|  |  |
| --- | --- |
| **1.**  | **TEST FACILITY ORGANIZATION AND PERSONNEL**  |
| **1.1**  | **Test Facility Management’s Responsibilities**  |  |  |  |  |  |  |
| 1.1.1  | Does the Test Facility Management ensure that Principles of Good Laboratory Practice are complied with, in its test facility?  |  |  |  |  |  |  |
| 1.1.2 (a)  | Does a statement exist to identify the individual(s) within a test facility who fulfil the responsibilities of management as defined by these Principles of Good Laboratory Practice?  |  |  |  |  |  |  |
| (b)  | Is there a sufficient number of qualified personnel, appropriate facilities, equipment and materials available for the timely and proper conduct of the study? |  |  |  |  |  |  |
| (c)  | Does the management maintain proper record of the qualifications, training and experience and job description for each professional and technical individual?  |  |  |  |  |  |  |
| (d)  | Does the management ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions? |  |  |  |  |  |  |
| (e)  | Are appropriate and technically valid Standard Operating Procedures (SOPs) established and followed? Are all the original and revised SOPs approved?  |  |  |  |  |  |  |
| (f)  | Is there a Quality Assurance Programme with designated personnel? Is the quality assurance responsibility being performed in accordance with the Principles of GLP? |  |  |  |  |  |  |
| (g)  | Does the management ensure that for each study, an individual with the appropriate qualifications, training, and experience is appointed as Study Director before the initiation of the study? Does a procedure exist for replacement of a Study Director and is this procedure documented?  |  |  |  |  |  |  |
| (h) | Are there multi-site studies available and if yes and if needed, a Principal Investigator is designated who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study? Does a procedure exist for replacement of a Principal Investigator and is this procedure documented?  |  |  |  |  |  |  |
| (i)  | Does the management ensure that there is a documented approval of the study plan by the Study Director?  |  |  |  |  |  |  |
| (j)  | Does the management ensure that the Study Director makes the approved study plan available to the Quality Assurance personnel?  |  |  |  |  |  |  |
| (k)  | Does the management ensure the maintenance of a historical file of all SOPs? |  |  |  |  |  |  |
| (l)  | Does the management ensure that an individual is identified as responsible for the management of the archive(s)?  |  |  |  |  |  |  |
| (m)  | Does the management ensure that a master schedule is maintained?  |  |  |  |  |  |  |
| (n)  | Does the management ensure that test facility supplies meet requirements appropriate to their use in a study?  |  |  |  |  |  |  |
| (o)  | Does the management ensure that for a multi-site study, clear lines of communication exist between the Study Director, Principal Investigator(s), the Quality Assurance Programme(s) and study personnel?  |  |  |  |  |  |  |
| (p)  | Does the management ensure that test and reference items are appropriately characterized?  |  |  |  |  |  |  |
| (q)  | Has the management established procedures to ensure that computerized systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with the Principles of Good Laboratory Practice?  |  |  |  |  |  |  |
| 1.1.3  | When a phase(s) of a study is conducted at a test site, does the test site management have the responsibilities as defined above, with the exceptions of 1.1.2(g), (I), (j) and (o)?  |  |  |  |  |  |  |
| 1.1.4 | **Number 8 - The Role and responsibilities of Study Director** |
| 1.1.4.1 | Is the management responsible for ensuring that the facility operates in compliance with GLP? |  |  |  |  |  |  |
| 1.1.4.2 | Is the management responsible for appointment of effective number of qualified and experienced staff including Study Directors and Principal Investigators? |  |  |  |  |  |  |
| 1.1.4.3 | Is there a procedure for selection and appointment of Study Directors, their deputies and Principal Investigators?  |  |  |  |  |  |  |
| 1.1.4.4 | Is there a training documentation including a training programme for Study Director’s work?Are training related records maintained? |  |  |  |  |  |  |
| 1.1.4.5 | Are minimum qualification criteria with communication, problem solving and managerial skills set for Study Director and are they documented in the personnel records? |  |  |  |  |  |  |
| 1.1.4.6  | Are the lines of authorities and communication and assigned responsibilities documented for and between Study Directors, Principal Investigators, the QA programmes and the study personnel? |  |  |  |  |  |  |
| 1.1.4.7 | Are there procedures and documentation necessary to replace a Study Director? |  |  |  |  |  |  |
| 1.1.4.8 | Does the Study Director assume responsibility for the performance of the study in compliance with GLP principles? |  |  |  |  |  |  |
| **1.1.5** | **Number 10 - Application of GLP Principles to Computerized Systems** |
| 1.1.5.1 | Is the management responsible for ensuring that computerized systems are suitable for intended purpose? |  |  |  |  |  |  |
| 1.1.5.2 | Are procedures established to ensure that systems are developed, validated, operated and maintained?  |  |  |  |  |  |  |
| 1.1.5.3 | Are personnel designated with specific responsibility for the development, validation, operation and maintenance of computerized systems? |  |  |  |  |  |  |
| 1.1.5.4 | Are designated personnel suitably qualified with relevant experience and appropriate training to perform their duties? |  |  |  |  |  |  |
| 1.1.5.5 | Are personnel who develop, validate, operate and maintain computerized systems responsible for performing such activities? |  |  |  |  |  |  |
| 1.1.5.6 | Are QA responsibilities for computerized systems defined and described in written policies and procedures? |  |  |  |  |  |  |
| **1.2**  | **Study Director’s Responsibilities**  |
| 1.2.2 (a)  | Does the Study Director approve the study plan and any amendments to the plan by dated signature?  |  |  |  |  |  |  |
