COMPARISON OF EPA/FDA/OECD GLPS

Preface

Public Comment

Comments and suggestions may be submitted at any time to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs (ORA), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please refer to the exact title of this document when submitting comments or suggestions. For questions regarding the use or interpretation of this chart contact James F. McCormack at (301) 827-0425 or email **james.mccormack@fda.gov**.

Additional Copies

Additional copies are available from the Internet at: **http://www.fda.gov/ora/compliance_ref/bimo/fda_epa_oecd.html**. Submit written requests for single copies of the guidance entitled "Comparison Chart of FDA and EPA Good Laboratory Practice (GLP) Regulations and the OECD Principles of GLP" to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs (ORA), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests.

Comparison of FDA, EPA, OECD GLP			Scope and Authority
Topic	**FDA**	**EPA**	**OECD**
Scope	Sec. 58.1 (a) This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 706, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.	792.1 a. This part prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing. This part is intended to ensure the quality and integrity of data submitted pursuant to testing consent agreements and test rules issued under section 4 of the Toxic Substances Control Act (TSCA). b. This part applies to any study described by paragraph "a." of this section which any person conducts, initiates, or supports on or after September 18, 1989. c. It is EPA's policy that all data developed under section 5 of TSCA be in accordance with provisions of this part. If data are not developed in accordance with provisions of this part, EPA will consider such data insufficient to evaluate the health and environmental effects of the chemical substances unless the submitter provides additional information demonstrating that the data are reliable and adequate.	Section I (1) These Principles of Good Laboratory Practice should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment. Non-clinical health and environmental safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory, in greenhouses, and in the field. Unless specifically exempted by national legislation, these Principles of Good Laboratory Practice apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products veterinary drug products and

			similar products, and for the regulation of industrial chemicals.
Studies Conducted Under Contracts	58.10 When a sponsor conducting a nonclinical laboratory study intended to be submitted to or reviewed by the Food and Drug Administration utilizes the servcies of a consulting laboratory, contractor, or grantee to perform an analysis or other service, it shall notify the consulting laboratory, contractor, or grantee that the service is part of a nonclinical laboratory study that must be conducted in compliance with the provisions of this part.	792.10 When a sponsor or other person utilizes the services of a consulting laboratory, contractor, or grantee to perform all or a part of a study to which this part applies, it shall notify the consulting laboratory, contractor, or grantee that the service is, or is part of, a study must be conducted in compliance with the provisions of this part.	
Inspection Authority	58.15 (a) A testing facility shall permit an authorized employee of the Food and Drug Administration, at reasonalble times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens requried to be maintained regarding studies whithin the scope of this part. The records inspection and copying requirements shall not apply to quality assurance until records of findings and problems, or to actions recommended and taken.	792.15 (a) A testing facility shall permit an authorized employee of duly designatedrepresentative of EPA or FDA, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies to which this part applies. The records inspection and copying requirements shall not apply to quality assurnace unit records of findings and problems, or to actions recommended and taken, except the EPA may seek production of these records in litigation of formal adjudicatory hearings.	

Consequences of Refusing to Permit Inspection	58.15 (b) The Food and Drug Administration will not consider a nonclinical laboratory study in support of an application for a research or marketing permit if the testing facility refuses to permit inspection. The determination that a nonclinical laboratory study will not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any applicable statute or regulation to submit the results of the study to the Food and Drug Administration.	792.15 (b) EPA will not consider reliable for purposes of showing that a chemical substance or mixture does not present a risk of injury to health or the environment any data developed by a testing facility or sponsor that refuses to permit inspection in accordance with this part. The determination that a study will not be considered reliable does not, however, relieve the sponsor of a required test of any obligation under any applicable statute or regulation to submit the results of the study to EPA.	
Statement of Compliance or Non-Compliance		792.12 Any person who submits to EPA a test required by a testing consent agreement or a test rule issued under section 4 of TSCA shall include in the submission a true and correct statement, signed by the sponsor and the study director, of one of the following types: a. A statement that the study was conducted in accordance with this part; or b. A statement describing in detail all differences between the practices used in the study and those required by this part; or c. A statement that the person was	

		not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with this part.	

Comparison of FDA, EPA, OECD GLP			Definitions
Topic	**FDA**	**EPA**	**OECD**
Good Laboratory Practice			Section I 2.1.1. Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.
Nonclinical Laboratory Study	58.3 (d) Nonclinical laboratory study means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article.	792.3 Study means any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy studies only as required by 40 CFR 158.640), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. The term " study" does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.	Section I 2.3.1. Non-clinical health and environmental safety study, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.
Short-Term Study			Section I 2.3.2. Short-term study means a study of short duration with widely used, routine techniqu
	58.3	792.3	Section I

Sponsor	(f) Sponsor means a person who initiates and supports, by provision of financial or other resources, a nonclinical laboratory study; (2) A person who submits a nonclinical study to the Food and Drug Administration in support of an application for a research or marketing permit; or (3) A testing facility, if it both initiates and actually conducts the study.	1. A person who initiates and supports, by provision of financial or other resources, a study; 2. A person who submits a study to the EPA in support of an application for a research or marketing permit; or 3. A testing facility, if it both initiates and actually conducts the study.	2.2.5. Sponsor means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study.
Testing Facility	58.3 (g) Testing facility means a person who actually conducts a nonclinical laboratory study, i.e., actually uses the test article in a test system. Testing facility includes any establishment required to register under section 510 of the act that conducts nonclinical laboratory studies and any consulting laboratory described in section 704 of the act that conducts such studies. Testing facility encompasses only those operational units that are being or have been used to conduct nonclinical laboratory studies.	792.3 Testing facility means a person who actually conducts a study, i.e., actually uses the test substance in a test system. "Testing facility" encompasses only those operational units that are being or have been used to conduct studies.	Section I 2.2.1. Test facility means the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multi-site studies, those which are conducted at more than one site, the test facility comprises the site at which the Study Director is located and all individual test sites, which individually or collectively can be considered to be test facilities.
Testing Facility Management			Section I 2.2.3. Test facility management means the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these Principles of Good Laboratory Practice.
			Section I 2.2.2. Test site means the

Test Site			location(s) at which a phase(s) of a study is conducted.
Test Site Management			Section I 2.2.4. Test site management (if appointed) means the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these Principles of Good Laboratory Practice.
Person	58.3 (h) Person means an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.	792.3 Person includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.	
QAU	58.3 (l) Quality Assurance Unit means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of nonclinical laboratory studies.	792.3 Quality Assurance Unit means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies.	Section I 2.2.8. Quality Assurance Programme means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these Principles of Good Laboratory Practice.
Study Director	58.3 (m) Study director means the individual responsible for the overall conduct of a nonclinical laboratory study.	792.3 Study director means the individual responsible for the overall conduct of a study.	Section I 2.2.6. Study Director means the individual responsible for the overall conduct of the nonclinical health and environmental safety study.
			Section I 2.2.7. Principal Investigator means an individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibility for delegated phases of the study. The Study Director's

Principal Investigator			responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable Principles of Good Laboratory Practice are followed.
Study plan			Section I 2.3.3. Study plan means a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.
Study Plan Amendment			Section I 2.3.4. Study plan amendment means an intended change to the study plan after the study initiation date.
Study Plan Deviation			Section I 2.3.5. Study plan deviation means an unintended departure from the study plan after the study initiation date.
SOP			Section I 2.2.9. Standard Operating Procedures (SOPs) means documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines.
Test System	58.3 (i) Test system means any animal, plant, microorganism, or subparts thereof to which the test or control article is administered or added for study. Test system also includes appropriate groups or	792.3 Test system means any animal, plant, microorganism, chemical or physical matrix, including but not limited to soil or water, or subparts thereof, to which the test, control, or reference substance is administered or added for	Section I 2.3.6. Test system means any biological, chemical or physical system or a combination thereof used in a study.

	components of the system not treated with the test or control articles.	study. "Test system" also includes appropriate groups or components of the system not treated with the test, control, or reference substance.	
Specimen	58 (j) Specimen means any material derived from a test system for examination or analysis.	792.3 Specimen means any material derived from a test system for examination or analysis.	Section I 2.3.8. Specimen means any material derived from a test system for examination, analysis, or retention.
Batch	58.3 (n) Batch means a specific quantity or lot of a test or control article that has been characterized according to Sec. 58.105(a).	792.3 Batch means a specific quantity or lot of a test, control, or reference substance that has been characterized according to Sec. 160.105(a).	Section I 2.4.3. Batch means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.
Test Article	58.3 (b) Test article means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act.	792.3 Test substance means a substance or mixture administered or added to a test system in a study, which substance or mixture: 1. Is the subject of an application for a research or marketing permit supported by the study, or is the contemplated subject of such an application; or 2. Is an ingredient, impurity, degradation product, metabolite, or radioactive isotope of a substance described by paragraph (1) of this definition, or some other substance related to a substance described by that paragraph, which is used in the study to assist in characterizing the toxicity, metabolism, or other characteristics of a substance described by that paragraph.	Section I 2.4.1. Test item means an article that is the subject of a study.

