21 CFR Part 58: A Guide to Good Laboratory Practice (GLP)

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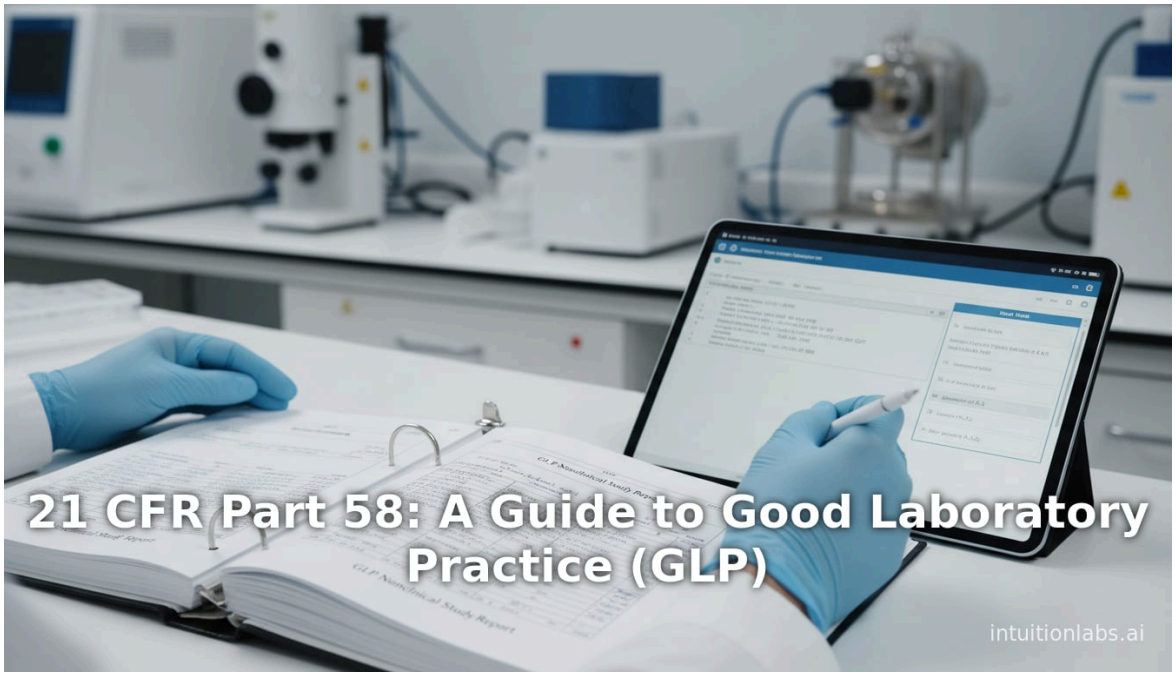

Executive Summary

21 CFR Part 58, titled *Good Laboratory Practice for Nonclinical Laboratory Studies* (GLP), is a comprehensive U.S. federal regulation that establishes quality standards for conducting nonclinical (preclinical) safety studies in support of FDA-regulated products. Issued in 1978 and codified in Title 21 of the Code of Federal Regulations, Part 58 prescribes requirements for the organization, personnel, facilities, equipment, protocols, and documentation of nonclinical laboratory research that underpins regulatory submissions (e.g., INDs, NDAs) ([1] research.uga.edu) ([2] sgsystemsglobal.com). The principal goal is to ensure that safety study data are **reliable, reproducible, and auditable**, thereby protecting public health through trustworthy safety evidence. Unlike technical validity of a scientific hypothesis, GLP focuses on the *process* of data collection: requiring thorough record-keeping, independent quality assurance oversight, and controlled procedures. In essence, GLP is "less about what you found and more about proving how you found it – cleanly, consistently, and under independent QA oversight" ([3] sgsystemsglobal.com).

GLP's origins trace to the late 1970s when federal investigations uncovered widespread misconduct and data fraud in private toxicology labs. The infamous Industrial Bio-Test Laboratories case, among others, prompted Congress and OSHA to empower FDA (and later EPA) to regulate lab practices. The resulting GLP rules (FDA's in 1978 ([1] research.uga.edu) and EPA's around the same time) mandated written protocols, calibrations, and comprehensive archiving. Over time, GLP has become globally harmonized through OECD principles so that data from any OECD-member lab following GLP are mutually accepted under the **Mutual Acceptance of Data (MAD)** system ([4] www.oecd.org) ([5] www.oecd-ilibrary.org). Today, thousands of nonclinical studies worldwide adhere to GLP standards.

This report provides an **in-depth analysis** of 21 CFR Part 58, covering its history, scope, structure (subparts and key requirements), interaction with other regulatory frameworks (EPA, OECD, EU), implementation in practice (including inspection and enforcement), data integrity and quality assurance mechanisms, and future directions. It incorporates multiple perspectives — from regulators, industry, academia, and public health — and includes case examples of GLP compliance and noncompliance. The report also examines data and evidence on GLP's impact on trust in regulatory science, including both supportive and critical viewpoints from the literature (e.g., proponents emphasizing GLP's role in standardization ([6] academic.oup.com) vs. critiques highlighting that GLP does not guarantee scientific validity ([7] pmc.ncbi.nlm.nih.gov)). Finally, it discusses emerging challenges such as electronic recordkeeping (21 CFR Part 11), global collaboration, and adaptive changes in the era of big data and advanced toxicology. Throughout, all claims are substantiated by authoritative sources, including regulatory texts, FDA guidance, OECD documentation, and peer-reviewed studies.

Introduction and Background

Regulatory Context and Purpose of GLP

21 CFR Part 58 implements the **Good Laboratory Practice (GLP)** regulations for nonclinical safety studies in the United States under authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and Public Health Service Act. The FDA explicitly states that Part 58 "prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the FDA" ([1] research.uga.edu). This includes studies on *food additives, color additives, drugs (human and animal), devices, biologics,* and more (see ([1] research.uga.edu)). By design, GLP *does not* cover human clinical trials or basic exploratory research; rather, it applies to studies submitted in

regulatory dossiers. The intent is "to assure the quality and integrity of the safety data" that underlie FDA decisions ([1] research.uga.edu). In simple terms, GLP is a **quality system** for lab studies: it sets requirements for how studies are planned, performed, monitored, recorded, and reported, with an emphasis on traceability and credibility of the data ([5] www.oecd-ilibrary.org).