| (b)  | Does the Study Director ensure that the Quality Assurance personnel have a copy of the study plan and any amendments in a timely manner? Does the Study Director communicate effectively with the Quality Assurance personnel as required during the conduct of the study?  |  |  |  |  |  |  |
| (c)  | Does the Study Director ensure that study plans and amendments and SOP’s are available to study personnel? |  |  |  |  |  |  |
| (d)  | Does the Study Director ensure that the study plan and the final report for a multi-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? |  |  |  |  |  |  |
| (e)  | Does the Study Director ensure that the procedures specified in the study plan are followed? Does the Study Director 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?  Does the Study Director acknowledge deviations from the SOP’s during the conduct of the study? |  |  |  |  |  |  |
| (f)  | Does the Study Director ensure that all raw data generated are fully documented and recorded?  |  |  |  |  |  |  |
| (g)  | Does the Study Director ensure that computerized systems used in the study have been validated?  |  |  |  |  |  |  |
| (h)  | Does the Study Director 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 the Principles of Good Laboratory Practice?  |  |  |  |  |  |  |
| (i)  | Does the Study Director ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting material are archived?  |  |  |  |  |  |  |
| 1.2.3 | **Number 8 - The role and responsibilities of Study Director** |
| 1.2.3.1 | Is the Study Director responsible for the scientific conduct of a study?Can Study Director confirm the compliance of the study with respect of study initiation, study conduct, final report, archives, subcontracting and study plan amendments and deviations? |  |  |  |  |  |  |
| 1.2.4 | **Number 10 - Application of GLP Principles to Computerized Systems** |
| 1.2.4.1 | Is the Study Director aware of the involvement of computerized systems? |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1.3** | **Principal Investigator’s Responsibilities** |  |  |  |  |  |  |
| 1.3.1  | Does the Principal Investigator ensure that the delegated phases of the study are conducted in accordance with the applicable Principles of Good Laboratory Practice? |  |  |  |  |  |  |
| **1.4**  | **Study Personnel’s Responsibilities**  |
| 1.4.1  | Are all personnel involved in the conduct of the study knowledgeable in those parts of the Principles of Good Laboratory Practice, which are applicable to their involvement in the study? |  |  |  |  |  |  |
| 1.4.2  | Do the Study Personnel have access to the study plan and appropriate SOP’s applicable to their involvement in the study? Do they comply with the instructions given in these documents? Do they document and communicate all deviations from these instructions directly to the Study Director, and/or if appropriate, the Principal Investigator?  |  |  |  |  |  |  |
| 1.4.3 | Do the Study Personnel record raw data promptly and accurately and in compliance with the Principles of Good Laboratory Practice? Are they responsible for the quality of their data? |  |  |  |  |  |  |
| 1.4.4 | Do the Study Personnel exercise health precautions to minimize risk to themselves and to ensure the integrity of the study? Do they 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? |  |  |  |  |  |  |
| 1.5 | **Number 6 - Field studies** |
| 1.5.1 | Are field studies involved with GLP? If yes, are responsibilities of test facility management, Study Director and Principal Investigator defined? |  |  |  |  |  |  |
| 1.6 | **Number 7 - Short Term Studies** |
| 1.6.1 | Are short-term studies involved with GLP? If yes, are responsibilities of Study Director defined? |  |  |  |  |  |  |
| 1.7 | **Number 10 - Application of GLP Principles to Computerized Systems** |
| 1.7.1 | Are personnel who develop, validate, operate and maintain computerized systems responsible for performing such activities in accordance with the GLP Principles and recognized technical standards? |  |  |  |  |  |  |
| 1.7.2 | Has test facility appropriately qualified and experienced personnel including for computerized systems?  |  |  |  |  |  |  |
| 1.7.3 | Are there documented training programmes including both on-the-job training and external training courses for all personnel including computerized systems?  |  |  |  |  |  |  |
| 1.7.4 | Is attendance at external training courses and records of such training maintained? |  |  |  |  |  |  |

|  |  |
| --- | --- |
| **2**  | **QUALITY ASSURANCE PROGRAMME**  |
| **2.1**  | **General**  |
| 2.1.1  | Does a documented Quality Assurance Programme exist in the test facility to ensure that studies performed are in compliance with the Principles of Good Laboratory Practice?  |  |  |  |  |  |  |
| 2.1.2  | Is the Quality Assurance Programme carried out by an individual(s) designated by, and directly responsible to management and who is familiar with the test procedures?  |  |  |  |  |  |  |
| 2.1.3  | Is this individual(s) free of involvement in the conduct of the study being assured?  |  |  |  |  |  |  |
| **2.2**  | **Responsibilities of the Quality Assurance Personnel**  |
| 2.2.1 (a)  | Do the QA personnel maintain copies of all approved study plans and SOP’s in use in the test facility and have access to an up-to-date copy of the master schedule? |  |  |  |  |  |  |
| (b)  | Do the QA personnel verify that the study plan contains the information required for compliance with the Principles of Good Laboratory Practice, and is this verification documented?  |  |  |  |  |  |  |
| (c)  | Do the QA personnel conduct inspections to determine if all studies are conducted in accordance with the Principles of Good Laboratory Practice? Do they determine through inspections that study plans and SOP’s have been made available to study personnel and are being followed? Are records of such inspections (study-based inspectors, facility-based inspections, and process-based inspections) retained?  |  |  |  |  |  |  |
| (d)  | Do the QA personnel 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?  |  |  |  |  |  |  |
| (e)  | Do the QA personnel promptly report any inspection results in writing to the management and to the Study Director, and to the Principal Investigator(s) and the respective management, when applicable?  |  |  |  |  |  |  |
