

A2F FILTERS

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A2F filter 9 sarang society garkheda aurangabad

Filtration Dictionary

ABSORPTION: The process by which a liquid or a gas is taken into the filter media & held there.

ADSORPTION: A natural phenomenon of a gas, liquid, vapour or fine particles being attracted & held on to the molecular surface structure of a material. Not normally a reversible phenomenon as absorption is.

AEROSOL: An assembly of small particles, solid or liquid, suspended in air. The diameter of the particles may vary from 100 microns down to 0.01 microns ex. dust, smoke, fog.

AEROSOL PHOTOMETER: A light scattering mass concentration indicator, used for testing leaks in HEPA Filters.

AEROSOL SPECTROMETER: A device for measuring particle size distribution in air.

AGGLOMERATION: The formation of a larger airborne particles by the collision of two or more smaller particles. Agglomeration takes place when the attractive forces between the particles is greater than the kinetic energy of collision.

AIR CHANGE: A measure of amount of air moving into and out of a space because of leakage or mechanical ventilation. One air change is a volumetric flow of air equal to the cubic content of the space.

AIR FILTER: A device for removing particulate material from an air- stream.

AMBIENT AIR: Air which surrounds the occupant or process in a space.

ARRESTANCE: A measure of the ability of an air filtration device to remove a synthetic dust from the air. ASHRAE arrestance is a measure of the ability of a device to remove ASHRAE dust from test air.

ASHRAE: American society of Heating, Refrigerating, and Air – Conditioning Engineers.

ATMOSPHERIC PRESSURE: The pressure exerted upon the earth's surface by the weight of the atmosphere above it.

BLOWER: A fan used to move air under pressure.

BROWAIN MOVEMENT: The continuous zig- zag motion of particles (aerosols) in suspension. The motion is caused by the impact of the molecules of the fluid (air) upon the particles.

CFM: Cubic feet per minute. A measure of the volume of air being used in a system. An air handling system rated at 20000 CFM would have a volume of air equal 20000 cubic feet entering the plenum every minute. $CFM = FEM \times SQUARE\ AREA.$

CONTAMINANTS: Airborne dirt, dust, spores virus, bacteria & allergens which are some times referred to as AEROSOLS.

Delta P: See pressure drop.

DEPTH LOADING: characteristics of fiber media. Measured as the ability of the media to retain dirt through its total depth, as opposed to surface of face loading.

DOWNSTREAM: The air exiting side of a filter or such equipment or area located after the filter system.

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DUST HOLDING CAPACITY: The gram weight of dust, or contaminants, that fed into the filter media before the resistance rises to a specified level at a specified velocity.

DIFFERENTIAL PRESSURE: (See pressure drop.)

DOP: Dioctylphthalate (diethylhexylphosphate), an oily liquid used in an aerosol form as a challenge for efficiency and leak testing HEPA filters.

DUST: An aerosol of particles of any solid material, usually with particle size less than 100 microns.

DUST SPOT EFFICIENCY: (See efficiency)

EFFICIENCY: The ability of a device to remove particulate or gaseous material from an air stream by measuring the concentration of the material upstream and down stream of the device. In the ASHRAE 52.1 Standard test method, it is a measure of the ability of a filter to remove the staining portion of atmospheric dust from the test air. This is officially termed Atmospheric Dust Spot Efficiency.

ELECTROSTATIC PRECIPITATOR: In electrical apparatus consisting of an ionizing section becomes positively charge. The dust particles are then attracted to the grounded (Collector) section. The particle is trapped on the collector plates.

FACE AREA: The area of an air filter or other air treatment device normal to the flow of air through it.

FACE LOADING: The phenomenon by which contaminants in the air load upon the surface of the filter media causing an abnormal rises in resistance.

FILTER LIFE: Measure of duration a filters is full service. This based on the amount standard contaminant required to cause differential pressure to increase to an unacceptable level-typically 2-4 times the initial differential pressure, 50-80 % drop in initial flow, or a down stream measure of unacceptable particulate.

FILTER MEDIA: Material that makes up the filter element. Glass fibers & polyester fibers are examples of filter media. ("Media" is the plural of "medium" Common practice allows it to be used as the singular form & "medias" as the plural).

FILTRATION: Remove of particles, normally solids, from a fluid. These can be contaminants of valuable products.

FOG: An aerosol of fine water droplets in a gas.

FPM: Feet per minute.

FUME: An aerosol of fine particles formed by the condensation of vapours of solid materials.

GASKET: (Filter) Material used to prevent air leakage between filter media surface and its holding device.

HEPA: High Efficiency Particulate Air (Filter), "a throw-away extended-media dry-type filter in a rigid frame, having minimum particles-collection efficiency of 99.97 % for 0.3 micro meter (micron) thermally-generated dioctylphthalate (DOP) particles or specified alternative aerosol, and the maximum clean-filter pressure drop of 1.0 in w.g. when tested at rated air flow capacity."

HOUSING: Device used to hold filter.

IMPINGEMENT: The process in which particles are removed from airstream because of their inertia. As air containing a particle flows towards a filter fiber or other collecting surface, the particle does not flow

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the air streamlines because of its inertia. Instead it moves in a straight line colliding with the filter fiber or surface to which it may become attached.

INERTIA: The tendency of a body in motion to move in the same straight line unless acted upon by some external force.

INCHES OF WATER GAUGE(IN.W.G.): A unit used in measuring pressure. The equivalent measurement in SI is Pascal's, 1inch w.g.equals to 48.8 Pascal's (Pa).

INTERCEPTION: The process in which a particle is removed from an air stream as it follows the streamlines around a fiber. The particles come in contact with a fiber and stay attached to it.

MAGNEHELIC: Registered trade name for a diaphragm-activated dial gauge for measuring resistance.

MEDIA AREA: Gross : The total area of media used in the production of a filter.
Net effective: The measure of usable media in a filter.

MEDIAN EFFICIENCY: In a series of efficiency tests, the median efficiency is the one which has an equal no. of test results higher & lower than it.

MICRON: One millionth of meter. A micron is more correctly known as micrometer(μm).

MIGRATION: The process by which the adhesive or oily substance releases itself from the media fibers & enters the air stream & becomes a contaminant. Migration may cause clogged coils & dirty ducts as the adhesive or oil collects in the system.

MPPS: Most Penetrating Particle Size.

NON-SUPPORTED MEDIA: Filters in which the pleats are extended & supported in the air stream only by the airflow with no separate media support.

PARTICLE: A relatively small subdivision of matter ranging in diameter from a few angstroms (as with gas molecules) to a few millimeters. The particles have various shapes and dimensions.

PARTICLE COUNTER: A device for measuring the no. & size distribution of particles in a fluid. It depends on the measurement of the amount of light reflected by individual particles. The strength and the coherent nature of light emitted by a laser result in more light being reflected by particles & so allows for the accurate sizing of very small particles.

PENETRATION: A measure, in percent, of the material passing through a filter. Mathematically penetration is 2% (100-98). Penetration is used to measure the performance of very high efficiency filters.

PHOTOMETER: A device which measures the mass concentration of an aerosol by the amount of light the aerosol scatters.

PITOT TUBE: A device used to measure the velocity pressure of an air stream by simultaneously measuring its static and total pressures. Velocity pressure is the total pressure minus the static pressure. Velocity of air at standard condition can be calculated by using the formula V (fpm) $4005 \sqrt{VP}$ (in. wg.) where: V = velocity of air and VP = velocity pressure from pitot tube readings.

PLENUM CHAMBER: An air compartment maintained under positive or negative pressure and connected to one or more distributing ducts.

PPM: Parts per million.

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PRESURE DROP: The resistance of a device to the flow of a liquid through it. The pressure drop of filter is a measure of its resistance to airflow through it. Resistance is measured in inches w.g. in the FPS system of measurement in Pascals in the SI system.

RATED FILTER CAPACITY: The specified quantity of air recommended by a filter manufacturer to handled by a filter.

RESISTANCE: (See pressure drop.)

RETURN AIR: Air which has been return to the plenum from the building for re-circulation. A return air duct will generally be found before the filter media where the return air is mixed with incoming fresh air also referred as to RE-CIRCULATED AIR.

SEALANT: The adhesive or other material intended to create a leak-proof seal between the filter pack and the filter frame.

SEPARATORS: Devices which support the media and provide channels through which the air can flow to reach the media and then, after passing through the media, flow out of filter.

STATIC PRESSURE: The potential pressure exerted in all direction by a fluid. For a fluid in a motion it is measured in the direction normal to th direction of the flow. it has the potential to either burst or collapse a duct or enclosure.

SUPPORTED MEDIA: Filters in which the pleats are externally supported and separated for their full length.

TACKIFIER: A substance applied to filter media to increase the retention of dust. It can be applied to the surface of media or throughout its depth. It may be an oil, a pressure-sensitive resin, or a solvent which imparts a tacky surface to the media.

ULPA: Filter is one that has a minimum efficiency of 99.999% for particles in the most penetrating particles size at the specified media velocity.

SULPA: (Super ULPA) Filters are available where maximum cleanliness is required. These filters have an efficiency of 99.9999% on the same basis as ULPA filters.

UL RATINGS-CLASS 1 & 2: Smoke contribution ratings applied to the filters by UL test standard 900 (Underwriter Laboratories).

UNLOADING: The process by which dirt, originally stopped by the filter, is released back into the air stream.

VAN DER WAALS FORCES: The forces of attraction between molecules.

VELOCITY: The distance travelled in a given time. Air velocity is measured in feet per minute(fpm) or meters per second (m/s).

VELOCITY, APPROACH: The actual velocity of the air as it approaches the filtration bank. Approach velocity can be determined by dividing the CFM of a system by the area of the filter bank opening. A 20,000 CFM system with a filter bank opening 10 feet high, by 10 feet wide (an area of 100 sq. ft.) would have an approach velocity of 200 feet per minute.

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CLEANROOM TERMINOLOGY - GLOSSARY

Air lock: A small room between two rooms of different air pressure, with interlocked doors to prevent loss of pressure in the higher pressure room.

Air showers: Chambers located between the cleanroom and outside environment that remove particulate contamination from cleanroom garments as personnel pass through. The chambers may include HEPA filter, interlocking doors, recirculating air system, and air nozzles through which filtered air is blown on to the personnel.

Ceiling grid systems: Framework of parallel and perpendicular bars used to house filter and light fixtures in cleanroom ceilings.

Certification: Written report generated by an accredited testing agency stating that a cleanroom has been tested and is performing in accordance with contractually agreed-to specification and environmental parameters.

Contamination, Molecular: Typically vapours originating from solid or liquid organic materials.

Cleanroom: A specially constructed enclosed area environmentally controlled with respect to at least one or more of the following parameters ; particulate, temperature, humidity, air pressure, velocity and directionality of air flow, vibration, noise, viable particulate, and lighting.

Cleanroom, As-built: A cleanroom that is complete and ready for operation, with all services connected and functional, but without production equipment or personnel in the room.

Cleanroom, At-rest: A clean that is complete with production equipment installed and operating, but without personnel in the room.

Cleanroom, Operational: A cleanroom in normal operation with all services functionally and with production equipment and personnel present and performing their normal work functions.

Cleanroom, Aseptic: A cleanroom designed and operated such that viable contamination is controlled to within specific, acceptable limits.

Cleanroom, Conventional Flow: A cleanroom having non-unidirectional or mixed airflow patterns and velocities, including eddies.

Critical Parameter: A cleanroom variable that affects products strength, identity, safety, purity, or quality.