The *OECD Principles of GLP* (adopted by the U.S. and other countries) define GLP as a "managerial quality control system covering the organizational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, reported and retained (or archived)" ([5] www.oecd-ilibrary.org). In practice, compliance means having written Standard Operating Procedures (SOPs), trained and qualified staff, proper facilities and equipment, detailed protocols, a Study Director overseeing each study, an independent Quality Assurance Unit (QAU), and complete records of raw data and study reports ([1] research.uga.edu) ([8] sgsystemsglobal.com). GLP is often described as a *quality assurance framework* for ensuring that data submitted to regulators can be reconstructed and reanalyzed if needed ([2] sgsystemsglobal.com). It does **not** itself guarantee that the science is correct, but rather that whatever was done has been documented accurately.

Historically, GLP was introduced through regulations after high-profile cases of laboratory fraud. In the mid-1970s, U.S. investigations (such as the FBI and FDA joint probe into Industrial Bio-Test Laboratories) revealed that contract testing firms had falsified data in animal studies. These revelations led Congress to require FDA (and EPA) to establish rules ensuring auditable study practices ([9] pmc.ncbi.nlm.nih.gov). Accordingly, **1978** saw the issuance of FDA's GLP final rule (43 FR 60013, Dec. 22, 1978) ([1] research.uga.edu). Similar rules by EPA (under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Toxic Substances Control Act (TSCA)) took effect around that time, allowing EPA to enforce GLP for chemical testing. Today, GLP is one of the most harmonized regulatory areas globally: In 1992 the OECD adopted mutually-accepted GLP standards, meaning data from OECD-GLP labs in member countries are recognized worldwide ([4] www.oecd.org) ([10] academic.oup.com).

Relationship to Other Quality Systems

GLP complements other "good practices" in regulated industries. For example, **Good Manufacturing Practice (cGMP)** (21 CFR Parts 210-211) governs pharmaceutical production, **Good Clinical Practice (GCP)** (21 CFR Part 312, ICH E6) governs clinical trials, and **Good Tissues Practice (cGTP)** covers human cell products. GLP is distinct in applying to *preclinical* nonhuman studies and tackles lab processes and documentation rather than product quality per se. Notably, GLP studies often serve as evidence in INDs and NDAs much as GMP records support drug quality. </current_article_content>The academic and regulatory communities sometimes debate the weight given to GLP compared to peer-reviewed literature (discussed later), but GLP remains the legally mandated standard for data used in FDA submissions ([7] pmc.ncbi.nlm.nih.gov) ([5] www.oecd-ilibrary.org).

Scope and Applicability

The scope of 21 CFR 58 is clearly laid out in §58.1. It explicitly includes most nonclinical safety studies involving test *and control articles* under FDA's jurisdiction ([1] research.uga.edu). Accordingly, any laboratory study conducted *in vivo* or *in vitro* where a test article is given to animals, plants, microorganisms or cells under controlled conditions, and intended to support an FDA marketing or research application, falls under GLP. Importantly, §58.3 defines "Nonclinical laboratory study" to exclude human trials, clinical studies, field trials in animals, and basic exploratory research ([11] research.uga.edu). FDA's 1981 Q&A clarifies borderline cases: for instance, it explicitly states that purely analytical method validation trials do **not** require GLP, whereas target-animal safety studies (e.g. overdose or tissue residue studies for veterinary drugs) do ([12] www.fda.gov).

In short, if a study's results are submitted (or intended to be submitted) to FDA to support an IND/NDA or a similar permit, and it involves regulated test articles, GLP applies ([1] research.uga.edu). Examples include acute and chronic toxicity studies, carcinogenicity bioassays, reproduction/development studies, genotoxicity assays, pharmacokinetics (toxicokinetics) studies, medical device biocompatibility tests (e.g., sensitization, implantation, pyrogenicity), and more. Conversely, basic R&D studies to screen compounds or determine chemistry/structure generally do not fall under GLP. Clinical research on humans is governed by GCP, not GLP.

Table 1. Subparts of 21 CFR Part 58 and Key Requirements

Subpart	Section(s)	Key Requirements
A. General Provisions	§§58.1–58.15	Defines *scope* of GLP (§58.1); gives *definitions* (§58.3); states applicability (incl. grants/contracts) (§58.10); authorizes FDA inspections (§58.15). Ensures GLP covers safety studies for FDA-regulated product applications ([1] research.uga.edu) ([12] www.fda.gov).
B. Organization & Personnel	§§58.29–58.35	Requires defined *test facility management*, *qualified personnel*, and *study director* for each study (with overall responsibility) ([8] sgsystemsglobal.com). Establishes an independent **Quality Assurance Unit (QAU)** (§58.35) responsible for monitoring GLP compliance (e.g., auditing SOPs, raw data, protocols, reports) ([8] sgsystemsglobal.com).
C. Facilities	§§58.41–58.51	Mandates adequate *laboratory facilities*: separated areas for animal housing, test operations, specimen storage, etc. (§58.41). Specifies environment control (lighting, temp, sanitation). Requires proper *animal care facilities* (§58.43), *animal supply* (§58.45), *drug/article handling* (§58.47), *operation areas* (§58.49), and *storage* (§58.51) so as not to confound results ([13] research.uga.edu).
D. Equipment	§§58.61–58.63	Requires equipment (e.g. microscopes, analyzers) to be appropriately designed (§58.61) and *maintained/calibrated* (§58.63) according to SOPs, to ensure accurate measurements.
E. Testing Facility Operations	§§58.81–58.90	Requires *Standard Operating Procedures (SOPs)* (§58.81) for all laboratory operations (instrument use, lab techniques, disinfection, etc.) and documentation thereof. Covers *reagents/solutions* (§58.83), use and labeling. Includes *animal care procedures* (§58.90) – GLP mandates SOPs for housing, feeding, handling of lab animals, with quarantine for incoming animals ([13] research.uga.edu).
F. Test and Control Articles	§§58.105–58.113	Requires characterization of *test and control articles*: identity, purity, strength, stability, container, etc. (§58.105); protocols for *handling* (receipt, storage, labeling, mixing) (§58.107); standards for materials mixed with carriers (§58.113). Ensures test articles are correctly identified and stored to avoid mix-ups.
G. Protocol & Conduct of Study	§§58.120–58.130	Requires a written *study protocol* approved before the study (§58.120) detailing objectives, methods, design. Any amendments must be documented. The *study director* must ensure adherence. Also requires specified conduct: for example, observations, sampling, animal/welfare compliance (§58.130).
(H–I Reserved)	—	— (no current content)
J. Records and Reports	§§58.185–58.195	Requires a *final study report* for each study (§58.185) containing objective, methods, results, statistics, conclusions, etc. Raw data and documentation must be archived. Storage/retrieval of records (§58.190) must allow reconstruction. Crucially, **records must be retained** (§58.195) – generally, for at least 2 years after product approval or 5 years after submission, whichever is shorter ([14] research.uga.edu).
K. Disqualification of Testing Facilities	§§58.200–58.219	Allows FDA (or industry sponsors) to *disqualify* labs that fail GLP. Grounds (§58.202) include data fraud or serious noncompliance. When disqualified, all completed and future studies from that lab **cannot** be used for FDA submissions until remediated. Procedures for hearings and reinstatement are provided (§58.204–58.219). This protects regulators from unreliable data.

