Care, Housing and Containment of Biological Test Systems to Ensure Quality and Compliance

Dr. Labhu Sanghani, Director Global QA, Jai Research Foundation, Gujarat, India

JAI RESEARCH FOUNDATION

Abstract

A GLP test facility requires, adequate support facilities and conditions for the care, housing, and containment of animals and other biological test systems, to prevent stress and other potential problems which could affect the test system thereby, compromising the quality of data. The results of safety testing principally depends on the selection, health, handling, and containment of the test system and quality standards of the facility.

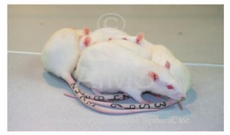
Various requirements to address and ensure quality standards are:

- Procedure for receipt, housing, quarantine, evaluation of health status, isolation of test system, treatment of diseased animals and its documentation.
- Identification and characterisation of the test system, from receipt to use in study.
- Cleaning and sanitisation of animal rooms, cages, racks and accessory equipment at appropriate intervals.
- Periodic analysis of all feed, water and bedding used for animals for contaminants that may interfere with the study.
- Monitoring and controlling of temperature, humidity, lighting, ventilation and drainage.
- Adequate number of qualified and trained personnel to assure treatment, care and handling of test system.
- Periodic inspection of test system facilities and documentation of such inspections.
- Isolation of test systems to ensure that the probability of potential contamination or cross-contamination or mix-up of test systems can be minimized.

Procurement-Quarantine-Health Status

- Selection of vendor with evaluation of acceptance criteria.
- Specification of age, weight, sex and number.
- Transportation in compliance with law of the land
- Receipt, housing, quarantine and veterinary examination.
- Isolation of sick test system, treatment and documentation

Identification and Characterization

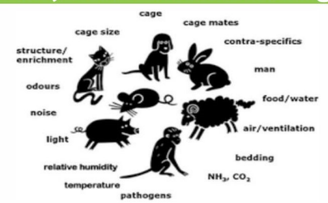


- Characterisation for strain and species
- Documentation/certification for characterisation.
- Unique identification from receipt, housing, issue, use to discard

Food-Water-Environment

- Acceptance quality criteria for food, water and bedding
- Periodic analysis and documentation
- Controlling and monitoring of environmental factors

Treatment, Care and Handling



- Qualified and trained personnel
- Standardized and validated procedures
- Monitoring, inspection and documentation
- Separation of species and adequate space
- Cleaning and sanitization of cages, racks and accessories
- Equipment and supplies to maintain sanitation and minimize interference

Key Requirements for Compliance

- Newly received test system should be quarantined, closely observed and isolation of diseased test system, if appropriate.
- Treatment of diseased test system (including diagnosis, authorization of treatment, description and date of treatment) is documented and retained.
- Unique identification of all test system using a permanently attached code, such as a tattoo, ear tag, toe clip, ear punch or neck chain.
- All information needed to specifically identify each test system appears on the outside the housing unit
- Test system of different species are housed separately when appropriate.
- Test system of the same species but different studies housed in the same room are differentiated by space and identification.
- Cages, racks and accessory equipment are cleaned and sanitized at appropriate intervals.
- Test system rooms are adequately cleaned and sanitized before, during and after housing of test system in a study.
- All feed, water and bedding material used is analyzed periodically for contaminants that may reasonably be expected to interfere with the outcome of the study.
- Bedding material used in test system cages and pens does not interfere with the purpose or conduct of the study, is changed as often as necessary to keep the animals dry and clean
- Use of any pest control materials is documented and does not interfere with the outcome of the study.
- Vivarium with adequate space and provision for controlling and monitoring of temperature, humidity, lighting and ventilation.
- Facility for emergency power generation systems are required to assure continued operation in critical areas and include routine maintenance and testing programs to assure continued operation

- Food supplies are stored such a way that prevent contamination, mix-up and infestation. Batch production or expiration date documented.
- Equipment and supplies are of design and composition to maintain adequate sanitation practices and to minimize interference with the conduct of studies.
- Preventive maintenance scheduled and performed to prevent any case of equipment malfunction. Documentation of all equipment malfunctions, cause and the corrective action taken.
- Any changes that are observed in the test system and can be attributed to environmental change resulting from equipment malfunction are documented.
- There is adequate trained and competent personnel to assure treatment, care and handling of test system.
- Test System care facilities are periodically inspected by the veterinarian in charge of animal health and records of such inspections are maintained.
- Test System facilities are designed, constructed, and located so as to minimize disturbances that interfere with the study.
- Facilities exist for the collection and disposal of all test system waste and are operated such a way to minimize vermin infestation, odors, disease hazards, and environmental contamination.
- Health, behavior or other aspects, as appropriate to the test system is monitored and recorded.
- Record of any incident resulting in minor or major personal injury (including animal bites) or probable personnel exposure to test chemicals are maintained.
- All dose preparation, gavage, filling of treated feed containers, skin painting, intraperitoneal injection, and inhalation administration performed in hoods or other vented enclosures.