Designing Risk-Based Facilities for Ancillary Material Manufacturing in Regulated Biopharmaceutical Environments

Executive Overview

With the success of cell and gene therapies (CGT), the scrutiny of the ancillary materials going into the CGT products are facing higher evaluation from the regulatory bodies around the world. Even though ancillary materials may not be present in the final product formulations, these materials are critical for the production of CGT that are safe and efficacious. The risk identification and risk mitigations start at the manufacture of these materials as items that are produced in an uncontrolled environment and production process can cause safety and efficacy concerns that put the patients' health at risk. By being proactive in the design of a facility and the procedures within that facility, a number of risks can be mitigated with proper design and control methods even before manufacturers initiate production.

Purpose

The purpose of this white paper is to define a comprehensive, risk-based framework for the design, operation, and control of facilities used in the manufacture of ancillary materials, including critical reagents, media supplements, and other process-related components that support the research, development, and commercial manufacture of pharmaceutical and biological products.

Although ancillary materials are not administered directly to patients, they are recognized by regulatory authorities as critical raw materials whose quality, consistency, and control can directly affect the safety, identity, strength, purity, and quality of the final drug product. As such, regulatory agencies, including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and others, expect ancillary material manufacturing operations to be managed using principles consistent with current Good Manufacturing Practice (cGMP) and Quality Risk Management.

This white paper outlines:

The role of ancillary materials within regulated pharmaceutical and biologics manufacturing processes

- Applicable regulatory expectations and guidance, including FDA, EMA, and ICH principles
- Facility design considerations necessary to prevent contamination, ensure control of critical process parameters, and support inspection readiness
- Core operational systems required to maintain compliance, including quality management, validation, utilities, environmental monitoring, documentation, training, and contamination control
- The business and compliance value of a fit-for-purpose ancillary materials facility in reducing regulatory risk, preventing supply disruptions, and supporting timely product development and commercialization

By establishing a purpose-built and well-controlled operating environment, organizations can demonstrate systematic control of ancillary material manufacturing, support regulatory inspections and submissions, and ensure ancillary materials are suitable for their intended use throughout the product lifecycle.

Key Material Considerations

Facilities for pharmaceutical fill/finish, active pharmaceutical ingredient (API), and biologics manufacturing are supported by well-defined regulatory guidance governing design, validation, cleaning, and monitoring. The same regulatory rigor applies to facilities producing ancillary materials. Although ancillary materials are not administered directly to patients, regulatory authorities assess them as critical components when they have the potential to affect the safety, quality, identity, strength, or performance of the final product.

Regulatory evaluation is driven by a fundamental question: **Does the ancillary material have the potential to alter the form, fit, or function of the final product, and could such an alteration pose a risk to patient safety?** As a result, facilities manufacturing ancillary materials must be designed using a risk-based approach that evaluates material characteristics, process requirements, and contamination control strategies.

Key considerations during facility planning and design include the following:

Facility Purpose

The intended purpose of the facility must be clearly defined during conceptual design. Single-product versus multipurpose use significantly impacts facility complexity, cost, and risk profile. Early decisions should account for potential use of organic solvents, antibiotics, or materials of animal and non-animal origin, as each introduces distinct design, segregation, and control requirements. Addressing these factors upfront minimizes costly redesigns, change orders, and compliance gaps.

Types of Materials Produced

Water and Water Systems

Water is a critical input for media, buffers, and reagents. The required water quality for production and cleaning must be established during design. Water systems should be evaluated for long-term maintainability and control of emerging contaminants such as per- and polyfluoroalkyl substances (PFAS) and nitrosamines. While distillation can produce Water for Injection (WFI) quality water, modern reverse osmosis/deionization (RO/DI) systems—when properly designed with activated carbon and 254 nm UV treatment—can achieve equivalent quality with reduced energy demand.

Antibiotics and Potent Materials

Facilities handling antibiotics or biologically active compounds must be designed to prevent cross-contamination through controlled material receipt, storage, personnel access, production segregation, and waste handling. Materials flows for these products are critical.

