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| **TERM** | **DEFINITION** | **REFERENCE or STANDARD** |
| ALCOA | * **Attributable**: information is captured in the record so that it is uniquely identified as having been executed by the originator of the data (e.g. a person or computer system).   •**Legible, traceable, and permanent**: data are readable, understandable, and allow a clear picture of the sequencing of steps or events in the record so that all activities conducted can be fully reconstructed by the people reviewing these records at any point during the records retention period.  •**Contemporaneous**: recorded at the time data are generated or observed.  •**Original (or “True Copy”)**: data in the format in which it was originally generated, preserving the integrity (accuracy, completeness, content and meaning) of the record.  World Health Organization: Original data include the first or source capture of data or information and all subsequent data required to fully reconstruct the conduct of the activity  •**Accurate**: data are correct, truthful, complete, valid and reliable. | **FDA**  **WHO** |
| Data Integrity | The extent to which all data are complete, consistent, accurate and traceable throughout the data lifecycle.   * From initial data generation and recording through processing (including transformation or migration), use, retention, archiving, retrieval and destruction; * Applies to paper and electronic data and records, within the scope of a quality management system * Assumes systems and /or equipment (balances, and analytical devises) used for the generation of original data have been appropriately calibrated, maintained and/or verified to be accurate.   For paper based data:   * Handwritten data entries should be made in clear, legible, indelible way. * Records should be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture of medicinal products are traceable. * Any alteration made to the entry on a document should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded. | **FDA-EPA-OECD MHRA, ISO 9001, PDA, WHO** |
| Design Controls | Design controls are an interrelated set of practices and procedures that are incorporated  into the design and development process, i.e., a system of checks and balances. Design  controls make systematic assessment of the design an integral part of development. As a  result, deficiencies in design input requirements, and discrepancies between the proposed  designs and requirements, are made evident and corrected earlier in the development  process. Design controls increase the likelihood that the design transferred to production  will translate into a device that is appropriate for its intended use. | **FDA Design Control Guidance 1997**  **21CFR820.30** |
| Experiment Requirements Document (ERD) | A living document that is developed by the investigator team as the source for communication for all key study stakeholders. The ERD is the source necessary to help meet the objectives of a specific study through careful planning. The ERD acts as the guide to a study by identifying key elements such as: authority, study personnel roles and responsibilities, test animals and groups, data collection requirements (e.g. data collection forms), key study timepoints, statistical methods, test device or article characterization, use, handling and disposition; data collection and/or case report form requirements, study timeline and other key factors.  The ERD may also serve as the document demonstrating careful study planning and can provide instructions between the investigator and study support personnel during preclinical research efforts that are well documented. If refined through revision, the ERD can be refined and evolve throughout the research continuum as a source for the eventual development of a *Study Protocol* to support regulated – safety stage (GLP level) testing.  Experiment Requirement Templates are available for all MPWRM investigators | **MPWRM QA Core** |
| Good Documentation Practices (GDP) | Methods for recording, correcting and managing data, documents and records, to ensure the reliability and integrity of information and data throughout all aspects of a product's lifecycle by establishing the use of the ALCOA Principles | **FDA-EPA- MHRA ISO 9001, PDA, WHO** |
| Good Laboratory Practices Regulations  (GLP) | The FDA regulations – 21CFR58 - Good Laboratory Practice (GLP) Regulations- is a **quality system** concerned with the organizational process and the conditions under which nonclinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. The scope of the GLPs focuses on safety of a prospective therapeutic product intended for use in humans and animals. The GLP regulations are not concerned and do not apply to basic research - exploratory studies carried out to to define a potential utility of a therapeutic. | **FDA**  **MPWRM QA Core** |
| Good Manufacturing Practices  (GMP) | Good Manufacturing Practices (GMP, also referred to as 'cGMP' or 'current Good Manufacturing Practice') is the aspect of quality assurance that ensures that therapeutics (including pharmaceuticals, medical devices, biologics and combination products) are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification. | **FDA**  **WHO**  **MPWRM QA Core** |
| Nonclinical Study or  GLP- Regulated Study | in vivo or in vitro experiments in which test articles are studied prospectively in test systems (animals) 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. | **US-FDA**  **21CFR 58.3 (d)** |