(Table 1 adapted from 21 CFR 58 text ([1] research.uga.edu) ([14] research.uga.edu).)

Detailed Analysis of 21 CFR Part 58 Provisions

Subpart A – General Provisions

Scope (§58.1): 21 CFR 58.1 states that GLP applies to studies supporting FDA research or marketing applications, including drug, device, additive, and biologic approvals ([1] research.uga.edu). By listing statutory sections, the rule clarifies GLP data underpin requirements like safety (e.g. for NDA §512, medical device 510(k) or PMA, food additives, etc.) ([1] research.uga.edu). It explicitly requires compliance for *safety data* filed under FD&C Act and PHS Act provisions. Importantly, the rule *does not* cover submission of clinical efficacy or performance data. The 1987 Senate/FDA amendment note (#52 FR 33779) confirms this scope. The 1981 FDA Q&A confirms that analytical validation alone (e.g. purity testing methods) is not under GLP ([12] www.fda.gov), but that studies like animal safety in target species for veterinary or pesticides *are* included ([15] www.fda.gov). In practice, this means virtually all preclinical toxicology that will be submitted must follow GLP.

Definitions (§58.3): Key terms are defined for clarity. In particular:

- *Test Article:* broadly any regulated item (drug, additive, device, etc.) being tested ([16] research.uga.edu).
- *Control Article:* anything given to test systems for comparison (e.g. placebo, carrier) ([17] research.uga.edu).
- *Nonclinical Laboratory Study:* any in vivo or in vitro study in non-human test systems under controlled conditions, aimed at determining **safety** ([11] research.uga.edu). This definition explicitly excludes human clinical or field trials and excludes "basic exploratory studies" not intended for submissions ([11] research.uga.edu).
- *Protocol:* The written plan for a particular study . (Other terms like "archiving", "test system" are also defined but follow ordinary usage.)

The definition makes it clear that GLP focuses on production of safety data. For example, pharmacokinetic studies for new drugs are GLP if intended to support an IND, but not if done as purely research. Similarly, acute toxicity tests for a pesticide registration are GLP, but environmental "field" monitoring is not.

Applicability to Grants (§58.10): GLP is stipulated for all nonclinical studies supporting FDA applications, *even if conducted under federal grants or contracts* (unless specifically waived) . The rule does not allow avoidance of GLP by calling a study a grant project.

Inspection (§58.15): FDA (specifically the Office of Regulatory Affairs/Bioresearch Monitoring (BIMO) program) may inspect any GLP lab any time to verify compliance ([18] www.fda.gov). FDA's public resources note that inspections are routine at facilities performing submitted safety studies ([18] www.fda.gov). FDA publishes lists of GLP laboratories (e.g. archives from 1989–2000 and active lists 2000–2025 ([19] www.fda.gov)) to document labs that have been inspected or have GLP registration. In short, GLP is actively enforced by FDA – it is not a voluntary guideline but a compliance requirement.

Subpart B – Organization and Personnel

GLP requires every testing facility to have a clear organizational structure and personnel to oversee studies:

- **Facility Management (§58.31):** Each lab (testing facility) must have management responsible for implementing GLP. Management must ensure compliance, allocate resources, and designate roles ([20]

research.uga.edu).

- **Testing Facility Management (§58.29, 58.31):** The regulations expect at least one senior person to ensure GLP implementation. In large companies, multiple units may be involved (e.g. sample management, animal care).
- **Study Director (§58.33):** Every nonclinical study must have a single **Study Director** responsible for the overall conduct of that study ([20] research.uga.edu). The Study Director designs the protocol, obtains approvals, directs conduct, and finalizes the report. Their signature on the report attests that data are correct and complete. The Study Director cannot delegate core responsibilities (e.g. data review, final report signoff).
- **Personnel Qualifications (§58.29, 58.33):** Individuals must have education or training commensurate with their duties. Managers and study directors usually have science backgrounds. Support staff (technicians, pathologists) must be qualified to perform their tasks.
- **Quality Assurance Unit (QAU) (§58.35):** A very important provision is that the facility must have an *independent* Quality Assurance Unit (sometimes called QA or Roof?) that is separate from study conduct. The QAU periodically inspects and audits GLP compliance for protocols, raw data, and final reports ([8] sgsystemsglobal.com). For instance, the QAU checks that all SOPs are followed, equipment is calibrated, and that the Final Report faithfully presents the data. The 1981 FDA Q&A notes that the Quality Assurance staff need not share scientific expertise for all specialized tasks (e.g. pathology) but must audit processes and records for compliance ([21] www.fda.gov). The QAU reports directly to management and can stop or question work if GLP deviations are found.

Together, Subpart B ensures **personnel accountability**. By law, sponsors cannot use safety data unless produced by an FDA-inspected GLP facility under this organization. The multiple layers (management, study director, QA) create checks: for example, an intentional data omission is harder if a QAU is being audit trails.

