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Glossary of terms

A

- ▶ **Active immunity** - is a type of immunity that is acquired in order to build up disease resistance. Such immunity can be acquired either by having the disease or through vaccination against it.
- ▶ **Active site** - This is a part of a protein that must be maintained in a particular shape if the protein is to function. For example, the part to which the substrate binds in an enzyme (where the enzymatic function is performed).
- ▶ **Adherent cells** - are **anchorage-dependent** and grow as a **monolayer** attached to the cell culture vessel.
- ▶ **Adjuvant** - a nonspecific stimulator of the immune response. It is mixed with an **antigen**, which is injected into a host animal to elicit an immune response and thereby result in the production of **antibodies** in the host animal. The adjuvant is not a substitute for a **carrier protein** as it cannot render **haptens** immunogenic. Its function is to help deposit or sequester the injected material and cause a dramatic increase in the antibody response.
- ▶ **Adult Bovine Serum (ABS)** - is defined as the liquid fraction of clotted blood derived from healthy, slaughtered cattle 12 months of age or older deemed to be fit for human consumption by ante- and/or post-mortem inspection. It is collected in abattoirs inspected by the competent authority of the country of origin. There are no deletions or additions (including preservatives) allowed.
- ▶ **Adventitious agents** - are defined as microorganisms, which are unintentionally introduced into the manufacturing processes of a biological product.
- ▶ **Agglutinin** - a substance that causes particles to coagulate to form a thickened mass. Agglutinins can be **antibodies** that cause **antigens** to aggregate by binding to the antigen-binding sites of antibodies. Agglutinins can also be any substance other than antibodies such as sugar-binding protein lectins. Agglutinins work by clumping on particles causing the particles to change from fluid-like state to thickened-mass state. When an agglutinin is added to a uniform suspension of particles such as bacteria or blood, agglutinin binds to the agglutinin-specific structure on the particle causing the particles to aggregate and fall to the bottom leaving a clear suspension. This phenomenon known as agglutination is of great importance to the medical world as it serves as a diagnostic tool.
- ▶ **Albumin** - globular proteins, the most common of which is **serum albumin**. The albumin family consists of all proteins that are water-soluble, are moderately soluble in concentrated salt solutions, and experience heat denaturation. Albumins are commonly found in blood plasma,
- ▶ **Allergen** - A substance, usually a protein that can stimulate an abnormal immune response in the body leading to what is known as an allergic reaction. Allergens come from a variety of sources, including dust mite excretion, pollen and pet dander.
- ▶ **Anchorage dependant** - cells or cultures that will survive and maintain function only when attached to an inert substrate.
- ▶ **Animal-component free** - a term used to describe cell culture media which does not contain **animal-derived** components such as galactose or cod liver oil, but may still contain **recombinant proteins** or undefined components.

- ▶ **Animal-derived components** - any product that has its original source as being from an animal. Includes animal, yeast and plant.
- ▶ **Animal-protein free** - a term used to describe cell culture media which does not contain animal proteins, but may still contain **animal-derived components**.
- ▶ **Antibacterial** - an agent that selectively kills bacteria.
- ▶ **Antibiotic** - an agent that selectively inhibits bacterial growth or kills bacteria. However, the term *antibiotic(s)* has come to denote a broader range of antimicrobial compounds, including anti-fungal and other compounds.
- ▶ **Antibody** - a protein that is secreted into the blood or other bodily fluids in response to an antigenic stimulus or a foreign substance such as bacterium, virus, parasite or a transplanted organ. Also known as **immunoglobulins**, antibodies are infection-fighting molecules that bind specifically to **antigens** in order to neutralise and help destroy foreign microorganisms or toxins.
- ▶ **Antigen** - a substance that, when introduced into the body, induces an immune response. Each antigen may contain more than one site capable of binding to a particular **antibody**. An immunogen can cause the production of a number of antibodies with different specificities
- ▶ **Antimycotic** - a fungicidal agent that is used to kill or inhibit fungi or fungal spores.
- ▶ **Antisera** - is blood **serum** containing polyclonal **antibodies**.
- ▶ **Anticoagulant** - a substance that prevents **coagulation** (clotting) of blood. Such substances occur naturally in leeches and blood-sucking insects. A group of pharmaceuticals called anticoagulants can be used *in vivo* as a medication for thrombotic disorders such as in deep vein thrombosis where a blood clot forms in the veins following prolonged periods of inactivity (for example during a long-haul flight, or during prolonged post-operative care).
- ▶ For purposes of blood product production for research applications, an anticoagulant is simply a chemical that inhibits the clotting process of blood components. This material is added to the collection bag / container. Common anticoagulants are Sodium citrate, Acid Citrate Dextrose (ACD), CDP, CDP-A, EDTA and Na Heparin.
- ▶ **Aseptic processing/ filling** – is the processing and or packaging of sterile liquid reagents that are packaged into previously sterilized containers under sterile conditions. Aseptic techniques are used to promote asepsis, a condition that is clear from harmful pathogens, viruses, parasites, fungi, and harmful spores. In contrast, **sterilisation** is a process of eliminating living microorganisms by thermal or irradiation treatment, or by filtration.
- ▶ **Attachment factors** - structural proteins or protein-like substances that have adherent capabilities and increase cell-substrate interactions. A number of glycoproteins have been identified that promote and/or influence *in-vitro* cell attachment to the surface of the culture vessel. While some cells are able to synthesize these components, others require an **exogenous** source, particularly when grown in **serum-free** culture. The growth and **differentiation** of **anchorage-dependent** cells are often strongly influenced by either glass or plastic culture flasks utilized as a substrate.
- ▶ **Australian Origin** - material sourced from AQIS registered facilities in Australia.

