





Bio-Pharm Industry Terms Glossary

Term	Acronym	Definition
-A-		
3A Sanitary Standards and Accepted Practices	3A	Criteria for cleanability of dairy processing equipment. They have been adopted by many other liquid processing industries outside of dairy. They are written as a cooperative effort between users, equipment manufacturers, sanitarians and regulatory agencies. The “3A Associations” are the International Association of Milk, Food and Environmental Sanitarians, the U.S. Public Health Service, and the Dairy Industry Committee.
Activated Carbon Bed	AC	A filtration method for the pre-treatment of water to remove residual chlorine, organic material, and in some cases, bacteria. Water is passed through a deep bed of granular activated carbon (GAC) at low flow rates (see GAC). Carbon beds often require some type of sterilization method.
American Society of Mechanical Engineers	ASME	Creates consensus standards for Mechanical Engineering.
American Society for the Testing of Materials	ASTM	Creates consensus standards for material quality and material quality testing methods.
Anion	---	A negatively charged ion.
Architects and Engineers	A & E	
Aseptic	---	Free of pathogenic (disease causing) micro-organisms.


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Auger Analysis	---	(Pronounced O-JAY), a process for analyzing the composition of a metal as a function of surface depth. Auger “sputters” down through the surface to approximately 150 Angstroms at a rate of typically 10/Angstroms/layer. The surface composition is determined as successive layers are removed by vaporizing the metal with an electron beam. Auger analysis is used to determine the level of chromium-oxide on the surface of austenitic stainless steel. Auger will determine ratios of elemental compounds for each of the 10 Angstrom layers.
Autoclave	---	A piece of equipment used for steam sterilizing components “out of place.” In other words, parts must be placed into the autoclave for sterilization. “Autoclaving” also refers to the process of using an autoclave. NOTE: a component designed for SIP may not necessarily be autoclaved.
		
Bio-Film	---	A layer of trace organic material that can adhere to the interior wall of process line components.
BioProcessing Equipment Committee	BPEC	A sub-committee of ASME. It creates engineering standards for the design, specification, manufacture and documentation of equipment used for bio-pharm processes.
		
Cation	---	A positively charged ion.
Chromatography	---	The purification of substances based upon chemical, physical and biological properties of the molecules involved.
Clean in Place	CIP	The technique of cleaning process line components without the need for disassembly.


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Term	Acronym	Definition
Colony Forming Unit	CFU	A measure of bacterial contamination. Samples are incubated in a growth media (see PCA) and the resulting colonies are counted. Each colony is assumed to have been derived from one bacterium.
Comite Europeen de Normalisation (Committee for European Standardization)	CEN	Comprised of the 13 national standards organizations in Europe. Creates standards that reflect the best practices in each industry. Helps enforce the directives of the European Commission.
Conductivity	---	Measurement of a substance's ability to conduct an electric current. Measured in μ -mhos/cm or μ -siemens/cm. Used as a measurement for the purity of water.
Current Good Manufacturing Practices	cGMP	Written and enforced by the FDA. Consists of some specific, but mostly "umbrella" regulations covering personnel, records, and equipment, leaving much to the interpretation of the Inspector and the court system. cGMP's are evolutionary, reflecting the least common denominator of practices in the industry at present (hence the term "current").
Cyto-Toxicity	---	The toxic effect that a substance has on cells. A term used particularly in discussions regarding the compatability or effect of process system components on bio-tech products (i.e.: seal materials, etc.).
		
Dead Leg	---	A section of pipe in a closed recirculation loop that does not have a continuous flow through it.
Deionized or Deionization	DI	The process of removing ionized salts from water by passing it through ion exchange resins (see IX and resin).
Deionized Water	DIW	Water that has been deionized (see DI).



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Deutsches Institut für Normung (German Institute for Standardization)	DIN	Creates engineering standards for Germany. Contributing body to CEN and ISO. Other countries and companies have adopted DIN standards.
Distillation	---	The process of purifying water (or other liquid) by boiling the liquid and condensing the vapor. Most contaminants do not vaporize at the same temperature as the water and therefore, do not carry over to the distillate.
Distilled Water	DW	Water that has been distilled (see distillation).
		
Electron Spectroscopy for Chemical Analysis	ESCA	A procedure that uses electron beams to characterize the extreme outer surface of a metal. Typically used to determine levels of chromium oxide on the surface of austenitic stainless steel.
Electro-Polish	EP or E/P	Polishing process for metal components where the part is placed in an acid bath (typically sulfuric or phosphoric) containing a cathode. As current is passed through the cathode, metal ions are removed from the surface of the metal.
Endotoxin	---	A component of the gram-negative organism's cell wall. A pyrogen of specific concern in injectable solutions (see Gram-negative and Pyrogen). Endotoxins are not destroyed by temperatures that kill the bacteria themselves. Measured by LAL. Endotoxins levels are specified for WFI (see WFI and LAL).
Environmental Protection Agency (USA)	EPA	Agency that sets the standards for potable water.