Critical Surface: The surface of the work part to be protected from particulate contamination.

First Air: The air that issues directly from a HEPA filter and then passes over the critical surface.

Exfiltration: Leakage of air from a cleanroom through cracks around doors, pass through, material transfer openings, etc., due to the difference in air pressure.

Design Conditions: The environmental conditions for which the cleanroom is designed.

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Disinfectant: An agent, chemical or physical, designed to reduce the population of extant microorganisms.

EMI: Electromagnetic interference.

ESD: Electrostatic discharge.

FS209: United States Government (Federal) Standard that specifies airborne cleanliness classes in cleanroom. Now superseded by ISO Standard 14644-1, the internationally accepted standard. The contract between the cleanroom purchaser and the cleanroom provider must clearly state the standard to be used, the cleanroom classification, and the operational state.

HEPA filter: High Efficiency Particulate Air Filter. i.e. filter with an efficiency of 99.99% or greater at a 0.3 micron most penetrating particle size.

ULPA filter: Ultra Low Penetration Air. A filter with a minimum of 99.999% efficiency at a 0.12 micron most penetrating particle size.

Micron: A micrometer or one millionth of a meter (approximately 0.00003937 inch).

Cleanroom Classification: Under conditions of "As-built", "At-rest", or "Operational" the number of particles permitted per unit volume of air (i.e., particle concentration). For example, FS209 Class 100 is defined as a particle count not to exceed 100 particles of a size 0.5 micron & larger per cft of air.

Make-up Air: Air introduced to the HVAC system for purposes of ventilation, pressurization, and replacement of exhaust air.

Recirculated air: That portion of cleanroom air that is Recirculated through air handling equipment.

Latent heat: the change in enthalpy accompanying a change in state, expressed in Btu per lb.

Sensible heat: heat associated with a change in temperature.

dBA: the a-weighted decibel scale (sound level).

Fpm: feet per minute (unit of velocity or speed).

cfm: cubic feet per minute (volumetric unit).

HVAC: heating, ventilating and air conditioning.

Monitoring : The routine, periodic determination of airborne particle concentration, as well as other relevant parameters.

Mini-environment/isolator: A barrier, enclosure, or glove box that isolates products from production workers and other contamination sources.

Outgassing: The spontaneous releases of molecular contamination from the adsorbed or absorbed condition.

Parenteral products : A therapeutic agent introduced into the human body by injection directly into the bloodstream. Such products must be free of all contamination including any and all pyrogens and pathogens.

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Particle counter: A laser-based instrument which measures airborne particles in a number of size ranges and displays the number of particles in each range as a cumulative or differential count.

Pass-through: Opening in walls, with two doors through which materials and objects are passed. The doors interlock so that one door is always closed when the other is open.

Plenum : An enclosed, typically positive pressure section of an air supply system, designed to promote even distribution of airflow. Often referred to as “tunnel modules” when used for cleanroom construction.

Prefilters : Replaceable filters installed before a final filter to remove gross contamination and protect the final filter. the prefilters have a lower efficiency than the ones they protect.

Pressure, static: The pressure exerted by a fluid perpendicular to its direction of flow.

Pressure, velocity: The impact pressure associated with the velocity of a flowing fluid.

Pressure, total: The sum of static and velocity pressure at the point of measurement.

Mono-dispersed particles: an aerosol with a narrow band of particle sizes general used for challenging and rating HEPA & ULPA filters.

Poly-dispersed particles: An aerosol with a broad range of particle sizes general used to leak test filters and filter framing and ceiling systems for leakage.

Qualification : Formal commissioning and operating of a cleanroom system through the execution of written established procedures including HEPA & ULPA filter leak testing, Airborne Particulate, “Viable Particle” airborne & surface Microbial testing, Airflow Parallelism and Air patterns Studies, Process Exhaust System Air balancing, Room Temp. & Relative Humidity testing, Electromagnetic Interface (EMI) Testing, Floor & Surface Conductivity Testing, Light Intensity Testing, Light Spectrum Testing, & HEPA workstation Certification.

Unidirectional flow: Formerly incorrectly referred to as “laminar flow”. air flowing at a constant and uniform velocity (over a cross –section) in a parallel stream and in the same direction.

Workstation: An open or enclosed work surface with direct air supply.

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"As-Built" Cleanroom	ISO 14644-1 defines the "as built" occupancy state as "condition where the installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present".
"At-Rest" Cleanroom	ISO 14644-1 defines "at rest" occupancy state as "condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present". European Community (EC) defines "at rest" state as "the condition where the installation is complete with production equipment installed and operating but with no operating personnel present". The Medicines Inspectorate, however, further clarifies, "It should normally be taken to mean that ventilation systems are operating and other equipment is present in an operational condition but not in use".
"Operational" Cleanroom	ISO 14644-1 defines "operational" occupancy state as "condition where the installation is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon".
"Salvage" Plasma	Plasma obtained by centrifugation of outdated (older than 21 days) whole blood. This type of plasma is difficult to convert to serum because most coagulation factors have lost their activity
Acclimatization	The biological process whereby an organism adapts to a new environment. One example is the process of developing microorganisms that degrade toxic wastes in the environment.
Accommodation Schedule	Defines all areas that can influence unit operations required for manufacturing, and relationships and flows between them.
Account Policy	Specifies how passwords must be defined and employed for all user accounts on a system. It specifically addresses the issues of password aging, password uniqueness, and locking a user account because of invalid logon attempts. CFR 21 Part 11 mandates technical controls in these areas specifically.
Acid	A compound of an electronegative element or radical with hydrogen; it form salts by replacing all or part of the hydrogen with an electropositive element or radical. Or, a hydrogen-containing substance that when dissolved in water dissociates to produce one or more hydrogen ions (H+).
Acid Feed	Injection of an acid into a liquid stream to make it less alkaline (pH adjustment).
Action Point	A value set to identify when a parameter has drifted outside the operating

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range (Acceptance Criteria). A documented response is usually required.

Activated Carbon	Material used to adsorb organic impurities from water. Derived from wood, lignite, pulp-mill char, blood, etc. The source material is initially charred at high temperature to convert it to carbon. The carbon is then "activated" by oxidation from exposure to high temperature steam. It comes in granular or powdered form.
Active Immunity	The formation of an antibody that can be stimulated by infection or vaccination.
Active Ingredient	Any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and are present in the drug product in a modified form intended to furnish the specified activity or effect.
Active Site	The region of a protein molecule that binds the specific substrate and chemically modifies it into the new product (in an enzyme) or interacts with it (in a receptor).
Active Transport	Energy-requiring transport of a solution across a membrane in the direction of increasing concentration.
Actual Yield	The quantity that is actually produced at any appropriate phase of manufacture, processing, or packaging of a particular drug product.
Adenine (A)	A purine base, 6-aminopurine, occurring in RNA (ribonucleic acid) and DNA (deoxyribonucleic acid) and as a component of adenosine triphosphate.
ADR	see: Adverse Drug Reaction
Adsorption	Adhesion of the molecules of a gas, liquid or dissolved substance to a surface because of chemical or electrical attraction - typically accomplished with granular activated carbon to remove dissolved organics and chlorine. The attachment of charged particles to the chemically active groups on the surface and in the pores of an ion exchanger.
Adventitious Agents	Acquired, sporadic, accidental contaminants.
Adverse Agents	Undesired effects or toxicity due to exposure (often but not limited to a drug or medical device).
Adverse Drug Reaction (ADR)	An undesirable effect that may be caused by a study drug.
Advisory Alarm	An alarm indicating a drift of a monitored parameter toward an out-of-spec condition. It is advisory in that no GMP violation has occurred, and is used to advise corrective action before an action alarm can happen.

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Aerobe	An organism that can live and grow only in the presence of oxygen. 1. Facultative aerobe: one which normally thrives in the absence of oxygen, but which may acquire the faculty of living in the presence of oxygen. 2. Obligate aerobe: one that cannot live without air.
Aerobia	The plural of aerobe
Aerobic	Living in air.
Aerobic Bacteria	Bacteria capable of growing in the presence of Oxygen.
Aerobion	see: Aerobe
Aerosol Photometer	Light-scattering mass concentration indicating instrument with a threshold sensitivity of at least 10 to the negative third power microgram per liter for 0.3µm diameter DOP (Dioctyl Phthalate) concentrations over a range of 10 to the fifth power times the threshold sensitivity. Photometers may include hand-held remote meter probes that can scan for airborne contaminants in HEPA filters, in penetrations around frames, seals and plenums, and in hoods and work stations.
AES	see: Auger Electron Spectroscopy
Agar	A complex mixture of polysaccharides obtained from marine red algae, used as an emulsion stabilizer in foods, as a sizing in fabrics, as a gelling agent and as a solid substrate or media for the laboratory culture of microorganisms. Agar melts at 100°C and when cooled below 44°C forms a stiff and transparent gel. Microorganisms are seeded and grown on the surface of the gel.
Agarose	A highly purified form of agar.
Agarose Gel Electrophoresis	A method used to separate, identify, and purify molecules of different molecular weight and/or structure. It is specifically applied to the separation of protein or DNA fragments where it is rapid, simple, and accurate, and the separated molecules can be visualized directly by staining with dyes. The electrophoretic migration rate of molecules through agarose gel is dependent on the following parameters: 1. Molecular size: molecules pass through the gel at rates that are inversely proportional to the log of their molecular weight. 2. Agarose concentration: a molecule of a given size migrates at different rates through gels containing different concentrations of agarose. 3. Molecular conformation: a molecule of the same molecular weight but of a different conformation will migrate at different rates. Generally, closed circular or globular forms will migrate faster than linear forms. 4. Electric current: at low voltages the rate of migration is proportional to the voltage, but as the voltage is increased the rate of migration of high molecular weight fragments is increased differentially.
Agene	Nitrogen Trichloride (NCl ₃).
Agglomerate	Suspended solids clustered together to form larger clumps or masses that are easier to remove by filtration or settling.

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Agglutination	The sticking together of insoluble antigens such as bacteria, viruses or erythrocytes by a particular antibody. Agglutination assays are used to type human blood before a transfusion.
AHF (Antihemophilic Factor)	In the clotting of blood it is also known as Factor VIII.
Air Change Rate	The number of times the total air volume of a defined space is replaced in a given unit of time. This is computed by dividing the total volume of the subject space (in cubic feet) into the total volume of air exhausted from (or supplied to) the space per unit of time.
Air Cleaners	Filtration systems that may be freestanding or installed in a ceiling or wall to remove contaminants such as bacteria, viruses, and dust from the air. Air cleaners may incorporate HEPA filters.
Air Velocity Meters/Monitors	Meters to measure and indicate the force and speed of airflow. Meters may use a variety of probes for measuring near HEPA filters and at right angles. Monitors check and record air velocity.
Air-Lift Bioreactor	A reactor in which the source of agitation is air sparged upwards through a draft tube - most widely used for cell culture applications and monoclonal antibody production.
Airborne Particulate Cleanliness Classes	Statistically allowable number of particles equal to, or larger than 0.5µm in size per cubic foot of air. According to ISO 14644-1, a classification number, N, shall designate airborne particulate cleanliness.
Airflow Visualization	Using chemical smoke or fog to visualize flow patterns in a cleanroom or clean space.
Airlock	A room or space designed to act as a means of segregating areas of different air classification or quality. It may contain a method to remove particulate contamination from clean room garments as personnel pass through, and usually includes HEPA filtered air supply and interlocking doors. Airlocks pressure will "float" between those of the spaces being protected. With all doors closed, the airlock pressure will be somewhere between that of the highest adjoining room and that of the lowest adjoining room as air flows through it from room to room. "Ventilated airlocks" are in neutral ducted air balance (supply CFM = return CFM).
Alarms	Audible or visual signals used to warn of unacceptable conditions at monitored sites. They may be buzzers, horns, speakers, bells, or warning lights. They can be Advisory, Alert, or Action alarms. The first two are for operation and maintenance information, to alert of abnormal situations that do not compromise product SISPQ. The Action alarm is for GMP records, indicating that product SISPQ may have been compromised, but Alert alarms are also usually recorded.
Albumin	Commonly, the white of egg is a simple protein widely distributed throughout the tissues and fluid of plants and animals. Soluble in pure

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water it is also precipitable from a solution by mineral acids, and coagulable by heat in acid or neutral solution.