| (f)  | Do the QA personnel 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 also serves to confirm that the final report reflects the raw data).  |  |  |  |  |  |  |
| 2.3 | **Number 10 - Application of GLP Principles to Computerized Systems** |
| 2.3.1 | Does QA programme include procedures and practices that will assure that established standards are met for all phases of the validation, operation and maintenance of computerized systems? |  |  |  |  |  |  |
| 2.3.2 | Does QA programme include procedures and practices for the introduction of purchased systems and for the process of in-house development of computerized systems? |  |  |  |  |  |  |
| 2.3.4 | Do the QA personnel monitor the GLP compliance of computerized systems and are they given training in specialist techniques necessary? |  |  |  |  |  |  |
| 2.3.5 | Do QA personnel have, for review, direct read-only access to the data stored within a computerized system? |  |  |  |  |  |  |
| **3.**  | **FACILITIES**  |
| **3.1**  | **General** |
| 3.1.1  | Is the test facility of suitable size, construction and locations to meet the requirements of the study and to minimize disturbance that would interfere with the validity of the study? |  |  |  |  |  |  |
| 3.1.2  | Does the design of the test facility provide an adequate degree of separation of the different activities to assure the proper conduct of the study?  |  |  |  |  |  |  |
| **3.2**  | **Test system Facilities**  |
| 3.2.1  | Does the test facility 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 bio-hazardous?  |  |  |  |  |  |  |
| 3.2.2  | Are suitable rooms or areas available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems?  |  |  |  |  |  |  |
| 3.2.3  | Are there storage rooms or areas as needed for supplies and equipment? Are these separated from rooms or areas housing the test systems and do they provide adequate protection against infestation, contamination and/or deterioration?  |  |  |  |  |  |  |
| **3.3**  | **Facilities for Handling Test and Reference Items**  |
| 3.3.1  | To prevent contamination or mix-ups, are there separate rooms or areas for receipt and storage of the test and reference items, and for the mixing of the test items with a vehicle?  |  |  |  |  |  |  |
| 3.3.2  | Are the storage rooms or areas separate from rooms or areas containing the test systems? Are they adequate to preserve identity, concentration, purity and stability, and to ensure safe storage for hazardous substances? |  |  |  |  |  |  |
| 3.4  | **Archive Facilities**  |
| 3.4.1 | Are archive facilities provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens? Does the archives design and conditions protect the contents from untimely deterioration? |  |  |  |  |  |  |
| 3.5 | **Waste disposal** |  |
| 3.5.1 | Is the handling and disposal of wastes carried out in such a way that the integrity of studies is not jeopardized? (This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures)  |  |  |  |  |  |  |
| 3.6 | **Number 6 - Field studies** |
| 3.6.1 | Are field studies involved with GLP? If yes, has due concern been given for the aspects addressed above especially with regard to handling test and reference items and waste disposal? |  |  |  |  |  |  |
| 3.7 | **Number 7 - Short Term Studies** |
| 3.7.1 | Are short-term studies involved with GLP? If yes, are procedures established to prevent and/or control potential contamination of the test system? |  |  |  |  |  |  |
| 3.8 | **Number 10 - Application of GLP Principles to Computerized Systems**  |
| 3.8.1 | Are adequate facilities and equipment giving consideration to the physical location of computer hardware, peripheral components, communications equipment and electronic storage media available for proper conduct of studies in compliance with GLP? |  |  |  |  |  |  |
| 3.8.2 | Are extremes of temperature and humidity, dust, electromagnetic interference and proximity to high voltage cables avoided, unless the equipment is specially designed to operate under such conditions? |  |  |  |  |  |  |
| 3.8.3 | Are electrical supply for computer equipment and, where appropriate back-up or uninterrupted supplies for computerized systems, whose sudden failure would affect the results of a study available? |  |  |  |  |  |  |
| 3.8.4 | Are adequate facilities provided for the secure retention of electrical storage media? |  |  |  |  |  |  |
| 3.8.5 | Are raw data from original laboratory records and documentation including data directly entered into a computer through an instrument interface (eg. electronic storage media, computer or instruments printouts and microfilm/fiche copies) defined for each computerized system? |  |  |  |  |  |  |
| 3.8.6 | Where computerized systems are used to capture, process, report or store raw data electronically, does system design provide for the retention of full audit trails to show all changes to the data without obscuring the original data with timed and dated (electronic) signatures and reasons for change? |  |  |  |  |  |  |
| 3.8.7 | Are documented security procedures in place for protection of hardware, software and data from corruption or unauthorized modification or loss? |  |  |  |  |  |  |
| 3.8.8 | Are there written management policies covering the acquisition, requirements, design, validation, testing, installation, operation, maintenance, staffing, control, auditing, monitoring and retirement of computerized systems? |  |  |  |  |  |  |
| 3.8.9 | Are SOPs available for operation, security, authorization for programme changes, authorization for changes to equipment, periodic testing, maintenance, software development and acceptance testing, stored data and contingency plans, archiving or retrieval, monitoring and auditing of computerized systems? |  |  |  |  |  |  |
| 3.8.10 | Are archiving data applied consistently to all data types? |  |  |  |  |  |  |
| 3.9 | **Number 10 - Application of GLP Principles to Computerized Systems Contd.** |
| 3.9.1 | Are electronic data stored with the same levels of access control, indexing and expedient retrieval as other types of data? Are raw data from original laboratory records and documentation including data directly entered into a computer through an instrument interface (eg. electronic storage media, computer or instruments printouts and microfilm/fiche copies) defined for each computerized system? |  |  |  |  |  |  |