Control Article	58.3 (c) Control article means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any article other than a test article, feed, or water that is administered to the test system in the course of a nonclinical laboratory study for the purpose of establishing a basis for comparison with the test article.	792.3 Control substance means any chemical substance or mixture, or any other material other than a test substance, feed, or water, that is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance for known chemical or biological measurements.	Section I 2.4.2. Reference item ("control item") means any article used to provide a basis for comparison with the test item.
Reference Substance		792.3 Reference substance means any chemical substance or mixture, or analytical standard, or material other than a test substance, feed, or water, that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test substance for known chemical or biological measurements.	Section I 2.4.2. Reference item ("control item") means any article used to provide a basis for comparison with the test item.
Carrier		792.3 Carrier means any material, including but not limited to, feed, water, soil, and nutrient media, with which the test substance is combined for administration to a test system.	
Vehicle		792.3 Vehicle means any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.	Section I 2.4.4. Vehicle means any agent which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the

			test system.
Raw Data	58.3 (k) Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a nonclinical laboratory study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.	792.3 Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. "Raw data" may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.	Section I 2.3.7. Raw data means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in section 10, below.
Master Schedule			Section I 2.2.10. Master schedule means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.
Experimental Starting Date		792.3 Experimental start date means the first date the test substance is applied to the test system.	Section I 2.3.9. Experimental starting date means the date on which the first study specific data are collected.
Experimental		792.3 Experimental end date means	Section I 2.3.10. Experimental completion

End Date		the last date on which data are collected directly from the study.	date means the last date on which data are collected from the study.
Study Initiation Date	58.3 (o) Study initiation date means the date the protocol is signed by the study director.	792.3 Study initiation date means the date the protocol is signed by the study director.	Section I 2.3.11. Study initiation date means the date the Study Director signs the study plan.
Study Completion Date	58.3 (p) Study completion date means the date the final report is signed by the study director.	792.3 Study completion date means the date the final report is signed by the study director.	Section I 2.3.12. Study completion date means the date the Study Director signs the final report.

Compliance References (GLP)

Comparison Chart - FDA/EPA & OECD

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Comparison of FDA, EPA, OECD GLP			**Organization & Personnel**
Topic	**FDA**	**EPA**	**OECD**
Training & Experience of Personnel	58.29 (a) Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.	792.29 (a) Each individual engaged in the conduct of or responsible for the supervision of a study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.	Section II 1.4.1 All personnel involved in the conduct of the study must be knowledgeable in those parts of the Principles of Good Laboratory Practice which are applicable to their involvement in the study.
Summary of Training & Job Descriptions	58.29 (b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a nonclinical laboratory study.	792.29 (b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a study.	Section II 1.1.2 (c) ensure the maintenance of a record of the qualifications, training, experience and job description for each professi and technical individual;
Personnel Access to & Responsibility to Follow SOPs			Section II 1.4.2 Study personnel will have access to the study plan and appropriate Standard Operating Procedures applicable to their involvement in the study. It is their responsibility to comply with the instructions given in these documents. Any deviation from these instructions should be documented and communicated directly to the Study Director, and/or if appropriate, the Principal Investigator(s).
Personnel			Section II 1.4.3 All study personnel are

Responsibility to Record Data			responsible for recording raw data promptly and accurately and in compliance with these Principles of Good Laboratory Practice, and are responsible for the quality of their data.
Sufficient Personnel	58.29 (c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.	792.29 (c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.	Section II 1.1.2 (b) ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study;
Personnel Health Precautions	58.29 (d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test and control articles and test systems.	792.29 (d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test, control, and reference substances and test systems.	Section II. 1.4.4 Study personnel should exercise health precautions to minimise risk to themselves and to ensure the integrity of the study.
Clothing for Personnel	58.29 (e) Personnel engaged in a nonclinical laboratory study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test and control articles.	792.29 (e) Personnel engaged in a study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test, control, and reference substances.	
	58.29 (f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the nonclinical laboratory study shall be excluded from direct contact with test systems, test and control	792.29 (f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the study shall be excluded from direct contact with test systems, test, control, and reference substances and any	Section II 1.4.4 They should communicate to the appropriate person any relevant known health or medical condition in order that they can be excluded from operations that may affect the study.

Personnel Illness Precautions	articles and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a nonclinical laboratory study.	other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a study.	
Statement Identifying Testing Facility Management (TFM)			Section II 1.1.2 (a) ensure that a statement exists which identifies the individual(s) within a test facility who fulfil the responsibilities of management as defined by these Principles of Good Laboratory Practice;
TFM - Assure Compliance with GLPs			Section II 1.1.1 Each test facility management should ensure that these Principles of Good Laboratory Practice are complied with, in its test facility.
TFM - Designate a Study Director	58.31 (a) Designate a study director as described in Sec. 58.33, before the study is initiated.	792.31 (a) Designate a study director as described in Sec. 792.33 before the study is initiated.	Section II 1.1.2 (g) ensure that for each study an individual with the appropriate qualifications, training, and experience is designated by the management as the Study Director before the study is initiated.
TFM - Replace a Study Director	58.29 (b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.	792.31 (b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.	Section II 1.1.2 (g) Replacement of a Study Director should be done according to established procedures, and should be

			documented.
TFM - Assure dy Director Approves Protoco			Section II 1.1.2 (i) ensure documented approval of the study plan by the Study Director;
TFM - Assure Study Director Provides Protocol to QAU			Section II 1.1.2 (j) ensure that the Study Director has made the approved study plan available to the Quality Assurance personnel;
TFM - Establish a QAU	58.31 (c) Assure that there is a quality assurance unit as described in Sec. 58.35.	792.31 (c) Assure that there is a quality assurance unit as described in Sec. 792.35.	Section II 1.1.2 (f) ensure that there is a Quality Assurance Programme with designated personnel and assure that the quality assurance responsibility is being performed in accordance with these Principles of Good Laboratory Practice;
TFM - Assure Appropriate Testing	58.31 (d) Assure that test and control articles or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.	792.31 (d) Assure that test, control, and reference substances or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.	Section II 1.1.2 (p) ensure that test and reference items are appropriately characterised;
TFM- Assure Availability of Resources	58.31 (e) Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.	792.31 (e) Assure that personnel, resources, facilities, equipment, materials and methodologies are available as scheduled.	Section II 1.1.2 (n) ensure that test facility supplies meet requirements appropriate to their use in a study;
TFM - Assure Personnel ıderstand	58.31 (f) Assure that personnel clearly understand the functions they are to perform.	792.31 (f) Assure that personnel clearly understand the functions they are to perform.	Section II 1.1.2 (d) ensure that personnel clearly understand the

Their Functions			functions they are to perform and, where necessary, provi training for these functions;
TFM - Assure Corrective Actions	58.31 (g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.	792.31 (g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.	
TFM - Assure Appropriate SOPs			Section II 1.1.2 (e) ensure that appropriate and technically valid Standard Operating Procedures are established and followed, and approve all original and revised Standard Operating Procedures;
TFM - Assure Historical SOPs			Section II 1.1.2 (k) ensure the maintenance of an historical file of all Standard Operating Procedures;
TFM- Assure there is a PI			Section II 1.1.2 (h) ensure, in the event of a multi-site study, that, if needed, a Principal Investigator is designated, who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study. Replacement of a Principal Investigator should be done according to established procedures, and should be documented.
TFM - Assure there is			Section II 1.1.2 (l) ensure that an individual is