Albuminoid	Resembling albumin, a simple protein present in horny and cartilaginous tissues, insoluble in neutral solvents. Keratin, elastin, and collagen are albuminoids.
Alert Point	Used in determining when a parameter is drifting toward extremes of the operating range.
Aliquot	Of, pertaining to, or designating an exact divisor or factor of a quantity, specially of an integer. To divide out a sample to multiple containers for multiple analytical tests.
Alkalinity	An expression of the total amount of basic anions (hydroxyl groups) present in a solution. In water analysis, it also represents the presence of carbonate, bicarbonate, and occasionally borate, silicate, and phosphate salts that react to produce hydroxyl groups. Bicarbonate and carbonate ions are expected to be in most waters. Hydroxide may occur in water that has been softened by the lime soda process or has been in contact with fresh concrete. Alkalinity furnishes a guide in choosing appropriate treatment of either raw water or plant effluents.
Allantoic Fluid	The clear white portion of an egg. In influenza vaccine manufacturing, the virus is propagated in the embryonic chick and sloughed into the allantoic fluid that is harvested to produce the vaccine.
Allele	Alternative form of a genetic locus; a single allele for each locus is inherited separately from each parent (e.g., at a locus for eye color the allele might result in blue or brown eyes)
Allergenic Extract	An extract in a solvent of a substance that causes an allergic reaction. They are relative crude drugs by contemporary standards and are manufactured by specialty companies and in some cases, by a practicing allergist. Also, allergenic extracts are generally difficult to filter since they most frequently are extracts of natural substances such as foods, house dust, animal hair, etc.
Alum	Aluminum sulfate, commonly added during municipal water treatment to cause insoluble colloids to coalesce into larger particles that can be removed by settling.
Alzheimer's Disease	A disease that causes memory loss, personality changes, dementia and, ultimately, death. Not all cases are inherited, but genes have been found for familial forms of Alzheimer's disease
Ambient	The normal environment conditions such as temperature, relative humidity, or room pressure of a particular area under consideration.

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Ames Test	A simple bacterial test for carcinogens.
Amine	A substance that may be derived from ammonia by the replacement of one or more of the hydrogen atoms by hydrocarbon radicals.
Amino Acids	<p>Any of a group of twenty hydrocarbon molecules (containing the radical group NH₂) linked together in various combinations to form proteins in living things. Synthesized by living cells or obtained as essential components of the diet of human and animals, these twenty amino acids are divided into four (4) groups on the basis of their side-chain properties:</p> <ol style="list-style-type: none">1. Neutral, hydrophobic side chains,2. Neutral, hydrophilic side chains,3. Acid, hydrophilic side chains,4. Basic, hydrophilic side chains. <p>In addition to the twenty common amino acids there are less common derivatives (e.g. hydroxyproline, found in collagen) formed by the modification of a common amino acid.</p>
Ampholyte	Amphoteric electrolyte. Electrolyte that can either give up or take on a hydrogen ion and can thus behave as either an acid or a base.
Amphoteric	Having two opposite characteristics.
Ampicillin	An antibiotic widely used in clinical treatment and rDNA research. It is a derivative of penicillin, which kills bacteria by interfering with the synthesis of the cell wall.
Amplification	An increase in the number of copies of a specific DNA fragment; can be In Vivo or In Vitro.
Ampoule or Ampule	A small glass vial sealed after filling and one of the earliest devices developed for safe storage of sterile injectable unit.
Amyotrophic Lateral Sclerosis	An inherited, fatal degenerative nerve disorder, also known as Lou Gehrig's disease.
Anabolism	The intracellular process involved in the synthesis of more complex compounds than those involved in catabolism (for example, glucose to glycogen) and requires energy.
Anaerobe	<p>A microorganism that thrives best, or only, when deprived of oxygen.</p> <ol style="list-style-type: none">1. Facultative anaerobe: one able to grow in the presence or absence of free oxygen.2. Obligate or obligatory anaerobe: one that will grow only in the absence of free oxygen.
Anaerobic	Relating to an anaerobe.
Anaerobic Bacteria	Bacteria capable of growing in the absence of Oxygen.
Analogue	Pertaining to data that consists of continuously variable physical qualities.

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Analytical Data Interchange (ANDI)	A generic file format. It was common practice before CFR 21 Part 11 to save information from analytical instruments in this file format. The disadvantage now is that the approach does not allow replaying of data on a different system to yield the same result.
Analytical Method	Small scale process used to characterize and/or separate a mixture, a compound, or an unknown material into its constituent parts or elements.
Ancillary Material	Material used in preparing drugs that does not become a component of the drug (e.g. steam, air, N ₂ , DI water).
Anemometer	A device that measures air speed.
Angstrom (?)	A unit of length equal to one hundred-millionth of a centimeter (one ten-thousandth of a micron) used especially to specify radiation wavelengths
Anion	A negatively charged particle or ion.
Anion Exchange Resin	An ion exchange material that removes anions from solution by exchanging them with hydroxyl ions.
Anneal	The process by which the complementary base pairs in DNA strands combine.
Annealing	A treatment process for steel in which the metal is heated and held at a suitable temperature and then cooled at a suitable rate for the purpose of reducing hardness, improving machinability, facilitating cold working, producing a desired microstructure, or obtaining desired mechanical, physical, or other properties.
Anti-interferon	An antibody to an interferon. Used for the purification of interferons.
Antibody	A modified protein molecule present in the blood serum or plasma (and other body fluids), whose activity is associated chiefly with gamma globulin. Produced by the immune system in response to exposure to a foreign substance, it is the body's protective mechanism against infection and disease. An antibody is characterized by a structure complementary to the foreign substance, the antigen that provokes its formation, and is thus capable of binding specifically to the foreign substance to neutralize it.
Antigen	Any of various foreign substances such as bacteria, viruses, endotoxins, exotoxins, foreign proteins, pollen, and vaccines, whose entry into an organism induces an immune response (antibody production, lymphokine production, or both) directed specifically against that molecule. Response may be demonstrated as an increased reaction, such as hypersensitivity (usually protein or a complex of protein and polysaccharide, or occasionally a polysaccharide of high molecular weight), a circulating antibody that reacts with the antigen, or some degree of immunity to infectious disease if the antigen was a microorganism or its products.

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Antiseptic	Acting against sepsis. An antiseptic agent is one that has been formulated for use on living tissue such as mucous membranes or skin to prevent or inhibit growth or action of organisms. Antiseptics should not be used to decontaminate inanimate objects.
Antiserum	The blood serum obtained from an animal after has been immunized with a particular antigen. It contains antibodies specific for that antigen as well as antibodies specific for any other antigens with which the animal has previously been immunized.
Antistatic	Reducing static electric charges by retaining enough moisture to provide electrical conduction.
Antistatic Cleaners	Liquid cleaners that enhance surface conductivity of cleanroom tabletops, workstations, and other surfaces.
Antitoxin	An antibody that is capable of neutralizing the specific toxin that stimulated its production in the body. Antitoxins are produced in animals for medical purposes by injection of a toxin or toxoid, with the resulting serum being used to counteract the toxin in other individuals.
API (Active Pharmaceutical Ingredient)	Also called Drug Substance. Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that when used in the production of a drug becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
API Starting Material	A material used in the production of an API which is itself or is incorporated as a significant structural fragment into the structure of the API. A starting material may be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or it may be produced in-house. Starting materials are normally of defined chemical properties and structure.
Apoenzyme	The protein moiety of an enzyme - determines the specificity of the enzyme reaction.
Application Software	Any executable program developed or modified specially for customer applications.
Appropriated login or Impersonation	Someone using the authorization code, usually user ID and password of another person to secure access to network resources for which he or she does not have privileges or authorization. Can be intentional or not. CFR 21 Part 11 mandates technical controls that prevent this.
Aquifer	An underground layer of permeable rock, sand, or gravel that contains water for wells or springs.
Arithmetic Average Roughness (Ra)	The arithmetic average height of roughness component irregularities from

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the mean line measured within the sample length (L). This measurement conforms to ANSI/ASME B46.1 "Surface Texture - Surface Roughness, Waviness and Lay". Ra (formerly known as AA or Arithmetic Average in the U.S., and CLA Centerline Average in the U.K.) is usually expressed in microinches (μin), and performed by moving a stylus or profilometer in a straight line along the surface. A consistent and measurable surface finish can be specified for a desired roughness i.e., 9-11 microinch.

Ascomycetes

A family of fungi marked by long spore-containing cells. Form sexual spores called ascospores, which are contained within a sac (a capsule structure). Ergot, truffles, some molds of the genera Neurospora and Aspergillus, and yeasts belong to this category.

Asepsis

A condition in which living pathogenic (causing or capable of causing disease) organisms are absent.

Aseptic

Marked by or relating to asepsis.

Aseptic Processing

Processing conditions designed to achieve a sterile product.

Aseptic Processing Area

Area in which sterile product is formulated, filled into containers, and sealed.

Aseptic Transfer (in Isolators)

The key issue in all contained aseptic environments. Aseptic transfer is essential for change parts, components, and even product to enter and exit an isolator system without sterility challenges. There are an increasing number of ways to make an aseptic transfer. The following is a brief list of some of the key techniques:

1. Alpha Beta Systems Double Door Systems: also called RTPs (Rapid Transfer Ports) and HCT (High Containment Transfer). When mated, the two ports act as one door, protecting the internal and external environments.
2. Alpha Beta Dry Heat Sterilized: similar to Alpha Beta port with the additional safeguard of a heat sterilized seal.
3. UV and Pulsed Light: light sterilization/sanitization. Sterilizing the system by making use of a wide spectrum of light within the transfer chamber.
4. One Shot Systems: basically, two halves coming together. Similar to an Alpha Beta port but simpler, cheaper, and capable of only a single connection.
5. Heat Welded Bag Systems: passed in or passed out using a continuous polyethylene liner which is heat sealed and cut to maintain the integrity of the internal and external environments.
6. Steam Sterilized: the liquid component or powder path is clean steam sterilized after connection and prior to transfer.
7. Autoclave/Depyrogenation/Dryheat: pass through for batch. Use of conventional autoclave to sterilize a canister provided with an Alpha Beta port and filters to allow the passage of steam and safe aspiration on cooling. Depyrogenation/Dryheat uses dry heat to sterilize and at sufficient temperature depyrogenate components, typically glassware, in a batch oven
8. Depyrogenation Tunnel: standard volume glassware entry. Depyrogenation/Dry heat uses dry heat to sterilize and at sufficient temperature to depyrogenate components, typically glassware, in a tunnel allowing continuous input.

