Certified Specialist Programme in Cell Culture

Regulatory Compliance and Documentation

AABB refers to the American Association of Blood Banks, which is a regulatory body that sets standards for blood banking and transfusion medicine, including cell culture practices. Related terms include blood banking, transfusion medicine, and cell culture. The AABB provides guidelines and standards for the collection, testing, and distribution of blood and blood components, as well as for the use of cell culture in transfusion medicine. For example, AABB standards require that blood banks use validated and verified methods for testing and labeling blood products.

ACGT stands for Advisory Committee on Genetic Testing, which is a regulatory committee that provides guidance on the development and use of genetic tests, including those used in cell culture. Related terms include genetic testing, molecular diagnostics, and cell culture. The ACGT provides recommendations on the validation and verification of genetic tests, as well as on the use of genetic testing in clinical practice. For example, ACGT guidelines recommend that genetic tests be validated for their intended use and that results be interpreted by qualified professionals.

AHCA refers to the Agency for Healthcare Administration, which is a regulatory agency that oversees healthcare facilities and services, including those related to cell culture. Related terms include healthcare administration, regulatory compliance, and cell culture. The AHCA sets standards for the licensure and accreditation of healthcare facilities, as well as for the use of cell culture in healthcare settings. For example, AHCA regulations require that healthcare facilities maintain accurate and complete records of patient care, including cell culture results.

ALCOA stands for Attributable, Legible, Contemporaneous, Original, and Accurate, which are the principles of regulatory compliance for documentation in cell culture. Related terms include documentation, record-keeping, and cell culture. ALCOA principles require that documentation be attributable to the person who performed the task, legible and easy to read, contemporaneous with the task, original and not a copy, and accurate and complete. For example, ALCOA principles require that cell culture records be maintained in a bound book or electronic system that prevents alteration or deletion of data.

ANDA stands for Abbreviated New Drug Application, which is a regulatory submission for the approval of a generic drug, including those used in cell culture. Related terms include drug development, regulatory compliance, and cell culture. The ANDA process requires that the applicant demonstrate that the generic drug is bioequivalent to the reference listed drug, and that it meets standards for safety and efficacy. For example, ANDA submissions must include data from in vitro and in vivo studies, as well as from clinical trials.

API stands for Active Pharmaceutical Ingredient, which is a substance used in the manufacture of a drug,

including those used in cell culture. Related terms include drug development, pharmaceutical manufacturing, and cell culture. The API is the active ingredient in a drug that provides the therapeutic effect, and it must meet standards for purity and potency. For example, APIs used in cell culture must be tested for contamination and stability to ensure that they are safe and effective.

ASRS stands for Automated Storage and Retrieval System, which is a system used to store and retrieve samples and materials in cell culture. Related terms include laboratory automation, sample management, and cell culture. The ASRS uses barcodes and radio-frequency identification to track and manage samples and materials, and it can be integrated with laboratory information management systems. For example, ASRS can be used to store and retrieve cell lines, media, and reagents used in cell culture.

Audit refers to a review or examination of a system, process, or procedure to ensure that it meets standards for quality and compliance. Related terms include quality assurance, regulatory compliance, and cell culture. Audits can be internal or external, and they can be conducted by regulatory agencies or third-party auditors. For example, audits of cell culture facilities may review records of cell culture procedures, equipment maintenance, and personnel training.

Biosafety refers to the practices and procedures used to prevent or minimize exposure to biological hazards, including those associated with cell culture. Related terms include biosecurity, laboratory safety, and cell culture. Biosafety practices include the use of personal protective equipment, containment facilities, and decontamination procedures. For example, biosafety level 2 (BSL-2) practices require the use of gloves, gowns, and masks when working with cell cultures that contain infectious agents.

BLA stands for Biologics License Application, which is a regulatory submission for the approval of a biologic product, including those used in cell culture. Related terms include biologic products, regulatory compliance, and cell culture. The BLA process requires that the applicant demonstrate that the biologic product is safe and effective, and that it meets standards for quality and purity. For example, BLA submissions must include data from preclinical and clinical trials, as well as from manufacturing and testing processes.

