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GMP Experts for the Healthcare Industry

**Acronyms Frequently Used in The Pharmaceutical Industry**

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| AALAC | American Association For Accreditation of Laboratory Animal Care |
| AAPS | American Association of Pharmaceutical Scientists |
| AC/HR | Air Changes per Hour |
| ACL | Access Control List |
| ADR | Adverse Drug Reactions |
| AGV | Automated Guided Vehicle |
| AICHE | American Institute of Chemical Engineers |
| ALX | Autologon Exerciser Facility |
| AMDM | Association of Medical Device Manufacturers |
| ANDA | Abbreviated New Drug Application |
| ANSI | American National Standards Institute |
| AOS/VS | Advanced Operating System/Virtual Storage |
| API | Active Pharmaceutical Ingredient (replaces BPC) |
| APPC | Advanced Program to Program Communication |
| ARCnet | Attached Resource Computer network |
| AS/RS | Automated Storage/Retrieval System |
| ASCII | American Standard Code for Information Interchange |
| ASHRAE | American Society of Heating, Refrigeration and Air Conditioning Engineers |
| ASME | American Society of Mechanical Engineers |
| BAS | Building Automation System |
| BFS | Blow/Fill/Seal (Packaging Technology) |
| BIMO | Bioresearch Monitoring |
| BIO | Biotechnology Industry Organization (www.bio.org) |
| BIOS | Basic I/O System |
| BLA | Biological License Application |
| BOD | Biological Oxygen Demand |
| BPC | Bulk Pharmaceutical Chemical |
| BSL | Bio Safety Level (defined by NIH) |
| CAAA | Clean Air Act Amendment |
| CAPA | Corrective Action and Preventive Actions |
| CAU | Controlled Access Unit |
| CBER | Center for Biologics Evaluation and Research (FDA Associated) |
| CCD | Charge Coupled Device |
| CDER | Center for Drug Evaluation and Research (FDA Associated) |
| CFR | Code of Federal Regulations (as in 21 CFR 210 & 211 which defines GMP) |
| CGA | Compressed Gas Association |
| CGMP | Current Good Manufacturing Practice |
| CIM | Computer Integrated Manufacturing |
| CIP | Clean In Place |
| CLI | Command Line Interpreter |
| CMC | Chemical Manufacturing Control (Regulatory) |
| CMG | Compressed Medical Gas |
| CMMS | Computerized Maintenance Management System |
| CO | Certificate of Occupancy; or Change Order |
| COD | Chemical Oxygen Demand |
| CPG | Compliance Policy Guide (FDA) |
| CQ | Control/Computer Qualification (Validation Term) |
| CRO | Contract Research Organizations |
| CRS | Computer Related System |
| CRT | Cathode Ray Tube |
| CSMA/CD | Carrier Sense Multiple Access with Collision Detection |
| DCS | Digital Control Systems |
| DDC | Direct Digital Controller |
| DIP | Dual Inline Packet switch |
| DMF | Drug Master File (Regulatory) |
| DNS | Domain Name System/Service |
| DOP | Dioctyl Pthalate (filter test method) |
| DOP | Dioctyl Pthalate (Filter Testing Method) |
| DRG | Diagnostic Related Group |
| DUN | Dial-Up Networking |
| EDO | Extended Data Output |
| EEC | European Economic Community |
| EIS | Environmental Impact Statement |
| EMI | Electromagnetic Interference |
| EPA | Environmental Protection Agency |
| EPROM | Erasable, Programmable, Read-only Memory |
| ETO | Ethylene Oxide (Sterilization) |
| EU | Endotoxin Unit |
| FAT | Factory Acceptance Test |
| FDA | Food and Drug Administration (www.fda.gov) |
| FDAAA | Food and Drug Administration Amendment Act |
| FDA-483 | Notice of Adverse Finding (FDA) |
| FDAMA | FDA Modernization Act |
| FDDI | Fiber Distributed Data Interface |
| FG | Finished Goods |
| FMEA | Failure Mode Effects Analysis (EN ISO 9001:2000) |
| FMECA | Failure Mode, Effects and Criticality Analysis |
| FR | Federal Register |
| FS-209E | Federal Standard 209E – Clean Room Specification |
| FTA | Fault Tree Analysis |
| FTP | File Transfer Protocol |
| GAMP | Good Automated Manufacturing Practices |
| GC | Gas Chromatographer |
| GCP | Good Clinical Practices |
| GLP | Good Laboratory Practices |
| GMP | Good Manufacturing Practices |
| GUI | Graphical User Interface |
| HACCP | Hazard Analysis of Critical Control Points |