ASME Bioprocessing Equipment (BPE- 1997)

An American National Standard that covers, either directly or by reference,

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requirements for materials, design, fabrication, examination, inspection, testing, certification (for pressure systems), and pressure relief (for pressure systems) of vessels and piping for bioprocessing systems, including sterility and cleanability (Part SD), dimensions and tolerances (Part DT), surface finish requirements (Part SF), material joining (Part MJ), and equipment seals (Part SG) for the bioprocessing systems in which the pressure vessels and associated piping are involved. This Bioprocessing Equipment (BPE) Standard does not address all aspects of these activities, and those aspects that are not specifically addressed should not be considered prohibited.

Requirements of this Standard apply to:

1. All parts that contact the product, raw materials, and/or product intermediates during manufacturing, process development, or scale-up.
2. All equipment or systems that are critical part of product manufacture, such as Water For Injection (WFI), clean steam, ultrafiltration, intermediate product storage, and centrifuges. ASME/ANSI B31 Code for Pressure Piping

A number of individually published Sections, each an American National Standard. Rules for each Section reflect the kinds of piping installations considered during its development, as follows:

1. B31.1 Power Piping: piping typically found in electric power generating stations, in industrial and institutional plants, geothermal heating systems, and central and district heating and cooling systems.
2. B31.3 Process Piping: piping typically found in petroleum refineries, chemical, pharmaceutical, textile, paper, semiconductor, and cryogenic plants, and related processing plants and terminals. Certain piping within a facility may be subject to other codes and standards, including but not limited to: (a) ANSI Z223.1 National Fuel Gas Code: piping for fuel gas from the point of delivery to the connection of each fuel utilization device. (b) NFPA Fire Protection Standards: fire protection systems using water, carbon dioxide, halon, foam, dry chemical, and wet chemicals. (c) NFPA 99 Health Care Facilities: medical and laboratory gas systems. (d) Building and plumbing codes, as applicable, for potable hot and cold water, and for sewer and drain systems.
3. B31.4 Pipeline Transportation Systems for Liquid Hydrocarbons and Other Liquids: piping transporting products that are predominately liquids between plants and terminals and within terminals, pumping, regulating, and metering stations.
4. B31.5 Refrigeration Piping: piping for refrigerants and secondary coolants.
5. B31.8 Gas Transportation and Distribution Piping Systems: piping transporting products that are predominately gas between sources and terminals, including compressor, regulating, and metering stations; gas gathering pipelines.
6. B31.9 Building Services Piping: piping typically found in industrial, institutional, commercial, and public buildings, and in multi-unit residences, which does not require the range of sizes, pressures, and temperatures covered in B31.1.
7. B31.11 Slurry Transportation Piping Systems: piping transporting aqueous slurries between plants and terminals and within terminals, pumping, and regulating stations.

Assay

A technique (test) for measuring a biological response or for determining characteristics such as composition, purity, activity, and weight.

Assimilation

The formation of cellular material utilizing small food molecules and energy.

At Rest

HVAC room condition when unmanned, and without machinery operating.

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Previously called "static condition".

Atmospheric Tank (Fire Code)	A storage tank designed to operate at pressures from atmospheric through 0.5 pounds per square inch (psig) (3.4 kPa).
Atomic Absorption Spectrophotometry	A highly sensitive instrumental technique for identifying and measuring metals in water.
Audit Comment	A feature of the audit trail that aids both originator and reviewer in understanding why the originator performed a specific action. CFR 21 Part 11 does not require entering the reason for a record change, but some predicate rules (such as GLPs) do expect an explanation. It is important that the user interface for entering audit comments prevents users from changing the audit trail itself.
Audit Trail	A computer-generated and time-stamped record of who did what, when. CFR 21 Part 11 requires audit trails to be generated independently of operators. An audit trail must capture all activities related to creating, modifying, and destroying records on a system.
Auger Electron Spectroscopy (AES)	An alternative surface analysis that can detect all elements with an atomic number greater than that of helium with the additional ability to analyze sub micron-diameter features. It is not as quantitative as ESCA and cannot determine the chemical state of an element. The primary advantage of Auger is that when combined with etching, a chemical depth profile can be measured rapidly and can image the distribution on the surface of spatial limitation resolution of 100 to 1,000 angstroms (depending on the equipment capability).
Austenite	A face-centered cubic crystal with high solubility for carbon (about 2%); an allotropic form of iron resulting from steel being heated above the transformation temperature.
Autegoneous Weld	A weld made by fusion of the base material without the addition of filler.
Authentication	The process of identifying a person, system, or company sufficiently to allow access to a system or part of a system.
Authentication Mechanisms	Also known as authority checks, or authorized signers are mechanisms distinct from authorization that grants or denies access to a network resource, authentication programs are used by system administrators to establish and verify as conclusively as possible that a person logging in to the network is who he or she claims to be. FDA says that "authority checks" are to "ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system, input or output device, alter a record, or perform operations".
Auto Immune Disease	A disease in which the body produces an immunogenic response against self-antigens. In some cases, predominantly one organ is affected (e.g. hemolytic anemia and chronic thyroiditis); in others, the disease process is diffused through many tissues (e.g. SLE (Systemic Lupus Erythematosis).

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Autoclave	<p>An apparatus into which moist heat (steam) under pressure is introduced to sterilize or decontaminate materials placed within (e.g. filter assemblies, glassware, etc.). Steam pressure is maintained for pre-specified times and then allowed to exhaust. There are two types of autoclaves:</p> <ol style="list-style-type: none">1. Gravity displacement autoclave: this type of autoclave operates at 121°C. Steam enters at the top of the loaded inner chamber, displacing the air below through a discharge outlet.2. Vacuum autoclave: this type of autoclave can operate with a reduced sterilization cycle time. The air is pumped out of the loaded chamber before it is filled with steam.
Automated System	<p>Any facility system or piece of equipment that is controlled with limited or no manual intervention.</p>
Automatic Welding	<p>Welding with equipment that performs the welding operation without adjustment of the controls by a welding operator. The equipment may or may not perform the loading and unloading of the work.</p>
Autoradiography	<p>A technique that uses X-ray film to visualize radioactively labeled molecules or fragments of molecules; used in analyzing length and number of DNA fragments after they are separated by gel electrophoresis.</p>
Autosome	<p>A chromosome not involved in sex determination. The diploid human genome consists of 46 chromosomes, 22 pairs of autosomes, and 1 pair of sex chromosomes.</p>
Autotrophs	<p>One of two categories in which microorganisms are classified on the basis of their carbon source. Autotrophs use carbon dioxide as a carbon source.</p>
BAC (Bacterial Artificial Chromosome)	<p>A vector used to clone DNA fragments (100-kb to 300-kb insert size; average, 150-kb) in E. Coli cells. Based on naturally occurring F-factor plasmid found in the bacterium E. coli.</p>
Back-up Copy	<p>A magnetic copy of data, software, user-developed application, or operating parameters associated with an automated system and not considered the original.</p>
Background Contamination	<p>Contamination introduced accidentally in reagents, dilution water, solvents, rinse water, etc., which can be confused with constituents in samples being analyzed.</p>
Background Environment	<p>The environment that surrounds a critical area.</p>
Backward Compatibility	<p>A new version of a computer program that can use files and data created with an older version of the same program. A computer is said to be backward compatible if it can run the same software as the previous model. Backward compatibility is important because it eliminates the need to start over when you upgrade to a newer product, but is sometimes sacrificed in favor of a new technology</p>

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Backwash	The countercurrent flow of water through equipment, usually to clean or to recover performance, such as in a resin bed (flow-in at the bottom of the exchanger unit and out at the top) to clean and reclassify the bed after exhaustion. This process of reversing flow may also be applied to filters in order to force contaminants out of plugged pores and passages.
Bacteria	The plural of Bacterium.
Bactericide	An agent that kills vegetative bacteria but not mycobacteria or spores.
Bacteriophage	A virus that exclusively infects bacteria. A protein coat surrounds the genome (DNA or RNA). One of the bacteriophages most extensively studied is the lambda phage, which is also one of the most important viral vectors used in rDNA work. Lambda promoters have been used to express eukaryotic proteins in E.coli.
Bacteriostatic	Inhibiting growth of bacterial organisms without necessarily killing them or their spores.
Bacteriostatic Water	For Injection, U.S.P. Water that serves the same purposes as Sterile Water for Injection, it meets the same standards, with the exception that it may be packaged in either single-dose or multiple-dose containers of not larger than 30-mL size.
Bacterium	Any of a large group of microscopic organisms having round, rod-shaped, spiral, or filamentous unicellular or noncellular bodies that are often aggregated into colonies, are enclosed by a cell wall or membrane (prokaryotes), and lack fully differentiated nuclei. Bacteria range in size from 0.4µm to 2.0µm and may exist as free-living organisms in soil, water, organic matter, or as parasites in the live bodies of plants. Some are disease producing, but most perform necessary functions such as digestion, fermentation, and nitrification. Most of the forms are variously grouped under generic names such as: Alcaligenes, Dialister, Escherichia, Klebsiella, Kurthia, Pasteurella, Salmonella, and Shigella.
Barrier Isolator	A containment device that utilizes barrier technology for the enclosure of a controlled workspace. There are two main types of isolator: 1. Type 1 Isolator: An isolator designed to protect the product from process-generated and external factors that would compromise its quality. 2. Type 2 Isolator: An isolator designed to protect the product from process-generated and external factors that would compromise its quality and to protect the operator from hazards associated with the product.
Barrier Technology	The technology of using separating environments, whether protecting the world from a product or the product from the world. Containment, barrier isolation and isolation all refer to the same technology, which is enclosing an environment. There are, however, some redefining terms that are gaining favor: 1. Containment - protect the world from the product (as in the case of highly potent compounds or a toxic). 2. Isolation - protect the product from the world (as in the case of a sterile product). 3. ISO 14644-7 "Minienvironments and Isolators" will define further levels of devices

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Base

An electropositive element or radical that unites with an acid to form a salt. Or, a substance that when dissolved in water, dissociates to produce one or more hydroxyl ions (OH⁻).

Base Pair (bp)

Two nucleotides that are in different nucleic acid chains and whose bases pair by hydrogen bonding. In DNA, the nucleotide bases are adenine (A) that always pairs with thymine (T) and guanine (G) which pairs with cytosine (C). In RNA molecules, adenine (A) joins the uracil (U). Two strands of DNA are held together in the shape of a double helix by the bonds between these pairs.

Base Sequence

The order of nucleotide bases in a DNA molecule.

Baseline

In some analytical procedures a sample is dissolved in water or combined with other reagents for analysis. A "blank" or standard consisting of the same reagents may be analyzed without sample present. This provides a comparative reference point, or baseline, so that the test results can be attributed solely to the sample itself.

Baseline® Pharmaceutical Engineering Gui

A series of industry publications developed in partnership with the US Food and Drug Administration (FDA). Each volume in the series is a collaborative effort of industry leaders representing a broad cross-section of manufacturers and other industry experts. The Guides document current industry practice for facilities and systems used for production of pharmaceutical products and medical devices. They are intended to:

- Establish a baseline approach to new and renovated facility design, construction, commissioning, and qualification that is based upon clear understanding of the type of product and its manufacturing process.
- Prioritize facility design features based upon the impact on product and process.
- Avoid unnecessary spending on facility features that do not contribute to consistent production of quality products.