Archivist			identified as responsible for the management of the archive(s);
TFM - Assure Master Schedule			Section II 1.1.2 (m) ensure the maintenance of a master schedule;
TFM - Clear Lines of Communication			Section II 1.1.2 (o) ensure for a multi-site study that clear lines of communication exist between the Study Director, Principal Investigator(s), the Quality Assurance Programme(s) and study personnel;
TFM - Validation of Computerized Systems			Section II 1.1.2 (q) establish procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with these Principles of Good Laboratory Practice.
Test Site Management Responsibilities			Section II 1.1.3 When a phase(s) of a study is conducted at a test site, test site management (if appointed) will have the responsibilities as defined above with the following exceptions: 1.1.2 g), i), j) and o).
General Responsibilites of	58.33 For each nonclinical laboratory study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director	792.33 For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for	Section II 1.2.1 The Study Director is the single point of study control and has the responsibility for the overall conduct of the study and for its final report.

a Study Director	has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of study control.	the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control.	
Study Director - Protocol Approval & Compliance	58.29 (a) The protocol, including any change, is approved as provided by Sec. 58.120 and is followed.	792.33 (a) The protocol, including any change, is approved as provided by Sec. 792.120 and is followed.	Section II 1.2.2. (a) approve the study plan and any amendments to the study plan by dated signature; (e) ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; acknowledge deviations from Standard Operating Procedur during the conduct of the study;
Study Director - Assure QAU has Protocol			Section II 1.2.2 (b) ensure that the Quality Assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the Quality Assurance personnel as required during the conduct of the study;
Study Director - Assure Personnel have Protocol			Section II 1.2.2 (c) ensure that study plans and amendments and Standard Operating Procedures are available to study personnel;
Study Director -			Section II 1.2.2

Assure Personnel have Protocol			(c) ensure that study plans and amendments and Standard Operating Procedures are available to study personnel;
Study Director - Assure PI Role			Section II 1.2.2 (d) ensure that the study plan and the final report for a multi-site study identify and define the role of any Principal Investigator(s) and any test facilities and test sites involved in the conduct of the study;
Study Director - Recording & Verification of Data	58.33 (b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.	792.33 (b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.	Section II 1.2.2 (f) ensure that all raw data generated are fully documented and recorded;
dy Director - Unforseen Circumstances	58.33 (c) Unforeseen circumstances that may affect the quality and integrity of the nonclinical laboratory study are noted when they occur, and corrective action is taken and documented.	792.33 (c) Unforeseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented.	
Study Director - Test Systems	58.33 (d) Test systems are as specified in the protocol.	792.33 (d) Test systems are as specified in the protocol.	
Study Director - GLP Compliance	58.33 (e) All applicable good laboratory practice regulations are followed.	792.33 (e) All applicable good laboratory practice regulations are followed.	Section II 1.2.2 (h) sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with these Principles of Good Laboratory Practice;
	58.33	792.33	Section II

Study Director - Archiving	(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.	(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.	1.2.2 (i) ensure that after complet (including termination) of the study, the study plan, the final report, raw data and supporting material are archived.
Study Director - Validation of Computerized Systems			Section II 1.2.2 (g) ensure that computerised systems used in the study have been validated;
Principal Investigator			Section II 1.3 The Principal Investigator will ensure that the delegated phases of the study are conducted in accordance with the applicable Principles of Good Laboratory Practice.
QAU General Responsibilities	Sec. 58.35 (a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part.	Sec. 792.35 Quality assurance unit. (a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. The quality assurance unit shall conduct inspections and maintain records appropriate to the study.	Section II 2.1.1 The test facility should have a documented Quality Assurance Programme to assure that studies performed are in compliance with these Principles of Good Laboratory Practice. 2.1.2. The Quality Assurance Programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.
QAU Independence	Sec. 58.35 (a) For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the	Sec. 792.35 Quality assurance unit. (a) For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel	Section II 2.1.3 This individual(s) should not be involved in the conduct of the study being assured.

	direction and conduct of that study.	engaged in the direction and conduct of that study.	
QAU - Maintain Copy of Master Schedule	58.29 (b) (1) Maintain a copy of a master schedule sheet of all nonclinical laboratory studies conducted at the testing facility indexed by test article and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director.	792.35 (b) (1) Maintain a copy of a master schedule sheet of all studies conducted at the testing facility indexed by test substance and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director.	Section II 2.2.1 (a) have access to an up-to-date copy of the master schedule;
QAU - Maintain Copies of Protocols	58.35 (b) (2) Maintain copies of all protocols pertaining to all nonclinical laboratory studies for which the unit is responsible.	792.35 (b) (2) Maintain copies of all protocols pertaining to all studies for which the unit is responsible.	Section II 2.2.1 (a) maintain copies of all approved study plans and Standard Operating Procedures in use in the test facility
QAU - Verify Content of Protocol			Section II 2.2.1 (b) verify that the study plan contains the information required for compliance with these Principles of Good Laboratory Practice. This verification should be documented;
QAU - Maintain copies of SOPs			Section II 2.2.1 (a) maintain copies Standard Operating Procedures in use in the test facility
	58.35 (b) (3) Inspect each nonclinical laboratory study at intervals adequate to assure the integrity of the study and	792.35 (b) (3) Inspect each study at intervals adequate to ensure the integrity of the study and maintain written and properly	Section II 2.2.1 (c) conduct inspections to determine if all studies are conducted in accordance with these Principles of Good

QAU - Inspections	maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection.	signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for re-inspection.	Laboratory Practice. Inspections should also determine that study plans and Standard Operating Procedures have been made available to study personnel and are being followed. Inspections can be of three types as specified by Quality Assurance Programme Standard Operating Procedures: ■ Study-based inspections, ■ Facility-based inspections, ■ Process-based inspections. Records of such inspections should be retained.
QAU - Reporting	58.35 (b) (3) Any problems found during the course of an inspection which are likely to affect study integrity shall be brought to the attention of the study director and management immediately. Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.	792.35 a. 3. Any problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately. 4. Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.	Section II 2.2.1 (e) promptly report any inspection results in writing to management and to the Study Director, and to the Principal Investigator(s) and the respective management, when applicable;
QAU - Assure Deviations are Authorized	58.35 (b) (3) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and	792.35 (b) (5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and	

	documentation.	documentation.	
QAU - Review of Final Report	58.35 (b) (3) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the nonclinical laboratory study.	792.35 (b) (6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.	Section II 2.2.1 (d) inspect the final reports to confirm that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies;
QAU - Final Report Statement	58.35 (b) (3) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.	792.35 (b) (7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.	Section II 2.2.1 (f) prepare and sign a statement, to be included with the final report, which specifies types of inspections and their dates, including the phase(s) of the study inspected, and the dates inspection results were reported to management and the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.
QAU - Responsibilities & Procedures	58.35 (c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to	792.35 (c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized	

	authorized employees of the Food and Drug Administration.	employees or duly designated representatives of EPA or FDA.	
QAU - Management Certification of QAU Inspections	58.35 (d) A designated representative of the Food and Drug Administration shall have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented, and followed-up in accordance with this paragraph.	792.35 (d) An authorized employee or a duly designated representative of EPA or FDA shall have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented, and followed up in accordance with this paragraph.	

Comparison of FDA, EPA, OECD GLP			Facilities
Topic	**FDA**	**EPA**	**OECD**
General Facility Requirements	58.41 Each testing facility shall be of suitable size and construction to facilitate the proper conduct of nonclinical laboratory studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.	792.41 Each testing facility shall be of suitable size and construction to facilitate the proper conduct of studies. Testing facilities which are not located within an indoor controlled environment shall be of suitable location to facilitate the proper conduct of studies. Testing facilities shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.	Section II 3.1.1. The test facility should be of suitable size, construction and location to meet the requirements of the study and to minimise disturbance that would interfere with the validity of the study. 3.1.2. The design of the test facility should provide
Animal Care Facilities - Animal Rooms	58.43 a. A testing facility shall have a sufficient number of animal rooms or areas, as needed, to assure proper: 1. Separation of species or test systems, 2. isolation of individual projects, 3. quarantine of animals, and 4. routine or specialized housing of animals.	792.43 a. A testing facility shall have a sufficient number of animal rooms or other test system areas, as needed, to ensure: proper separation of species or test systems, isolation of individual projects, quarantine or isolation of animals or other test systems, and routine or specialized housing of animals or other test systems. 1. In tests with plants or aquatic animals, proper separation of species can be accomplished within a room or area by housing them separately in different chambers or aquaria. Separation of species is unnecessary where the protocol specifies the simultaneous exposure of two or more species in the same chamber, aquarium, or housing unit.	Section II 3.2.1 The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances or organisms known to be or suspected of being biohazardous.