| 3.9.2 | Where computerized systems are used to capture, process, report or store raw data electronically, does system design provide for the retention of full audit trails to show all changes to the data without obscuring the original data with timed and dated (electronic) signatures and reasons for change? |  |  |  |  |  |  |
| 3.9.3 | Are documented security procedures in place for protection of hardware, software and data from corruption or unauthorized modification or loss? |  |  |  |  |  |  |
| 3.9.4 | Are there written management policies covering the acquisition, requirements, design, validation, testing, installation, operation, maintenance, staffing, control, auditing, monitoring and retirement of computerized systems? |  |  |  |  |  |  |
| 3.9.5 | Are SOPs available for operation, security, authorization for programme changes, authorization for changes to equipment, periodic testing, maintenance, software development and acceptance testing, stored data and contingency plans, archiving or retrieval, monitoring and auditing of computerized systems? |  |  |  |  |  |  |
| 3.9.6 | Are archiving data applied consistently to all data types? |  |  |  |  |  |  |
| 3.9.7 | Are electronic data stored with the same levels of access control, indexing and expedient retrieval as other types of data? |  |  |  |  |  |  |
| 4.  | **APPARATUS, MATERIALS AND REAGENTS**  |
| 4.1  | Is the apparatus (including validated computerized systems) used for the generation, storage, and retrieval of data, and for controlling environmental factors relevant to the study, suitably located and of appropriate design and adequate capacity?  |  |  |  |  |  |  |
| 4.2 | Is the apparatus used in a study periodically inspected, cleaned, maintained and calibrated according to SOP’s? Are records of these activities maintained? Is calibration, where appropriate, traceable to national or international standards of measurement? |  |  |  |  |  |  |
| 4.3  | Do the apparatus and materials used in a study interfere adversely with the test systems?  |  |  |  |  |  |  |
| 4.4 | Are chemicals, reagents and solutions labeled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions? Is information concerning source, preparation date and stability available? (The expiry date may be extended on the basis of documented evaluation or analysis) |  |  |  |  |  |  |
| 4.5 | **Number 6 - Field studies** |
| **4.5.1** | Are field studies involved with GLP? If yes, are transportation of equipment and keeping records of periodic inspection, cleaning, maintenance and calibration described in SOPs? |  |  |  |  |  |  |
| 4.6 | **Number 7 - Short Term Studies** |
|  | Are short-term studies involved with GLP? If yes, does calibration provide for traceability of measurements to national or international physical quantities?Are apparatus checked periodically for continuing accuracy of measurement and is the calibration status of reference items retained? |  |  |  |  |  |  |
| 4.7 | **Number 10 - Application of GLP Principles to Computerized Systems** |
| 4.7.1 | Are procedures established to computerized systems understood, followed and effectively monitored? |  |  |  |  |  |  |
| 4.7.2 | Are GLP principles applied to both hardware (computer units and peripheral components) and software (programmes that control the operation of computerized system)? |  |  |  |  |  |  |
| 4.7.3 | Are appropriate communication controls for security and system integrity addressed during the development, validation, operation and maintenance of computerized system; between computers or between computers and peripheral components? |  |  |  |  |  |  |
| 4.7.4 | Are there documented procedures covering both routine preventive maintenance and fault repair with detailed roles and responsibilities of personnel involved?  |  |  |  |  |  |  |
| 4.7.5 | If maintenance activities have necessitated changes to hardware and/or software, is the system validated again? |  |  |  |  |  |  |
| 4.7.6 | Are records maintained of any problems or inconsistencies detected and any remedial action taken, during the daily operation of the system? |  |  |  |  |  |  |
| 4.7.7 | Are procedures in place describing the measures to be taken in the event of partial or total failure of a computerized system? |  |  |  |  |  |  |
| 4.7.8 | Are contingency plans (planned hardware redundancy to transition back to paper-based system) documented, validated and the personnel involved in the conduct of studies aware of such plans? Do they ensure continued data integrity and not compromise the study? |  |  |  |  |  |  |
| 4.7.9 | Are procedures available for the recovery of a computerized system including for maintaining back-up copies of all software and validating the system again after recovery? |  |  |  |  |  |  |
| **5.**  | **TEST SYSTEMS**  |
| **5.1** | **Physical/Chemical**  |
| 5.1.1  | Is the apparatus used for the generation of physical/chemical data suitably located and of appropriate design and adequate capacity? |  |  |  |  |  |  |
| 5.1.2  | Is the integrity of the physical/chemical test systems ensured?  |  |  |  |  |  |  |
| 5.2 | **Number 7 - Short Term Studies** |
| **5.2.1** | Are short-term studies involved with GLP? If yes, are apparatus periodically inspected, cleaned, maintained and calibrated according to SOPs? |  |  |  |  |  |  |
| **5.3** | **Biological**  |
| 5.3.1  | Are proper conditions established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data?  |  |  |  |  |  |  |
| 5.3.2 | Are newly received animal and plant test systems isolated until their health status has been evaluated? If any unusual mortality or morbidity occurs, is this lot excluded from use in the studies, and, when appropriate, humanely destroyed? At the experimental starting date of a study, are test systems checked to ensure that they are free of any disease or condition that might interfere with the purpose or conduct of the study? Are test systems that become diseased or injured during the course of the study isolated and treated, if necessary, to maintain the integrity of the study? Is all diagnosis and treatment of any disease before or during a study recorded? |  |  |  |  |  |  |