The Guides include five product manufacturing operation based guides (vertical guides), and three support system/function based guides (horizontal guides):

1. Volume I - Bulk Pharmaceutical Chemicals (1996)
2. Volume II - Oral Solid Dosage Forms (1998)
3. Volume III - Sterile Manufacturing Facilities (1999)
4. Volume VI - Biotech (in progress)
5. Volume -Oral Liquids and Aerosols
6. Volume IV - Water and Steam Systems (in progress)
7. Volume V - Commissioning and Qualification Guide (in progress)
8. Volume VII - Packaging and Warehousing

Basidiomycetes

Reproduce by basidiospores, which are extended from the stalks of specialized cells called the basidia. The class comprises Photobasidiomycetes (smuts and rusts) and the Hymenomycetes (mushrooms and puffballs).

Basis of Design

A design document that describes what the purpose of a given system is

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and how the system will accomplish its required task. This document is created and approved before the issuance of bid specifications and is often used to develop them. Until the system is developed this is a conceptual document.

Batch	A specific quantity of material produced in a process or series of processes so that is expected to be homogeneous within specified limits. In the case of continuous production a batch may correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size may be defined either by fixed quantity or the amount produced in a fixed time interval.
Batch Fermentation	<p>The process in which a fixed volume of sterile medium in a vessel is inoculated with a desired organism. The broth is fermented for a defined period to completion, without further additions of media. After discharging the batch, the fermenter is cleaned and rebatched with medium for another cycle. Two other types of fermentation cycles are fed batch and continuous.</p> <p>Batchwise Control The use of validated in-process sampling and testing methods such that results prove the process has done what it purports to do for the specific batch concerned, assuming control parameters have been appropriately maintained.</p>
Batch Number	A unique combination of numbers and/or letters which specifically identify a batch or lot and from which the production and distribution history can be determined.
Bed Depth	The height of the exchange or capture material in a column after proper backwashing for effective operation.
Bed Expansion	The effect produced during backwashing; resin particles separate and rise in the column. Regulating backwash flow may control bed expansion caused by the increase in space between resin particles.
Binary Explosive	An explosive material composed of separate components, each of which is safe for storage and transportation and would not in itself be considered as an explosive.
Bioactivity	A protein's ability to function correctly after it has been delivered to the active site of the body (in vivo).
Bioassay	The determination of the biological activity of a substance (e.g. a drug) by observing its effect on an organism (or organ) compared to a standard preparation.
Bioaugmentation	A strategy involved in bioremediation that increases the activity of an organism to break down or metabolize a pollutant. This involves reseeded a waste site with bacteria as they die.
Bioburden	The level and type of microorganisms which may be present in raw

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materials, API (Active Pharmaceutical Ingredient) starting materials, intermediates, or APIs which have defined limits and should not affect the quality of the API. Bioburden should not be considered contamination unless the levels have been exceeded or defined objectionable organisms have been detected.

Biochemical Oxygen Demand (BOD)	(also see: BOD (Biochemical Oxygen Demand)) Biochemistry The study of chemical processes in living things. Despite the dramatic differences in the appearance of living things, the basic chemistry of all organisms is strikingly similar. Even tiny, one-celled creatures carry out essentially the same reactions that each cell of a complex organism, such as man, carries out.
Biocide	An agent that can kill all pathogenic and non-pathogenic living organisms, including spores. More general than bactericide, biocide includes insecticides and any compound toxic to any living thing.
Biodegradable	Material that can be broken down by biological action.
Bioequivalency	A scientific basis on which generic and brand name drugs are compared with one another. Drugs are bioequivalent if they enter circulation at the same rate when given in similar doses under similar conditions.
Biogenerator	A contained system, such as a fermentor, into which biological agents are introduced along with other materials so as to effect their multiplication or their production of other substances by reaction with the other materials. Biogenerators are generally fitted with devices for regulation, control, connection, material addition, and material withdrawal.
Biohazard	An infectious agent(s), or part thereof, presenting a real or potential risk to human, other animals, or plants, directly through infection or indirectly through disruption of the environment.
Bioinformatics	The use of computers in the life sciences, electronic databases of genomes and protein sequences, and computer modeling of biomolecules and biologic systems.
Biologic	A therapeutic agent derived from living things.
Biological Barrier	An impediment (naturally occurring or introduced) to the infectivity and/or survival of a microbiological agent or eukaryotic cell once it has been released into the environment.
Biological Impurities	Impurities resulting from living matter (bacteria, virus, algae, protozoa, microfungi) and their by-products, including pyrogens (endotoxins).
Biological Indicators	Resistant microorganisms placed into or on various materials to confirm that a sterilization process is effective. They may for instance be placed within a filter in order to determine if a proposed autoclave cycle is effective. After autoclave, they are removed and culture tests are performed to see if the microorganisms were killed.

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Biological Oxygen Demand (BOD) (also see: BOD (Biological Oxygen Demand))

Biological Reactivity Tests, In Vivo

This classification is based on responses to a series of in vivo tests for which extracts, materials and routes of administration are specified. Six Plastic Classes are defined:

1. Class I - Uses a specified dosage of an extract of sample in Sodium Chloride Injection applied either intravenously or intracutaneously into a mouse or a rabbit.
2. Class II - Same as Class I but in addition uses an extract of sample in 1 in 20 Solution of Alcohol in Sodium Chloride Injection applied either intravenously or intracutaneously into a mouse or a rabbit.
3. Class III - Same as Class II but in addition uses an extract of sample in Polyethylene Glycol 400, and an extract of sample in Vegetable Oil, both applied either intraperitoneally or intracutaneously into a mouse.
4. Class IV - Same as Class II but in addition uses an extract of sample in Vegetable Oil applied intraperitoneally or intracutaneously into a mouse or a rabbit. Also uses implant strips of sample into a rabbit.
5. Class V - Same as Class II but in addition uses an extract of sample in Polyethylene Glycol 400, and an extract of sample in Vegetable Oil applied intraperitoneally or intracutaneously into a mouse or a rabbit.
6. Class VI - Same as Class V but in addition uses implant strips of sample into a rabbit.

These tests are designed to determine the biological response of animals to elastomers, plastics and other polymeric material with direct or indirect patient contact, or by the injection of specific extracts prepared from the material under test. Three tests are described:

1. Systemic Injection Test - Designed to determine the systemic biological responses of animals to plastics and other polymers by the single-dose injection of specific extracts prepared from a sample.
2. Intracutaneous Test - Designed to determine the local biological responses of animals to plastics and other polymers by the single-dose injection of specific extracts prepared from a sample.
3. Implantation Test - Designed to evaluate the reaction of living tissue to the plastic and other polymers by the implantation of the sample (specimen under test) itself into animal tissue. With the exception of the Implantation Test, the procedures are based on the use of extracts that, depending on the heat resistance of the material, are prepared at one of the three standard temperatures: 50°, 70°, and 121°. Therefore, the class designation of a plastic must be accompanied by an indication of the temperature of extraction e.g., IV - 121°, which represents a class IV plastic extracted at 121°).

Biological Safety Cabinets (BSCs)

Bench-top or freestanding cabinets with unidirectional airflow used for handling materials that present a health hazard. The National Institutes of Health (NIH) Guidelines classify them as:

1. Class I - A negative pressure, ventilated cabinet for personnel protection having an inward flow of air away from the operator. The exhaust air is filtered through a HEPA filter (located at rear or top) either into the laboratory or to the outside. This cabinet is designed for general microbiological research with low and

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moderate risk agents (BL-2 and BL-3 agents), and is used in three operational modes:

a) With a full width open front. The face velocity of the inward flow of air through the full width open front is at least 75' feet per minute.

b) With an installed front closure panel (having four 6-inch diameter openings) without gloves. The face velocity of the inward flow of air through the openings will increase to approximately 150' feet per minute.

c) With an installed front closure panel equipped with arm-length rubber gloves, and inlet air pressure relief for further protection. In this configuration, it is necessary to install a make-up air inlet fitted with a HEPA filter in the cabinet.

2. Class II - A ventilated cabinet for personnel and product protection having an open front with inward airflow for personnel protection (75' to 100' feet per minute), and HEPA filtered downward unidirectional airflow for product protection. The exhaust air is filtered through a HEPA filter for environmental protection. For selection and procurement of Class II cabinets refer to standards developed by the National Sanitation Foundation, Ann Arbor, Michigan. Cabinets are further classified as:

a) Type A - Suitable for microbiological research in the absence of volatile or toxic chemicals and radionuclides (BL-2 and BL-3), with 70% recirculated air through HEPA. They are exhausted through HEPA into the laboratory or to the outdoors via a "thimble" connection to the building exhaust system.

b) Type B - Hard ducted to the building exhaust system, contains negative pressure plenum, and face velocity of 100' feet per minute. Type B cabinets are further sub-typed into types: B1 (30% recirculated air through HEPA; exhaust via HEPA and hard ducted. BL2 and BL-3), B2 (No recirculation; total exhaust via HEPA and hard ducted. BL-2 and BL-3), and B3 (same as IIA, but plenum under negative pressure to room and exhaust air is ducted. BL-2 and BL-3).

Classes I and II should be located away from traffic patterns and doors, airflow from fans, room air supply louvers, and other air moving devices.

3. Class III - Closed-front ventilated cabinet of gas tight construction that provides the highest level of personnel protection from infectious aerosols, as well as protection of research materials from microbiological contaminants. The interior of the cabinet is protected from contaminants exterior to the cabinet. The cabinet is fitted with arm-length rubber gloves and is operated under negative pressure of at least 0.5 inches water gauge. All supply air is filtered through HEPA filters. Exhaust air is filtered through two HEPA filters in series or one HEPA filter and incinerator before being discharged to the outside environment. Class III cabinets are most suitable for work with hazardous agents that require Biosafety Level 3 or 4 containment. Cabinets must be connected to a double-door autoclave and/or chemical dunk tank used to sterilize or disinfect all materials exiting the cabinet, and to allow supplies to enter the cabinet.

Biologics

"Any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product... applicable to the prevention, treatment, or cure of diseases or injuries of man..."

Biomass

Organic matter grown by the photosynthetic conversion of solar energy.

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Biometabolism	Physical and chemical processes that occur within a cell or an organism, for example, the conversion of nutrients into energy.
Biometrics	A method of verifying an individual's identity based on measurement of his/her physical feature(s) or repeatable action(s) where those features and/or actions are both measurable and unique to that individual. The main types of biometrics are: face recognition, finger scanning, hand geometry, finger geometry, iris recognition, palm, retina, signature, and voice recognition.
Bionics	An interscience discipline for constructing artificial systems, which resemble or have the characteristics of living systems.
Biopharmaceuticals	Ethical pharmaceutical drugs derived through bioprocessing.
Bioprocess Engineering	Process that uses complete living cells or their components (e.g., enzymes, chloroplast) to effect desired physical or chemical changes.
Bioprocessing	The creation of a product utilizing a living organism.
Biopsy	The gross and microscopic examination of tissues or cells removed from a living patient, for the purpose of diagnosis or prognosis of disease, or for the confirmation of normal conditions.
Biopure Water	Water that is sterile, pyrogen free and has a total solids content of less than 1 ppm.
Bioreactor	A closed system used for bioprocessing (flask, roller bottle, tank, vessel, or other container), which supports the growth of cells, mammalian or bacterial, in a culture medium. A bacterial reaction usually is said to take place in a fermenter, and cell culture in a bioreactor.
Biosafety Level	<p>The National Institutes of Health (NIH) specifies physical containment levels and defines Biosafety Levels in their "Guidelines for Research Involving Recombinant DNA Molecules" - Appendix G - May 1999. There are four biosafety levels for operations performed with infectious agents:</p> <ol style="list-style-type: none">1. BL1: Practices, safety equipment, and facilities appropriate for work performed with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. The Basic Laboratory. This laboratory provides general space in which work is done with viable agents that are not associated with disease in healthy adults. Conventional laboratory designs are adequate. Areas known to be source of general contamination, such as animal rooms and waste staging areas, should not be adjacent to patient care activities. Public areas and general offices to which non-laboratory staff requires frequent access should be separated from spaces, that primarily support laboratory functions.2. BL2: Practices, safety equipment, and facilities appropriate for work performed with a broad spectrum of moderate risk agents present and associated with human disease of varying severity.