		2. Aquatic toxicity tests for individual projects shall be isolated to the extent necessary to prevent cross-contamination of different chemicals used in different tests.	
Animal Care Facilities - Isolation of Biohazardous Agents	58.43 (b) A testing facility shall have a number of animal rooms or areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test and control articles known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.	792.43 (b) A testing facility shall have a number of animal rooms or other test system areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test, control, and reference substances known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.	Section II 3.2.1 The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances or organisms known to be or suspected of being biohazardous.
Animal Care Facilities - Disease Control Areas	58.43 (c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory animal diseases. These areas shall provide effective isolation for the housing of animals either known or suspected of being diseased, or of being carriers of disease, from other animals.	792.43 (c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory test system diseases. These areas shall provide effective isolation for the housing of test systems either known or suspected of being diseased, or of being carriers of disease, from other test systems.	Section II 3.2.2. Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.
Animal Care Facilities - Waste Disposal	58.43 (d) When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be	792.43 (d) Facilities shall have proper provisions for collection and disposal of contaminated water, soil, or other spent materials. When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste	Section II 3.5. Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

	so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.	before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.	
Animal Care - Animal Supply Storage	58.45 There shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means.	792.45 a. There shall be storage areas, as needed, for feed, nutrients, soils, bedding, supplies, and equipment. Storage areas for feed, nutrients, soils, and bedding shall be separated from areas where the test systems are located and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means. b. When appropriate, plant supply facilities shall be provided. These include: 1. Facilities, as specified in the protocol, for holding, culturing, and maintaining algae and aquatic plants. 2. Facilities, as specified in the protocol, for plant growth, including but not limited to, greenhouses, growth chambers, light banks, and fields. c. When appropriate, facilities for aquatic animal tests shall be provided. These include but are not limited to aquaria, holding tanks, ponds, and ancillary equipment, as specified in the protocol.	Section II 3.2.3. There should be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against infestation, contamination and/or deteroriation.
Animal Care Facilities - Environmental Control		792.43 (e) Facilities shall have provisions to regulate environmental conditions (e.g., temperature, humidity, photoperiod) as specified in the	

		protocol.	
Animal Care Facilities - Marine Test Organisms	.	792.43 (f) For marine test organisms, an adequate supply of clean sea water or artificial sea water (prepared from deionized or distilled water and sea salt mixture) shall be available. The ranges of composition shall be as specified in the protocol.	
Animal Care Facilities - Freshwater Test Organisms		792.43 (g) For freshwater organisms, an adequate supply of clean water of the appropriate hardness, pH, and temperature, and which is free of contaminants capable of interfering with the study shall be available as specified in the protocol.	
Animal Care Facilities - Plants		792.43 (h) For plants, an adequate supply of soil of the appropriate composition, as specified in the protocol, shall be available as needed.	
Facilities for Handling Test & Control Aritcles	58.47 a. As necessary to prevent contamination or mixups, there shall be separate areas for: 1. Receipt and storage of the test and control articles. 2. Mixing of the test and control articles with a carrier, e.g., feed. 3. Storage of the test and control article mixtures.	792.47 a. As necessary to prevent contamination or mixups, there shall be separate areas for: 1. Receipt and storage of the test, control, and reference substances. 2. Mixing of the test, control, and reference substances with a carrier, e.g., feed. 3. Storage of the test, control, and reference substance mixtures.	Section II 3.3.1. To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.
	58.47 (b) Storage areas for the	792.47 (b) Storage areas for test,	Section II 3.3.2. Storage rooms or areas

Test & Control Aritcle Storage Areas	test and/or control article and test and control mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the articles and mixtures.	control, and/or reference substance and for test, control, and/or reference mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity,	for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.
Laboratory Operation Areas	58.49 Separate laboratory space shall be provided, as needed, for the performance of the routine and specialized procedures required by nonclinical laboratory studies.	792.49 Separate laboratory space and other space shall be provided, as needed, for the performance of the routine and specialized procedures required by studies.	
Archives	58.51 Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.	792.51 Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.	Section II 3.4. Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

Compliance References (GLP)

Comparison Chart - FDA/EPA & OECD

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Comparison of FDA, EPA, OECD GLP			**Equipment**
Topic	**FDA**	**EPA**	**OECD**
Equipment Design	58.61 Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.	792.61 Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.	Section II 4.1. Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.
Equipment Maintenance & Calibration	58.63 (a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated and/or standardized.	792.63 (a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.	Section II 4.2. Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to Stand Operating Procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement.
Equipment Affect on Test System			Section II 4.3. Apparatus and materials used in a study should not interfere adversely with the test systems.
SOPs for Equipment	58.63 (b) The written standard operating procedures required under Sec. 58.81(b)(11) shall set forth in sufficient detai the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or	792.63 (b) The written standard operating procedures required under Sec. 792.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or	

Maintenance & Calibration	standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.	standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.	
Records of Equipment Maintenance & Calibration	58.63 (c) Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.	792.63 (c) Written records shall be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.	

Comparison of FDA, EPA, OECD GLP			**Facility Operation**
Topic	**FDA**	**EPA**	**OECD**
Standard Operating Procedures (SOPs)	58.81 (a) A testing facility shall have standard operating procedures in writing setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study.	792.81 (a) A testing facility shall have standard operating procedures in writing, setting forth study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study.	Section II 7.1. A test facility should have written Standard Operating Procedures approved by test facility management that are intended to ensure the quality and integrity of the data generated by that test facility.
Deviations from SOPs	58.81 (a) All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data.	792.81 (a) All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data.	Section II 7.3. Deviations from Standard Operating Procedures related to the study should be documented and should be acknowledged by the Study Director and the Principal Investigator(s), as applicable.
Changes in SOPs	58.81 (a) Significant changes in established standard operating procedures shall be properly authorized in writing by management.	792.81 (a) Significant changes in established standard operating procedures shall be properly authorized in writing by management.	Section II 7.1. Revisions to Standard Operating Procedures should be approved by test facility management.
	58.81 (b) Standard operating procedures shall be established for, but not limited to, the following: 1. Animal room preparation. 2. Animal care. 3. Receipt, identification, storage, handling, mixing, and method of sampling of the test and control articles.	792.81 (b) Standard operating procedures shall be established for, but not limited to, the following: 1. Test system room preparation. 2. Test system care. 3. Receipt, identification, storage, handling, mixing, and method of sampling of the test, control, and reference substances.	Section II 7.4. Standard Operating Procedures should be available for, but not be limited to, the following categories of test facility activities. The details given under each heading are to be considered as illustrative examples. 1. Test and Reference Items Receipt, identification, labellin handling, sampling and

Required SOPs	4. Test system observations. 5. Laboratory tests. 6. Handling of animals found moribund or dead during study. 7. Necropsy of animals or postmortem examination of animals. 8. Collection and identification of specimens. 9. Histopathology. 10.Data handling, storage, and retrieval. 11.Maintenance and calibration of equipment. 12.Transfer, proper placement, and identification of animals.	4. Test system observations. 5. Laboratory or other tests. 6. Handling of test systems found moribund or dead during study. 7. Necropsy of test systems or postmortem examination of test systems. 8. Collection and identification of specimens. 9. Histopathology. 10.Data handling, storage and retrieval. 11.Maintenance and calibration of equipment. 12.Transfer, proper placement, and identification of test systems.	storage. 2. Apparatus, Materials and Reagents a. Apparatus Use, maintenance, cleaning and calibration. b. Computerised Systems Validation, operation, maintenance, security, change control and back-up. c. Materials, Reagents and Solutions Preparation and labelling. 3. Record Keeping, Reporting, Storage, and Retrieval Coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised systems. 4. Test System (where appropriate) a. Room preparation and environmental room conditions for the test system. b. Procedures for receipt, transfer, proper placement, characterisation, identification and care of the test system. c. Test system preparation, observations and examinations, before, during and at the conclusion of the study. d. Handling of test system individuals found moribund or dead during the study. e. Collection, identification and handling of specimens including necropsy and histopathology. f. Siting and placement of test systems in test plots. 5. Quality Assurance Procedures Operation of Quality Assurance

