

Glossary

	Glossary of Acronyms
AAFSC	Aquatic and Aquaculture Food Safety Training Center
ACOMS	Advisory Committee Oversight and Management Staff
ACSI	American Customer Satisfaction Index
ADA	American's with Disabilities Act
ADA	American Diabetes Association
ADUFA	Animal Drugs User Fee Act
AF	Acidified Food
AFRPS	Animal Feeds Regulatory Program Standards
AGDUFA	Animal Generic Drug User Fee Act
ALM	Automated Laboratory Management
ALS	Amyotrophic Lateral Sclerosis
AMP	Real Property Asset Management Plan
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
APCHO	Asian and Pacific Community Health Organizations
APDS	Artificial Pancreas Device Systems
APEC	Asia-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
APHL	Association of Public Health Laboratories
API	Active Pharmaceutical Ingredient
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine
ARL	Arkansas Regional Laboratory
ASPR	Assistant Secretary for Preparedness and Response
AV	Audio Visual
BA	Budget Authority
BACPAK	bacterial-pathogen knowledgebase
BAM	Bacteriological Analytical Manual
BARDA	Biomedical Advanced Research and Development Authority
BEQ	Bioequivalence
BIMO	Bioresearch Monitoring
BLA	Biologics License Application
Blood SCAN	Blood Safety Continuous Active-Surveillance Network
BMAR	Backlog of Maintenance and Repairs
BPA	Bisphenol A
BPA	Business Process Automation
BPCA	Best Pharmaceuticals for Children Act

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BRF	Beltsville Research Facility
BSE	Bovine Spongiform Encephalopathy
BSL	Biosafety Level
BsUFA	Biosimilar User Fee Act
CAP	Certificate Application Process
CBER	Center for Biologics Evaluation and Research
CBP	Customs and Border Protection
CBRN	Chemical, Biological, Radiological, and Nuclear
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CERSIs	Centers of Excellence in Regulatory Science and Innovation
CFIA	Canada Food Inspection Agency
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
cGMP	Current Good Manufacturing Practice
cGMP	current Good Manufacturing Practice
CGTP	Current Good Tissue Practice
CII-FACE	Coalition of India Industry-Food and Agriculture Center of Excellence
CJD	Creutzfeldt-Jakob
CMS	Centers for Medicare and Medicaid Services
COMPACT	Compendium of Microbiological Protocols and Chemical Tests
CORE	Coordinated Outbreak Response and Evaluation
CORES	Collaborative Opportunities for Research Excellence in Science
COTS	Commercial Off-The-Shelf
CP	Citizen Petition
CRADA	Cooperative Research & Development Agreement
CT	Computed tomography
CTP	Center for Tobacco Products
CVM	Center for Veterinary Medicine
DARPA	Defense Advanced Research Projects Agency
DFDT	Division of Food Defense Targeting (formerly known as Prior Notice Center)
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DIOP	Division of Import Operations and Policy

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DMAA	Dimethylamine
DNA	Deoxyribonucleic Acid
DNR	Domain Name Registrar
DOD	Department of Defense
DSP	Diarrhetic Shellfish Poisoning
DTC	Direct-To-Consumer
DWPE	Detention Without Physical Examination
ECG	Electrocardiogram
EDKB	Endocrine Disruptor Knowledge Base
EDSR	Electronic Document Submission and Review
EHEC	Enterohemorrhagic <i>E. Coli</i>
EIR	Entrepreneurs in Residence
eLEXNET	Electronic Laboratory Exchange Network
EMA	Economically Motivated Adulteration
EON	Emergency Operations Network (EON)
EON IMS	Emergency Operations Network Incident Management System
EPA	Environmental Protection Agency
ER	Entry Review
ESRD	End-stage renal disease
eSub	Electronic Submissions
EU	European Union
EUA	Emergency Use Authorization
FACA	Federal Advisory Committee Act
FACTS	Field Accomplishments and Compliance Tracking System
FCC	Forensic Chemistry Center
FCI	Facility Condition Index
FCN	Food Contact Notification
FCS	Food Contact Substances
FD&C Act	Food Drug and Cosmetic Act
FDA	Food and Drug Administration
FDA	Food and Drug Administration
FDA EOP	FDA Emergency Operations Plan
FDAAA	Food and Drug Administration Amendments Act of 2007
FDAMA	Food and Drug Administration Modernization Act of 1997
FDASIA	FDA Safety and Innovation Act
FDA-TRACK	FDA Transparency Results Accountability Credibility Knowledge