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The Basic Laboratory. This laboratory provides general space in which work is done with viable agents that are not associated with disease in healthy adults. Conventional laboratory designs are adequate. Areas known to be sources of general contamination, such as animal rooms and waste staging areas, should not be adjacent to patient care activities. Public areas and general offices to which non-laboratory staff requires frequent access should be separated from spaces, which primarily support laboratory functions.

3. BL3: Practices, safety equipment, and facilities appropriate for work performed with indigenous or exotic agents where the potential for infection by aerosols is real and the disease may have serious or lethal consequences. Just walking through the area and breathing the air could infect one. The Containment Laboratory. This laboratory has special engineering features that make it possible for laboratory workers to handle hazardous materials without endangering themselves, the community, or the environment. The unique features that distinguish this laboratory from the basic laboratory are the provisions for access control and a specialized ventilation system. The containment laboratory may be an entire building, a single module, or complex of modules within a building. In all cases, a controlled access zone from areas open to the public separates the laboratory.

4. BL4: Practices, safety equipment, and facilities appropriate for work performed with dangerous and exotic agents that pose a high individual risk of life-threatening disease. Exposure to the skin could cause infection. The Maximum Containment Laboratory. This laboratory has special engineering and containment features that allow activities involving infectious agents that are extremely hazardous to the laboratory worker or that may cause serious epidemic disease to be conducted safely. Although the maximum containment laboratory is generally a separate building, it can be constructed as an isolated area within the building. The laboratory's distinguishing characteristic is that it has secondary barriers to prevent hazardous materials from escaping into the environment. Such barriers include sealed openings into the laboratory, airlocks or liquid disinfectant barriers, a clothing-change and shower room contiguous to the laboratory, a double door autoclave, a biowaste treatment system, and a treatment system to decontaminate exhaust air.

(also see: Good Large Scale Practice, Containment Level, and Table II, Section II - Comparison of Good Large Scale Practice (GLSP) and Biosafety Level (BL) - Large Scale (LS) Practice)

Biosphere

All the living matter on or in the earth, the oceans and seas, and the atmosphere.

Biosynthesis

The production, by biological synthesis or degradation, of compounds by a living organism (e.g. amino acid synthesis, nucleotide synthesis).

Biotechnology

An industry that creates, develops, and markets a variety of techniques that use living organisms, or substances from those organisms, to make or modify a product by microbial and biochemical processes. A common misconception is that biotechnology refers only to recombinant DNA or gene splicing work. Recombinant DNA is only one of the many techniques used to derive products for organisms, plants, and parts of both for the biotechnology industry. A list of areas covered by the term biotechnology would more properly include: plant tissue culture, cell fusion techniques (especially for the production of monoclonal antibodies), enzyme systems,

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plant breeding, meristem culture, fermentation, and others.

Biowaste Inactivation	The inactivation or "killing" of biological organisms using heat or chemicals. This step is done at the end of the processing to ensure that there are no living organisms remaining in the effluent that is sent to the sanitary sewer system. Heat is usually applied at 130°C (266°F) for mammalian cells. Chemicals used include caustic or acid.
BLA (Biologics License Application)	The required application for marketing a biologic product in the United States. Most biopharmaceuticals are biologics.
Blank	A preliminary analysis omitting only the sample to provide an unbiased reference point or baseline for comparison. It is important to minimize extraneous contamination that could be confused with constituents in the sample itself.
Blind Weld	<p>A "blind weld" is defined as a pipe or tube joint welded automatically in which there is no physical way to inspect the weld either visually or with a borescope.</p> <p>Blinding Clinical trial technique in which, to eliminate bias in a research study, subjects and/or clinical investigators remain unaware of which investigational product is provided.</p>
Blood Corpuscle	A cell that circulates in the blood.
Blood Platelets	Small, disc-shaped, metabolically active cells circulating in the blood. They are essential in the blood clotting process since they aggregate to form a plug on the injured surface of the blood vessel.
Blood Serum	The liquid expressed from clotted blood or clotted blood plasma.
Blood-Borne Pathogens	Infectious microorganisms that are carried in the blood of infected humans or animals and that can be transmitted through contact with infected blood, body fluids, tissues, or organs. Blood-borne pathogens are implicated in diseases such as malaria, syphilis, brucellosis, tuberculosis, hepatitis B, and AIDS (Acquired Immunodeficiency Syndrome). Workplace transmission of a blood-borne pathogen can occur via accidental inoculation with a contaminated "sharp" exposure through open cuts, skin abrasions, and mucous membranes of eyes and mouth indirect transmission (e.g., touching mouth, eyes, nose or open cuts with contaminated hands).
Blow (Form) Fill, Seal	Refers to machines that combine formation of a plastic container by blow molding, aseptic filling of a liquid product and sealing of the final package. In the U.S., a major company is ALP, or Automatic Liquid Packaging (Weiler Engineering) and in Europe, Rommilog.
Blowdown	The bleeding-off of fixed quantities of accumulated feed water to reduce concentrated impurities. If these impurities are permitted to accumulate, they may pass through the distillation process and contaminate the distillate or foul the distillation system. Or

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The withdrawal of water from an evaporating water system to maintain a solids balance within specified limits of concentration of those solids.

- BME (Basic Medium Eagles)** One of the most common tissue culture media composed of isotonic salts, carbohydrates and vitamins. When combined with animal serum. BME is a good medium for cell proliferation.
- BOD (Biochemical Oxygen Demand)** The amount of oxygen required to oxidize the dissolved organic matter in a water sample by aerobic (bacterial) decay. A measure of the oxygen depletion that would result from discharging organic impurities into a waterway.
- BOD (Biological Oxygen Demand)** The oxygen used in meeting the metabolic needs of aerobic organisms in water containing organic compounds.
- BPC (Bulk Pharmaceutical Chemical)** A pharmaceutical product derived by chemical synthesis, in bulk form, for later dispensing, formulation or compounding, and filling in a pharmaceutical finishing facility.
- Breakthrough Passage of a substance through a bed, filter, or process designed to eliminate it. For ion exchange processes, the first signs are leakage of ions (in mixed beds, usually Silica) and the resultant increase in conductivity. For organic removal beds, usually small, volatile compounds (Trihalomethanes (THMs) are common in activated carbon).
- Braze Welding** A welding process using nonferrous filler metal that has a melting point below that of the base metals, but above 427°C (800°F). The filler metal is not distributed in the joint by capillary attraction. This type of welding has been also called Bronze welding, a misnomer.
- Brazing** A metal joining process wherein coalescence is produced by use of a nonferrous filler metal having a melting point above 427°C (800°F), but lower than that of the base metals being joined. The filler metal is distributed between the closely fitted surfaces of the joint by capillary action.
- Breakthrough** The first appearance in the effluent of an ion-exchange unit of unadsorbed components similar to those that deplete the activity of the resin bed. Breakthrough indicates that the resin is exhausted and needs to be regenerated.
- Breath Control Shields** Typically made of acrylic or plastic materials, shields protect product, equipment, or the work from particulate contamination expelled by people.
- Broad Spectrum** Over a wide range. A broad-spectrum disinfectant is effective against a wide range of microorganisms including bacterial spores, mycobacteria, non-lipid and lipid viruses, fungi, and vegetative bacteria.
- Broth** The liquid culture medium in which fermentation or cell culture takes place.

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BSE (Bovine Serum Albumin) A blood protein that makes up approximately 55-65% of the proteins in the bovine serum. Used as a size marker on gels and as carrier protein.

BSE (Bovine Spongiform Encephalopathy) Sometimes called "Mad Cow Disease". A disease of cattle presumably caused by a virus or other unidentified entity that affects the brain and causes the cow to behave erratically. Prevalent in parts of Europe but not in the United States. BSE is a contaminant that is undesirable in bovine sera. It is not known whether the causative agent can be filtered out since the causative agent itself is not known. In humans, it is believed to cause Creutzfeld-Jacob, a disease affecting the nervous system.

Btu (British thermal unit) The unit used to measure the amount of heat in a substance. One Btu is the heat required to produce a temperature rise of 1°F. in one lb. of water.

Bubble Point Test A filter leakage test in which the filter is wetted and air pressure is applied and slowly increased until water is expelled from the largest pores and bubbles appear from a submerged tube in a downstream collection vessel. Vigorous bubbling, as opposed to a diffusional airflow or occasional bubbles, is indicative of reaching the bubble point. This visual test can be fairly accurate for low area filters, such as discs. When used to evaluate high area filters, it is subject to limitations in observation, test time, collection conditions, and pressurization rates. The bubble point test is not recommended for integrity testing of filter cartridges.

Buffer A substance capable of neutralizing both acids and bases in solution, thereby maintaining the original acidity or causticity of the solution.

Buffer Prep Area Section of most biotech facilities devoted to the preparation of controlled bioburden buffer solutions for use in the chromatographic separation area of those facilities.

Building Occupancy Classification (Calif) Every building, whether existing or to be erected, is classified by the building official according to its use or the character of its occupancy. The occupancy groups are as follows:

1. Group A - Assembly (Section 303.1.1)
2. Group B - Business (Section 304.1)
3. Group C - Organized Camp (Section 431A)
4. Group E - Educational (Section 305.1)
5. Group F - Factory and Industrial (Section 306.1)
6. Group H - Hazardous (Section 307.1) (also see: Hazardous Occupancy - Group H)
7. Group I - Institutional (Section 308.1)
8. Group M - Mercantile (Section 309.1)
9. Group R - Residential (Section 310.1)
10. Group S - Storage (Section 311.1)
11. Group U - Utility (Section 312.1)

Bulk Handling The transferring of flammable or combustible liquids from tanks or drums into smaller containers for distribution.

Bulk Oxygen System An assembly of equipment, such as storage containers, pressure regulators, safety devices, vaporizers, manifolds, and interconnecting

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pipng that has a storage capacity of more than 12,000 cubic feet (340 m³) of oxygen at normal temperature and pressure, connected in service or ready for service, or more than 25,000 cubic feet (708 m³) of oxygen, including unconnected reserve on hand at the site.

Bulk Pharmaceutical Chemical (BPC)

(also see: BPC (Bulk Pharmaceutical Chemical))

BVD (Bovine Viral Diarrhea)

Viral contaminant found in bovine sera. Able to be filtered out using 0.1 µm nylon filters.

Bovine Of, relating to, or from a cow: such as Bovine Blood: blood from a cow.

Byte

An abbreviation for binary term. A storage unit capable of holding eight bits or the space required for a single letter or number, a single character.

Calcium

A metallic dyad element of a lustrous yellow color, symbol Ca, atomic number 20, atomic weight 40.09, melting point 810°, often found in water usually as dissolved calcium carbonate, chalk (CaCO₃). Soluble in water, it causes hardness and subsequent scaling.

Calcium Carbonate Equivalent

The value obtained when salts are calculated in terms of equivalent quantities of calcium carbonate. This is a convenient method of reducing all salts to a common basis for comparison.

$$\text{ppm CaCO}_3 = \text{ppm ion X} \times \frac{\text{Equivalent weight of CaCO}_3}{\text{Equivalent weight of ion}}$$

Where ion = magnesium, calcium, or other elements that contribute to hardness.