			personnel in planning, scheduling, performing, documenting and reporting inspections.
Availability of SOPs	58.81 (c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed. Published literature may be used as a supplement to standard operating procedures.	792.81 (c) Each laboratory or other study area shall have immediately available manuals and standard operating procedures relative to the laboratory or field procedures being performed. Published literature may be used as a supplement to standard operating procedures.	Section II 7.2. Each separate test facility unit or area should have immediately available current Standard Operating Procedures relevant to the activities being performed therein. Published text books, analytical methods, articles and manuals may be used as supplements to these Standard Operating Procedures.
Historical file of SOPs	58.81 (d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.	792.81 (d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.	Section II 10.1. (f) The historical file of all Standard Operating Procedures;
Labeling of Reagents	58.83 All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.	792.83 All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.	Section II 4.4. Chemicals, reagents, and solutions should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available. The expiry date may be extended on the basis of documented evaluation or analysis.
Records of Test System Receipt			Section II 5.2.3. Records of source, date of arrival, and arrival condition of test systems should be maintained.
Test System	58.90 (a) There shall be standard operating procedures for the housing, feeding, handling,	792.90 (a) There shall be standard operating procedures for the housing, feeding, handling, and	Section II 5.2.1. Proper conditions shoul be established and maintaned for the storage, housing,

Care SOPs	and care of animals.	care of animals and other test systems.	handling and care of biological test systems, in order to ensure the quality of the data.
Isolation of New Test Systems	58.90 (b) All newly received animals from outside sources shall be isolated and their health status shall be evaluated in accordance with acceptable veterinary medical practice.	792.90 (b) All newly received test systems from outside sources shall be isolated and their health status or appropriateness for the study shall be evaluated. This evaluation shall be in accordance with acceptable veterinary medical practice or scientific methods.	Section II 5.2.2. Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, should be humanely destroyed. At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.
Test System Disease Conditions	58.90 (c) At the initiation of a nonclinical laboratory study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated, if necessary. These animals may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorizations of	792.90 (c) At the initiation of a study, test systems shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If during the course of the study, the test systems contract such a disease or condition, the diseased test systems should be isolated, if necessary. These test systems may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorization of treatment, description of	Section II 5.2.2. At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.

	treatment, description of treatment, and each date of treatment shall be documented and shall be retained.	treatment, and each date of treatment shall be documented and shall be retained.	
Test System Identifcation	58.90 (d) Warm-blooded animals, excluding suckling rodents, used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification. All information needed to specifically identify each animal within an animal-housing unit shall appear on the outside of that unit	792.90 (d) Warm-blooded animals, adult reptiles, and adult terrestrial amphibians used in laboratory procedures that require manipulations and observations over an extended period of time, or in studies that require these test systems to be removed from and returned to their test system-housing units for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification (e.g., tattoo, color code, ear tag, ear punch, etc.). All information needed to specifically identify each test system within the test system-housing unit shall appear on the outside of that unit. Suckling mammals and juvenile birds are excluded from the requirement of individual identification unless otherwise specified in the protocol.	Section II 5.2.5. All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification, wherever possible.
Housing of	58.90 (e) Animals of different species shall be housed in separate rooms when necessary. Animals of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to control or test articles or animal mixup could affect the outcome of either study.	792.90 (e) Except as specified in paragraph (e)(1) of this section, test systems of different species shall be housed in separate rooms when necessary. Test systems of thesame species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to test, control, or reference substances or test	Section II 5.2.1. Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data. 5.2.7. Test systems used in field studies should be located so as to avoid interference in the study from spray drift and from past usage of pesticides.

Test Systems	If such mixed housing is necessary, adequate differentiation by space and identification shall be made.	system mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made. 1. Plants, invertebrate animals, aquatic vertebrate animals, and organisms that may be used in multispecies tests need not be housed in separate rooms, provided that they are adequately segregated to avoid mixup and cross contamination.	
Cleaning of Cages & Equipment	58.90 (f) Animal cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals.	792.90 (f) Cages, racks, pens, enclosures, aquaria, holding tanks, ponds, growth chambers, and other holding, rearing, and breeding areas, and accessory equipment, shall be cleaned and sanitized at appropriate intervals.	Section II 5.2.6. During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented.
Animal Feed & Water	58.90 (g) Feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.	792.90 (g) Feed, soil, and water used for the test systems shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed, soil, or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.	Section II 5.2.6. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study.

Animal Bedding	58.90 (h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean.	792.90 (h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean.	Section II 5.2.6. Any material that come into contact with the test syste... should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice.
Pest Control Program	58.90 (i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used.	792.90 (i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used.	Section II 5.2.6. Use of pest control agents should be documented.
Acclimation of Test System		792.90 (j) All plant and animal test systems shall be acclimatized to the environmental conditions of the test, prior to their use in a study.	Section II 5.2.4. Biological test systems should be acclimatised to the test environment for an adequate period before the first administration/application of t test or reference item.

Comparison of FDA, EPA, OECD GLP			Article
Topic	**FDA**	**EPA**	**OECD**
Article Characterization	58.105 (a) The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented. Methods of synthesis, fabrication, or derivation of the test and control articles shall be documented by the sponsor or the testing facility. In those cases where marketed products are used as control articles, such products will be characterized by their labeling.	792.105 (a) The identity, strength, purity, and composition, or other characteristics which will appropriately define the test, control, or reference substance shall be determined for each batch and shall be documented before its use in a study. Methods of synthesis, fabrication, or derivation of the test, control, or reference substance shall be documented by the sponsor or the testing facility, and such location of documentation shall be specified.	Section II 6.2.1. Each test and reference item should be appropriately identified (e.g., code, Chemical Abstracts Service Registry Number [CAS number], name, biological parameters). 6.2.2. For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known. 6.2.3. In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in cooperation between the sponsor and the test facility, to verify the identity of the test item subject to the study.
Article Stability	58.105 b. The stability of each test or control article shall be determined by the testing facility or by the sponsor either: 1. Before study initiation, or 2. concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.	792.105 (b) The stability of the test, control or reference substance shall be determined before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.	Section II 6.2.4. The stability of test and reference items under storage and test conditions should be known for all studies.
		792.105 (b) When relevant to the conduct of the study the	.

Solubility of Articles		solubility of each test, control, or reference substance shall be determined by the testing facility or the sponsor before the experimental start date.	
Labeling & Storage Containers for Articles	58.105 (c) Each storage container for a test or control article shall be labeled by name, chemical abstract number or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test or control article. Storage containers shall be assigned to a particular test article for the duration of the study.	792.105 (c) Each storage container for a test, control, or reference substance shall be labeled by name, chemical abstracts service number (CAS) or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test, control, or reference substance. Storage containers shall be assigned to a particular test substance for the duration of the study.	Section Ii 6.1.3. Storage container(s) should carry identification information, expiry date, and specific storage instructions.
Reserve Samples of Articles	58.105 (d) For studies of more than 4 weeks' duration, reserve samples from each batch of test and control articles shall be retained for the period of time provided by Sec. 58.195.	792.105 (d) For studies of more than 4 weeks experimental duration, reserve samples from each batch of test, control, and reference substances shall be retained for the period of time provided by Sec. 792.195..	Section Ii 6.2.6. A sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies.
Stability of Articles Under Storage Conditions		792.105 (e) The stability of test, control, and reference substances under storage conditions at the test site shall be known for all studies.	Section II 6.2.4. The stability of test and reference items under storage and test conditions should be known for all studies.
	58.107	792.107	Section II

Article handling	Procedures shall be established for a system for the handling of the test and control articles to ensure that: a. There is proper storage. b. Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage. c. Proper identification is maintained throughout the distribution process. d. The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.	Procedures shall be established for a system for the handling of the test, control, and reference substances to ensure that: a. There is proper storage. b. Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage. c. Proper identification is maintained throughout the distribution process. d. The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.	6.1.1. Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained. 6.1.2. Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mix-up are precluded.
Uniformity of Mixtures of Articles with Carriers	58.113 a. For each test or control article that is mixed with a carrier, tests by appropriate analytical methods shall be conducted: 1. To determine the uniformity of the mixture and to determine, periodically, the concentration of the test or control article in the mixture.	792.113 a. For each test, control, or reference substance that is mixed with a carrier, tests by appropriate analytical methods shall be conducted: 1. To determine the uniformity of the mixture and to determine, periodically, the concentration of the test, control, or reference substance in the mixture..	Section II 6.2.5. If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (e.g., tank mixes), these may be determined through separate laboratory experiments.
	58.113 a. For each test or control article that is mixed with a carrier, tests by appropriate analytical methods shall be conducted: 2. To determine the stability	792.113 a. For each test, control, or reference substance that is mixed with a carrier, tests by appropriate analytical methods shall be conducted: 3. To determine the stability	Section II 6.2.5. If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (e.g., tank mixes), these may