| 5.3.3  | Are records maintained of source, date of arrival, and arrival conditions of test systems?  |  |  |  |  |  |  |
| 5.3.4  | Are biological test systems acclimatized to the test environment for an adequate period before the first administration or application of the test or reference item?  |  |  |  |  |  |  |
| 5.3.5  | Does all the information needed to properly identify the test systems appear on their housing or containers? Is appropriate identification given, wherever possible, to individual test systems that are to be removed from their housing or containers during the conduct of the study?  |  |  |  |  |  |  |
| 5.3.6  | During use, is the housing or containers for test systems cleaned and sanitized at appropriate intervals? Is any material that comes into contact with the test system checked for being free of contaminants at levels that would interfere with the study? Is bedding for animals changed as required by sound husbandry practice? Is the use of pest control agents documented?  |  |  |  |  |  |  |
| 5.3.7  | Are test systems used in field studies located so as to avoid interference in the study from spray drift and from past usage of pesticides?  |  |  |  |  |  |  |
| 5.4 | **Number 6 - Field studies** |
| **5.4.1** | Are field studies involved with GLP? If yes, are test systems utilized in field visits identified in the study plan with necessary pre-treatment controls? |  |  |  |  |  |  |
| 5.5 | **Number 7 - Short Term Studies** |
| **5.5.1** | Are short-term studies involved with GLP? If yes, is due consideration given to test system information, characterization of the test system, isolation of test systems, control of interfering materials in in vitro studies, characterization of culture media and test system use? |  |  |  |  |  |  |
| **6.**  | **TEST AND REFERENCE ITEMS**  |
| **6.1**  | **Receipt, Handling, Sampling and Storage**  |
| 6.1.1  | Are records maintained for test item and reference item characterization, date of receipt, expiry date, and quantities received and used in studies?  |  |  |  |  |  |  |
| 6.1.2  | Are handling, sampling and storage procedures identified in order that the homogeneity and stability are assured to the degree possible and contamination or mix-up is precluded?  |  |  |  |  |  |  |
| 6.1.3  | Do storage container(s) carry identification information, expiry date, and specific storage instructions?  |  |  |  |  |  |  |
| 6.2 | **Number 6 - Field studies** |
| **6.2.1** | Are field studies involved with GLP? If yes, when test and reference items are received, handled, sampled and stored, is documentation with regard to source, mode of transfer with retention of shipping documents, date of receipt, condition of substance on receipt, storage location and conditions, log documenting distribution, accounting for the total amount of the test item and final disposal available at the site? |  |  |  |  |  |  |
| **6.3**  | **Characterization**  |
| 6.3.1  | Is each test and reference system appropriately identified e.g. code, CAS number (Chemical Abstract Service Registry Number), name, and biological parameters?  |  |  |  |  |  |  |
| 6.3.2  | For each study, is the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items, known? |  |  |  |  |  |  |
| 6.3.3  | In cases where the sponsor supplies the test item, is there a mechanism developed in cooperation between the sponsor and the test facility, to verify the identity of the test item subject to the study?  |  |  |  |  |  |  |
| 6.3.4 |  Is the stability of test and reference items under storage and test conditions known for all studies?  |  |  |  |  |  |  |
| 6.3.5  | If the test item is administered or applied in a vehicle, is the homogeneity, concentration and stability of the test item in that vehicle determined? (For test items used in field studies (e.g. tank mixes), these may be determined through separate laboratory experiments)  |  |  |  |  |  |  |
| 6.3.6 | Is a sample for analytical purposes taken from each batch of test items retained for all studies except short-term studies?  |  |  |  |  |  |  |
| 6.4 | **Number 6 - Field studies** |
| 6.4.1 | Are field studies involved with GLP? If yes, are all characterization records and data available at each site? |  |  |  |  |  |  |
| 6.5 | **Number 7 - Short Term Studies** |
| 6.5.1 | Are short-term studies involved with GLP? If yes, is characterization information available for each batch of test and reference item? |  |  |  |  |  |  |
| **7.**  | **STANDARD OPERATING PROCEDURES**  |
| 7.1  | Does the test facility have management approved written SOP’s intended to ensure the quality and integrity of the data generated by that test facility? Are revisions to SOPs approved by the test facility management?  |  |  |  |  |  |  |
| 7.2  | Does each separate test facility unit or area have current SOP’s relevant to the activities being performed therein available immediately? (Published text books, analytical methods, articles and manuals may be used as supplements to these SOPs)  |  |  |  |  |  |  |
| 7.3  | Are deviations from SOPs related to the study documented, and acknowledged by the Study Director and the Principal Investigator(s), as applicable?  |  |  |  |  |  |  |
| 7.4  | Are SOP’s available for, but not limited to, the following categories of test facility activities (the details given under each heading are to be considered as illustrative examples?):  |  |  |  |  |  |  |
| **7.5** | **Test and Reference Items**  |
| **7.5.1** | Receipt, identification, labelling, handling, sampling and storage.  |  |  |  |  |  |  |
| **7.6** | **Apparatus, Materials and Reagents** **Apparatus:** Use, maintenance, cleaning and calibration  |  |  |  |  |  |  |
| 7.6.1 | **Computerized systems:** Validation, operation, maintenance, security, changes control and back up.  |  |  |  |  |  |  |
| 7.6.2 | **Materials, Reagents and Solutions** Preparation and labelling.  |  |  |  |  |  |  |