B

- ▶ **B lymphocytes** - Also known as **B cells**, B lymphocytes are a type of **white blood cell** that is responsible for the production of **antibodies** which adhere to **receptors** on the surface of microbes and other foreign substances and alert the immune system to the presence of intruders. B cells develop from **stem cells** in the bone marrow.
- ▶ **Biotechnology** - refers to the use of cellular and living organisms or their components, including genes, to develop products that improve human health, food and the environment.
- ▶ **Bacteriostatic** - see **Antibacterial**.
- ▶ **Bactericidal** - see **Antibiotic**.
- ▶ **Balanced Salt Solution (BSS)** - all tissue culture media contain a synthetic mixture of inorganic salts that is known as a "physiological" or balanced salt solution (BSS). It provides an environment that will maintain the structural and physiological integrity of cells *in vitro*. It is also important in the maintenance of the proper pH and the ideal osmotic pressure, and also provides a source of energy for the cells.
- ▶ **Batch testing** - A laboratory testing procedure in which one test is done simultaneously using multiple batches of the same reagent. In relation to the testing of suitable batches of **serum** (eg. **FBS** or Human serum), for **cell culture** applications, several different batches of serum will be tested in order to select the best one for the specific application/cell types in use.
- ▶ **Bovine Calf Serum (BCS)** - see **Calf Serum**.
- ▶ **Bovine Serum Albumin (BSA)** - is a serum albumin protein derived from cows. It is often used as a protein concentration standard in lab experiments. BSA has numerous biochemical applications including **ELISAs (Enzyme-Linked Immunosorbent Assay)**, immunoblots, and immunohistochemistry. It is also used as a nutrient in cell and microbial culture.
- ▶ **Buffer** - a buffer solution is one which resists changes in pH when small quantities of an acid or an alkali are added to it. In tissue culture media, the buffer added to the medium is matched with a defined CO₂ level for correct pH maintenance. Commonly used buffering agents include Sodium Bicarbonate and inorganic salts such as **HEPES**.

C

- ▶ **Calf Serum** - also referred to as **Bovine Calf Serum (BCS)** is defined as the liquid fraction of clotted blood derived from healthy, slaughtered bovine calves, aged from 20 days up to 12 months, deemed fit for human consumption by ante-and/or post-mortem inspection. It is collected in abattoirs inspected by the competent authority of the country of origin. There are no deletions or additions (including preservatives) allowed.
- ▶ **Canadian Origin** - serum sourced from CFIA registered facilities in Canada.
- ▶ **Carrier proteins** - are proteins involved in the movement of large molecules in and out of a cell. Also, in the context of antibody production, a **carrier protein** is used to couple with peptides or other **haptens** that are not large enough or sufficiently complex to induce an immune response in a host animal. A carrier protein increases the size of the antigen and aids with presentation of the antigen to B-lymphocytes. Due to its size, antibodies will be produced to epitopes on both the antigen and the carrier protein.

- ▶ **Cell culture** - the complex process by which cells are grown under controlled conditions, generally outside of their natural environment.
- ▶ **Cell line** - a culture of a particular type of cell, reproduced indefinitely. When cells from the first culture are used to make subsequent cultures, a cell line is established. Immortal cell lines can replicate indefinitely, as a result of genetic or other manipulations. The term 'cell line' implies that resulting cultures consist of generations of the cells originally present in the **primary culture**.
- ▶ **Certificate of Analysis (COA)** - a document issued by **Quality Assurance** that confirms that a regulated product meets its product specification. They commonly contain the actual results obtained from testing performed as part of **quality control** of an individual batch of a product.
- ▶ **Central American and Caribbean Origin** - serum sourced from locally approved facilities in Panama, Costa Rica, Nicaragua, El Salvador, Honduras, Guatemala, Belize, Cuba, Dominican Republic, Haiti and /or Jamaica.
- ▶ **Charcoal Stripped Foetal Bovine Serum** - serum that has been filtered through an activated carbon adsorbent filter to remove lipophilic material such as hormones and insulin. Ideal for cell culture work using immunoassay systems and insulin assay methods.
- ▶ **Chelator - Chelation** describes a particular way that ions and molecules bind metal ions. To remove (a heavy metal, such as lead or mercury) from the bloodstream by means of a chelate, such as EDTA. A chelating agent is a substance whose molecules can form several bonds to a single metal ion. EDTA is a versatile chelating agent.
- ▶ **Chemically defined** - term used to describe a product in which every component's chemical and physical properties are known, including the component's molecular weight and structure. Chemically defined items include animal components, defined proteins and other defined components such as insulin and amino acids, salts and vitamins. Defined components do not include **hydrolysates, BSA, transferrin and serum**.
- ▶ **Clarified Foetal Bovine Serum** - is semi-processed FBS, that has been thawed, pooled and subjected to some level of filtration before being dispensed into final packaging. No further processes, treatment, additions or deletions are allowed. Clarified FBS is stored frozen pending further treatment.
- ▶ **Cleanroom** - a laboratory facility ordinarily utilized as a part of specialized industrial production or scientific research.
- ▶ **Coagulation** - is the process by which blood forms clots. It is an important part in the cessation of blood loss from a damaged vessel, wherein a damaged blood vessel wall is covered by a **platelet** and **fibrin**-containing clot to stop bleeding and begin repair of the damaged vessel. Disorders of **coagulation** can lead to an increased risk of bleeding (haemorrhage) or obstructive clotting (thrombosis).
- ▶ **Cohn cold-ethanol fractionation** - a **BSA** purification method that is based on a multi-step process developed by Dr. Edwin J. Cohn, a researcher at Harvard University in the 1940's. Dr. Cohn found that blood proteins could be separated from each other by manipulating pH, salt, temperature and using varying concentrations of an organic solvent over five successive steps or fractions. BSA produced via this method is referred to as 'Cohn Fraction V' and this naming convention comes from the fact that the serum albumin is separated from other serum proteins in the fifth ethanol fraction.

