GLP Nonclinical Laboratory Quality System Consulting

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What to have ready

Each item ties to 21 CFR Part 58 (current eCFR text, read October 2026) unless another source is named.

- A list of studies, marked for whether each supports or is intended to support an FDA application for research or marketing permits (58.1(a) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-58/section-58.1]).
- An organization chart showing a quality assurance unit "entirely separate from and independent of the personnel engaged in the direction and conduct of that study" (58.35(a) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-58/section-58.35]).
- A QA inspection schedule set at "intervals adequate to assure the integrity of the study" (58.35(b)).
- Study directors identified in your study records. FDA's BIMO definitions describe the study director as "The individual responsible for the overall conduct of a nonclinical laboratory study" (FDA BIMO definitions [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/definitions]).
- A deviation procedure under which "All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data" (58.81(a) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-58/section-58.81]).
- SOPs for test and control article handling (58.81(b)).
- SOPs for data handling, storage and retrieval (58.81(b)).
- SOPs for equipment maintenance and calibration (58.81(b)).
- 58.81(b) lists twelve subjects (animal room preparation, animal care, test and control article receipt through sampling, test system observations, laboratory tests, handling of moribund or dead animals, necropsy, specimen collection and identification, histopathology, data handling storage and retrieval, equipment maintenance and calibration, animal transfer and identification), and states the list is "not limited to" them; 58.81(d) also requires a historical file of SOPs and revisions.
- For any pesticide studies, a map of which work falls under EPA's 40 CFR Part 160 instead (160.1(a) [https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-160/section-160.1]).