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|---|---|
| HAZOP | Hazard Operability Analysis |
| HEPA | High-Efficiency Particulate Air (filter) |
| HMI | Human Machine Interface |
| HPLC | High Performance Liquid Chromatography |
| HTTP | Hypertext Transfer Protocol |
| HVAC | Heating, Ventilation and Air Conditioning |
| IBC | Intermediate Bin Counter |
| ICH | International Conference on Harmonization |
| IDES | Investigational Device Exemptions |
| IEEE | Institute of Electronic and Electrical Engineers |
| IES | Institute of Environmental Sciences |
| ILC | Intelligent LAN Controller |
| IMP | Investigational Medicinal Products |
| IND | Investigational New Drug |
| IPX/SPX | Internetwork Packet Exchange/Sequenced Packet Exchange |
| IQ | Installation Qualification |
| IRQ | Interrupt Request Number |
| ISA | Industrial Standard Architecture |
| ISO | Internal Standards Organization |
| ISPE | International Society for Pharmaceutical Engineering (www.ispe.org) |
| IVDS | In Vitro Diagnostics |
| JIT | Just In Time |
| LAL | Limulus Amebocyte Lysate (Endotoxin testing) |
| LAN | Local Area Network |
| LCE | Locally Controlled Environments (Containment) |
| LIMS | Laboratory Information Management System |
| LIN | Liquid Nitrogen |
| LOD | Loss on Drying |
| LOX | Liquid Oxygen |
| LVP | Large Volume Parenteral |
| MACT | Maximum Achievable Control Technology |
| MCP | Microbe-Containing Particles |
| MSAU or MAU | Multistation Access Unit |
| NADA | New Animal Drug Application |
| NADN | Nearest Active Downstream Neighbor |
| NAUN | Nearest Active Upstream Neighbor |
| NDA | New Drug Application |
| NEC | National Electric Code |
| NEMA | National Electrical Manufacturers Association |
| NetBEUI | NetBIOS Extended User Interface |
| NetBIOS | Network Basic Input/Output System |
| NF | National Formulary |
| NFS | Network File Service |
| NIAID | National Institute for Allergy & Infectious Diseases |
| NIC | Network Interface Card |
| NIH | National Institute of Health (www.nih.gov) |
| NIST | National Institute of Standards & Technology |
| NPDES | National Pollutant Discharge Elimination System |
| OAI | Official Action Indicated |
| ODBC | Open Database Manager |
| OEM | Original Equipment Manufacturer |
| OOS | Out of Specification |
| OOT | Out Of Trend |
| OQ | Operation Qualification |
| ORA | Office of Regulatory Affairs (FDA) |
| OSHA | Occupational Safety and Health Act |
| OTC | Over the Counter “Drugs” |
| OTS | Off-The-Shelf |
| PADER | Pennsylvania Department of Environmental Regulation |
| PAI | Pre-Approval Inspection |
| PAT | Process Analytical Technology |
| PCI | Peripheral Component Interconnect |
| PCM | Power/Cooling Module |
| PDA | Parenteral Drug Association (ww.pda.org) |
| PDMA | Prescription Drug Marketing Act (21 CFR 203) |
| PDUFA | Prescription Drug User Fees Act |
| PFD | Process Flow Diagram |
| PHA | Preliminary Hazard Analysis |
| PHRMA | Pharmaceutical Research and Manufacturers of America (www.phrma.org) |
| PID | Piping and Instrumentation Diagram |
| PL | Procedural Language |
| PLC | Programmable Logic Controller |
| PM | Project Manager |
| PMA | Pharmaceutical Manufacturers Association |
| PNSU | Probability of Non-Sterile Units |
| PQ | Performance Qualification |
| PQS | Pharmaceutical Quality System |
| PTC | Positive Temperature Coefficient |
| PV | Process Validation |
| QbD | Quality by Design |
| QC/QA | Quality Control/ Quality Assurance |
| QCU | Quality Control Unit |
| RACT | Reasonable Achievable Control Technology |
| RAID | Redundant Array of Independent Disks |
| RAPS | Regulatory Affairs Professional Society |
| RDBMS | Relational Database Management System |
| REMS | Risk Evaluation and Mitigation Strategy |
| RFI | Radio Frequency Interference |
| RFP | Request for Proposal |
| RFQ | Request for Quotation |
| RM | Raw Material |

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|---|---|
| RO | Reverse Osmosis |
| RPN | Risk Priority Number |
| SAL | Sterility Assurance Level |
| SCADA | Supervisory Control and Data Acquisition |
| SCFM | Single Character File Manager |
| SCSI | Small Computer System Interface |
| SFMECA | Software Failure Mode, Effects, and Critical Analysis |
| SFTA | Software Fault Tree Analysis |
| SIL | Scanware Interface Language |
| SIMM | Single In-line Memory Module |
| SIP | Steam In Place |
| SMTP | Simple Mail Transfer Protocol |
| SOP | Standard Operating Procedure |
| SOTA | State Of The Art |
| SPC | Statistical Process Control |
| SQL | Structured Query Language |
| SUPAC | Scale-Up and Post Approval Changes |
| SVP | Small Volume Parenteral |
| TCP/IP | Transmission Control Protocol/Internet Protocol |
| TNTC | Too Numerous To Count |
| TOC | Total Organic Carbon |
| TPP | Therapeutic Products Program |
| TQM | Total Quality Management |
| UF | Ultra Filtration |
| ULPA | Ultra-Low Penetration Air (Filter) |
| UPS | Uninterruptible Power Supply |
| USDA | United States Department of Agriculture |
| USP | United States Pharmacopeia |
| VAV | Variable Air Volume |
| VMP | Validation Master Plan |
| VOC | Volatile Organic Compound |
| WAN | Wide Area Network |
| WFI | Water For Injection |
| WHO | World Health Organization |
| WIP | Work In Process OR Work In Progress |

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