- ▶ **Complement (antibodies)**- The complement system helps or “complements” the ability of **antibodies** and **phagocytic** cells to clear **pathogens** from an organism. It is part of the immune system called the **innate immune system** that is not adaptable and does not change over the course of an individual's lifetime. However, it can be recruited and brought into action by the **adaptive immune system**.
- ▶ **Complement factor (serum)** - A soluble protein found in blood serum that is responsible for killing bacteria. The protein was originally called 'alexin' when it was discovered in the late 19th century, but the term was subsequently changed to reflect the fact its action 'complements' that of an antibody in the destruction of bacteria.
- ▶ **Control** - The term “Control” means different things to different people. For the purposes of **serum** production for life research applications, a “Control” is any plasma or serum based material to which the potency has been adjusted in some manner and is not neat out of the donor.
- ▶ **Cytokine** - small proteins secreted by a variety of cell types that function as signalling molecules in intercellular communication. They are important in both healthy and disease states and are involved in the inflammatory/immune response, and cell growth/development.

D

- ▶ **Delipidization** - This is the physical or chemical reduction or elimination of lipids to clarify the serum or plasma. Some IVD products require that the **defibrinated plasma** or **serum** be optically clear. Chloroform or Freon (1,1,2 trichlor-tri flour ethane) is most commonly used. Other methods include using fumed silica at 1 % W/V or Dextran sulfate depending on the intended use of the final product.
- ▶ **Delipidised Foetal Bovine Serum** - is serum that has been treated to remove lipids (fat). Used for growing hepatocytes and other cells used in numerous biological assays including research involving fatty acids, cholesterol, steroids, growth hormone and drug delivery.
- ▶ **Defibrination** – the removal of fibrin from blood plasma.
- ▶ **Defibrinated plasma** - This is essentially similar to **serum** as defined above except that the clotting process is done in the laboratory. Defibrination can be achieved by physical (diafiltration) or chemical means. The most popular processes involve using Calcium chloride in conjunction with (bovine) thrombin. In most cases, the Calcium chloride has to be removed as it may interfere with some assays. Bovine Thrombin can be used without added Calcium chloride.
- ▶ **Diagnostic** – a term often used in relation to the development of a test used for the diagnosis of a specific disease or condition.
- ▶ **Dialysed Foetal Bovine Serum** - is serum that has been treated by **dialysis** to remove small molecules such as glucose, salts and some non-protein bound serum molecules such as polypeptides. Particularly suitable for receptor studies (and radiolabelling assays).
- ▶ **Dialysis** - the process of separating molecules in solution by the difference in their rates of diffusion through a semipermeable membrane.
- ▶ **Differentiation** - the process by which cells or tissues undergo a change toward a more specialised form or function, especially during embryonic development. Differentiated cells maintain, in culture, the specialised structure and function typical of the cell type *in vivo*.
- ▶ **Donor Bovine Serum (DBS)** - is defined as the liquid fraction of clotted blood derived from healthy cattle 12 months of age or older, from controlled **donor herds** whose health status is confirmed by

regular inspection by competent, legally authorized veterinarians. There are no deletions or additions (including preservatives) allowed.

- ▶ **Donor Consent** - the donors of biological specimens are, as a rule, volunteers who participate in the research of their own free will and have given prior informed consent in accordance with established local, national or other regulations and practices.
- ▶ **Donor herd** - carefully monitored herd of cattle (in regards to diet) to ensure that the resulting serum product collected from donor animals is of the highest quality.

