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STANDARDS & GUIDANCE BRIEF · UNITED STATES · REGULATION

21 CFR Part 58

Good Laboratory Practice for Nonclinical Laboratory Studies

DOCUMENT	QES-WP-161, Rev B	DATE	November 7, 2026
ISSUED BY	US Food and Drug Administration	PREPARED BY	Conner Davidson
EDITION	Current as published in the eCFR	STATUS CHECKED	October 24, 2026
INDUSTRIES	Laboratories & Calibration, Pharmaceutical, Medical Devices	ONLINE	qesisbest.com/standard-21-cfr-58.html

IN FORCE Applies to nonclinical safety studies that support FDA research or marketing applications.

What It Covers

How nonclinical laboratory studies are organized, conducted, recorded, and reported so their data can support an FDA application.

Who It Applies To

Testing facilities and sponsors of nonclinical safety studies for drugs, devices, biologics, food additives, and other regulated products.

Key Requirements

- A study director with overall responsibility, and an independent quality assurance unit (§58.33, §58.35).
- Written protocols and standard operating procedures (§58.81, §58.120).
- Equipment, facilities, and test article characterization controlled.
- Raw data, records, and specimens retained and archived (§58.190, §58.195).

What an Auditor Asks to See

- The protocol, raw data, and QA inspection records for a study.
- The archive index and retention records.

Where Systems Fall Short

- QA inspections scheduled around convenience rather than the study's critical phases.

How QES helps. GLP readiness reviews of protocols, QA programs, and archives. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. eCFR — 21 CFR Part 58 — www.ecfr.gov/current/title-21/part-58.

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