

Acronym	Definition
21 CFR Part II	Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES).
314 Stainless Steel	304 stainless steel has 18% chromium and 8% nickel added to it to enable it to be resistant to oxidation and corrosion
316 Stainless Steel	316 stainless steel has 16% chromium, 10% nickel and 2% molybdenum added to it. 316 stainless steel has greater resistance to chemical attack than 304 stainless steel due to the addition of molybdenum. The molybdenum makes 316 stainless steel more resistant to sulfuric acids, chlorides/salts, bromides, iodides and fatty acids than 304 stainless steel.
316 vs 316L Stainless Steel	316 stainless steel has a midrange level of carbon in it ~ typically a maximum of 0.08% carbon. 316L stainless steel has the "L" suffix to designate low carbon content ~ typically a maximum of 0.03% carbon. 316L stainless steel is more weld friendly than 316 stainless steel due to the lower carbon content.
3A	3-A Sanitary Standards, Inc. 3-A SSI is an independent, not-for-profit corporation dedicated to advancing hygienic equipment design for the food, beverage, and pharmaceutical industries. 3-A SSI represents the interests of three stakeholder groups with a common commitment to promoting food safety and the public health—regulatory sanitarians, equipment fabricators and processors
A & E	Architectural and Engineering firms
ADC	Antibody-Drug Conjugate
ADI	Animal Derived Ingredients
AIA	American Institute of Architects
AL6XN	AL-6XN is a type of weldable stainless steel that consist of an alloy of nickel (24%), chromium (22%) and molybdenum (6.3%) with other trace elements such as nitrogen. This metal is commonly used in lieu of 300 series stainless steels in high temperature and low pH applications. AL-6XN will better resist corrosion while still offering the beneficial properties of stainless steel.
API	The Active Pharmaceutical Ingredient (API) is the part of any drug that produces its effects.
ASME BPE	American Society of Mechanical Engineers: Bioprocessing Equipment (ASME BPE) is the leading standard on how to design and build equipment and systems used in the production of biopharmaceuticals. It covers materials, design, fabrication, inspections, testing and certification.
ASTM	Currently known as ASTM International, "American Society for Testing and Materials", ASTM is a developer of international voluntary consensus standards. ASTM standards are developed by committees of relevant industry professionals who meet regularly to deliver standards, test methods, specifications, guides, and practices.
ATEX	ATEX is the name commonly given to the two European Directives for controlling explosive atmospheres
BPE	BioProcessing Equipment. A body of standards for bioprocessing equipment developed by American Society of Mechanical Engineers (ASME)
BSPT	British Standard Pipe Thread
BSL	Bio Safety Level
CAR-T	CAR T-cell therapy (CAR T) is a type of immunotherapy that uses T cells from your immune system to make your treatment.
CBER	Center for Biologics Evaluation & Research
CDER	Center for Drug Evaluation & Research
CDMO	Contract Design & Manufacturing Organization
cGMP	Current GMP (cGMP) refers to the Good Manufacturing Practice Regulations promulgated by the US FDA
CGT	Cell & Gene Therapy
CHO	Chinese Hamster Ovary cell
CIP	Clean in Place (cleaning in the area where the equipment is used)
CMO	Contract Manufacturing Organization
CoA	Certificate of Analysis
CoC	Certificate of Compliance/Conformance
COP	Clean out of Place (cleaning area where equipment is not used)
cPVC	Chlorinated Polyvinyl Chloride (cPVC) is altered by a free radical chlorination reaction which allows CPVC to withstand a wider range of temperatures than PVC (see PVC, PVCu)
CT	Clinical trial
DO	Dissolved Oxygen
ECS	Electro-Chemical Sensor, uses analog signal (~nanoAmps)