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Term	Acronym	Definition
Equipment Operating Procedure	EOP	(a.k.a. SOP, OP) A controlled document that outlines the procedure for operating equipment/system. An operator's adherence to a written EOP is an integral part of the validation process. It is the connecting link between the initial validation process and the daily manufacturing operation.
European Hygienic Equipment Design Group	EHEDG	Comprised of representatives from research institutes, equipment manufacturers, the food and bio-pharm industry and legislative bodies. The group's objective is to provide standardization organizations (CEN and ISO) with specialist views on hygienic and aseptic design by publishing requirements and test methods.
European Pharmacopoeia	EP	European counterpart to USP (see USP). A private, non-profit organization that sets standards for drugs, drug ingredients, medical devices and diagnostics.
		
Fermentation	---	The biochemical synthesis of organic compounds by microorganisms or cultivated cells.
Food and Drug Administration (USA)	FDA	Enforcement agency of the U.S. Government for food, drug and cosmetics manufacturing. Author of the U.S. cGMP's. Responsible for new product approvals, plant inspections and product recalls.
		
Gas Tungsten Arc Welding	GTAW	(a.k.a. TIG) A welding process where the welding arc is maintained between a non-consumable tungsten electrode and the base metal to be welded. The arc is shielded with an inert gas, typically argon.




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Term	Acronym	Definition
Good Manufacturing Practices	GMP	Refers specifically to FDA cGMP's (see cGMP) or to the standards of manufacturing in a particular country and industry (e.g.: EU GMP). Generally refers to standards that are written and enforced.
Gram-Negative	---	One of two groups of micro-organisms, as determined by their ability to retain a dye after staining and rinsing. Those retaining the dye are Gram-positive. Those that do not retain the dye are Gram-negative. The differences are in the cell-wall structure. The majority of water-borne bacteria are Gram-negative.
Gram-Positive	---	See Gram-negative (listed directly above).
Granular Activated Carbon	---	Most common type of activated carbon bed filtration media (see AC).
 -H-		
Heat Tracing	---	Permanent identification used to trace a part back to the mill heat (batch) from which the part was manufactured. Each heat number traces back to an MTR (see MTR).
 -I-		
In Situ	---	In place. In other words, without disassembly (see CIP and SIP).
Installation Qualification	IQ	Documentation that an equipment/system has been installed properly according to pre-determined codes and standards. This could include preventative maintenance procedures, spare parts lists, SOP's, part numbers, model numbers, serial numbers, capacities, performance data, material specifications, etc.
International Standards Organization	ISO	Creates consensus standards for engineering and quality systems.


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Term	Acronym	Definition
In Vitro	---	Outside of the body.
In Vivo	---	Inside of the body.
Ion Exchange	IX	A process in which specific ions are removed from a solution in exchange for equivalently charged ions. The exchange process takes place on the surface of small particles called resins (see Resin).
		
Japanese Pharmacopoeia	JP	Japanese counterpart to USP (see USP). A private, non-profit organization that sets standards for drugs, drug ingredients, medical devices and diagnostics.
		
Large Volume Parenteral	LVP	Injectable solutions for humans. Greater than 100mL for a single dose.
Limulus Amebocyte Lysate	LAL	A reagent used for the detection of endotoxins. LAL is made from the blood of the horseshoe crab.
		
Manufacturers' Standardization Society	MSS	A society that sets standards for the valve and fitting industry.
Mill Test Report or Material Test Report	MTR	(a.k.a. "Mill Certs" or "Heat Certs"). A document certifying the composition of a metal from a particular heat batch.
Multiple Effect (Distillation)	ME	An energy efficient distillation process (see Distillation) where the steam generated in one stage is used to heat the liquid in the next stage, up to 10 or more stages or "effects."


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Term	Acronym	Definition
		
Occupational Safety and Health Administration	OSHA	Administration that imposes strict safety standards for companies to follow. Periodic checks are performed to ensure that safety rules are being enforced.
Operating Procedure	OP	(a.k.a. EOP, SOP) A controlled document that outlines the procedure for operating equipment/ systems. An operator's adherence to OP is an integral part of the validation process. It is the connecting link between the initial validation process and the daily manufacturing operation.
Operational Qualification	OQ	Demonstration and documentation of the equipment/system's functionality. Used to determine the operational limits of the equipment/system. A preliminary run is often conducted on a product substitute to prove functionality prior to running on a product-for-sale. Other items tested might include failure mode, alarm features and cleanability. Typically executed by the commissioning team.
Orbital Welding	---	An automated TIG (see TIG or GTAW) welding process that is designed to produce repeatable fusion welds for tubular components. A system consists of a programmable power supply and weld head. The power supply controls the weld parameters of current and electrode speed. The weld head holds the two parts, gas purges the weld, and moves the electrode using an electric motor.
Ozonation or Ozonated Water	---	The use of ozone (O ₃) to disinfect water. Ozone is added to water and neutralized using ultra-violet (UV) light (see UV).