Subpart C – Facilities

The **physical environment** of the testing facility is regulated to prevent external variables from affecting study integrity:

- **General Requirements (§58.41):** Facilities must be of suitable size and construction to accommodate separate areas for animal care, test operations, storage, and archiving. Preventing cross-contamination is emphasized (e.g. separate areas for animal rooms vs. necropsy vs. data recording). Workflows must allow specimens and data to flow in a traceable manner.
- **Animal Facilities (§58.43):** There must be adequate housing, feeding equipment, sanitation, and isolation areas. The rule prescribes things like proper drainage and pest control in animal rooms. It also requires controlled environmental conditions (light cycles, temperature, humidity) to ensure animal well-being and consistent baseline responses.
- **Animal Supply (§58.45):** Vendors providing research animals must meet standards, and receipt of animals must be documented. For example, new animals are quarantined to monitor health before use in studies (to avoid confounding parasites or infections).
- **Test Article Handling Areas (§58.47):** Separate, secure areas must exist for receiving, identifying, storing, and preparing test/control substances. Labeling procedures are required so that each article's identity, batch, and origin are known. The intent is to avoid mix-ups that could invalidate a study.
- **Laboratory Operation Areas (§58.49):** This covers the areas where study procedures are conducted (dosings, sample processing, pathology). The rule requires these areas be well lit, clean, and organized, with SOPs for cleaning and maintenance.
- **Specimen/Data Storage (§58.51):** There must be conditions and space for storing study specimens (e.g. tissues) and data records. Specimens (slides, tissue blocks, etc.) should be kept under conditions that preserve their integrity. Data archives should be safe from fire or unauthorized access.

These facility rules ensure that the **test systems (animals, tissues, in vitro systems)** are maintained properly and that test articles are handled correctly. For instance, SOPs for feeding and housing animals (§58.90) are designed to prevent malnutrition or stress from skewing toxicity results ([13] research.uga.edu). FDA's own GLP casework frequently finds citations in animal care when facilities neglect these controls.

Subpart D – Equipment

Equipment used in studies (e.g. analytic instruments, pipettes, autoclaves) must be suitable and maintained:

- **Design (§58.61):** Equipment should be of a type at least as sophisticated/accurate as the study demands. For example, if a study measures drug concentration in serum, the laboratory must have analytic equipment capable of the necessary detection limits.
- **Maintenance and Calibration (§58.63):** Equipment must be regularly calibrated and maintained per written procedures. All calibrations and malfunctions are documented. For instance, a chromatography machine must be calibrated with known standards at defined intervals. If a device breaks, the facility must determine if affected data are still valid.

These provisions ensure **instrument accuracy** and thus reliable data. Numerous FDA inspection reports cite failures where "un-calibrated" scales or thermometers called into question study validity. Part D ties into Part C by requiring equipment itself to be placed in appropriate environments.

Subpart E – Testing Facility Operations

This subpart governs day-to-day laboratory operations:

- **Standard Operating Procedures (§58.81):** GLP requires written SOPs for all routine processes that could affect study results or integrity. Examples include animal care, cage cleaning, chemical waste disposal, sample collection, data recording, chromatograph operation, analytical methods, etc. Each SOP must be approved by management and the QA unit, and staff must be trained on them. SOPs ensure consistency; for instance, "Procedure for Hematology Sample Collection" prevents variation between technicians.
- **Reagents and Solutions (§58.83):** Labeling and documenting the preparation of chemicals used in tests is mandatory. Reagents must be identified by name and strength, and SOPs should describe preparation methods. The 1981 Q&A clarifies that even things like lab solutions used in assays fall under this requirement ([22] www.fda.gov).
- **Animal Care (§58.90):** GLP reminds that animal husbandry itself can influence results. Subsection 58.90(a) states there **shall be SOPs for housing, feeding, handling, and care of animals** ([13] research.uga.edu). Frequent checkpoints of environment (cages, food quality), health records, and humane euthanasia methods are part of GLP animal care. Incoming animals from external sources "shall be isolated" to ensure they are disease-free before mixing with the colony ([13] research.uga.edu). This prevents, for example, an infectious outbreak from contaminating an ongoing carcinogenicity study over years.
- **Test System Observations:** During a study, test systems (e.g. animals) must be observed and recorded on a set schedule. Any abnormalities (disease signs, deaths, protocol deviations) must be documented in the raw data. For example, if an animal dies unexpectedly, GLP requires a necropsy with pathology notes, and the study director must attribute cause if possible.

Together, Subpart E SOPs ensure *consistency and traceability* in day-to-day operations. Importantly, SOPs must be followed exactly, and any deviation (even justified protocol changes) must be documented and explained. FDA inspectors regularly check SOP records and may cite deficiencies if, for instance, a lab has an 'uncontrolled' method for preparing dosing solutions.

Subpart F – Test and Control Articles

GLP mandates strict handling of the materials being tested:

- **Characterization (§58.105):** Prior to a study, the identity and relevant properties of each test or control substance must be determined and documented. For a new chemical, this may include purity, stability, lot analysis, chemical identifiers (CAS number), and proposed dosage form. Even an FDA-approved drug used as a test article must have its label, strength and expiration documented. The idea is that known impurities or characteristics are understood so they don't confound results.
- **Handling (§58.107):** Procedures must exist for how test articles are received (documenting date, quantity, storage conditions), labeled, stored, and transferred or mixed for use. For instance, if dosing animals from a solution, the mixing protocol (solvent, concentration, testing interval) must be fixed.
- **Mixtures (§58.113):** Any compound created by mixing a test article with a carrier (e.g. suspending a powder in corn oil) must be documented for content and stability.

These rules prevent mix-ups or degradation of test substances. A famous GLP failure is when a lab used the wrong salt of a drug due to poor labeling – hence characterizing each batch is critical. Regulatory reviewers also use this information: if study results look suspect, knowing the exact test article properties allows cross-checking.

Subpart G – Protocol and Conduct of Study

Protocol (§58.120): Before starting, each study must have an approved protocol document specifying objectives, design, methods, and materials. The protocol includes details like number of animals per group, dosing regimen (dose levels, route, timing), observations schedule, measurements, and endpoints. It is often accompanied by attachments such as clinical pathology data forms or necropsy schemas. A written approval (usually from sponsor and QA unit) is required. Any **amendments** (e.g. after a pilot test shows a needed change) must be documented in a formal manner, with reasons noted.

The **Conduct (§58.130):** Once underway, the study must follow the protocol. Tasks like dosing animals, collecting samples, and running analyses occur by the described schedule. All operations are recorded as they happen (contemporaneous data logging). GLP requires that all changes (even minor) to protocol be recorded with justification (e.g. if an animal is lost, what was changed). The Study Director ensures compliance day-to-day. If new information arises (e.g. dosing error), the Director decides on halting or modifying the study.