E

- ▶ **Erythrocyte** - see also **Red Blood Cells (RBC)**. The most common type of blood cell and the principal means of delivering oxygen (O₂) to the body tissues via the blood flow through the circulatory system. They take up oxygen in the lungs or gills and release it while squeezing through the body's capillaries. These cells' cytoplasm is rich in haemoglobin, an iron-containing biomolecule that can bind oxygen and is responsible for the blood's red color.
- ▶ **Endotoxin** - a toxin found within bacteria which is released after destruction of the bacterial cell wall and which can negatively affect the growth of cells in culture; in the form of a fat/sugar complex (lipopolysaccharide).
- ▶ **Endogenous** - any substance/s that originates from within an organism, tissue, or cell.
- ▶ **Enzyme-linked immunosorbent assay (ELISA)** - A method that uses antibodies to detect specific proteins.
- ▶ **Epitope** - also known as antigenic determinant, an epitope is the part of an **antigen** that is recognized by the immune system - specifically by antibodies, B cells, or T cells. The epitope is the specific piece of the antigen that an **antibody** binds to.
- ▶ **EU Grade Origin ("Approved")** - material sourced in countries approved for import into the European Union by the European Commission. Currently this includes Central and South America, USA, Canada, Australia and New Zealand and South Africa. This material is collected and processed in facilities registered and inspected by the competent veterinary authority in the country of origin.
- ▶ **EU Origin** - material sourced from EU registered facilities inside the European Union.
- ▶ **Eukaryote** - any organism whose cells contain a nucleus (containing its DNA) and other structures (i.e. organelles such as mitochondria and chloroplasts) enclosed within membranes.
- ▶ **Exogenous** - any substance that is present and active in an individual organism or living cell but that originated outside of that organism.
- ▶ **Ex vivo** - refers to experimentation or measurements done in or on tissue in an artificial environment outside the organism with the minimum alteration of natural conditions. *Ex vivo* conditions allow experimentation under more controlled conditions than is possible in *in vivo* experiments (in the intact organism), at the expense of altering the "natural" environment. A primary advantage of using *ex vivo* tissues is the ability to perform tests or measurements that would otherwise not be possible or ethical in living subjects.
- ▶ **Expression system** - generally a cell-based 'system' that can be defined as the combination of an expression vector, its cloned DNA, and the host for the vector that enables the production of proteins at a high level. Expression is often done to a very high level and therefore referred to as

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overexpression. Common hosts are bacteria or yeast, whereas common sources of DNA (and delivery mechanisms) are viruses and plasmids.

F

- ▶ **Foetal / Fetal bovine serum (FBS)** - also referred to as **fetal calf serum (FCS)**. The blood fraction remaining after the natural coagulation of blood, followed by centrifugation to remove any remaining **red blood cells**. Comes from blood drawn from a bovine foetus via a closed system of collection at the slaughterhouse. The most widely used serum-supplement for *in vitro* cell culture and is very low level of **antibodies** and contains more **growth factors** than other sources of bovine serum.
- ▶ **FDA** - US Food and Drug Administration. An agency of the United States Department of Health and Human Services, responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), and veterinary products.
- ▶ **Fresh whole blood** - see also **Whole Blood**. Is an animal by-product and is not modified, treated or processed and contains no additives. *Blood collected in this state will have a very short shelf-life and will start to clot after a short period of time exposed to air.*
- ▶ **Fibrin** - a fibrous, non-globular protein involved in the clotting of blood. Fibrin works in conjunction with **platelets** to form a "mesh" or clot over a wound site, and thereby stop bleeding, create a barrier to entry into the body by microorganisms, and enable healing of the wound.

G

- ▶ **Gamma irradiation** - the process of treating material with gamma irradiation, providing greater assurance that low levels of microorganisms will be inactivated or reduced and the risks associated with animal-derived components minimized.
- ▶ **GMO / Genetically Modified Organism** - an organism whose genetic material has been altered using genetic engineering techniques. Organisms that have been genetically modified include microorganisms such as bacteria and yeast, insects, plants, fish, and mammals. GMOs are the source of genetically modified foods, and are also widely used in scientific research and to produce goods other than food.
- ▶ **Good Manufacturing Practice (GMP)** - are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of reagents (as well as many other products such as pharmaceuticals, food/drink and cosmetics). These guidelines provide minimum requirements that a manufacturer must meet, in order to provide assurance that the products are of consistently high in quality, from batch to batch, for their intended use.
- ▶ **Growth factors** - a substance, such as a vitamin or hormone, which is required for the stimulation of growth in living cells.

H

- ▶ **Haemagglutinin (H)** - A type of protein molecule found on surface of a virus particle that enables a virus to enter host cells.