Stability of Mixtures of Articles with Carriers	of the test and control articles in the mixture as required by the conditions of the study either: i. Before study initiation, or ii. Concomitantly according to written standard operating procedures which provide for periodic analysis of the test and control articles in the mixture.	of the test, control or reference substance in the mixture before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.	be determined through separate laboratory experiments.
Solubility of Articles in a Mixture		792.113 a. For each test, control, or reference substance that is mixed with a carrier, tests by appropriate analytical methods shall be conducted: 2. When relevant to the conduct of the experiment, to determine the solubility of each test, control, or reference substance in the mixture by the testing facility or the sponsor before the experimental start date.	
Expiration of Article Mixtures	58.113 (c) Where any of the components of the test or control article carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown	792.113 (b) Where any of the components of the test, control, or reference substance carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown.	
Interference of		792.113 (c) If a vehicle is used to facilitate the mixing of a test	

Vehicle with Article		substance with a carrier, assurance shall be provided that the vehicle does not interfere with the integrity of the test.	
Physical / Chemical Characterization Studies		792.135 a. All provisions of the GLPs shall apply to physical and chemical characterization studies designed to determine stability, solubility, octanol water partition coefficient, volatility, and persistence (such as biodegradation, photodegradation, and chemical degradation studies). b. The following GLP standards shall not apply to studies designed to determine physical and chemical characteristics of a test, control, or reference substance: Section 792.31 (c), (d), and (g) Section 792.35 (b) and (c) Section 792.43 Section 792.45 Section 792.47 Section 792.49 Section 792.81(b) (1), (2), (6) through (9), and (12) Section 792.90 Section 792.105 (a) through (d) Section 792.113 Section 792.120(a) (5) through (12), and (15) Section 792.185(a) (5) through (8), (10), (12), and (14) Section 792.195 (c) and (d) Subparts H-I [Reserved]	Section II 5.1.1. Apparatus used for the generation of physical/chemical data should be suitably located and of appropriate design and adequate capacity. 5.1.2. The integrity of the physical/chemical test systems should be ensured.

Comparison of FDA, EPA, OECD GLP			**Protocol & Conduct**
Topic	**FDA**	**EPA**	**OECD**
Requirement for a Protocol	58.120 (a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study.	792.120 (a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study.	Section II 8.1.1. For each study, a written plan should exist prior to the initiation of the study. The study plan should be approved by dated signature of the Study Director and verified for GLP compliance by Quality Assurance personnel as specified in Section 2.2.1.b., above. The study plan should also be approved by the test facility management and the sponsor, if required by national regulation or legislation in the country where the study is being performed.
	58.120 a. The protocol shall contain, as applicable, the following information: 1. A descriptive title and statement of the purpose of the study. 2. Identification of the test and control articles by name, chemical abstract number, or code number. 3. The name of the sponsor and the name and address of the testing facility at which the study is being conducted. 4. The number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system. 5. The procedure for identification of the test	792.120 a. The protocol shall contain but shall not necessarily be limited to the following information: 1. A descriptive title and statement of the purpose of the study. 2. Identification of the test, control, and reference substance by name, chemical abstracts service (CAS) number or code number. 3. The name and address of the sponsor and the name and address of the testing facility at which the study is being conducted. 4. The proposed experimental start and termination dates. 5. Justification forselection of the test system.	Section II 8.2 The study plan should contain, but not be limited to the following information: 1. Identification of the Study, the Test Item and Reference Item a. A descriptive title; b. A statement which reveals the nature and purpose of the study; c. Identification of the test item by code or name (IUPAC; CAS number, biological parameters, etc.); d. The reference item to be used. 2. Information Concerning the Sponsor and the Test Facility. a. Name and address of the sponsor; b. Name and address of any test facilities and test sites involved;

Protocol Content	system. 6. A description of the experimental design, including the methods for the control of bias. 7. A description and/or identification of the diet used in the study as well as solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control articles before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications. 8. Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control article to be administered and the method and frequency of administration. 9. The type and frequency of tests, analyses, and measurements to be made. 10.The records to be maintained. 11.The date of approval of the protocol by the sponsor and the dated signature of the study director. 12.A statement of the proposed statistical methods	6. Where applicable, the number, body weight, sex, source of supply, species, strain, substrain, and age of the test system. 7. The procedure for identification of the test system. 8. A description of the experimental design, including methods for the control of bias. 9. Where applicable, a description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test, control, or reference substances before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications. 10.The route of administration and the reason for its choice. 11.Each dosage level, expressed in milligrams per kilogram of body or test system weight or other appropriate units, of the test, control, or reference substance to be administered and the method and frequency of administration. 12.The type and frequency of tests, analyses, and	c. Name and address of the Study Director; d. Name and address of the Study Director; e. Name and address of the Study Director; f. Name and address of the Study Director; g. Name and address of the Principal Investigator(s), and the phase(s) of the study delegated by the Study Director and under the responsibility of the Principal Investigator(s). 3. Dates a. The date of approval of the study plan by signature of the Study Director. The date of approval of the study plan by signature of the test facility management and sponsor if required by national regulation or legislation in the country where the study is being performed. b. The proposed experimental starting and completion dates. 4. Test Methods Reference to the OECD Test Guideline or other test guideline or method to be used. 5. Issues (where applicable) a. The justification for selection of the test system; b. Characterisation of the test system, such as the species, strain, substrain, source of supply, number, body weight range, sex, age and other pertinent information; c. The method of administration and the reason for its choice;

	to be used.	measurements to be made. 13.The records to be maintained. 14.The date of approval of the protocol by the sponsor and the dated signature of the study director. 15.A statement of the proposed statistical method.	d. The dose levels and/or concentration(s), frequency, ar duration of administration/ application; e) Detailed information on the experimental design, including a description of the chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed, and statistical methods to be used (if any). 6. Records A list of records to be retained.
Protocol Amendment	58.120 (b) All changes in or revisions of an approved protocol and the reasons therefore shall be documented, signed by the study director, dated, and maintained with the protocol.	792.120 (b) All changes in or revisions of an approved protocol and the reasons therefor shall be documented, signed by the study director, dated, and maintained with the protocol.	Section II 8.1.2. a) Amendments to the study plan should be justified and approved by dated signature of the Study Director and maintained with the study pla
Protocol Deviation			Section II 8.1.2. b) Deviations from the study plan should be described, explained, acknowledged and dated in a timely fashion by the Study Director and/or Principal Investigator(s) and maintained with the study raw data.
Protocol for Short-term Studies			Section II 8.1.3. For short-term studies, a general study plan accompanied by a study specific supplement may be used.
Conduct of a Study in Accordance with the Protocol	58.130 (a) The nonclinical laboratory study shall be conducted in accordance with the protocol.	792.130 (a) The study shall be conducted in accordance with the protocol.	Section II 8.3.2. The study should be conducted in accordance with the study plan.
Test System	58.130	792.130	

Conformity with the Protocol	(b) The test systems shall be monitored in conformity with the protocol.	(b) The test systems shall be monitored in conformity with the protocol.	
Labeling of Specimens	58.130 (c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.	792.130 (c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.	Section II 8.3.1. A unique identification should be given to each study. All items concerning this study should carry this identification. Specimens from the study should be identified to confirm their origin. Such identification should enable traceability, as appropriate for the specimen and study.
Availability of Gross Findings to Pathologists	58.103 (d) Records of gross findings for a specimen from postmortem observations should be available to a pathologist when examining that specimen histopathologically.	792.130 (d) In animal studies where histopathology is required, records of gross findings for a specimen from postmortem observations shall be available to a pathologist when examining that specimen histopathologically.	
Manual Recording of Data	58.130 (e) All data generated during the conduct of a nonclinical laboratory study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data.	792.130 (e) All data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data.	Section II 8.3.3. All data generated during the conduct of the study should be recorded directly, promptly, accurately, and legibly by the individual entering the data. These entries should be signed or initialled and dated.
Changes to Manually Recorded Data	58.130 (e) Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change.	792.130 (e) Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change.	Section II 8.3.4. Any change in the raw data should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or initialled by the individual making the change.