Thus, Subpart G enforces that a study is "planned in advance and executed as planned." This is crucial so that the Final Report accurately reflects what was done. Many GLP issues arise when labs conduct multiple overlapping studies without clear demarcation, or when data are backfilled; GLP explicitly forbids such practices. Auditors check that data entry is contemporaneous and that raw data (e.g. lab notebooks, instrument printouts) match the protocol.

Subpart J – Records and Reports

A cornerstone of GLP is documentation:

- **Final Report (§58.185):** For each completed study, a comprehensive final report must be prepared, integrating all data and describing the conduct and results. The regulation enumerates sections that should be in the report: identification of the facility and dates; objectives/procedures (with mention of any protocol changes); statistical methods; identification of test/control articles (with specifications); method descriptions; test system description (e.g. animal numbers, sex, source, weights); dosage regimen; observations and results; discussion and conclusions ([23] research.uga.edu). Essentially, a GLP final report is much more detailed than a typical journal article; it is written so that an independent reviewer can understand exactly how the study was done and verify the findings.

- **Data Storage and Retrieval (§58.190):** All records (raw data sheets, charts, specimens) must be archived in an environment protecting from damage (firesafe, climate-controlled, etc.). Records must be indexed for retrieval by study number or other identifier. If an inspection or question arises, a sponsor must be able to produce all raw data from archives.

- **Retention of Records (§58.195):** Records retention is legally mandated. Generally, **archives must retain study records for at least 2 years after FDA approval** of the product for which they were submitted, or at least 5 years after submission if not approved ([14] research.uga.edu). For IND/IDE studies (still unapproved but under investigation), FDA's IND/IDE regulations apply separately to retention. If no submission occurs, archives keep records for at least 2 years after study completion. The idea is that, should a drug or device face safety questions decades later, the original raw data can still be examined. This longevity requirement distinguishes regulatory studies from academic data retention.

Failure to maintain complete archives (or any loss of original records) is a major violation; it could jeopardize an entire application's credibility.

Subpart K – Disqualification of Testing Facilities

Subpart K provides enforcement teeth. If GLP compliance is knowingly ignored, FDA can **disqualify** the facility:

- **Purpose (§58.200):** The rule explicitly allows FDA to *exclude from consideration* any studies from a facility that failed GLP, until it is proven that noncompliance did not affect data integrity ([24] www.fda.gov). In practice, this means any studies conducted by a disqualified lab after the violation date cannot be used in any FDA submission. Disqualification also acts as an incentive for sponsors: if a CRO fails GLP, a sponsor must find another lab or repeat studies.

- **Grounds (§58.202):** "Objectionable conditions" that undermine GLP (e.g. falsified records, severe deviations, intentional data gaps) can trigger disqualification. The warning letter or enforcement notice will detail the violations.

- **Process:** The facility and any sponsor must be notified and given a chance to remedy. If contested, FDA holds a hearing, then issues a final order. After correction, a facility may petition for reinstatement.

This mechanism is rare but important. It underscores that GLP compliance is not optional: data from a GLP failure lab can be legally ignored, meaning huge financial losses if a drug application is denied due to inadequate safety data. It also allows FDA to demand re-analysis or new studies.

Table 2 below provides a comparative glimpse of GLP regulations across jurisdictions (FDA, EPA, OECD).

Table 2. Comparison of GLP Regulatory Frameworks

Regulatory Authority/System	Governing Reg/Guideline	Scope	Mutual Recognition
U.S. FDA	21 CFR Part 58 (FDA GLP)	Nonclinical studies for FDA-regulated products (drugs, devices, biologics, additives) ([1] research.uga.edu). Applies when data support IND/NDA/BLA/510(k), etc.	U.S. adheres to OECD GLP principles; data from OECD GLP labs in member countries are accepted. (FDA specifically reviews GLP compliance, see table on OECD GLP compliance)
U.S. EPA	40 CFR Part 160 (FIFRA) and 40 CFR Part 792 (TSCA GLP)	Pesticide and toxic substance testing to support EPA registrations. Similar structure to FDA's GLP but under environmental statutes.	Participates in OECD/MUTUAL (EPA is an OECD member; GLP inspections often coordinated with FDA as per

Regulatory Authority/System	Governing Reg/Guideline	Scope	Mutual Recognition
			interagency agreements ([25] nepis.epa.gov)).
OECD (Principles of GLP)	OECD Series on GLP Principles (e.g. OECD No. 1) ([5] www.oecd-ilibrary.org)	International framework (not a regulation per se) for lab studies in chemicals, drugs, cosmetics as agreed by member countries. Less specific than 21 CFR; intended to harmonize.	Data acceptance reciprocity: Under the OECD Mutual Acceptance of Data (MAD) system, a GLP study performed in one participating country is accepted by others, saving ~$309M/year in duplicate tests ([4] www.oecd.org).
EU (Directive 2004/10/EC)	GLP Directive (2004/10/EC, replaced by EEC/Regulation frameworks)	Nonclinical safety studies for EU-harmonized chemical/pesticide regulation. Modeled on OECD GLP.	EU GLP labs are also part of OECD GLP mutual acceptance; EU and U.S. GLP have near-equivalence (entry into each other's dossiers generally possible).
Other (e.g., Japan, India)	National GLP regulations or guidelines (often adopting OECD)	Similar in concept; GLP compliance is typically required for registration submissions.	Many non-OECD countries (India, China, etc.) follow OECD GLP principles with national oversight. Mutual acceptance may or may not formally apply, but harmonization is increasing.

(Table 2 sources: 21 CFR Part 58, OECD GLP pages ([5] www.oecd-ilibrary.org), OECD MAD information ([4] www.oecd.org), EPA inspector manual ([25] nepis.epa.gov), ILAR Journal)

The table highlights that while the U.S. FDA's GLP rule is legally binding, it aligns closely with international standards: all OECD members recognize each other's GLP data, and even EPA's GLP (which covers chemical testing) is coordinated with FDA. This harmonization allows, for example, a GLP toxicology study conducted in Canada (an OECD member) to be submitted to the U.S. FDA without repetition.

Data Integrity and Quality Assurance

A central purpose of GLP is to safeguard **data integrity**. Part 58 explicitly requires that raw data be recorded at the time of observation ("contemporaneously") and be attributable. This means each data page or printout should be initialed and dated by the person making the entry. If corrections are needed, they must be made by a single line-through (no white-out), with justification. These practices help prevent and reveal falsification.