- ▶ **Haemoglobin (hb)** - A protein molecule present in red blood cells that delivers oxygen to cells in the body.
 - ▶ **Haematopoietic cells** - cells derived from blood, spleen, or bone marrow; some transformed cell lines can be grown in **suspension**.
 - ▶ **Haemolysis** - is the breakdown of **red blood cells**. In an *in vitro* setting, haemolysis can be caused by improper technique during collection of blood specimens, by the effects of mechanical processing of blood, or by bacterial action in cultured blood specimens.
 - ▶ **Hapten** - a small molecule that can elicit an immune response only when attached to a large carrier such as a protein; the **carrier protein** may be one that also does not elicit an immune response by itself. In general, only large molecules, infectious agents, or insoluble foreign matter can elicit an immune response in the body.
 - ▶ **Heat inactivation** - Sterile filtered **serum** is heated to 56°C for 30 minutes with continuous mixing, to inactivate various components of the serum including complement factors. Often required to preserve the integrity of **immunoassays**.
 - ▶ **Heat shock fractionation** - a **BSA** purification method that relies on stabilisation of the BSA to enable it to tolerate the increased temperature and pH adjustment used to separate the whole blood into different fractions. Most other plasma proteins denature and precipitate during this process yielding an albumin with increased purity compared to cold-ethanol processing.
 - ▶ **HEPES** - 4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid) is a zwitterionic organic chemical buffering agent. Widely used in **cell culture**, largely because it is better at maintaining physiological pH despite changes in carbon dioxide concentration (produced by cellular respiration) when compared to bicarbonate buffers, which are also commonly used in cell culture.
 - ▶ **Hormone** - a chemical released by a cell, a gland, or an organ in one part of the body that affects cells in other parts of the organism. Generally, only a small amount of hormone is required to alter cell metabolism. In essence, it is a chemical messenger that transports a signal from one cell to another.
 - ▶ **Hybridoma** - Hybridoma technology is a technology of forming hybrid cell lines (called **hybridomas**) by fusing an **antibody**-producing B cell with a myeloma (B cell cancer) cell that is selected for its ability to grow in tissue culture and for an absence of antibody chain synthesis. The antibodies produced by the hybridoma are all of a single specificity and are therefore **monoclonal antibodies**.
 - ▶ **Hydrolysate** - the product of hydrolysis. In cell culture medium, hydrolysates are an undefined source of amino acids, peptides, some lipids and trace amounts of low molecular weight substances. Its use in mammalian and insect cell culture media significantly improves cell growth and culture longevity of most cell lines.
- |
- ▶ **ISO 9001:2015** specifies requirements for a quality management system when an organization:
 - a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements; and
 - b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

- ▶ **ISO 13408-7:2012** specifies requirements and provides guidance on alternative approaches to process simulations for the qualification of the aseptic processing of medical devices and combination products that cannot be terminally sterilized and where the process simulation approach according to ISO 13408-1 cannot be applied.
- ▶ **ISO 13485:2016** specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.
- ▶ An **immunoassay** is a biochemical test that measures the presence or concentration of a macromolecule in a solution through the use of an **antibody**.
- ▶ **Immunity** - The ability of an organism to resist infection.
- ▶ **Immunogen** - An **antigen** is any substance that may be specifically bound by components of the immune system (antibody, lymphocytes). The term antigen arises from its ability to induce generation of **antibodies** (antigen = antibody generation). Despite the fact that all antigens are recognized by specific lymphocytes or by antibodies, not every antigen can evoke an immune response. Those antigens that are capable of inducing an immune response are said to be immunogenic and are called immunogens. Sometimes the term immunogen is used interchangeably with the term antigen. But only an immunogen can evoke an immune response.
- ▶ **Immunoglobulin** - Also see **Antibody**. Any of a group of a large Y-shaped glycoproteins produced by B cells that is used by the immune system to identify and neutralize foreign objects such as bacteria and viruses. The antibody recognizes a unique part of the foreign target, called an **antigen**. There are five classes: IgA, IgD, IgE, IgG and IgM.
- ▶ **Intellectual property (IP) rights** – the rights given to a person or company for an invention, including new technologies or new organisms. Such rights allow the owner to control their use and to earn rewards from their use. Examples of IP includes patents, copyrights and registered trademarks.
- ▶ **International Organisation for Standardization (ISO)** - The source of ISO 9000 and more than 14,000 international standards for business, government and society; a network of national standards institutes from 148 countries working in partnership with international organizations, governments, industry, business and consumer representatives.
- ▶ **International Serum Industry Association (ISIA)** - major companies that collect and sell FBS globally are members of the ISIA. Mission Statement states: "ISIA shall establish, promote and assure compliance with uncompromised standards of excellence and ethics in the business practices of the global animal serum and animal derived products supply industry. Our primary focus will be on safety and safe use of serum and animal derived products through proper origin traceability, truth in labelling and appropriate standardization and oversight."

- ▶ ***In vitro*** - a biological or biochemical process occurring in an artificial environment outside of a living organism, such as in a laboratory setting within a petri dish or other cell culture vessel (*in vitro* is Latin for "in glass").
- ▶ ***In vivo*** - a biological or biochemical process occurring within living organism or taking place in a cell.
- ▶ **IRB / Institutional Review Board** - an independent ethics committee or ethical review board that has been formally designated to approve, monitor, and review biomedical and behavioural research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be done. The number one priority of IRBs is to protect human subjects from physical or psychological harm.

J

K

L

- ▶ **Leucocytes** - see also **White Blood Cells**. Leucocytes (also known as **Leukocytes**) are cells of the immune system involved in defending the body against both infectious disease and foreign materials. There are several different types of white blood cells including neutrophils, basophils, eosinophils, lymphocytes, monocytes, and macrophages.
- ▶ **Lyophilisation** - the process of isolating a solid substance from solution by freezing the solution and evaporating the ice under vacuum. Also known as freeze-drying.

