccines, Virology, and Immunology (USP Expert Committee designation)

**WAN:** Wide Area Network

**WFI:** Water for Injection

**WHO:** World Health Organization

**WHOART:** World Health Organization Adverse Reaction Terminology

**WIP:** Work in Progress

**WL:** Warning Letter (most serious Food & Drug Administration postaudit letter; demands immediate action within 15 days)

**WMA:** World Medical Association

**WRAIR:** Walter Reed Army Institute of Research (DoD)

**WTO:** World Trade Organization

**W/V:** Percent Weight in Volume

**W/W:** Percent Weight in Weight

**WWW:** World Wide Web

**XML:** Extensible Markup Language

**XRD:** X-Ray Diffraction

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Please send suggested additions to Stefan Schuber, PhD, Director of Scientific Reports at USP: [sps@usp.org](mailto:sps@usp.org)