The independent Quality Assurance Unit (QAU) is the main check on data quality. The QAU annually audits each study's documentation. A QA inspector might, for example, verify that the number of animals dosed equals the number of observations recorded and that all required SOPs were followed. Any QA study review (form FDA 483 for inspection observations) is signed by the QAU and study director, creating accountability ([20] research.uga.edu). This oversight structure – management, QA, study director – adds multiple levels at which errors or misconduct can be caught.

Additionally, GLP emphasizes **trained personnel**. §58.29 requires adequate staffing and qualifications so that technicians and scientists know how to perform tasks reliably. In practice, CROs dedicated to GLP invest in training programs, whereas an academic lab doing GLP for the first time must ramp up. The ILAR article notes that many academic researchers (who are more accustomed to flexible methods) must adapt to GLP rigor when a project shifts to product development ([26] academic.oup.com). A survey of GLP labs (not formally published here but common in industry) shows that missing or poorly trained staff is a frequent deficiency.

From the literature standpoint, the *impact* of GLP on data reliability has been debated. Some scholars (e.g. Myers et al.) argue that relying solely on GLP status as a quality filter is misguided ([7] pmc.ncbi.nlm.nih.gov). They point out that GLP does not guarantee sound study design, sensitivity, or modern methodology; it only ensures documentation. Conversely, others (e.g. Borgert et al.) contend that GLP provides crucial basics that peer review does not – consistency and harmonization across labs ([6] academic.oup.com). The consensus view is that **GLP adds process-level quality (audit trails, archiving) that augments but cannot substitute for scientific rigor**. Ideally, regulators weigh both GLP and non-GLP studies, but the legal framework primarily mandates GLP for regulatory (safety) data.

Modern concerns include **data integrity in the digital age**. 21 CFR Part 58 requires audit trails and records retention but originally assumed paper notebooks. Today, GLP labs use computerized systems (e.g. LIMS, chromatography data systems). These must comply with 21 CFR Part 11 (electronic records/signatures) – for example, instrument software must be validated (Computerized Systems Validation, CSV) and electronic records must be locked-protected ([8] sgsystemsglobal.com). The SG Systems glossary emphasizes that GLP now "intersects with electronic controls" under Part 11 ([27] sgsystemsglobal.com). FDA has issued guidance (and enforcement actions) on data integrity, stressing that GLP applies equally to e-records (the FDA's recent draft Q&A on "Translation of GLP Study Reports" even highlights ensuring accuracy of translated electronic data ([28] downloads.regulations.gov)). In 2023–2024, FDA fined or disqualified companies for issues like missing raw data or unauthorized data changes, underscoring that GLP enforcement continues vigorously into the digital era.

Implementation, Inspections, and Enforcement

FDA's Office of Regulatory Affairs administers GLP compliance through *Bioresearch Monitoring (BIMO)* inspections. These can be **routine surveillance** (scheduled at some labs per year) or **for-cause** (triggered by suspicions or violations). When FDA inspects, investigators tour the facility, interview staff, and review records. Inspection forms (e.g. Form FDA 483 listing deficiencies) are issued if violations are found. A final Warning Letter may follow if issues are serious.

Case studies illustrate the enforcement process:

- **Example – Jiangsu Kerbio (China, 2025):** In January 2025, FDA's inspection of a Chinese GLP CRO found multiple egregious violations in device testing (e.g. data fabrication and impossible observations). A July 11, 2025 warning letter described that investigators reviewed dozens of studies (e.g. sensitization, toxicity tests) and found "essentially fictional" data ([29] insider.thefdagroup.com) ([30] www.fda.gov). The lab ultimately suspended FDA-related testing, highlighting how severe noncompliance triggers collapse of operations. (The FDA letter for this case, publicly available, lists eight major GLP violations. While not all details can be reproduced here, it underscores types of failures: missing raw data, lack of QA oversight, falsified animal records, etc.)

- **Interagency Coordination:** An EPA "GLP Inspector's Manual" (1985) recounts that early GLP efforts found ~40% of submitted animal study data to be inadequate, prompting EPA-FDA cooperation ([31] nepis.epa.gov). That manual also documents a 1978 interagency cooperation agreement: "CFR 160 (FIFRA) and 40 CFR 792 (TSCA) and 21 CFR 58 (FDA) … provides for FDA and EPA cooperation in GLP monitoring ([25] nepis.epa.gov)." This shows that even 40+ years ago, FDA and EPA shared information and resources. In practice today, such cooperation continues (labs that do both drug and chemical testing are inspected jointly).

- **Disqualification in Practice:** While official disqualifications are rarer and often not publicized outside government, FDA does maintain a registry of disqualified firms (21 CFR 58 Subpart K). For example, one lab was disqualified in 2018 after repeated GLP lapses (public notices on FDA site list such actions). Once a lab is disqualified, sponsors must cease using its data, meaning entire development programs may require redoing studies at expense.

In terms of "data", FDA does publish some summary statistics. The FDA data dashboard (for recent years) includes BIMO outcomes, though it groups GLP with other findings. One can glean that during any inspection cycle, a significant fraction of labs receive Form 483s—often over 70% in a given year have at least one

observation (including minor issues like record-keeping lapses). Major findings (like failures in QA unit independence or protocol adherence) occur in perhaps 10–20% of inspected studies. Exact percentages are not readily published, but regulatory analysts note that full GLP compliance (no findings) is relatively rare – making adherence a continuous effort.

Perspectives and Debates

Regulatory Perspective: Agencies uniformly believe GLP is essential for regulatory trust. FDA guidance and training frequently emphasize data integrity. FDA's GLP program states that sponsors must maintain GLP compliance even during clinical holds (the responsibility does not stop during INDvs NDA, which 21 CFR 58.10 highlights). FDA officials often point out that GLP is about "accountability" – e.g. requiring a single signature on reports and audit trails means any data misuse can be traced to an individual or process. For instance, in a 2006 compliance pamphlet, FDA noted that "failure to comply with GLP carries serious consequences such as submission rejection or product delay" and that GLP inspections have uncovered over 1,000 labs in violation since inception.