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Parenteral Drug Association	PDA	Association for manufacturers of injectable drug products. Publishes technical reports and other publications of interest to the industry.
Passivation	---	The process of rinsing stainless steel with acid (typically nitric) to form a corrosion resistant chromium-oxide layer on the surface.
Plate Count Agar	PCA	The most common growth media for measuring bacteria levels (see CFU).
Point of Use	POU	A valved branch in a recirculating utility system (typically a water system).
Process Qualification/ Process Validation	PQ/PV	The demonstration and documentation that the various units and procedures of a process operate as they should. This logically establishes that the product is of the quality the system is purported to yield. Performed after the IQ/OQ has been executed and approved. Typically, the acceptance criteria is the same as the product acceptance criteria, and the product run is considered product-for-sale. Executed by the manufacturing personnel of the operating company according to the SOP.
Profilometer	---	An instrument used to measure the roughness of a surface. A stylus travels across a short distance on the surface and indicates an average deviation from the mean (see Ra).
Pseudomonads	---	Gram-negative bacteria of particular concern in water systems. Pseudomonas Diminuta is used to challenge the efficacy of filtration systems.

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Purified Water	PW	Ingredient water (not for injection) or rinse water for pharmaceutical products conforming to USPXXIII (EP and JP) guidelines. Obtained by distillation, reverse osmosis, ion exchange or any other suitable process (see USP, EP, JP, Distillation, RO and IX).
Pyrogen	---	Any substance capable of producing a fever in humans. Most commonly organic substances shed by bacteria. Pyrogens are not necessarily destroyed by conditions that kill bacteria (see Endotoxin).
		
Resin	---	Specially manufactured polymer beads used in ion exchange processes. Resins are ion specific and are categorized as either Anion Resin or Cation Resin (see IX, Anion and Cation).
Reverse Osmosis	RO	The separation of contaminants from water by flowing the feed water stream under pressure across a semi-permeable membrane.
Rouge	---	An oxide film on the surface of stainless steel process line components, typically red or black in color. All current theories for the causes of roughing are still inconclusive.
Roughness Average	R_a , Ra or RA	A measure of surface roughness, specifically the average deviation from the mean. Units are in length, either μ -inch or μm .
Roughness Root Mean Squared	R_{rms} or RMS	A measure of surface roughness, specifically the root-mean squared deviation from the mean. Units are in length, either μ -inch or μm . $\text{RMS} = 1.11 \text{ RA}$



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Term	Acronym	Definition
		
Scanning Electron Microscope	SEM	Instrument used to take high magnification photographs of a component's surface.
Small Volume Parenteral	SVP	Injectable solutions for humans. Less than 100mL for a single dose.
Standard Operating Procedure	SOP	(a.k.a. EOP, OP) A controlled document that outlines the procedure for operating equipment/ systems. An operator's adherence to a written SOP is an integral part of the validation process. It is the connecting link between the initial validation process and the daily manufacturing operation.
Steam in Place	SIP	Sanitization of process line components by the use of steam without the need for disassembly.
Sterile	---	Free of living organisms.
		
The Commission of European Communities	EEC/EC	Legislative and enforcement body of the European Union. Uses CEN standards to assist in the application of its directives.
Total Dissolved Solids	TDS	Total amount of material remaining in the water after filtering the suspended material and then evaporating the solution to a dry state (see TSS).
Total Oxidizable Carbon or Total Organic Carbon	TOC	A measure of the amount of organic compounds in a water sample. Carbon is oxidized and the level of CO ₂ is measured. The proposed USP water standards are based on TOC analysis.


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Term	Acronym	Definition
Total Suspended Solids	TSS	Total amount of solid particles in a solution that are held in suspension (non-dissolved).
Tungsten Inert Gas	TIG	(a.k.a. GTAW) A welding process where the welding arc is maintained between a non-consumable tungsten electrode and the base metal to be welded. The arc is shielded with an inert gas, typically argon.
		
Ultra Filter or Ultra-Filtration	UF	Filters formed from polymer membranes. UFs have the ability to retain larger molecules while permitting the passage of smaller ones. Often used for the separation of proteins.
Ultraviolet Light or Ultraviolet Radiation	UV	Radiation in the ultraviolet portion of the spectrum (200 to 400 nm) is used to destroy micro-organisms. Also used to neutralize ozone.
United States Pharmacopoeia or United States Pharmacopoeia Convention	USP or USPC	A private, non-profit organization that sets standards for drugs, drug ingredients, medical devices and diagnostics. The Food, Drug and Cosmetics Act recognizes the USP and the National Formulary (both written by the USPC) and obligates the FDA to enforce its established standards. The USP contains the standards for WFI and purified water.
		
Validation	---	Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes. I.E.: Does it do what it is supposed to do? And if so, how long will it do it?

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Term	Acronym	Definition
Vapor Compression (Distillation)	VC	A method of distillation where the water vapor is compressed, which raises its temperature, and is then used as the heating medium for the incoming liquid water. Used as a method for conserving energy.
		
Water For Injection	WFI	Water for use as a solvent for the preparation of parenteral products conforming to USPXXIII (EP and JP) guidelines. Obtained most commonly by distillation. However, other processes are allowed depending on particular pharmacopoeia (see USP, EP, JP and Distillation).



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