Automated Recording of Data	58.130 (e) In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input.	792.130 (e) In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input.	Section II 8.3.5. Data generated as a dir computer input should be identified at the time of data input by the individual(s) responsible for direct data entries.
Changes to Data Recorded by Automated Systems	58.130 (e) Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.	792.130 (e) Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.	Section II 8.3.5. Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.

Comparison of FDA, EPA, OECD GLP			Records & Reports
Topic	**FDA**	**EPA**	**OECD**
Final Report for each Study	58.185 (a) A final report shall be prepared for each nonclinical laboratory study	792.185 (a) A final report shall be prepared for each study	Section II 9.1.1. A final report should be prepared for each study. In the case of short term studies, a standardised final report accompanied by a study specific extension may be prepared.
	58.185 (a) A final report shall be prepared for each nonclinical laboratory study and shall include, but not necessarily be limited to, the following: 1. Name and address of the facility performing the study and the dates on which the study was initiated and completed. 2. Objectives and procedures stated in the approved protocol, including any changes in the original protocol. 3. Statistical methods employed for analyzing the data. 4. The test and control articles identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics. 5. Stability of the test and control articles under the conditions of administration. 6. A description of the methods used. 7. A description of the test system used. Where applicable, the final report shall include the	792.185 (a) A final report shall be prepared for each study and shall include, but not necessarily be limited to, the following: 1. Name and address of the facility performing the study and the dates on which the study was initiated and was completed, terminated, or discontinued. 2. Objectives and procedures stated in the approved protocol, including any changes in the original protocol. 3. Statistical methods employed for analyzing the data. 4. The test, control, and reference substances identified by name, chemical abstracts service (CAS) number or code number, strength, purity, and composition, or other appropriate characteristics. 5. Stability, and when relevant to the conduct of the study, the solubility of the test, control, and reference substances under the conditions of	Section II 9.2 Content of the Final Report The final report should include, but not be limited to, the following information: 1. Identification of the Study, the Test Item and Reference Item a. A descriptive title; b. Identification of the test item by code or name (IUPAC, CAS number, biological parameters, etc.); c. Identification of the reference item by name; d. Characterisation of the test item including purity, stability and homogeneity. 2. Information Concerning the Sponsor and the Test Facility a. Name and address of the sponsor; b. Name and address of any test facilities and test sites involved; c. Name and address of the Study Director; d. Name and address of the Principal Investigator(s) and the phase(s) of the study delegated, if

Content of Final Report	number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification. 8. A description of the dosage, dosage regimen, route of administration, and duration. 9. A description of all circumstances that may have affected the quality or integrity of the data. 10.The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study. 11.A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis. 12.The signed and dated reports of each of the individual scientists or other professionals involved in the study. 13.The locations where all specimens, raw data, and the final report are to be stored. 14.The statement prepared and signed by thequality assurance unit as described in Sec. 58.35(b)(7).	administration. 6. A description of the methods used. 7. A description of the test system used. Where applicable, the final report shall include the number of animals or other test organisms used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification. 8. A description of the dosage, dosage regimen, route of administration, and duration. 9. A description of all circumstances that may have affected the quality or integrity of the data. 10.The name of the study director, the names of other scientists or professionals and the names of all supervisory personnel, involved in the study. 11.A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis. 12.The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was	applicable; e. Name and address of scien having contributed reports to the final report. 3. Dates Experimental starting and completion dates. 4. Statement A Quality Assurance Programme statement listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data. 5. Description of Materials and Test Methods a. Description of methods and materials used; b. Reference to OECD Test Guideline or other test guideline or method. 6. Results a. A summary of results; b. All information and data required by the study plan; c. A presentation of the results, including calculations and determinations of statistical significance; d. An evaluation and discussion of the results and, where appropriate, conclusions. 7. Storage The location(s) where the study plan, samples of test and reference

		completed. 13.The locations where all specimens, raw data, and the final report are to be stored. 14.The statement prepared and signed by the quality assurance unit as described in Sec. 792.35(b)(7).	items, specimens, raw data and the final report are to be stored.
Reports of Individual Scientists or Other Professionals	58.185 (a) (12) The signed and dated reports of each of the individual scientists or other professionals involved in the study.	792.185 (a) (12) The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was completed.	Section II 9.1.2. Reports of Principal Investigators or scientists involved in the study should be signed and dated by them.
Signining of the Final Report	58.185(b) The final report shall be signed and dated by the study director.	792.185 (b) The final report shall be signed and dated by the study director.	Section II 9.1.3. The final report should be signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these Principles of Good Laboratory Practice should be indicated.
Corrections & Additions to the Final Report	58.185 (c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated	792.185 (c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and	Section II 9.1.4. Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director.

	by the person responsible.	dated by the person responsible. Modification of a final report to comply with the submission requirements of EPA does not constitute a correction, addition, or amendment to a final report.	
Reformatting of the Final Report			Section II 9.1.5. Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.
Copies of the Final Report		792.185 (d) A copy of the final report and of any amendment to it shall be maintained by the sponsor and the test facility.	
Storage & Retrieval of Records & Data	58.190 (a) All raw data, documentation, protocols, final reports, and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study shall be retained.	792.190 (a) All raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study shall be retained. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained after quality assurance verification. Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained.	Section II 10.1. The following should be retained in the archives for the period specified by the appropriate authorities: a. The study plan, raw data, samples of test and reference items, specimens, and the final report of each study; b. Records of all inspections performed by the Quality Assurance Programme, as well as master schedules; c. Records of qualifications, training, experience and job descriptions of personnel; d. Records and reports of the maintenance and calibration of apparatus; e. Validation documentation for computerised systems;

			f. The historical file of all Standard Operating Procedures; g. Environmental monitoring records.
Archives	58.190 (b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.	792.190 (b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents of specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.	Section II 3.4. Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.
Archivist	58.190 (c) An individual shall be identified as responsible for the archives.	792.190 (c) An individual shall be identified as responsible for the archives.	
Authorization to Enter Archives	58.190 (d) Only authorized personnel shall enter the archives.	792.190 (d) Only authorized personnel shall enter the archives.	Section II 10.3. Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.
Indexing of Archive	58.190 (e) Material retained or referred to in the archives shall be indexed to permit	792.190 (e) Material retained or referred to in the archives shall be indexed to permit	Section II 10.2 Material retained in the archives should be indexed so as to facilitate orderly storage and

	expedient retrieval.	expedient retrieval.	retrieval..
Record retention period	58.195 a. Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this chapter. b. Except as provided in paragraph (c) of this section, documentation records, raw data and specimens pertaining to a nonclinical laboratory study and required to be made by this part shall be retained in the archive(s) for whichever of the following periods is shortest: 1. A period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the nonclinical laboratory study were submitted, is approved by the Food and Drug Administration. This requirement does not apply to studies supporting investigational new drug applications (IND's) or applications for investigational device exemptions (IDE's), records of which shall be governed by the provisions of paragraph (b)(2) of this section. 2. A period of at least 5 years following the date on which the results of the nonclinical laboratory study are submitted to the Food and Drug Administration in support of an application for a research or marketing permit.	792.195 (a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this subchapter. (b) 1. Except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for a period of at least ten years following the effective date of the applicable final test rule. 2. In the case of negotiated testing agreements, each agreement will contain a provision that, except as provided in paragraph (c) of this section, documentation records, raw data,and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for a period of at least ten years following the publication date of the acceptance of a negotiated test agreement. 3. In the case of testing submitted under section 5, except for those items listed in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study	Section II 10.1. In the absence of a required retention period, the final disposition of any study materials should be documented. When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.