| **7.7**  | **Record-keeping, Reporting, Storage and Retrieval:** Coding of studies, data collection, preparation of reports, indexing systems, handling of data including the use of computerized systems.  |  |  |  |  |  |  |
| **7.8**  | **Test System (where appropriate)**  |
| 7.8.1 | Room preparations and environmental room conditions for the test system.  |  |  |  |  |  |  |
| 7.8.2 | Procedures for receipt, transfer, proper placement, characterization, identification and care of the test system.  |  |  |  |  |  |  |
| 7.8.3 | Test system preparation, observations and examinations, before, during, and at the conclusion of the study.  |  |  |  |  |  |  |
| 7.8.4 | Handling of test system individuals found moribund or dead during the study.  |  |  |  |  |  |  |
| 7.8.5 | Collection, identification and handling of specimens including necropsy and histopathology.  |  |  |  |  |  |  |
| 7.8.6 | Siting and placement of test systems in test plots.  |  |  |  |  |  |  |
| 7.8.7  | Quality Assurance Procedures Operation of Quality Assurance personnel in planning, scheduling, performing, documenting and reporting inspections.  |  |  |  |  |  |  |
| 7.9 | **Number 6 - Field studies** |
|  | Are field studies involved with GLP? If yes, are test item storage, data collection, in the field, application equipment calibration, test item application, and specimen collection and transportation described in SOPs and methodologies included in the study plan? |  |  |  |  |  |  |
| **7.10** | **Number 7 - Short Term Studies** |
| **7.10.1** | Are short-term studies involved with GLP? If yes, are appropriate SOPs are produced for the studies performed?  |  |  |  |  |  |  |
| **8.**  | **PERFORMANCE OF THE STUDY**  |
| **8.1**  | **Study Plan**  |
| 8.1.1  | Does a written plan exist prior to the initiation of each study? Is the study plan approved by dated signature of the Study Director and verified for GLP compliance by QA personnel as specified in Section 2.2.1(b)? Is the study plan 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? |  |  |  |  |  |  |
| 8.1.2 a)  | Are amendments to the study plan justified and approved by dated signatures of the Study Director and maintained with the study plan?  |  |  |  |  |  |  |
| b)  | Are deviations from the study plan 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?  |  |  |  |  |  |  |
| 8.1.3  | For short-term studies, is the general study plan accompanied by a study specific supplement? (Optional)  |  |  |  |  |  |  |
| 8.1.4 | **Number 6 - Field studies** |
| **8.1.4.1** | Are field studies involved with GLP? If yes, is the flexibility needed for field visits is reflected in the study plans and are communication procedures established between the personnel at the test sites and the Study Director when approving study plan amendments? |  |  |  |  |  |  |
| **8.1.5** | **Number 7 - Short Term Studies** |
| **8.1.5.1** | Are short-term studies involved with GLP? If yes, is a written study plan approved by dated signature of Study Director and verified for GLP compliance by QA personnel and also approved by test facility management and the sponsor with study specific supplement available?  |  |  |  |  |  |  |
| **8.2**  | **Content of the Study Plan**  |
|  | Does the study plan contain at least the following information? |  |  |  |  |  |  |
| 8.2.1  | 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.  |  |  |  |  |  |  |
| 8.2.2  | Information Concerning the Sponsor and 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 phases of the study delegated by the Study Director and under the responsibility of the Principal Investigator(s).  |  |  |  |  |  |  |
| 8.2.3  | Dates  |  |  |  |  |  |  |
| a)  | The date of approval of the study plan by signature of the Study Director.  |  |  |  |  |  |  |
| b)  | The proposed experimental starting and completion dates.  |  |  |  |  |  |  |
| 8.2.4  | Test Methods Reference to the OECD Guideline or other test guideline or method to be used.  |  |  |  |  |  |  |
| 8.2.5  | Issues (where applicable)  |  |  |  |  |  |  |
| a)  | The justification for selection of the test system.  |  |  |  |  |  |  |
| b)  | Characterization 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.  |  |  |  |  |  |  |
| d)  | The dose levels and/or concentration(s), frequency, and 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).  |  |  |  |  |  |  |
| 8.2.6  | Records A list of records to be retained |  |  |  |  |  |  |
| 8.2.7 | **Number 7 - Short Term Studies** |
|  | Are short-term studies involved with GLP? If yes, does the study plan contain as given in II.8.2 of Number 07? |  |  |  |  |  |  |
| **8.3**  | **Conduct of the Study**  |
| 8.3.1  | Is a unique identification given to each study, and do all items concerning that study carry this identification? Are specimens from the study identified to confirm their origin? (Such identification should enable traceability, as appropriate for the specimen and study).  |  |  |  |  |  |  |
| 8.3.2  | Is the study conducted in accordance with the study plan?  |  |  |  |  |  |  |
| 8.3.3  | Are all data generated during the conduct of the study recorded directly, promptly, accurately, and legibly by the individual entering the data, and have all entries been signed or initialed and dated?  |  |  |  |  |  |  |
| 8.3.4  | Are any changes in the raw data made so as not to obscure the previous entry and have the reasons for the changes been indicated, and dated and signed?  |  |  |  |  |  |  |
| 8.3.5 | Is data generated as a direct computer input identified at the time of data input by the individual(s) responsible for direct data entries? Does computerized system design 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 these changes, for example, by use of timed and dated (electronic) signatures). Are the reasons for the changes given? |  |  |  |  |  |  |
| 8.3.6 | **Number 6 - Field studies** |
| **8.3.6.1** | Are field studies involved with GLP? If yes, are quality control measures for evaluation of reproducibility, freedom from interferences and confirmation of analyticdentity etc. addressed in SOPs and/or in the study plan? |  |  |  |  |  |  |

|  |  |
| --- | --- |
| **9.**  | **REPORTING OF STUDY RESULTS**  |
| **9.1**  | **General**  |