M

- ▶ **Major histocompatibility complex (MHC)** - is a set of cell surface molecules encoded by a large gene family which controls a major part of the immune system in all vertebrates. The major function of MHCs is to bind to peptide fragments derived from pathogens and display them on the cell surface for recognition by the appropriate T-cells.
- ▶ **Mexican Origin** - serum sourced from locally approved facilities in Mexico.
- ▶ **Monoclonal antibody** - also known as mAb or moAb, Monoclonal Antibodies are monospecific antibodies that are made by identical immune cells that are all clones of a unique parent cell, in contrast to **polyclonal antibodies** which are made from several different immune cells. Monoclonal antibodies have monovalent affinity, in that they bind to the same **epitope**.
- ▶ **Monolayer** - a single layer of uniformly orientated **anchorage-dependant** cells growing on a substrate.
- ▶ **Mycoplasma** - The name given to the genus of the smallest and simplest form of bacteria. Mycoplasmas are self-replicating and have no cell walls. These prokaryotes are spherical to filamentous in shape and can cause diseases in humans, animals and plants. These are recognised as a contaminant of cell cultures. Once they have contaminated a cell line, they can easily spread to other cell lines in the laboratory. Mycoplasma testing of cell culture media and the individual components of the media is paramount to avoiding infection of cell lines.

N

- ▶ **Neo-natal Bovine Calf Serum** - is defined as the liquid fraction of clotted blood derived from newborn calves that have not suckled from the mother cow. There are no deletions or additions (including preservatives) allowed.
- ▶ **Newborn Calf Serum (NBCS)** - is defined as the liquid fraction of clotted blood derived from healthy, slaughtered bovine calves aged less than 20 days, deemed fit for human consumption through ante- and/or post- mortem inspection. It is collected in abattoirs inspected by the competent authority of the country of origin. There are no deletions or additions (including preservatives) allowed.
- ▶ **New Zealand Origin** - material sourced from NZFSA registered facilities in New Zealand.

O

- ▶ **OEM** refers to an **original equipment manufacturer**, a company that produces parts and equipment that may be marketed by another manufacturer.
- ▶ **Off clot serum** - serum collected from blood that is allowed to coagulate naturally after collection. It has not been exposed to any **anticoagulant**. Tends to be more expensive than **plasma derived serum**. This contains all of the blood protein excluding the clotting factors.
- ▶ **Osmolality** - osmolality regulation (osmotic pressure) is important to regulate flow of substances in/out of the cell, maintained by addition of salt.

P

- ▶ **Passaging** - (also known as **subculture** or splitting cells) involves transferring a small number of cells into a new vessel. Cells can be cultured for a longer time if they are split regularly.
- ▶ **Pathogen** - a bacterium, virus, or other microorganism that can cause disease.
- ▶ **Peripheral Blood Mononuclear Cells (PBMC)** - describes any blood cell having a round nucleus i.e. lymphocytes, monocytes and macrophages (see **Leucocyte**). Does not include **Red Blood Cells** which have no nucleus.
- ▶ **Phagocytes** - are the cells that protect the body by ingesting (phagocytosing) harmful foreign particles, bacteria, and dead or dying cells. Phagocytes include cells called neutrophils, monocytes, macrophages, dendritic cells, and mast cells.
- ▶ **Plasma** - is the liquid fraction of un-clotted (whole) blood. After the addition of an **anticoagulant** to fresh whole blood, plasma is prepared by centrifuging the mixture until the red and white blood cells separate from the liquid phase. The plasma is then removed and may be stored frozen pending further use or processing. This contains all of the blood proteins including the clotting factors.
- ▶ **Plasma derived serum** - serum produced by **defibrinating** pooled human blood collected in the presence of an **anticoagulant**, such as sodium citrate. Plasma derived serum is generally more economical and popular than the **off-the-clot serum**.
- ▶ **Plasmapheresis** - is the removal, treatment, and return of (components of) blood **plasma** from blood circulation. The method is also used during plasma donation: blood is removed from the body, blood cells and plasma are separated, the blood cells are returned while the plasma is collected and frozen to preserve it for eventual use in the manufacture of a variety of medications.
- ▶ **Plasmid** - a small DNA molecule that is physically separate from, and can replicate independently of, chromosomal DNA within a cell. Most commonly found as small circular, double-stranded DNA

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molecules in bacteria. In nature, plasmids carry genes that may benefit survival of the organism (e.g. antibiotic resistance), and can frequently be transmitted from one bacterium to another. Artificial plasmids are widely used as vectors in molecular cloning, serving to drive the replication of **recombinant DNA** sequences within host organisms.