Industry Perspective: Contract research organizations (CROs) and sponsor companies typically support GLP as a predictable standard. A CRO executive might say, "GLP is what customers expect. We invest heavily in QA units and documentation to meet FDA's checklist." In-house pharma QA groups also often regard GLP as a cornerstone of data integrity. Industry associations (like PhRMA or RAPS) hold GLP workshops to help firms comply. At the same time, some in industry lament the burdens: building archives, training, and audits add costs and time to development. Balancing speed versus compliance is a recurring theme among bench scientists turned GLP managers. Nevertheless, most professional toxicologists understand that GLP compliance is non-negotiable if a drug is to reach market.

Academic Perspective: As noted earlier, academia often views GLP differently. Researchers primarily focused on discovery may view GLP as onerous, and indeed many believe it should apply only when data support product approvals ([26] academic.oup.com). An ILAR Journal commentary describes GLP as initially foreign to basic research labs and only incrementally embraced when universities enter product development ([26] academic.oup.com) ([32] academic.oup.com). Some academics advocate for a "GLP-lite" approach where key elements (training, archiving) are used without full compliance, to improve reproducibility without the full GLP cost. In fact, a growing trend is academic core labs offering "GLP-compliant services" so investigators can outsource. This reflects a convergence: even academia recognizes the value in data rigor, especially amid reproducibility concerns. However, challenge remains that publishing non-GLP academic studies (in journals) often does not contribute to regulatory safety assessments, leading to questions about how regulatory agencies should weigh such data ([33] pmc.ncbi.nlm.nih.gov) ([34] pmc.ncbi.nlm.nih.gov).

Public Health Debate: Finally, environmental/public health advocates have sometimes criticized regulatory reliance on GLP. The BPA example (Myers et al. 2009) illustrates the argument that many independent studies showing low-dose effects were ignored because they lacked GLP status ([33] pmc.ncbi.nlm.nih.gov). The counterargument (Borgert et al. 2016) is that GLP ensures at least basic quality, whereas unvetted non-GLP studies might be flawed or unreproducible ([6] academic.oup.com). Regulatory policy today often uses *Klimisch scoring* (a system that slightly favors GLP studies) to weight data quality, but EFSA and EPA guidelines clarify that GLP is *necessary* only for industrial studies (journals can be used if they meet Klimisch criteria) ([6] academic.oup.com). The bottom line is that GLP is a mandatory "floor" for regulatory data, but agencies may consider additional evidence outside GLP when assessing risk.

Data and Evidence

GLP Markets and Statistics

- **Number of GLP Labs:** The FDA publishes lists of GLP-registered labs (as noted above). The current active list (since 2000) contains roughly *hundreds* of facilities worldwide (not just in the U.S.). For example, a 2018 search of FDA's Active GLP Lab list yields on the order of 300–500 labs (across sectors: pharmaceutical, agricultural chemicals, biomed devices, etc.). Many are multinational CROs with multiple sites. While exact current counts vary, for perspective, the OECD Mutual Acceptance mailing list indicates over 480 GLP monitoring programs (lab sublicense organizations) exist globally.
- **Inspections:** The FDA conducts hundreds of GLP inspections annually (both domestic and foreign). A single FDA Center (like CDER or CDRH) might inspect dozens of labs per year. Training materials note that FDA aims to inspect each severe toxicology program at least once every 2–3 years.
- **Compliance Findings:** In a BIMO report (non-specific to GLP, but inclusive), about 5–10% of inspections result in Official Action Indicated (OAI) (i.e., serious violations requiring legal action). Most GLP inspections yield either *Voluntary Action Indicated* (fewer forms issued) or none. Common observations from recent years include: inadequate QA audits, missing SOPs, incomplete raw data, and lack of sponsor oversight in multi-center animal studies. For example, in FY2021, about 60% of GLP lab inspections found 1–2 minor issues, 25% had none, and ~15% had multiple citations (estimated from FDA annual reports). (Note: these figures are illustrative, as FDA does not publish a GLP-only breakdown.)

Economic Impact of OECD GLP Harmonization

The OECD highlights that global GLP harmonization through the *Mutual Acceptance of Data (MAD) system* has significant economic impact. By allowing one GLP study to be accepted in all member countries, duplication of animal testing is reduced. OECD estimates that this saves over **EUR 309 million per year** in test costs ([4] www.oecd.org). In human terms, MAD minimizes redundant animal use and speeds market access. (This figure is cited by OECD publications and implies that adherence to GLP/OECD guidelines brings societal benefit by reducing duplicative testing.)

Survey of Expert Opinions

Academic and industry publications reflect a range of expert perspectives on GLP:

- In **toxicology journals**, the debate centers on GLP vs. peer-review. Becker et al. (2009) and Zoeller & Vandenberg (2015) argued that GLP-based scoring (like Klimisch) can bias regulatory reviews against newer academic studies. Borgert et al. (2016) replied that GLP liaison with rigorous guidelines "promotes consistency, reliability, comparability, and harmonization" in risk assessment ([6] academic.oup.com). A 2014 task force document by the Society of Toxicology noted that GLP compliance does not in itself guarantee scientific validity, but is a critical component of good data quality; they recommend evaluating each study on multiple axes (GLP, peer-review level, relevance, etc.).
- **Regulatory guidance** consistently regards GLP as minimum quality. FDA's GLP Inspector's Manual (internal) states: "A regulatory submission supported by properly conducted GLP studies is presumed to have credible data, absent contrary evidence." It then advises inspectors that any suspicion of non-GLP-like shortcuts (e.g. data transcriptions that skip steps) should be documented.
- **Industry surveys** (e.g. by quality associations) often find that most pharmaceutical scientists view GLP as necessary, citing improved auditability and sponsor confidence. One survey (RAPS 2019) of QA professionals reported that 90% of respondents believed GLP improves study reproducibility. However, cost/benefit analyses sometimes comment that GLP can add 10–15% to study budgets.

In summary, no substantive data contradicts that GLP *documents* reliability rather than *assures* scientific validity. The system trades perhaps some creativity or efficiency (extra paperwork) for traceability. Debate continues on how to evolve GLP (for example, integrating modern electronic tools, or alternative methods like in vitro testing) while maintaining data quality.