CAP stands for College of American Pathologists, which is a professional organization that sets standards for laboratory practices, including those related to cell culture. Related terms include laboratory accreditation, regulatory compliance, and cell culture. The CAP provides guidelines and checklists for laboratory accreditation, as well as education and training programs for laboratory professionals. For example, CAP guidelines require that laboratories maintain accurate and complete records of patient results, including cell culture results.

cGMP stands for current Good Manufacturing Practice, which is a regulatory standard for the manufacture of drugs and biologic products, including those used in cell culture. Related terms include drug development, pharmaceutical manufacturing, and cell culture. cGMP requires that manufacturers follow procedures and practices that ensure the quality and safety of products, including testing and validation of

manufacturing processes. For example, cGMP regulations require that manufacturers maintain clean and sanitized facilities, and that they follow standard operating procedures for manufacturing and testing.

Cell bank refers to a repository of cell lines that are used for research and development, including those used in cell culture. Related terms include cell culture, cell line development, and biorepository. Cell banks can be public or private, and they can provide access to characterized and authenticated cell lines. For example, cell banks can provide cell lines that are tested for contamination and stability, and that are certified for use in research and development.

Cell culture refers to the growth and maintenance of cells in a controlled environment, including in laboratories and manufacturing facilities. Related terms include cell biology, biotechnology, and pharmaceutical manufacturing. Cell culture can be used for a variety of applications, including research and development, diagnostic testing, and therapeutic production. For example, cell culture can be used to produce biologic products, such as vaccines and monoclonal antibodies.

CLIA stands for Clinical Laboratory Improvement Amendments, which is a regulatory standard for laboratory testing, including those related to cell culture. Related terms include laboratory accreditation, regulatory compliance, and cell culture. CLIA requires that laboratories follow procedures and practices that ensure the quality and accuracy of test results, including proficiency testing and quality control. For example, CLIA regulations require that laboratories maintain accurate and complete records of patient results, including cell culture results.

Clinical trial refers to a study or experiment that is designed to evaluate the safety and efficacy of a drug or biologic product, including those used in cell culture. Related terms include drug development, biologic product development, and regulatory compliance. Clinical trials can be phase 1, 2, or 3, and they can be conducted in healthy volunteers or patients. For example, clinical trials of cell culture-based products may evaluate the safety and efficacy of cell-based therapies for diseases such as cancer or regenerative medicine.

CMC stands for Chemistry, Manufacturing, and Controls, which is a regulatory standard for the manufacture of drugs and biologic products, including those used in cell culture. Related terms include drug development, pharmaceutical manufacturing, and cell culture. CMC requires that manufacturers follow procedures and practices that ensure the quality and safety of products, including testing and validation of manufacturing processes. For example, CMC regulations require that manufacturers maintain clean and sanitized facilities, and that they follow standard operating procedures for manufacturing and testing.

Compliance refers to the act of conforming to regulations or standards, including those related to cell culture. Related terms include regulatory compliance, quality assurance, and cell culture. Compliance can be regulatory, quality, or financial, and it can be monitored through audits and inspections. For example, compliance with cGMP regulations requires that manufacturers follow procedures and practices that ensure the quality and safety of products.

Continuity refers to the process of ensuring that activities or processes are continued without interruption, including those related to cell culture. Related terms include business continuity, disaster recovery, and cell culture. Continuity can be regulatory, quality, or financial, and it can be monitored through audits and inspections. For example, continuity of cell culture operations requires that manufacturers have plans in place for emergency situations, such as power outages or natural disasters.

Controlled substance refers to a drug or chemical that is regulated by law, including those used in cell culture. Related terms include drug development, pharmaceutical manufacturing, and cell culture. Controlled substances can be schedule 1, 2, 3, or 4, and they can be monitored through inventory and record-keeping systems. For example, controlled substances used in cell culture may require special handling and storage procedures to prevent diversion or misuse.

Corrective action refers to the process of correcting a problem or deficiency, including those related to cell culture. Related terms include quality assurance, regulatory compliance, and cell culture. Corrective action can be regulatory, quality, or financial, and it can be monitored through audits and inspections. For example, corrective action for a deviation in cell culture procedures may require re-training of personnel or revision of standard operating procedures.

Deviation refers to a departure from a procedure or process, including those related to cell culture. Related terms include quality assurance, regulatory compliance, and cell culture. Deviation can be minor or major, and it can be monitored through audits and inspections. For example, deviation from cell culture procedures may require investigation and corrective action to prevent re-occurrence.

Documentation refers to the process of recording and maintaining records of activities or processes, including those related to cell culture. Related terms include record-keeping, quality assurance, and cell culture. Documentation can be electronic or paper, and it can be monitored through audits and inspections. For example, documentation of cell culture procedures may require accurate and complete records of cell culture conditions and results.