- ▶ **Platelet** - are small, disk shaped clear cell fragments that circulate in the blood of mammals and are involved in clotting. Platelets are a natural source of **growth factors**.
- ▶ **Polyclonal antibody** - (pAbs) are antibodies that are secreted by different B cell lineages within the body (whereas monoclonal antibodies come from a single cell lineage). They are a collection of immunoglobulin molecules that react against a specific **antigen**, each identifying a different **epitope**.
- ▶ **Pre-Qualified or Screened Foetal Bovine Serum** - is sterile-filtered FBS that has been screened or qualified for suitability for a variety of specific applications. Examples may include Hybridoma screened, Stem Cell screened, Insect Cell screened, Low Endotoxin tested or Low IgG tested. Pre-Qualified or Screened FBS may be labelled according to the application for which it has been qualified.
- ▶ **Prokaryote** - a group of organisms whose cells lack a membrane-bound nucleus. Most prokaryotes are unicellular organisms (though there are a few exceptions).
- ▶ **Primary culture** - a culture from an explant of cells, tissues or organs taken from an organism. A culture is a primary culture until it is **subcultured** for the first time, at which point it becomes a cell line.
- ▶ **Prion** - an infectious protein similar to a virus but having no detectable nucleic acid (DNA / RNA). Prions are the agents responsible for several degenerative disease of the nervous system such as **Bovine Spongiform Encephalopathy (BSE)** in cattle, Scrapie in sheep and Creutzfeldt Jakob Disease (CJD) in humans. **Transmissible spongiform encephalopathy (TSE)** diseases are caused by prions and lead to rapid neurodegeneration, causing the brain tissue to develop holes and take a more sponge-like texture.
- ▶ **Proliferation** - the increase in cell number by division.
- ▶ **Prospective sample** - clinical samples that are collected from a network of IRB approved collection sites and standardized protocols. They are only collected once a suitable donor is located.

Q

- ▶ **Quality assurance (QA)** - the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production. QA is the process of making sure products are made to a set standard. In contrast, **QC** is the process of testing to ensure the results are as expected.
- ▶ **Quality control (QC)** - a system of maintaining standards in manufactured products by testing a sample of the output against the specification. QC results for a batch of product will be provided on a **Certificate of Analysis (COA)** as confirmation that product is of good quality.

R

- ▶ **Receptor** – a specialized protein on a cell's surface that binds to substances that effect the activities of the cell.

- ▶ **Recovered Plasma** - the plasma collected (separated) from a single donor bleed. The volumes are usually less than 300 ml / bleed.
- ▶ **Red Blood Cells (RBC)** - also known as **erythrocytes**.
- ▶ **Recombinant DNA (rDNA)** - molecules are DNA molecules formed by laboratory methods of genetic recombination to bring together genetic material from multiple sources, creating sequences that would not otherwise be found in biological organisms.
- ▶ **Recombinant protein** - is one that has been synthesised from **recombinant DNA**, in a 'host' organism. Bacteria, yeast, plant cells, insect cells, animal cells.
- ▶ **Remnant sample** - these are pre-existing, diagnostic clinical specimens that are 'de-linked' from their original source. In other words, these are samples that are left over once a clinical diagnosis of a patient has been made. Any information that would link the sample to a known person has been removed.

S

- ▶ **Semi-processed Foetal Bovine Serum** - is obtained from the blood of foetuses of healthy, pre-partum bovine dams that have been deemed fit for human consumption through ante-and/or post-mortem veterinary inspection. It is collected in abattoirs inspected by the competent authority in the country of origin. Foetal blood is collected aseptically using cardiac puncture, thereby reducing the risk of microbial contamination and resultant endotoxins. Collection occurs in an area of the abattoir specifically set aside for this purpose to minimize the risk of contamination by other fluids. Foetal blood is allowed to clot and is then centrifuged. Semi-processed FBS is the liquid fraction of the clotted foetal blood. After separation by centrifugation, no further processing or treatment of the semi-processed FBS is allowed. Also no additions (including preservatives) or deletions are allowed. Semi-processed FBS is stored frozen pending further processing.
- ▶ **Serotype** – In humans, the blood serotype is largely determined by **human leukocyte antigen (HLA)**, the human version of the **major histocompatibility complex**. Cells determined to be non-self are usually recognized by the immune system as foreign, causing an immune response, such as **haemagglutination**.
- ▶ **Serum (Off Clot Serum)** - is the liquid fraction of clotted blood. It is depleted of cells, **fibrin** and clotting factors. Serum differs from plasma in that **anticoagulant** is never added to the blood after collection from the animal. Serum is prepared by centrifuging until the clot is separated from the liquid phase. The serum is then removed and may be stored frozen pending further use or processing. This contains all of the blood protein excluding the clotting factors.
- ▶ **Serum albumin** - often referred to simply as **albumin**. Albumin functions primarily as a carrier protein for steroids, fatty acids, and thyroid hormones and plays a role in stabilizing extracellular fluid volume.
- ▶ **Serum-free medium** - a medium which does not require serum supplementation, but may contain other proteins, **growth factors**, **animal-derived** components and **hydrolysates**.
- ▶ **Source Plasma** - the plasma collected from donors that are aphoresised. Aphoresis is the process of taking whole blood out and separating the cellular portion from the liquid portion and returning the cellular portion back with fluid. A donor can be aphoresed up to twice a week depending on disease process. The volumes are usually greater than 600 ml and less than 880 ml depending on the size and weight of the donor.