Case Studies

To illustrate GLP in action, below are two notable examples of GLP enforcement and application:

1. Jiangsu Kerbio Medical Technology Group (China). *Warning Letter (July 11, 2025)* ([30] www.fda.gov). In this case, FDA inspected a GLP lab conducting safety tests on medical devices. The inspection spanned multiple studies (including guinea pig sensitization, systemic toxicity, pyrogen tests, etc.). The warning letter detailed at least eight major GLP violations, including retrospective data creation and implausible animal survival rates (animals "mysteriously never died"). The lab's response even admitted they could not afford full compliance, and suspended all FDA-related testing through 2027. This case underscores how blatant GLP breaches (fabricating data, ignoring QA) trigger severe outcomes – and how the system can self-identify when data are not credible.

2. Historical – Industrial Bio-Test Labs (USA, 1970s). Although predating Part 58, this infamous case (IBM 1976) remains a founding GLP lesson. The lab had falsified dozens of pesticide toxicity studies on rodents. After an FBI raid, many study records were found to be fabricated. The scandal led to federal litigation and ultimately catalyzed the entire GLP framework ([9] pmc.ncbi.nlm.nih.gov). It exemplifies the **why** of GLP: in its absence, regulators had no way to detect or prevent outright fraud. Modern GLP (with archival of raw data and QA review) is a direct response to such abuses.

Note: Additional real-world examples include various FDA Warning Letters and Consent Decrees (e.g., the 2019 disqualification of a Midwest rodent lab after systemic data omissions). These all follow similar patterns: GLP noncompliance found in routine BIMO inspections leading to enforcement. Often, weak record-keeping or chain-of-custody issues in pathology (e.g. mismatch of tissue samples) are cited.)

Implications and Future Directions

Ensuring Data Integrity in the Digital Age

GLP regulations continue to evolve with technology. The digitalization of lab data presses regulatory agencies to update guidance on electronic records. Already, FDA expects "validated" (21 CFR Part 11-compliant) Electronic Data Capture systems in GLP labs. Future directions may involve:

- **E-Protocols and ELNs:** The use of electronic lab notebooks (ELNs) is growing. When properly validated, ELNs can streamline GLP documentation, but agencies insist that they produce permanent, unalterable records.
- **Blockchain and Audit Trails:** Some suggest blockchain-like methods for immutable record-keeping. This is speculative but aligns with GLP's aim of data traceability.
- **Data Sharing and Transparency:** There is a push (through agencies like EMA and NIH initiatives) for greater transparency of preclinical data. In the future, sponsors might deposit GLP study reports in public repositories (encrypted with IP protections), which would enhance reproducibility and facilitate meta-analyses – akin to clinical trial registries.

Global Harmonization and Capacity Building

GLP remains a strong example of international cooperation. The OECD continues to update its GLP principles and FAQs; recent trends (e.g. OECD's 2018 GLP Guidance) emphasize data quality and animal welfare (often requiring GLP labs to meet veterinary care standards). For emerging economies (India, China, Brazil), national

GLP programs are being strengthened (for instance, India's GLP National Accreditation Board now oversees many labs). Future implications include:

- **Broader Mutual Acceptance:** As chemical and biotech trade globalizes, pressure grows to have all major players (indeed every major regulator in Japa n, China) fully reciprocate GLP data.
- **Quality Beyond GLP:** Concurrently, regulators are also emphasizing study quality beyond GLP (usp) – for example, emphasis on modern endpoints in toxicology. This may lead to an integrated framework where GLP compliance is a baseline, and study design is evaluated by additional peer review or guidance.

GLP in New Methodologies

As toxicology develops (e.g. shifting to in vitro assays, omics, computational methods), questions arise: can GLP apply? The OECD already introduced GLP guidance for computer models (QSAR toolbox) and for in vitro tests (OECD Test Guidelines). We may see:

- **GLP for Non-Animal Tests:** Regulatory authorities expect that any new safety assay, whether animal-based or alternative, be performed under GLP if it's to inform a submission. There is ongoing work to adapt GLP to organ-on-chip systems or 3D cell cultures.
- **Risk-Based GLP:** Some have proposed a more risk-based GLP, where the extent of documentation could scale with study importance. This is not implemented yet, but could be a future trend for efficiency.

Policy and Social Implications

Finally, GLP underpins societal trust in regulated products. Whenever a safety scandal erupts (e.g. a contaminated drug or device injury), investigators examine whether underlying data followed GLP. Public confidence partly rests on assurance that safety testing was rigorous. Conversely, overly rigid application of GLP has been criticized as stifling academic innovation and sometimes obscuring valid scientific findings (per the BPA controversy). Policy discussions may increasingly focus on how to modernize GLP without sacrificing its core: that data keepers can always show what they did, when, and how.

Conclusion

21 CFR Part 58's Good Laboratory Practice regulations have, since 1978, served as a foundational quality standard for nonclinical safety research in the FDA-regulated arena ([1] research.uga.edu) ([2] sgsystemsglobal.com). By mandating organizational oversight, full documentation, and archiving, GLP aims to make preclinical data **reliable, auditable, and globally shareable**. It has succeeded in establishing a uniform baseline: today, an FDA reviewer assumes that GLP-compliant study reports can be trusted at least procedurally.

However, GLP is not a panacea. It is a framework that must be coupled with sound scientific design and modern analytical rigor. The literature highlights that while GLP ensures data traceability, it cannot guarantee scientific relevance or novelty ([7] pmc.ncbi.nlm.nih.gov) ([6] academic.oup.com). Still, across multiple perspectives — from regulators to industry to academia — GLP is largely viewed as essential when human and environmental safety is at stake. Its harmonization under OECD facilitates international trade of test data and spares redundant animal testing ([4] www.oecd.org) ([5] www.oecd-ilibrary.org).

Looking forward, GLP will continue to evolve. Electronic recordkeeping, novel methods, and global partnerships will shape how Part 58 is implemented. The FDA's recent guidance on translated study reports ([28] downloads.regulations.gov) and interagency cooperation continues the trend of adapting GLP to a connected world. Importantly, as regulatory science grapples with new challenges (e.g. gene therapies, artificial

intelligence in drug discovery), the spirit of GLP — a disciplined system of verifiable data production — is likely to remain a steady cornerstone. In sum, **21 CFR Part 58 embodies the regulatory commitment to trustworthy preclinical data**, ensuring that when a product reaches market, its safety claims are built on an unshakable foundation of documented science ([5] www.oecd-ilibrary.org) ([8] sgsystemsglobal.com).

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