Calibration

A comparison of a measurement standard or instrument of unknown accuracy to detect, correlate, report, or eliminate by adjustment of any variation in the accuracy of the unknown standard or instrument.

Calibration (ICH API defintion)

The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.

Calorie

Any of several approximately equal units of heat, each measured as the quantity of heat required to raise the temperature of one (1) gram of water by °C from a standard initial temperature, specially from 3.98°C, 14.5°C, or 19.5°C, at a constant pressure of one (1) atmosphere. Also called "gram calorie", "small calorie".

The unit of heat equal to 1/100 the quantity of heat required to raise the temperature of one (1) gram of water from 0°C to 100°C at one (10 atmosphere pressure. Also called "mean calorie".

The unit required to raise the temperature of one (1) Kilogram of water by 1°C at one (1) atmosphere pressure. Also called "kilogram calorie", "large calorie".

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Calorimetry	Analytical method that measures heat loss or gain resulting from physical or chemical changes in a sample. Differential scanning calorimetry compares the results of heating a sample to those for heating a reference material. For example, a method to measure the temperature at which the sample crystallizes, changes phases, or decomposes.
Capsid	The external protein shell or coat of a virus particle.
Carbohydrates	A large class of carbon-hydrogen-oxygen compounds that includes the sugars and their polymers (mainly starch, glycogen and cellulose). Most carbohydrates are produced by photosynthesis in plants. They are the major food compounds for both plants and animals. One group of carbohydrates, cellulose, is the primary structural material of plants.
Carbon Filter	A vessel loaded with activated carbon and used to remove organics, chlorine, tastes, and odors from liquids, operating on the principle of adsorption.
Carbon Thickness	A measurement of surface organic material. Carbon thickness values typically range from 5 to 20 angstroms (Å). Significantly contaminated surfaces can show surface carbon thickness of 20 angstroms (Å) or more.
Carbonate Hardness	That hardness in water caused by bicarbonates and carbonates of calcium and magnesium. If alkalinity exceeds total hardness, all hardness is carbonate hardness; if hardness exceeds alkalinity, the carbonate hardness equals the alkalinity.
Carcinogenic	Cancer-causing. Many agents that are carcinogenic are mutagens.
Carrier	A person who has a recessive mutated gene, together with its normal allele. Carriers do not usually develop disease but can pass the mutated gene on to their children.
Catabolism	The intracellular phase of metabolism involved in the energy-yielding degradation of nutrient molecules (for example, glucose to CO ₂ and H ₂ O). Waste products are called catabolites.
Catalase	An enzyme that catalyzes the decomposition of hydrogen peroxide and molecular oxygen and water.
Catalyst	A compound that increases the rate of a chemical reaction without being consumed or changed. In the biosciences, the term enzyme is used. Enzymes catalyze biological reactions.
Cation	A positively charged particle or ion.
Cation Exchange	The displacement of one positively charged particle by another on a cation-exchange material.

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Cation Exchange Resin	An Ion exchange resin, which removes positively charged ions (cations) by exchanging them for hydrogen ions.
Cavitation	A condition of liquid flow where, after partial vaporization of the liquid, the subsequent collapse of vapor bubbles can produce surface damage.
CBER	(also see: center for Biologics Evaluation and Research)
Cell	The fundamental unit of life. The living tissue of almost every organism is composed of these fundamental living units. Unicellular organisms, such as yeast or a bacterium, perform all life functions within the one cell. In a higher organism, a multicellular organism, entire populations of cells may be designated a particular task. The cells of muscle tissue, for example, are specialized for movement.
Cell Bank	Master Cell Bank: The bank of cells, which contain the original unused mutated cells from which, the Manufacturing Working Cell Bank is taken. This is usually kept under lock with very limited access. Manufacturing Working Cell Bank: The bank of cells derived from the Master Cell Bank, which are used to seed the fermentation manufacturing process.
Cell Culture	The in vitro propagation of cells removed from organisms in a laboratory environment that has strict sterility, temperature, and nutrient requirement; also used to refer to any particular individual sample. Usually, cell culture takes place in a bioreactor.
Cell Differentiation	The process whereby descendants of a common parental cell achieve and maintain specialization of structure and function. Muscle cells become muscle cells and bone cells develop. In humans all the different types of cells differentiate from the simple sperm and egg.
Cell Fusion	The fusing together of two or more cells to become a single cell. This technique has had important consequences in immunology, developmental biology, and genetics. For example, monoclonal antibodies are produced by fusing a spleen cell (producing an antibody specific for the antigen of interest) with a mouse myeloma cell to produce a hybridoma which has an indefinitely long life because of the myeloma component and which secretes a specific antibody. When a human cell is fused with a mouse cell, the human chromosomes are progressively lost from the resultant hybrid and by correlating the presence of proteins in the hybrid with the presence of particular human chromosomes, genes can be assigned to individual chromosomes.
Cell Lines	When cells from the first culture (taken from the organism) are used to make subsequent cultures, a cell line is established. "Immortal" cell lines can replicate indefinitely.
Cellulose	A polymer of six-carbon sugars found in all plant matter, the most abundant biological compound on earth.

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Celsius

Of or pertaining to a temperature scale that registers the freezing point of water as 0°C and the boiling point as 100°C under normal atmospheric pressure. Also called "centigrade". The designation Celsius has been official since 1948, but centigrade remains in common use.

Center For Biologics Evaluation and Rese

The FDA successor to the Bureau of Biologics concerned with biologic drugs, and most importantly, with the new protein and peptide drugs emanating from biotechnology.

Center For Drug Evaluation and Research

The successor to the Bureau of Drugs of the FDA concerned with all SVPs (Small Volume Parenterals), LVPs (Large Volume Parenterals), and non-biological drugs.

Centimorgan (cM)

A unit of measure of recombination frequency. One centimorgan is equal to a 1% chance that a marker at one genetic locus will be separated from a marker at a second locus due to crossing over in a single generation. In human beings, one centimorgan is equivalent, on average, to one million base pairs.

Centrifugation

Mechanical means of separation based on differences in sedimentation rates due to differences in density between the suspended particles in the liquid.

Centrifuge

A centrifuge operates on the principle of centrifugal force, the inertial reaction by which a body tends to move away from a center about which it revolves. This technique is commonly used to separate solids from liquids or liquids of different densities. Centrifugal equipment is divided into two major types, sedimenters and filters:

Centromere

A specialized chromosome region to which mitotic or meiotic spindle fibers attach during cell division.

Certification

Documented testimony by qualified authorities that a system qualification, calibration, validation, or revalidation has been performed appropriately and that the results are acceptable. Personnel certification is proof that a person has achieved a certain level of qualification.

Certified Vendor Drawings

Drawings prepared by vendors for the fabrication of equipment, specialty components and skid mounted systems. These are certified as fabricated by the vendor and become the official document for the equipment involved.

CFR (Code of Federal regulations) Title

The U.S. regulations that directly apply to biopharmaceutical development are contained in Title 21 parts 58 (Good Laboratory Practice for Nonclinical Laboratory Studies), 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General), 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals), and 600 (Biological Products: General). Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drugs) apply to critical trials. Part 11 provides criteria which will consider electronic records to be

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equivalent to paper records

Catabolism	The intracellular phase of metabolism involved in the energy-yielding degradation of nutrient molecules (for example, glucose to CO ₂ and H ₂ O). Waste products are called catabolites.
Catalase	An enzyme that catalyzes the decomposition of hydrogen peroxide and molecular oxygen and water.
Catalyst	A compound that increases the rate of a chemical reaction without being consumed or changed. In the biosciences, the term enzyme is used. Enzymes catalyze biological reactions.
Cation	A positively charged particle or ion.
Cation Exchange	The displacement of one positively charged particle by another on a cation-exchange material.
Cation Exchange Resin	An ion exchange resin, which removes positively charged ions (cations) by exchanging them for hydrogen ions.
Cavitation	A condition of liquid flow where, after partial vaporization of the liquid, the subsequent collapse of vapor bubbles can produce surface damage.
CBER	(also see: center for Biologics Evaluation and Research)
Cell	The fundamental unit of life. The living tissue of almost every organism is composed of these fundamental living units. Unicellular organisms, such as yeast or a bacterium, perform all life functions within the one cell. In a higher organism, a multicellular organism, entire populations of cells may be designated a particular task. The cells of muscle tissue, for example, are specialized for movement.
Cell Bank	Master Cell Bank: The bank of cells, which contain the original unused mutated cells from which, the Manufacturing Working Cell Bank is taken. This is usually kept under lock with very limited access. Manufacturing Working Cell Bank: The bank of cells derived from the Master Cell Bank, which are used to seed the fermentation manufacturing process.
Cell Culture	The in vitro propagation of cells removed from organisms in a laboratory environment that has strict sterility, temperature, and nutrient requirement; also used to refer to any particular individual sample. Usually, cell culture takes place in a bioreactor.
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Centromere	A specialized chromosome region to which mitotic or meiotic spindle fibers

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attach during cell division.

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Standardization of equipment, facilities, and operational methods for cleanrooms and associated controlled environments. This includes procedural limits, operational limits and testing procedures to achieve desired attributes to minimize micro contamination. Topics of interest are non-viable particles, viable particles, surface cleanliness, room temperature and humidity profiles, airflow patterns and velocities, room vibration profiles, room light levels, room infiltration leakage, personnel procedures, personnel cleanroom clothing, equipment preparation, and any other topics related to optimizing cleanroom operations.

Total number of published ISO standards related to the TC and its SCs: 9

Number of published ISO standards under the direct responsibility of the TC 209 Secretariat: 9

Participating countries: 20

Observer countries: 21

Other ISO and IEC committees in liaison: ISO [TC 146](#), [TC 198](#), [TC 210](#), [TC 229](#)

International organizations in liaison: [ICCCS](#)

[ISO technical programme:](#)
(drafts and new work items under the direct responsibility of TC 209)

[Business plan](#) (PDF 41 KB)

[Working area on ISOTC](#)

Committee Title

TC 209/WG 1 Airborne particulate cleanliness classes

The convener can be reached through: [BSI](#)

TC 209/WG 2 Biocontamination

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The convener can be reached through: [BSI](#)

TC 209/WG 3 Metrology and test methods

The convener can be reached through: [JISC](#)

TC 209/WG 4 Design and construction

The convener can be reached through: [DIN](#)

TC 209/WG 5 Cleanroom operation

The convener can be reached through: [ANSI](#)

TC 209/WG 6 Terms, definitions and units

The convener can be reached through: [SNV](#)

TC 209/WG 7 Enhanced cleaning devices

The convener can be reached through: [ANSI](#) / [ANSI](#)

TC 209/WG 8 Molecular contamination

The convener can be reached through: [BSI](#)

Absolute filtration rating	The diameter of the largest hard spherical particle that will pass through a filter under specified test conditions. This is an indication of the largest opening in the filter cloth.
Absorption	Retention of liquids in the bulk of the fabric where the liquid is retained by filling up of void spaces, i.e. pores of the fiber, between fibers in a yarn and between yarns in the fabric.
Air flow/air permeability	Measure of the amount of air that flows through a filter—a variable of the degree of contamination, differential pressure, total porosity, and filter area. Expressed in either cubic feet/minute/square foot or liters/minute/square centimeter at a given pressure.
Antistatic	Material that minimizes static charge generation, provides "controlled" static charge dissipation, or both.
Aperture size	See Mesh Opening.
Attenuation	Reduction of the signal power or field strength as a function of distance through a material. Also refers to shielding effectiveness.
Autoclave	Vessel for heating materials under high steam pressure. Used for sterilization and other applications.
Betamesh®	A type of dutch weave wire cloth.
Bolting cloth (silk)	Screens woven of twisted multifilament natural silk.
Bolting grade (wire cloth)	Uniformly woven of stainless steel to provide high strength and the largest possible openings.
BOPP-SI™	Precision woven wire screens woven by G. Bopp & Co., Switzerland.
Bubble point test	A test to determine the maximum pore size opening of a filter.
Bulked yarn	A yarn that has been geometrically changed to give it the appearance of having greater volume than a conventional yarn of the same linear density.
Cake	The solids discharged from a dewatering apparatus.