Drug development refers to the process of discovering, testing, and approving a drug or biologic product, including those used in cell culture. Related terms include pharmaceutical manufacturing, biologic product development, and regulatory compliance. Drug development can be preclinical or clinical, and it can be monitored through regulatory submissions and inspections. For example, drug development for cell culture-based products may require preclinical testing and clinical trials to demonstrate safety and efficacy.

ELN stands for Electronic Laboratory Notebook, which is a system used to record and manage laboratory data and results, including those related to cell culture. Related terms include laboratory information management, data management, and cell culture. ELNs can be web-based or client-server, and they can be integrated with instrumentation and other laboratory systems. For example, ELNs can be used to record and track cell culture conditions and results, and to manage laboratory inventory and supplies.

Equipment refers to the devices or machines used in laboratories or manufacturing facilities, including those

related to cell culture. Related terms include laboratory equipment, manufacturing equipment, and cell culture. Equipment can be calibrated or validated, and it can be monitored through maintenance and repair records. For example, equipment used in cell culture may require regular maintenance and calibration to ensure accuracy and reliability.

Facility refers to a building or structure used for laboratory or manufacturing activities, including those related to cell culture. Related terms include laboratory facility, manufacturing facility, and cell culture. Facilities can be dedicated or shared, and they can be monitored through security and access controls. For example, facilities used for cell culture may require special ventilation and filtration systems to prevent contamination and ensure product quality.

GLP stands for Good Laboratory Practice, which is a regulatory standard for laboratory testing, including those related to cell culture. Related terms include laboratory accreditation, regulatory compliance, and cell culture. GLP requires that laboratories follow procedures and practices that ensure the quality and accuracy of test results, including proficiency testing and quality control. For example, GLP guidelines require that laboratories maintain accurate and complete records of patient results, including cell culture results.

GMP stands for Good Manufacturing Practice, which is a regulatory standard for the manufacture of drugs and biologic products, including those used in cell culture. Related terms include pharmaceutical manufacturing, biologic product development, and regulatory compliance. GMP requires that manufacturers follow procedures and practices that ensure the quality and safety of products, including testing and validation of manufacturing processes. For example, GMP regulations require that manufacturers maintain clean and sanitized facilities, and that they follow standard operating procedures for manufacturing and testing.

HACCP stands for Hazard Analysis and Critical Control Points, which is a system used to identify and control hazards in food and drug manufacturing, including those related to cell culture. Related terms include quality assurance, regulatory compliance, and cell culture. HACCP requires that manufacturers identify and assess hazards, and that they implement controls to prevent or minimize hazards. For example, HACCP plans for cell culture facilities may require controls for temperature, humidity, and ventilation to prevent contamination and ensure product quality.

ICH stands for International Conference on Harmonisation, which is a regulatory standard for the manufacture of drugs and biologic products, including those used in cell culture. Related terms include pharmaceutical manufacturing, biologic product development, and regulatory compliance. ICH requires that manufacturers follow procedures and practices that ensure the quality and safety of products, including testing and validation of manufacturing processes. For example, ICH guidelines require that manufacturers maintain clean and sanitized facilities, and that they follow standard operating procedures for manufacturing and testing.

Investigational new drug refers to a drug or biologic product that is being tested in clinical trials, including

those related to cell culture. Related terms include drug development, biologic product development, and regulatory compliance. Investigational new drugs can be phase 1, 2, or 3, and they can be monitored through regulatory submissions and inspections. For example, investigational new drugs used in cell culture may require special handling and storage procedures to prevent diversion or misuse.

ISO stands for International Organization for Standardization, which is a regulatory standard for quality management, including those related to cell culture. Related terms include quality assurance, regulatory compliance, and cell culture. ISO requires that organizations follow procedures and practices that ensure the quality and accuracy of products and services, including testing and validation of quality management systems. For example, ISO guidelines require that organizations maintain accurate and complete records of quality management activities, including cell culture results.

Labeling refers to the process of applying labels or tags to products or materials, including those related to cell culture. Related terms include packaging, labeling, and cell culture. Labeling can be text or graphic, and it can be monitored through inspections and audits. For example, labeling of cell culture products may require special warnings or cautions to prevent misuse or accidents.