| Preclinical Study | Non-regulated basic/exploratory research effort for purposes of efficacy and overall utility of a pharmaceutical, device, materials, biologic or other therapeutics intended as a potential treatment of a diseased state. | **FDA** |
| Pre-submission  (Pre-Subs)  Q-Submission  (Q-Subs) | A Pre-Sub includes a formal written request from a submitter5 for feedback from FDA that is provided in the form of a formal written response or, if the submitter chooses, formal written feedback followed by a meeting in which any additional feedback or clarifications are documented in meeting minutes. The program is entirely voluntary on the part of the submitter. However, early interaction with FDA on planned nonclinical and clinical studies and careful consideration of FDA’s feedback may improve the quality of subsequent submissions, shorten total review times, and facilitate the development process for new devices. Formerly known as the pre-IDE (Investigational Device Exemption) program, FDA has since expanded the program to include a multitude of medical device submissions:   * IDE – Investigational Device Exemption * 510(k) –Premarket Notification * PMA-Premarket Approval * HDE – Humanitarian Device Exemption * De novo petitions – Classification option for novel low to moderate risk devices without first being required to submit a 510(k) * CLIA-Clinical Laboratory Improvement Amendments-knowing whether a clinical study requires an IDE. * Certain INDs (Investigational New Drug Applications) and BLAs (Biologic License Applications)   All of the above are collectively referred to as Q-Submissions (Q-Subs).  Submissions are designated with a control number that begins with a “Q” hence the term “Q-Sub” | **FDA**  **(CDRH- CBER)** |
| Quality Assurance | Elements independent of study performance, whose activities provide general quality system inputs in the development and execution of a research study; offering of advisement in the development of study plans; inputs for data collection, development of SOPs; systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving the objectives and can be reconstructed. | **US FDA- OECD**  **MPWRM QA Core** |
| Quality Control | The preemptive use of a standardized processes and procedures that ensures outcomes of a specific measurement or analysis are accurate, reproducible, reliable and are in alignment with known specifications. |  |
| Regulatory Affairs | Ensuring organizations are meeting all of the applicable regulations, such as those established by the Food and Drug Administration by evaluating investigational products for compliance. Work with the drug or device development team to define and execute a regulatory strategy to ensure that the collective effort results in a product that is approvable by global regulators but is also differentiated from the competition in some way and also helps to ensure that the company’s activities, from non-clinical research through approval, advertising and promotion, are conducted in accordance with the regulations and guidelines established by regulatory authorities. | **US FDA**  **MPWRM RA Core** |
| Risk Management | The systematic application of management policies, procedures, and practices to the tasks of  identifying, analyzing, controlling, and monitoring risk. It is intended to be a framework  within which experience, insight, and judgment are applied to successfully manage risk | **FDA Design Control Guidance 1997**  **ICH Q9** |
| Standard Operating Procedure (SOP) | Provides a set of step-by-step instructions compiled to provide guidance to key study personnel to carry out complex and/or routine activities consistently. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with a specific requirement or method. SOPs ensure the outcome of a specific activity can be consistently reproduced when performed by qualified personnel.  SOPs must be maintained as living documents that are reviewed, refined and revised on a continuing basis to assure any changes to approaches used are captured assuring continual improvement to a specific activity. | **MPWRM QA Core** |
| Test Article | 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. | **FDA**  **21CFR58.3(b)** |
| Well Controlled Study | A study that integrates basic quality system principles (e.g. ALCOA, etc.), through careful pre-study planning activities, with use of tools such as Experiment Requirements Document /Study Plan; SOPs for critical processes and documented communications between the Investigator and those performing study activities. A well-controlled study may include the frequent monitoring of activities by individuals, as designated by the Principal Investigator, to review study activities and provide a level of assurance that study activities are performed as required, that data is collected and maintained as required by the study plan/ERD and conform to best practices. A well-controlled study should document any excursion from the original study plan and include corrective actions taken along with preventive actions to limit the potential for recurrence. A well-controlled study will provide elements of transparency to assure all potential impacts to the study, including errors, are reported. | **MPWRM QA Core** |
| Well Documented Study | Study supported by **ALCOA** required elements of traceability through the documentation of what was done, when it was done and by whom. | **MPWRM QA Core** |
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