Acronym	Definition
EHEDG	European Hygienic Engineering and Design Group: a European-based non-governmental organization devoted to the advancement of hygienic design and food engineering.
EPDM	Ethylene propylene diene monomer (EPDM) is an extremely durable synthetic rubber
ESD	Electrostatic Discharge
ETO	Ethylene Oxide: sterilization used to sterilize <i>pharmaceutical</i> products that cannot support conventional high temperature steam sterilization
EVOH	Ethylene Vinyl Alcohol: commonly used as an oxygen barrier in food packaging. It is better than other plastics at keeping air out and flavors in, is highly transparent, weather resistant, oil and solvent resistant, flexible, moldable, recyclable, and printable
FAT	Factory Acceptance Test
FDA	Food & Drug Administration: responsible for Pharmaceuticals adhering to drug safety and effectiveness & regulates their manufacturing process
FEP	Fluorinated ethylene propylene
FFKM	Perfluoroelstomer that has higher amounts of fluorine than standard FKM resulting in higher temperature ratings (up to 617°F/325°C) and improved chemical compatibility
FKM	FKM: a family of fluorocarbon-based fluoroelastomer materials defined by ASTM International standard D1418, and ISO standard 1629. May be listed as VITON™ after the popular brand
FM	Factory Mutual Insurance company
FMEA	Failure modes and effects analysis
FNPT	Female National Pipe Thread
FRP	Fiberglas Reinforced Plastic (or Polymer or Panels). Note: Europe uses GRP ~ Glass Reinforced Plastic
FRS	Functional Requirement Spec
GAMP	Good Automated Manufacturing Practice: a technical subcommittee of the International Society for Pharmaceutical Engineering (ISPE) and a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry.
GI	Gamma Irradiated
GMO	Genetically modified organism
GMP	Good Manufacturing Practice Regulations promulgated by the US FDA
HEPA Filter	High Efficiency Particulate Air filter
IAR	Improvement Action Request
ICER	Institute for Clinical and Economic Review produces reports, known as “cost effectiveness analyses” or “value assessment reports” that use a series of underlying assumptions to place a dollar value on how much new drugs should cost.
IQ Test Protocols	FDA and Health Canada guidance documents, and typically refer to equipment. IQ stands for Installation Qualification.
ISO	International Organization for Standardization: international standard-setting body composed of representatives from various national standards organizations
kGY	Kilogray: International standard for measuring radiation exposure. Gamma Irradiation metric
LAL	Limulus ameobocyte lysate: the test (a method of the Bacterial Endotoxin Test) for detecting the presence and level of Gram-negative bacterial endotoxins
MNPT	Male National Pipe Thread
MOC	Management of Change
MRO	Maintenance, Repair and Operations
MSAT	Manufacturing, Science & Technology: characterizes the process and helps to define the degrees of freedom allowed during mass production of the drug
MSDS	Material Safety Data Sheet
NDC	National Drug Code
NIH	National Institute of Health
NIR	Near infra-red
NIST	National Institute of Standards and Technology - NIST is an agency of the United States Department of Commerce whose mission is to promote American innovation and industrial competitiveness
NPT	National Pipe Thread: the most popular type of seal used in pressure calibration systems in the U.S. and Canada
NSF	Founded in 1944 as the National Sanitation Foundation, the name was changed to NSF International in 1990 as its services were expanded beyond sanitation and into global markets

Acronym	Definition
OQ Test Protocols	Operational Qualification: FDA and Health Canada guidance documents, and typically refer to equipment.
ORP	Oxidation Reduction Potential
PAT	Process Analytical Technology
P&ID	Piping and Instrumentation Diagram
PE	Polyethylene
PEEK	Polyether ether ketone: has excellent mechanical and chemical resistance properties that are retained to high temperatures
PFA	Perfluoroalkoxy alkanes: fluoropolymers commonly used as material for piping and fittings for aggressive chemicals, as well as corrosion-resistant lining of vessels in the chemical-processing industry
PG Thread	Panzer-Gewinde Thread
pH	potential of hydrogen: a scale of acidity from 0 to 14. It tells how acidic or alkaline or basic a substance is. More acidic solutions have lower pH. More alkaline solutions have higher pH. Substances that aren't acidic or alkaline (that is, neutral solutions) usually have a pH of 7
PLC	Programmable Logic Controller
PQ Test Protocols	Performance Qualification: FDA and Health Canada guidance documents, and typically refer to equipment
PTFE	Polytetrafluoroethylene: a synthetic fluoropolymer of tetrafluoroethylene. The best known brand name of PTFE-based formulas is Teflon.
PVA	Polyvinyl Alcohol
PVC	Polyvinyl chloride (see cPVC, PVCu)
PVCu	PVC with no plasticizers added so PVC is more rigid, used to be uPVC
PVDF	Polyvinylidene fluoride: a highly non-reactive thermoplastic fluoropolymer used in applications requiring the highest purity, as well as resistance to solvents, acids and bases
QMS	Quality Management System
Ra	Roughness average: using a number system to reflect surface finish. The smaller the number the smoother the finish.
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RMA	Returned Material Authorization: aka as RGA - Returned Goods Authorization
RTS	Ready to Sanitize
SAL	Sterility Assurance Level: assures the effectiveness of the sterilization method, normally expressed as 10 ⁻ⁿ with historically, a 10 ⁻³ or a 10 ⁻⁶ value being used
SAT	Site Acceptance Test
SCADA	Supervisory Control and Data Acquisition
SDS	Safety Data Sheet, aka as Material Safety Data Sheet (MSDS)
SF	Surface Finish: measure surface roughness, see Ra
SIP	Steam in Place
SLR	Steam Lock Release: orifice or hole on a steam trap to allow the immediate elimination of condensate where improved sensitivity is desired
SOP	Standard Operating Procedures: set of formal procedures governing how processes are to be conducted
SUA	Single Use Assemblies
SUT	Single Use Technologies
TFF	Tangential Flow Filter
TPE	Thermoplastic Elastomer
uPVC	unplasticized Polyvinyl Chloride. More rigid or stiffer than regular PVC
URS	User Requirement Spec
USP	The United States Pharmacopeia (USP) is a non-governmental, official public standards-setting authority for prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States. USP also sets widely recognized standards for food ingredients and dietary supplements. USP sets standards for the quality, purity, strength, and consistency of these products—critical to the public health.
USP Class VI	USP Class VI demonstrates that the materials utilized are biologically compatible when tested according to the U.S. Pharmacopoeia XXII, 1190 Class VI, Plastics Evaluation. As defined in the USP XXII, materials which pass the Class VI Plastic Evaluation are suitable as implantable materials.