| 9.1.1  | Is a final report prepared for each study? (In the case of short-term studies, a standardized final report accompanied by a study specific extension may be prepared).  |  |  |  |  |  |  |
| 9.1.2  | Are reports of Principal Investigators or scientists involved in the study signed and dated by them?  |  |  |  |  |  |  |
| 9.1.3 | Is the final report signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the data? Is the extent of compliance with GLP principles indicated? |  |  |  |  |  |  |
| 9.1.4 | Are corrections and additions to a final report made in the form of amendments? Do such amendments clearly specify the reason(s) for the corrections or additions and are they signed and dated by the Study Director? |  |  |  |  |  |  |
| 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). |  |  |  |  |  |  |
| 9.2 | **Number 6 - Field studies** |
| **9.2.1** | Are field studies involved with GLP? If yes, are reports of the Principal Investigator(s) attached to the overall study report by the Study Director as appendices? |  |  |  |  |  |  |
| 9.3 | **Number 7 - Short Term Studies** |  |  |  |  |  |  |
| **9.3.1** | Are short-term studies involved with GLP? If yes, is a standardized final report accompanied by a study specific extension prepared? |  |  |  |  |  |  |
| **9.4** | **Content of the Final Report**  |
| **9.4.1** | Does the final report contain at least the following information:  |  |  |  |  |  |  |
| 9.4.2  | 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)  | Characterization of the test item, including purity, stability and homogeneity.  |  |  |  |  |  |  |
| 9.4.3 | 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 applicable.  |  |  |  |  |  |  |
| e)  | Name and address of scientists having contributed reports to the final report  |  |  |  |  |  |  |
| 9.4.4 | Dates Experimental starting and completion dates. |  |  |  |  |  |  |
| 9.4.5 | Statement A QA 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).  |  |  |  |  |  |  |
| 9.4.6 | 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.  |  |  |  |  |  |  |
| 9.4.7 | 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.  |  |  |  |  |  |  |
| 9.4.8 |  Storage The location(s) where the study plan, samples of test and reference items, specimens, raw data and the final report are to be stored. |  |  |  |  |  |  |
| **10.**  | **Storage and retention of records and materials**  |  |  |  |  |  |  |
| 10.1  | Have the following been retained in the archives?  |  |  |  |  |  |  |
| 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 QA 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 computerized systems.  |  |  |  |  |  |  |
| f)  | The historical file of all SOP’s.  |  |  |  |  |  |  |
| g)  | Environmental monitoring records.  |  |  |  |  |  |  |
| 10.2  | Is the material retained in the archives indexed so as to facilitate orderly storage and retrieval?  |  |  |  |  |  |  |
| 10.3  | Is access to the archives limited to only personnel authorized by the management?  |  |  |  |  |  |  |
| **10.3.1** | Is movement of material in and out of the archives properly recorded?  |  |  |  |  |  |  |
| 10.4  | Is there a documented procedure for the transfer of material stored in the test facility archives to the archives of the sponsor(s) of the study(s), in case the test facility goes out of business and has no legal successor?  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 10.5 | **Number 6 - Field studies** |  |  |  |  |  |  |
|  | Are field studies involved with GLP? If yes, are temporary storage facilities at all test sites adequate to ensure the integrity of the study materials? |  |  |  |  |  |  |
| 11 | **Number 3 – Conduct of Laboratory Inspections & Study Audits** |
| 11.1 | Test Facility Inspections |  |  |  |  |  |  |
| 11.1.1 | Are management structure, physical layout of buildings and rage of studies pre-inspected? |  |  |  |  |  |  |
| 11.1.2  | Is an opening meeting conducted to inform the management and staff of the facility about the inspection? |  |  |  |  |  |  |
| 11.1.3 | Has the inspection covered the following? |  |  |  |  |  |  |
| **a)** | Organization and personnel; Organizational structure, sufficient qualified personnel, staff services and support services, training of staff and healthcare surveillance |  |  |  |  |  |  |
| **b)** | Quality Assurance Programme; Qualifications, systems and methods for QA inspection and monitoring of studies, system for recording observations made during QA monitoring |  |  |  |  |  |  |
| **c)** | Facilities: size, design and location, layout, environmental control and monitoring, housekeeping to meet the demand of studies |  |  |  |  |  |  |
| **d)** | Test systems: Procedures for handling and control of test systems |  |  |  |  |  |  |
| **e)** | T Test and reference substances: Procedures for identity, potency, quantity, composition, receive and store of test and reference substances in accordance with specifications |  |  |  |  |  |  |
| **f)** | Standard Operating Procedures: Availability of documented procedures for controlling facility operations |  |  |  |  |  |  |
| **g)** | Performance of the study: Availability and conducting of Study plans in accordance with GLP Principles |  |  |  |  |  |  |
| **h)** | Reporting of study results: Final reports |  |  |  |  |  |  |
| **i)** | Storage and retention of records: Provisions for safe storage and retention of records and materials |  |  |  |  |  |  |
| 11.2 | **Study audits** |
| 11.2.1 | Are there specific study audits? |  |  |  |  |  |  |
| 11.3 | Is a closing meeting conducted after completion of inspection and study audit? |  |  |  |  |  |  |
| 11.4 | **Number 9 - Preparation of GLP Inspection Reports** |
|  | Is the GLP inspection and audit report prepared including a summary, an introduction, a narrative of the exit discussion and annexes as per Number 9?Are the reports signed and dated by the lead inspector and other inspectors? |  |  |  |  |  |  |

|  |  |
| --- | --- |
| 12 | **Number 4 – Quality Assurance and GLP** |
| 12.1 | Is a copy of the study plan and any amendments made available to QA by Study Director in a timely manner? |  |  |  |  |  |  |