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FDCA	Federal Food, Drug, and Cosmetic Act
FEMP	Federal Energy Management Program
FERN	Food Emergency Response Network
FFDCA	Federal Food, Drug & Cosmetic Act
FMLS	Firms Master List Services
FOIA	Freedom of Information Act
FSMA	Food Safety Modernization Act
FSPCA	Food Safety Preventive Controls Alliance
FSPTCA	Family Smoking Prevention and Tobacco Contract Act (Tobacco Control Act)
FSVP	Foreign Supplier Verification Program
FTE	Full Time Equivalent
FURLS	FDA Unified Registration and Listing Systems
FVM	Food and Veterinary Medicine
FY	Fiscal Year
GAO	Government Accountability Office
GCP	Good Clinical Practices
GDUFA	Generic Drug User Fee Amendments of 2012
GIS	Geographic Information System
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GOTS	Government off-the-shelf software
GSA	General Services Administration
GSRS	Global Summit on Regulatory Science
HACCP	Hazard Analysis and Critical Control Point
HBV	Hepatitis B Virus
HC	Health Canada
HCT/P	Human Cells, Tissues and Cellular and Tissue-Based Product
HCV	Hepatitis C Virus
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HPHC	harmful and potentially harmful tobacco product constituent
HRSA	Health Resources and Services Administration
HSP	Human Subject Protection
HTLV	Human T-Lymphotropic Virus
HUD	Humanitarian Use Device

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HVAC	Heating, Ventilation, and Air Conditioning
ICA	Incident Command Alert
ICCR	International Cooperation on Cosmetics Regulation
ICH	International Conference on Harmonization
ICS	Incident Command Center
ICU	Intensive Care Unit
IDE	Investigational Device Exemption
IFSS	Integrated Food Safety System
IIT IFSH	Illinois Institute of Technology Institute for Food Safety and Health
IIWA	International Internet Week of Action
IJPA	International Jelly and Preserve Association
IND	Investigational New Drug
INDA	Investigational New Drug Application
INTERPOL	International Criminal Police Organization
IPT	International Programs Team
IRB	Institutional Review Board
iRISK	FDA's comparative risk assessment tool
ISO	International Organization for Standardization
ISP	Internet Service Provider
IT	Information Technology
ITACS	Import Trade Auxiliary Communications System
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
JLC	Jefferson Laboratories Complex
LACF	Low-Acid Canned Food
LDL	Low-density Lipoprotein
LIMS	Laboratory Information Management System
LLNL	Lawrence Livermore National Laboratory
LTKB	Liver Toxicity Knowledge Base
MAQC	MicroArray Quality Control
MARCS	Mission Accomplishment and Regulatory Compliance Services
MCMi	Medical Countermeasures initiative
MDIC	Medical Device Innovation Consortium
MDR	Medical Device Reporting
MDSAP	Medical Device Single Audit Program

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MDUFA	Medical Device User Fee Amendments
MDUFMA	Medical Device User Fee and Modernization Act
MFAEAR	Mammography Facility Adverse Event and Action Report
MFRPS	Manufactured Food Regulatory Program Standards
MFRPS	Manufactured Foods Regulatory Program Standards
MIN-DO	Minneapolis District Office
MOD	Module
MOU	Memorandum of Understanding
MQSA	Mammography Quality Standards Act
MR	Magnetic Resonance
MRC	Muirkirk Road Complex
MRI	Magnetic Resonance Imaging
MRS	Magnetic Resonance Spectroscopy
MS	Multiple Sclerosis
NACDS	National Association of Chain Drug Stores
NADA	New Animal Drug Application
NARMS	National Antimicrobial Resistance Monitoring System
NATS	National Adult Tobacco Survey
NCAPIP	National Council of Asian and Pacific Islander Physicians
NCATS	National Center for Advancing Translational Science
NCBI	National Center for Biotechnology Information
NCI	National Cancer Institute
NCSP	National Check Sample Program
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NGS	Next-Generation Sequencing
NICBR	National Interagency Confederation for Biological Research
NIH	National Institutes of Health
NIMS	National Incident Management System
NMFS	National Marine Fisheries Service
NSE	Not Substantially Equivalent
NYTS	National Youth Tobacco Survey
OASIS	Operational and Administrative System for Import Support
OCC	Office of the Chief Counsel
OCE	Office of Compliance and Enforcement
OCET	Office of Counterterrorism and Emerging Threats