	3. In other situations (e.g., where the nonclinical laboratory study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.	and required to be retained by this part shall be retained in the archive(s) for a period of at least five years following the date on which the results of the study are submitted to the agency.	
Retention of Wet ecimens	58.195 (c) Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material, which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraphs (a) and (b) of this section.	792.195 (c) Wet specimens, samples of test, control, or reference substances, and specially prepared material which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, biological fluids, do not need to be retained after quality assurance verification. In no case shall retention be required for longer periods than those set forth in paragraph (b) of this section.	
Retention of Master Schedule, Copies of Protocols, & Records of QA Inspections	58.195 (d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by Sec. 58.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified	792.195 (d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by Sec. 792.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time	

	in paragraphs (a) and (b) of this section.	specified in paragraph (b) of this section.	
Retention Training records & Job Descriptions	58.195 (e) Summaries of training and experience and job descriptions required to be maintained by Sec. 58.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraphs (a) and (b) of this section.	792.195 (e) Summaries of training and experience and job descriptions required to be maintained by Sec. 792.29 (b) may be retained along with all other testing facility employment records for the length of time specified in paragraph (b) of this section.	
Retention of Equipment Records & Reports	58.195 (f) Records and reports of the maintenance and calibration and inspection of equipment, as required by Sec. 58.63(b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.	792.195 (f) Records and reports of the maintenance and calibration and inspection of equipment, as required by Sec. 792.63 (b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.	
Retention of True Copies of Records	58.195 (g) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.	792.195 (i) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.	
Retention of Records When a Facility Goes Out of Business	58.195 (h) If a facility conducting nonclinical testing goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The Food and Drug Administration shall be notified in writing of such a transfer.	792.195 (g) If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer.	Section II 10.4. If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s).
		792.195	

Waiver of Retention of Retention Requirements		(h) Specimens, samples, or other non-documentary materials need not be retained after EPA has notified in writing the sponsor or testing facility holding the materials that retention is no longer required by EPA. Such notification normally will be furnished upon request after EPA or FDA has completed an audit of the particular study to which the materials relate and EPA has concluded that the study was conducted in accordance with this part.	

Compliance References (GLP)

Comparison Chart - FDA/EPA & OECD

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Comparison of FDA, EPA, OECD GLP			**Disqualification**
Topic	**FDA**	**EPA**	**OECD**
Purpose	58.200 a. The purposes of disqualification are: 1. To permit the exclusion from consideration of completed studies that were conducted by a testing facility which has failed to comply with the requirements of the good laboratory practice regulations until it can be adequately demonstrated that such noncompliance did not occur during, or did not affect the validity or acceptability of data generated by, a particular study; and 2. to exclude from consideration all studies completed after the date of disqualification until the facility can satisfy the Commissioner that it will conduct studies in compliance with such regulations.		
Obligation to Submit Studies from a Disqualified Facility	58.200 (b) The determination that a nonclinical laboratory study may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.		
Grounds for Disqualification	58.202 The Commissioner may disqualify a testing facility upon finding all of the following: a. The testing facility failed to comply with one or more of the regulations set forth in this part (or any other regulations regarding such facilities in this chapter); b. The noncompliance adversely affected the validity of the nonclinical laboratory studies; and c. Other lesser regulatory actions (e.g., warnings or rejection of individual studies) have not been or will probably not be adequate to achieve compliance with the good laboratory practice regulations.		
	58.204 a. Whenever the Commissioner has information indicating that		

Opportunity for a Hearing	grounds exist under Sec. 58.202 which in his opinion justify disqualification of a testing facility, he may issue to the testing facility a written notice proposing that the facility be disqualified. b. A hearing on the disqualification shall be conducted in accordance with the requirements for a regulatory hearing set forth in part 16 of this chapter.		
Final Order on Disqualification	58.206 a. If the Commissioner, after the regulatory hearing, or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, makes the findings required in Sec. 58.202, he shall issue a final order disqualifying the facility. Such order shall include a statement of the basis for that determination. Upon issuing a final order, the Commissioner shall notify (with a copy of the order) the testing facility of the action. b. If the Commissioner, after a regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, does not make the findings required in Sec. 58.202, he shall issue a final order terminating the disqualification proceeding. Such order shall include a statement of the basis for that determination. Upon issuing a final order the Commissioner shall notify the testing facility and provide a copy of the order.		
Review of Applications Containing Studies from a Disqualified Facility	58.210 (a) Once a testing facility has been disqualified, each application for a research or marketing permit, whether approved or not, containing or relying upon any nonclinical laboratory study conducted by the disqualified testing facility may be examined to determine whether such study was or would be essential to a decision. If it is determined that a study was or would be essential, the Food and Drug Administration shall also determine whether the study is acceptable, notwithstanding the disqualification of the facility. Any study done by a testing facility before or after disqualification may be presumed to be unacceptable, and the person relying on the study may be required to establish that the study was not affected by the circumstances that led to the disqualification, e.g., by submitting validating information. If the study		

	is then determined to be unacceptable, such data will be eliminated from consideration in support of the application; and such elimination may serve as new information justifying the termination or withdrawal of approval of the application.		
Acceptability of Studies Begun After Disqualification	58.210 (b) No nonclinical laboratory study begun by a testing facility after the date of the facility's disqualification shall be considered in support of any application for a research or marketing permit, unless the facility has been reinstated under Sec. 58.219. The determination that a study may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.		
Public Disclosure of Information	58.213 (a) Upon issuance of a final order disqualifying a testing facility under Sec. 58.206(a), the Commissioner may notify all or any interested persons. Such notice may be given at the discretion of the Commissioner whenever he believes that such disclosure would further the public interest or would promote compliance with the good laboratory practice regulations set forth in this part. Such notice, if given, shall include a copy of the final order issued under Sec. 58.206(a) and shall state that the disqualification constitutes a determination by the Food and Drug Administration that nonclinical laboratory studies performed by the facility will not be considered by the Food and Drug Administration in support of any application for a research or marketing permit. If such notice is sent to another Federal Government agency, the Food and Drug Administration will recommend that the agency also consider whether or not it should accept nonclinical laboratory studies performed by the testing facility. If such notice is sent to any other person, it shall state that it is given because of the relationship between the testing facility and the person being notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified. (b) A		

	determination that a testing facility has been disqualified and the administrative record regarding such determination are disclosable to the public under part 20 of this chapter.		
Alternatives to Disqualification	58.215 a. Disqualification of a testing facility under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, institute against a testing facility and/or against the sponsor of a nonclinical laboratory study that has been submitted to the Food and Drug Administration any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and prior to, simultaneously with, or subsequent to, disqualification. The Food and Drug Administration may also refer the matter to another Federal, State, or local government law enforcement or regulatory agency for such action as that agency deems appropriate. b. The Food and Drug Administration may refuse to consider any particular nonclinical laboratory study in support of an application for a research or marketing permit, if it finds that the study was not conducted in accordance with the good laboratory practice regulations set forth in this part, without disqualifying the testing facility that conducted the study or undertaking other regulatory action.		
Sponsor Suspension or Termination	58.217 Termination of a testing facility by a sponsor is independent of, and neither in lieu of nor a precondition to, proceedings or actions authorized by this subpart. If a sponsor terminates or suspends a testing facility from further participation in a nonclinical laboratory study that is being conducted as part of any application for a research or marketing permit that has been submitted to any Center of the Food and Drug Administration (whether approved or not), it shall notify that Center in writing within 15 working days of the action; the notice shall include a statement of the reasons for such action. Suspension or termination of a testing facility by a sponsor does not relieve it of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.		
	58.219		

Reinstatement of a Disqualified Testing Facility	A testing facility that has been disqualified may be reinstated as an acceptable source of nonclinical laboratory studies to be submitted to the Food and Drug Administration if the Commissioner determines, upon an evaluation of the submission of the testing facility, that the facility can adequately assure that it will conduct future nonclinical laboratory studies in compliance with the good laboratory practice regulations set forth in this part and, if any studies are currently being conducted, that the quality and integrity of such studies have not been seriously compromised. A disqualified testing facility that wishes to be so reinstated shall present in writing to the Commissioner reasons why it believes it should be reinstated and a detailed description of the corrective actions it has taken or intends to take to assure that the acts or omissions which led to its disqualification will not recur. The Commissioner may condition reinstatement upon the testing facility being found in compliance with the good laboratory practice regulations upon an inspection. If a testing facility is reinstated, the Commissioner shall so notify the testing facility and all organizations and persons who were notified, under Sec. 58.213 of the disqualification of the testing facility. A determination that a testing facility has been reinstated is disclosable to the public under part 20 of this chapter.		