Common Abbreviations – Pharmaceutical Industry

Abbreviation	Explanation
AAS	Automatic Air Sampler
ALCOA	Attributable, Legible, Contemporaneous, Original, Accurate
AMV	Analytical Methods Validation
AP	Analytical Protocol
API	Active Pharmaceutical Ingredient
APM	Appropriate Productive Maintenance
APQR	Annual Product Quality Review
ARC	Air Rate Changes
ATMP	Advanced Therapy Medicinal Product
AV	Air Velocity
BCLA (NL ONLY)	Begeleidende en Collegiaal Leverende Apotheken (NL)
BFD	Block Flow Diagram
BHR	Batch History Record
BOD	Bill of Documents
BOE	Bill of Equipment
BOT	Bill of Testing
BOX	Bill of X (see X) (etc.)
BPR	Batch Packaging Record
BR	Batch Record
BSL	Bio Safety Level
CAPA	Corrective Action AND Preventive Action
CBP (NL ONLY)	Charge Bereidings Protocol (NL)
CCR	Change Control Request
CFR	Code of Federal Regulations
CoA	Certificate of Analysis
CPP	Critical Process Parameter
CPV	Continued Process Verification
CQA	Critical Quality Attributes
CQA	Critical to Quality Attribute
CQP	Critical to Quality Parameter
CV	Cleaning Validation
CSV	Computerized Systems Validation
DQ	Design Qualification
DS	Design Specification
EDQM	Eur. Dir. for Quality of Medicines and Healthcare

Abbreviation	Explanation
EM	Environmental Monitoring
EMA	European Medicines Agency
ERP	Enterprise Resource Planning (System)
Excipient	Supporting compounds, non-API
FAT	Factory Acceptance Test
FME(C)A	Failure Mode Effect (Criticality) Analysis
FMEA	Failure Mode Effect Analysis
FMEA	Failure Mode and Effect Analysis (Tool)
FS	Functional Specification
FTA	Fault Tree Analysis
GAMP	Good Automated Manufacturing Practice
GCP	Good Clinical Practice
GDocP	Good Documentation Practice
GDP	Good Distribution Practice
GEP	Good Engineering Practice
GLP	Good Labaratory Practice
GMP	Good Manufacuring Practice
GXP	Good ((X) = any discipline such as Laboratory or Distribution) Practices, see (X)
HACCP	Hazard Analysis and Critical Control Points
HAZOP	Hazard Operability Analysis
HEPA	High-Efficiency Particulate Air
HVAC	Heating, Ventilation, and Air Conditioning
ICH Q10	Guideline on Pharmaceutical Quality Systems
ICH Q9	Guideline on Risk Management
IGJ	Inspectie voor de Gezondheidszorg en Jeugd (NL) Dutch Healthcare Inspectorate (EN)
IMP	Investigational Medicinal Product
IOQ	Installation/Operation Qualification
IQ	Installation Qualification
ISO	International Organization for Standardization
ISPE	International Society for Pharmaceutical Engineering
LAF	Laminair Air Flow
LSL	Lower Specification Limit
MA	Manufacturing Authorization
MAH	Marketing Authorization Holder
MHRA (UK)	Medicines and Healthcare Products Regulatory Agency
NVZA (NL ONLY)	Nederlandse Vereniging Voor Ziekenhuis Apothekers (NL)
OOL	Out of Limit
OOO	Out of Ordinary

Abbreviation	Explanation
OOS	Out of Specification
OOT	Out of Trend
OQ	Operational Qualification
OTJ	On-the-job training
PDE	Permitted Daily Exposure
Pest Control	Reducing the chance of pests entering the facility
PFD	Process Flow Diagrams
Ph.Eur.	European Pharmacopoeia
PHA	Preliminary Hazard Analysis
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PPQ	Process Performance Qualification
PQ	Performance Qualification
PQ	Performance Qualification
PQR	Product Quality Review
PQS	Pharmaceutical Quality System
PRA	Preliminary Risk Analysis
PV	Process Validation
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QP	Qualified Person
QRM	Quality Risk Management
RCA	Root Cause Analysis
RCM	Reliability - Centered Maintenance
Rh	Relative Humidity
RP	Responsible Person
RPN	Risk Priority Number
SAL	Sterility Assurance Level
SATs-FATs	Site Acceptance Test - Factory Acceptance Test
SME	Subject Matter Expert
SMF	Site Master File
SOP	Standard Operating Procedure
TAMC	Total Aerobic Microbial Count
TOC	Total Organic Carbon
TPM	Total Productive Maintenance
TRS	Technical Report Series
TSE	Transmissible spongiform encephalopathy
TYMC	Total combined Yeast/Mould Count
UAF	Unidirectional Air Flow
URS	User Requirement Specification

Abbreviation	Explanation
USL	Upper Specification Limit
USP	United States Pharmacopeia
VMP	Validation Master Plan
VPP	Validation Project Plan
WCL	Worst Case Locations
WCS	Worst Case Situations
WFI	Water For Injection
WHO	World Health Organization
X	Common Placeholder for Disciplines such as Distribution, Manufacturing, Laboratory, Documentation, Engineering, Documentation or other common terms in the pharmaceutical industry