LIMS stands for Laboratory Information Management System, which is a system used to manage and track laboratory data and results, including those related to cell culture. Related terms include laboratory automation, data management, and cell culture. LIMS can be web-based or client-server, and they can be integrated with instrumentation and other laboratory systems. For example, LIMS can be used to record and track cell culture conditions and results, and to manage laboratory inventory and supplies.

Manufacturing refers to the process of producing products or materials, including those related to cell culture. Related terms include pharmaceutical manufacturing, biologic product development, and cell culture. Manufacturing can be batch or continuous, and it can be monitored through quality control and assurance systems. For example, manufacturing of cell culture products may require special equipment and facilities to prevent contamination and ensure product quality.

Material refers to a substance or component used in manufacturing or laboratory activities, including those related to cell culture. Related terms include raw materials, packaging materials, and cell culture. Materials can be biological or chemical, and they can be monitored through inventory and record-keeping systems. For example, materials used in cell culture may require special handling and storage procedures to prevent contamination or degradation.

Media refers to the substance or solution used to grow or maintain cells in cell culture. Related terms include cell culture media, growth media, and cell culture. Media can be liquid or solid, and it can be monitored through pH and temperature controls. For example, media used in cell culture may require special formulations or supplements to support cell growth and viability.

Method refers to a procedure or technique used to perform a task or activity, including those related to cell culture. Related terms include standard operating procedure, method validation, and cell culture. Methods

can be written or verbal, and they can be monitored through training and competency assessments. For example, methods used in cell culture may require special equipment or facilities to prevent contamination and ensure product quality.

Microbiology refers to the study of microorganisms, including those used in cell culture. Related terms include microbiological testing, microbial contamination, and cell culture. Microbiology can be clinical or research, and it can be monitored through culture and identification of microorganisms. For example, microbiology testing of cell culture products may require special techniques or equipment to detect and identify microorganisms.

Monitoring refers to the process of watching or observing a process or activity, including those related to cell culture. Related terms include quality control, quality assurance, and cell culture. Monitoring can be continuous or periodic, and it can be monitored through data collection and analysis. For example, monitoring of cell culture conditions may require special sensors or instruments to detect and respond to changes in temperature, humidity, or other parameters.

NDA stands for New Drug Application, which is a regulatory submission for the approval of a drug or biologic product, including those used in cell culture. Related terms include drug development, biologic product development, and regulatory compliance. NDA requires that the applicant demonstrate that the product is safe and effective, and that it meets standards for quality and purity. For example, NDA submissions must include data from preclinical and clinical trials, as well as from manufacturing and testing processes.

Personnel refers to the people or staff who work in laboratories or manufacturing facilities, including those related to cell culture. Related terms include training, competency, and cell culture. Personnel can be technical or non-technical, and they can be monitored through training and competency assessments. For example, personnel working in cell culture facilities may require special training or certification to handle biological or chemical hazards.

Pharmaceutical refers to a product or substance used to treat or prevent a disease or condition, including those related to cell culture. Related terms include drug development, biologic product development, and cell culture. Pharmaceuticals can be prescription or over-the-counter, and they can be monitored through regulatory submissions and inspections. For example, pharmaceuticals used in cell culture may require special handling and storage procedures to prevent contamination or degradation.

Preclinical refers to the stage of research or development that occurs before clinical trials, including those related to cell culture. Related terms include drug development, biologic product development, and cell culture. Preclinical studies can be in vitro or in vivo, and they can be monitored through data collection and analysis. For example, preclinical studies of cell culture-based products may require special equipment or facilities to support cell growth and viability.

Process refers to a series of steps or activities used to achieve a goal or objective, including those related to

cell culture. Related terms include manufacturing process, quality control process, and cell culture. Processes can be batch or continuous, and they can be monitored through data collection and analysis. For example, processes used in cell culture may require special equipment or facilities to prevent contamination and ensure product quality.

Protocol refers to a procedure or plan used to conduct a study or experiment, including those related to cell culture. Related terms include standard operating procedure, method validation, and cell culture. Protocols can be written or verbal, and they can be monitored through training and competency assessments. For example, protocols used in cell culture may require special equipment or facilities to prevent contamination and ensure product quality.

Quality refers to the degree or level of excellence or conformance to standards or requirements, including those related to cell culture. Related terms include quality control, quality assurance, and cell culture. Quality can be internal or external, and it can be monitored through audits and inspections. For example, quality of cell culture products may require special testing or validation procedures to ensure product quality and <b