| 12.2 | For multi-site studies, does a communication exist between Study Director, Principal Investigator, QA programme(s) and study personnel? |  |  |  |  |  |  |
| 12.3 | Is there a documented QA programme? |  |  |  |  |  |  |
| 12.4 | Is QA programme carried out by person(s) responsible to management who are familiar with test procedures? |  |  |  |  |  |  |
| 12.5 | Are they not involved in the conduct of study being assured? |  |  |  |  |  |  |
| 12.6 | Are responsibilities of QA personnel defined? |  |  |  |  |  |  |
| 12.7 | Is SOP available for planning, scheduling, performing, documenting and reporting inspections? |  |  |  |  |  |  |
| 12.8 | Are records of inspections and master schedules maintained? |  |  |  |  |  |  |
| 12.9 | Have QA personnel direct access to the top management? |  |  |  |  |  |  |
| 12.10 | Have QA personnel training, expertise and experience necessary to fulfill their responsibilities? |  |  |  |  |  |  |
| 12.11 | Is there a documented training programme encompassing all aspects of QA work? |  |  |  |  |  |  |
| 12.12 | Are training of QA personnel documented and their competence evaluated and up-to-date records kept and retained? |  |  |  |  |  |  |
| 12.13 | Are SOPs reviewed before use by QA personnel and amendments to study plans are copied to them for effective monitoring? |  |  |  |  |  |  |
| 12.14 | Are study based inspections, facility based inspections and process based inspections performed? |  |  |  |  |  |  |
| 12.15 | Are all final reports for which GLP compliance is claimed audited by QA? |  |  |  |  |  |  |
| 12.16 | Is a quality assurance statement included in the final report? |  |  |  |  |  |  |
| 12.17 | Number 6 - Field visits |  |  |  |  |  |  |
| 12.17.1 | Are field visits involved with GLP? If yes, are there effective communications from Study Director/Principal Investigator to QA personnel? |  |  |  |  |  |  |
|  12.17.2 | Do written reports of QA personnel reach both management and the Study Director and are actual receipt of such reports by them documented in the raw data? |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 12.18 | **Number 7- Short Term Studies** |  |  |  |  |  |  |
|  | Are short-term studies involved with GLP? If yes, are study-based, facility-based and process-based inspections included?  |  |  |  |  |  |  |
| 12.19 | **Number 10 - Application of GLP Principles to Computerized Systems** |
| 12.19.1 | Are there procedures and practices that will assure that established standards are met for all phases of the validation, operation and maintenance of computerized systems? |  |  |  |  |  |  |
| 12.19.2 | Are there procedures and practices for the introduction of purchased systems and for the process of in-house development of computerized systems? |  |  |  |  |  |  |
| 12.19.3 | * Do QA personnel monitor the GLP compliance of computerized systems and are they given training on specialist techniques necessary?
 |  |  |  |  |  |  |
| 12.19.4 | Do QA personnel have, for review direct read-only access to the data stored within a computerized system? |  |  |  |  |  |  |
| 13 | **Number 5 – Compliance of Laboratory Suppliers with GLP principles** |
| 13.1 | Have the following means sought in selecting suppliers? |  |  |  |  |  |  |
| **13.2** | Test systems; characterization |  |  |  |  |  |  |
| **13.3** | Animal feed, bedding and water; Analysis of composition to avoid any potential interference or absence of contaminants |  |  |  |  |  |  |
| **13.4** | Radio-labeled chemicals; GLP compliance |  |  |  |  |  |  |
| **13.5** | Computer systems, applications software; Formal and documented acceptance-test by supplier before being put into service |  |  |  |  |  |  |
| **13.6** | Reference items; Meet GLP requirements for identity, purity and stability and any other characteristics |  |  |  |  |  |  |
| **13.7** | Apparatus; Calibration reports |  |  |  |  |  |  |
| **13,8** | Sterilized materials; Free from sources of infection or undesirable residues |  |  |  |  |  |  |
| **13.9** | Detergent and disinfectants; Removal the potential for contamination or interference |  |  |  |  |  |  |
| **13.10** | Products required for microbiology testing; Accreditation or validation document and labeling of source, identity, date of production, shelf life and storage conditions |  |  |  |  |  |  |
| **14**  | **Number 11 – The Role and Responsibilities of the Sponsor** |
| 14.1  | Does the sponsor understand the requirements of GLP in relation to the test facility management and the Study Director/Principal Investigator? |  |  |  |  |  |  |
| 14.2  | When commissioning a non-clinical health and environmental safety study, does sponsor ensure that the test facility is able to conduct the study in compliance with GLP? |  |  |  |  |  |  |

|  |  |
| --- | --- |
| 14.3  | Where several studies are presented to a regulatory authority in a single package, does the responsibility for the integrity of the assembled package on unaltered final reports lie with the sponsor? |
| 14.4 | Does the sponsor inform the test facility of any known potential risks of the test item to human health or the environment as well as any protective measures which should be taken by test facility staff? |
| 14.5 | If the characterization is conducted by the sponsor, is that mentioned in the final report? If the characterization data are not disclosed by the sponsor, is that fact explicitly mentioned in the final report? |
| 14.6 | Does the ultimate responsibility for the scientific validity lie with the Study Director and not with the sponsor? |

Note: The following OECD Documents are also applied and please refer to them as the case may be.

1. Number 13 – The application of the OECD Principles of GLP to the Organization and Management of Multi-Site Studies
2. Number 14 - The application of the Principles of GLP to in vitro Studies
3. Number 15 - Establishment and Control of Archives that Operate in compliance with the Principles of GLP

**For internal use only**

|  |  |  |
| --- | --- | --- |
| **Name of Test Facility** |  | **Acc. No.** |
| **Type of Visit** | **Document and Record Review/Pre-Assessment/ Initial Assessment / Surveillance / Re-Assessment**  |
| **Name of the Assessor** |  |
| **Date** |  |