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Calendering	A process by which fabric or wire is passed through a pair of heavy rollers to reduce thickness, to flatten the intersections of the threads/wires and to control air permeability. Rollers are heated when calendering synthetic materials.
Closed weave	Fabrics are constructed such that, when viewing the fabric perpendicular to its surface, you cannot see through the holes formed by the interwoven fibers. Closed weave fabrics tend to be thicker and stiffer than open weaves.
Decibel (dB)	A unit that expresses the relative difference in power, usually between acoustic or electromagnetic signals. One dB equals ten times the common logarithm of the ratio of incident and transmitted power; or twenty times the common logarithm of the ratio of incident and transmitted field strength.
Decitex (dtex)	The mass in grams of 10,000 meters of fiber or yarn. A direct yarn numbering system used to define size of fiber or yarn. The higher the number, the coarser (larger) the yarn.
Deionized water	Water that goes through an ion exchange process in which all positive and negative ions are removed.
Denier	The mass in grams of 9000 meters of fiber or yarn. A direct yarn numbering system used to define size of fiber or yarn. The higher the number, the coarser (larger) the yarn.
Depth filter	A filter medium consisting of randomly distributed particles or fibers resulting in openings with a non-uniform and tortuous path.
Differential pressure	The difference in pressure between two points of a system, such as between two sides of an orifice
Double layer fabric	By joining a fine filter layer with an open, coarser layer of mesh, these fabrics combine high flow capacity and fine particle capture efficiency with the extremely durable construction needed for large-scale process filtration.
Downstream side	The side of a product stream that has already passed through a given filter system; portion located after the filtration unit.
Dual chamber test method	Measures near-field shielding effectiveness by indicating the signal attenuation caused by passage through a test material.
Dutch weave	Warp and weft wire diameters are different in size and the weft wires are closer together to provide excellent strength and high density.
Dyeing	The process of adding color to textiles in either fiber, yarn or fabric form.
Effective area	The total area of the porous medium exposed to flow in a filter element.
Efficiency	The ability, expressed as a percent, of a filter to remove specified artificial contaminant at a given contaminant concentration under specified test conditions.
E-Field (Electric field)	The dominant component of a high impedance electromagnetic field produced by a near-field source such as a short dipole, or the electric component of a far-field plane wave. Expressed in V/m.
Electromagnetic Interference (EMI)	Electromagnetic energy that causes interference in the operation of electronic equipment. Can be conducted, coupled or radiated. Can be natural or man-made.

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Electromagnetic Capability (EMC)	The capability of electronic equipment on systems to be operated in the intended operational electromagnetic environment at designed levels of efficiency.
Endotoxin	A toxin produced by bacteria. The toxin is present in the environment only after the death of the bacteria.
Extractables	Substances that can be leached from a filter during the filtration process or under other specified conditions.
Faraday cage	A cage made of conductive material. Static fields and discharges do not pass through it. Electromagnetic energy passing through the skin or shield is attenuated to varying degrees.
Feed	The material entering a filter processing unit for treatment.
Filter life	Measure of the duration of a filter's useful service. This is based on the amount of standard contaminant required to cause differential pressure to increase to an unacceptable level-typically 2-4 times the initial differential pressure, a 50-80% drop in initial flow, or an unacceptable downstream measure of particulate.
Filter media	A porous material for separating suspended particulate matter from fluid.
Filter medium	The permeable portion of a filtration system that provides the liquid/solid separation, such as screens, papers, non-wovens, granular beds and other porous media.
Filtrate	The discharge liquor in filtration.
Filtration	A process of separating particulate matter from a fluid by passing it through a permeable material.
Flow rate	Measure of the amount of fluid passing through the filter. This is always a variable of filter area, porosity, contamination and differential pressure.
Frazier test	Measures the amount of air transmitted through a filter under selected differential pressures. Historically used for textile products. See Air flow.
Frequency	Number of complete cycles of current per second, expressed in Hertz (Hz).
G.M.P.	Good Manufacturing Practices. Food and Drug Administration regulations governing the manufacture of drugs and medical devices (Ref. Code of Federal Regulations 21CFR).
Hydrophilic	Having an affinity for water and aqueous solutions.
Hydrophobic	Cannot be wetted by aqueous and other high surface tension fluids.
Knit fabric	A fabric structure made by interlooping yarns.
LAB PAK®	A selection of precision-woven screens, pre-cut and packaged in standard sizes.
Loaded (plugged)	A filter element that has collected a sufficient quantity of insoluble contaminants such that it can no longer pass rated flow without excessive differential pressure.
Mean filtration rating	top Derived from Bubble Point test method. Data should be used as a guide only to compare overall retention capabilities between fabrics and should

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not be considered a guarantee of the particle size that the fabric will retain.

Membrane	A thin polymeric film with pores.
Mesh count	The number of threads in a linear centimeter or inch of fabric/wire cloth.
Mesh opening	Mesh opening is the difference between wires measured in the warp and weft direction in the projected plane of the wire mesh.
Monofilament	Single extruded filament.
Multifilament	Several monofilaments are bundled together to form a single textile yarn.
Non-woven	A porous web or sheet produced by mechanically, chemically or thermally bonding together polymers, fibers or filaments.
Open area	The proportion of total screen area that is open space. Expressed as a percentage.
Open weave	Fabrics are constructed such that, when viewing the fabric perpendicular to its surface, you can see through the holes formed by the interwoven fibers.
Particle	A relatively small subdivision of matter ranging in diameter from a few angstroms (as with gas molecules) to a few millimeters (as with large raindrops). A particle can have various shapes and dimensions.
Permeability	Ability of a membrane or other material to permit a substance to pass through it.
pH	Used to describe the hydrogen ion concentration of a solution. A pH of 7 is neutral. Below 7, acidity increases. Above 7 alkalinity increases.
Plain weave	Most basic weave- over and under pattern.
Plane wave	An electromagnetic wave with electric and magnetic components perpendicular to, and in phase with, each other.
Pore size	Filters are rated according to the size of particles they can remove. Particles which are bigger than indicated pore size, are removed. Smaller particles pass through the fabric The size of particles is measured in micro-meters or "microns" one micron being equal to one-millionth of a meter or one-thousandth of a millimeter, the size of coal dust or baking flour. The smallest bacteria are about 1/2.
PRD	Plain Reverse Dutch weave. High thread count in the warp direction, low thread count in the weft direction.
Pyrogenic	A fever-producing substance. The presence of these substances is determined by the Limulus Amebocyte Lysate (LAL) test and measured in EU/ml (endotoxin units per milliliter).
Radio frequency interference (RFI)	EMI in electronic equipment caused by radio frequencies.
Residual shrinkage	The amount of shrinkage remaining in a fabric after it has undergone all fabric weaving, washing and heat setting steps.
Retentate	Substance retained in the upstream side of a filter.
RF (radio frequency) welding	Utilizes specific bands of radio frequency waves which are directed through specially constructed tooling to form localized melting/joining of certain

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dielectric thermoplastic materials. Can be used to form hermetic seals. Also known as high frequency or dielectric welding.

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SEFAR CARBOTEX	Precision woven screens made with carbonized threads.
SEFAR FLUORTEX	Fluorocarbon precision woven screens.
SEFAR MEDIFAB®	Precision woven fabrics intended for medical applications.
SEFAR NITEX	Nylon precision woven screens.
SEFAR NYTAL	Sieving fabrics for milling applications.
SEFAR PASTAFAB	Dryer belts for pasta industry.
SEFAR PEEKTEX	PEEK precision woven screens.
SEFAR PETEX	Polyester precision woven screens.
SEFAR SHRINKTEX	Shrinkable fabrics.
SEFAR PROPYLEX	Polypropylene precision woven screens.
SEFAR TETEX DLW	Double layer weave fabrics for industrial solid / liquid separation.
SEFAR TETEX MONO	Monofilament filter fabrics for industrial solid / liquid separation.
SEFAR TETEX MULTI	Multifilament and staple fiber fabrics.
SEFAR TUBETEX	Precision woven tubular fabrics.
Selvage	A loom finished edge that prevents cloth unravelling.
Separation	This process divides or separates a mixture of particles or liquids into separate components.
Shielding effectiveness (SE)	Measure of a given material's ability to block interference. Expressed in dB. See Decibel.
Sieve	A screen with apertures of uniform size used for sizing granular materials.
Solution dyeing	Method of adding color to the polymer melt or spinning solution before the fiber is extruded. Also known as Spun dyeing or Dope dyeing.
Spinning	The process of extruding polymers to form fibers.
Spun yarn	A yarn produced from short fibers.
Square weave	See Plain Weave.
Surface media	Captures particles on the upstream surface with efficiencies in excess of depth media, sometimes close to 100% with minimal or no off-loading. Commonly rated according to the smallest particle the media can repeatedly capture. Examples of surface media include ceramic media, microporous membranes, synthetic woven screening media and in certain cases, wire cloth. The media characteristically has a narrow pore size distribution.
Surface resistivity (Ω/n)	Expressed in ohms/square. It is numerically equal to the resistance between two electrodes forming opposite sides of a square on the surface

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	of a material. The size of the square is irrelevant. For conductive materials, surface resistivity is the ratio of the volume resistivity to the fabric thickness (r/t).
Taffeta weave	Plain weave.
Tangential crossflow filtration	Process where the feed stream "sweeps" the membrane surface and the particulate debris is expelled, thus extending filter life. The filtrate flows through the membrane. Most commonly used in the separation of high and low molecular weight matter such as in ultrapure reverse osmosis, ultrafiltration, and submicron microfiltration processes.
Textured yarn	A yarn that has been geometrically altered to impart bulk, increase moisture absorption, add resiliency, etc.
Thread count	See Mesh count.
Thread diameter	The cross-sectional measurement of an individual fabric thread/yarn or wire.
Throughput	The amount of solution which will pass through a filter prior to clogging.
Tricot	A type of knitted fabric.
Twill weave	Formed by passing the warp or weft fiber over two or more fibers in the opposite direction.
Twist	Turns imparted to a length of yarn. Usually expressed in tpi (turns per inch).
Ultrasonic (processes)	Process that utilizes specially-designed tooling usually vibrating at 15-80 KHz. Processes are designed to cause localized heating of thermoplastic materials which, in turn, will provide some type of welded or fused joint. Benefits are elimination of fillers and minimized heat stress on surrounding materials.
Upstream side	The feed side of the filter.
Useful life	Determined when contamination causes an adverse flow rate, low efficiency or high differential pressure.
Volume resistivity	Or specific resistivity of a material, expressed in W.cm. Resistance to electrical current flow through the bulk of an object.
Warp	Fibers or wire running the length of the cloth as woven.
Weft	Fibers or wires running across the width of the cloth as woven.
Wicking	The rapid movement of moisture along the fiber surface, usually by capillary action.
Wire diameter	See Thread diameter.

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