- ▶ **South American Origin** - material sourced from a specific country in the sub-continent of South America, for example Argentina, Brazil, Uruguay, Paraguay, Venezuela, Columbia, Bolivia and Chile. This material is collected and processed in facilities registered and inspected by the competent veterinary authority, in the country of origin.
- ▶ **Specific Gravity** - The ratio of the density of a body to the density of water, the latter being taken as unity. Serum has a range of specific gravities according to serum type.
- ▶ **Speciality Foetal Bovine Serum** - also referred to as **Specialty Fetal Bovine Serum**. This is semi-processed FBS or sterile filtered FBS that has been subjected to one or more modification processes, or that has been enhanced or altered in any way. Examples are **Dialysed, Charcoal Stripped, IgG stripped, pH treated, Performance Enhanced, Dehydrated and Reconstituted**. Speciality FBS must be labelled in a manner that clearly identifies it as having been modified, enhanced or altered.
- ▶ **Standard Operating Procedure (SOP)** - A standard operating procedure (SOP) is a set of step-by-step instructions compiled by an organization to help workers carry out complex routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations.
- ▶ **Stem cells** - specialized cells of animals and plants that have the ability to grow and divide by mitosis. Cell division results in self-regeneration as well as differentiation. This means that stem cells can maintain their characteristic as stem cells (self-regeneration), but also change into a different cell type (differentiation).
- ▶ **Sterile filtered** – the process by which any living organisms are eliminated by filtration.
- ▶ **Sterile filtered Foetal Bovine Serum** - is semi-processed FBS, obtained as described above - **Semi-processed Foetal Bovine Serum** - that has been thawed, pooled and subjected to filtration (usually through a series of membrane filters culminating in a sterile 0.1 micron filter) before being aseptically dispensed into its final packaging, labelling and placing on the market. No further processes, additions or deletions are allowed. Sterile filtered FBS is stored frozen. Sterile filtered FBS may be treated using **gamma irradiation** or heat inactivation and additionally labelled to indicate the treatment method used.
- ▶ **Subculture** - the process of transferring or transplanting a cell population from one culture vessel to another. This usually involves 'splitting' or 'dividing' the cell culture by dilution. Synonymous with the term '**passage**'.
- ▶ **Suspension culture** - a culture in which cells have been adapted to grow and divide without being attached to a substrate.

T

- ▶ **Terminally sterilized** - Terminal sterilization is the process in which a liquid product/reagent is sterilized within its container. Sterilisation can be performed by thermal or irradiation processing techniques.
- ▶ **Tetracycline Negative Foetal Bovine Serum** - serum pre-tested to be free of tetracycline or tetracycline derivatives. Designed for studying **Tet-inducible gene expression systems**.
- ▶ **Tet-inducible gene expression system** - a method of inducible gene expression where transcription is reversibly turned on or off in the presence of the **antibiotic** tetracycline or one of its derivatives (e.g. doxycycline).

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- ▶ **Therapeutic** - of or relating to the treatment of disease or disorders by remedial agents or methods.
- ▶ **Titer** - this is the potency or the measurement of the amount of analyte in a specimen. This can be reported in several different ways. International Units (IU) may be used when there is a recognized reference standard available. (Check the WHO or the CDC website for available reference standards.) Relative Units (RU) may be utilized when no reference standard is available. And, finally, titer may also be expressed as a concentration such as weighted amount/ volume (i.e. mg/ml).
- ▶ **Transmissible spongiform encephalopathy (TSE)** - a family of diseases in humans and animals caused by **prions**, which are characterized by spongy degeneration of the brain, with severe and fatal neurological signs and symptoms.

U

- ▶ **USA Origin** - material sourced from USDA registered facilities in the United States of America.
- ▶ **USDA Grade/ Origin (“Approved”)** - material sourced in countries approved for import into the United States by the USDA. Currently this includes Central America, Canada, Australia and New Zealand and Chile. This material is collected and processed in facilities registered and inspected by the competent veterinary authority in the country of origin. In many instances the material cannot be distributed within the USA without successfully passing safety testing in USDA laboratories.

V

- ▶ **Vaccine** - A preparation of dead or weakened pathogen, or of derived antigenic determinants that is used to induce formation of antibodies or immunity against the pathogen.
- ▶ **Viral Marker Test** - used to identify whether donor blood carries any active infection e.g. HIV, HTLV, Hepatitis B & C, Syphilis, Chagas disease, West Nile etc.

W

- ▶ **White Blood Cells (WBC)** - see Leucocyte. WBCs are cells of the immune system involved in defending the body against both infectious disease and foreign materials.
- ▶ **Whole blood** - see also **Fresh whole blood**. Is an animal by-product that contains an **anticoagulant** and has not been depleted of any of its components i.e. it is not modified, treated or processed and contains no other additives. Recommended use within 7-10 days of the collection date i.e. very short shelf-life.

X

- ▶ **Xenogeneic** - derived from, originating in, or being a member of another species. In cell culture applications, xenogeneic serum-free culture medium (XFM) would mean the cultured cells and the serum used in the culture medium are of the same species. In contrast, xenogeneic serum-containing culture medium (SCM) would mean the serum used to supplement the cell culture medium was derived from a different species to the cultured cells.

Y

Z

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