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OCI	Office of Criminal Investigations
OCM	Office of Crisis Management
OCP	Office of Combination Products
OCS	Office of the Chief Scientist
OCTC	Office of the Counselor to the Commissioner
OCTGT	Office of Cellular, Tissue and Gene Therapies
OD	Office of the Center Director
OEA	Office of External Affairs
OER	Office of External Relations
OFVM	Office of Foods and Veterinary Medicine
OGCP	Office of Good Clinical Practice
OGROP	Office of Global Regulatory Operations and Policy
OHCE	Office of Health Communication and Education
OIP	Office of International Programs
OL	Office of Legislation
OM	Office of Management
OMB	Office of Management and Budget
OMH	Office of Minority Health
OMPT	Office of Medical Products and Tobacco
OOPD	Office of Orphan Products Development
OP	Office of Policy
OPA	Office of Public Affairs
OPAS	Online Program Analysis System
OPP	Office of Policy and Planning
OPT	Office of Pediatric Therapeutics
OR	Office of Regulations
ORA	Office of Regulatory Affairs
ORADSS	Online Reporting Analysis Decision Support System
ORISE	Oak Ridge Institute for Science and Education
ORSI	Office of Regulatory Science and Innovation
OS	Office of Science
OSCS	Oversulfated Chondroitin Sulfate
OSHI	Office of Special Health Issues
OSI	Office of Scientific Integrity
OSMP	Office of Special Medical Programs
OSPD	Office of Scientific and Professional Development
OTC	Over-The-Counter
OWH	Office of Women's Health

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PAC	Pediatric Advisory Committee
PAS	Post- Approval Studies
PATH	Population Assessment of Tobacco and Health
PCR	Polymerase Chain Reaction
PDC	Pediatric Device Consortia
PDMA	Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act
PET	Positron Emission Topography
PETNet	Pet Event Tracking Network
PFGE	Pulsed Field Gel Electrophoresis
PFR	Pet Food Report
PGx	Pharmacogenomics
PHEMCE	Public Health and Emergency Countermeasures Enterprise
PIC/S	Pharmaceutical Inspection Convention and Cooperation Scheme
PMA	Premarket Approval Application
PPD	Presidential Policy Directives
PPP	Public Private Partnerships
PREA	Pediatric Research Equity Act
PREDICT	Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
PRISM	Post-Licensure Rapid Immunization Safety Monitoring
PRV	Priority Review Voucher
PST	Paralytic Shellfish Toxin
QMIS	Quality Management Information Systems
QPRAM	Quantitative Predictive Risk Assessment Model
QSIT	Quality System Inspection Technique
RBIS	Regulatory Business Information Services
REMS	Risk Evaluation Mitigation Strategies
RFR	Reportable Food Registry
RNA	Ribonucleic Acid
RPS	Regulated Product Submissions
RRT	Rapid Response Team
SE	<i>Salmonella</i> Enteritidis
SEQC	Sequencing Quality Control

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SMG	Staff Manual Guide
SMSHA	Substance Abuse and Mental Health Services Administration
SNS	Strategic National Stockpile
SRL	Southeast Regional Laboratory (ORA)
SRMS	Stakeholder Relationship Management System
TAVR	Transcatheter Aortic Valve Replacement
TCA	Family Smoking Prevention and Tobacco Contract Act (Tobacco Control Act)
TIMS	Tobacco Inspection Management Systems
TPMP	Tobacco Product Manufacturing Practice
TPSAC	Tobacco Product Scientific Advisory Committee
UAMS	University of Arkansas for Medical Sciences
UAT	User Acceptance Testing
UC	UC Davis Western Center for Food Safety
UDI	Unique Device Identification
UDID	Unique Device Identification Database
UESC	Utility Energy Service Contract
UF	User Fee
UFI	Unique Facility Identifier
UN	United Nations
USDA	United States Department of Agriculture
USP	United States Pharmacopeia
UTMB	University of Texas Medical Branch
VA	Veterans Administration
VAERS	Vaccine Adverse Event Reporting System
Vet-LIRN	Veterinary-Laboratory Investigation and Response Network
Vet-LRN	Veterinary-Laboratory Response Network
VICH	Veterinary International Conference on Harmonization
VQIP	Voluntary Qualified Importer Program
WEAC	Winchester Engineering and Analytical Center
WGS	Whole Genome Sequencing
WHO	World Health Organization