

Abbreviations

Abbreviation	Meaning
ANSI	American National Standards Institute
API	Active Pharmaceutical Ingredient
ASTM	American Society for Testing and Materials
CANDA	Computer Assisted New Drug Application
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CDS	Chromatography Data System
CFR	Code of Federal Regulations (<i>e.g.</i> 21 CFR 11)
CPG	Compliance Policy Guide
CRO	Contract Research Organization
cGMP	Current Good Manufacturing Practice
COA	Certificate of Analysis
COTS	Commercial Off The Shelf
CSV	Computer System Validation
DHHS	Department of Health and Human Services (US)
DQ	Design Qualification
DS	Design Specification
EC	European Community
EDMS	Electronic Document Management System
EIR	Establishment Inspection Report
EMA	European Agency for the Evaluation of Medical Products
EP	European Pharmacopoeia (Ph.Eur.)
EU	European Union
FDA	Food and Drug Administration
FMEA	Failure Mode and Effects Analysis
FOI (A)	Freedom of Information (Act)
FR	Federal Register
F(D)S	Functional (Design) Specifications
GAMP	Good Automated Manufacturing Practice guidelines
GC	Gas Chromatography
GERM	Good Electronic Record Management

GLP	Good Laboratory Practice
GXP	Good X Practices (clinical, laboratory or manufacturing)
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
HPLC	High Pressure Performance Liquid Chromatography
ICH	International Conference on Harmonisation
IND	Investigational New Drug Application
IEEE	Institute of Electrical and Electronic Engineers, Inc.
IQ	Installation Qualification
ISO	International Organization for Standardization
ISPE	International Society of Pharmaceutical Engineers
LAN	Local Area Network
LIMS	Laboratory Information Management System
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MHLW	Ministry of Health, Labour and Welfare (Japan)
MOU	Memorandum of Understanding
MRA	Mutual Recognition Agreement
NCE	New Chemical Entity
NDA	New Drug Application
NIST	National Institute of Standards and Technology (Gaithersville, Maryland, USA)
OECD	Organization for Economic Cooperation and Development
OOS	Out of Specification
OOT	Out of Trend
OQ	Operational Qualification
ORA	Office of Regulatory Affairs (FDA)
PAI	Pre-Approval-Inspection
PDA	Parenteral Drug Association
PDF	Portable Document Format
Ph.Eur.	European Pharmacopoeia
PIC	Pharmaceutical Inspection Convention
PIC/S	Pharmaceutical Inspection Convention/Scheme
PKI	Public Key Infrastructure
PQ	Performance Qualification
QA	Quality Assurance
QAU	Quality Assurance Unit
QC	Quality Control
QMS	Quality Management System
R&D	Research and Development
SDLC	System Development Life Cycle
SLA	Service Level Agreement
SOP	Standard Operating Procedure
SQA	Society for Quality Assurance

SRS	System Requirements Specification (equivalent to URS)
UPS	Uninterruptible Power Supply
URS	User Requirement Specifications
USP	United States Pharmacopoeia
VMP	Validation Master Plan
WAN	Wide Area Network