Animal and Human-Derived Materials

Facilities manufacturing animal origin (AO) and animal origin-free (AOF) materials must employ segregation strategies to prevent cross-contamination. Consideration should also be given to different species sources within AO materials. Applicable testing expectations include:

- **Human origin materials:** Testing per 21 CFR 640, 610.40, and 1271 prior to release
- **Bovine origin materials:** Testing per 9 CFR 113.53
- **Other animal species:** Testing per applicable 9 CFR requirements

Where multiple species are handled, single-use systems are preferred to reduce contamination risk and cleaning validation complexity.

Organic Chemicals

Organic solvents introduce operator safety, fire, and explosion risks, as well as material compatibility concerns. All process solutions must undergo compatibility assessments to confirm suitability with construction materials (e.g., stainless steel) prior to equipment selection and installation.

Special Manufacturing Requirements

Chemical properties of materials must be evaluated to support safe and consistent processing. Endothermic or exothermic reactions may require temperature control to meet in-process testing requirements (typically 20–25 °C). High-concentration or viscous solutions require assessment of mixing efficiency, transfer capability, filtration feasibility, and aseptic dispensing performance.

Manufacturing Scale

Production scale directly influences equipment selection and cleaning strategy. Smaller batch sizes may support single-use technologies, while large-volume operations (e.g., >2,500 L) typically require reusable formulation tanks supported by validated cleaning-in-place (CIP) and, where applicable, sterilization-in-place (SIP) systems.

Waste Handling

Waste streams must be characterized early to determine appropriate handling, neutralization, storage, and disposal requirements. Design considerations should address waste volumes, hazardous material classification, temporary storage limits, and applicable permitting or environmental regulations.

Facility Design Requirements

Facilities producing ancillary materials must be designed to minimize contamination risk and ensure consistent control of processes that may impact final product critical quality attributes (CQAs). A risk-based, engineering-driven approach should be applied during design to support product quality, operational efficiency, and regulatory compliance.

Key design considerations include the following:

Process Flows

Material, personnel, and waste flows should be clearly defined and segregated to minimize contamination risk. From raw material receipt through finished goods shipment, process flows should support controlled movement and prevent unnecessary crossings.

- Raw materials are frequently received in cardboard packaging, a known source of particulate and microbial contamination. Design provisions should ensure removal of cardboard and external packaging prior to entry into classified areas.
- In multiproduct facilities, crossing of material streams—particularly animal origin (AO) and animal origin-free (AOF)—should be minimized and, where unavoidable, managed outside classified spaces.
- Spill scenarios should be evaluated during design, with appropriate containment and cleaning strategies incorporated.
- Personnel and material flows should be aligned, recognizing that personnel are the primary vector for material movement and contamination risk.

- Waste and refuse removal streams should be segregated spatially and/or temporally from production activities to prevent impact on product quality, particularly during extended manufacturing operations.

Personnel flows must support progressive gowning and de-gowning requirements as operators transition between classification levels. Adequate infrastructure should be provided for gowning rooms, lockers, handwashing, and controlled entry/exit to minimize disruption of environmental conditions and environmental monitoring performance.

Classified Space Design

Cleanroom classification requirements must be driven by product and process needs. Design decisions should consider whether operations involve open manipulations requiring Grade A (ISO 5) environments or closed processing supported by isolators, RABS, or tubing welders.

- Pressure differentials between adjacent classified areas should meet regulatory expectations (minimum 0.02 inches water column/~15 Pa).
- Pressure cascade strategy (positive or negative) should be selected based on contamination risk, including potential ingress of contaminants or egress of hazardous or potent materials.
- Positive pressure cascades are commonly used for ancillary materials production; however, negative pressure designs may be warranted where powder handling or plume generation poses a contamination risk to adjacent areas.
- Anterooms may be required to stabilize pressure differentials and support controlled transitions.

Future manufacturing needs and product configurations (e.g., bags versus bottles) should be considered during design to avoid limiting flexibility or requiring significant retrofit.

Utilities and Infrastructure

Utilities must be designed to support contamination control and reliable operation.

- HEPA-filtered air is required for all classified spaces, with serviceability designed to minimize production disruption and additional cleaning.
- Reusable stainless-steel mixing systems require validated clean-in-place (CIP) and, where applicable, steam-in-place (SIP) capabilities for tanks, piping, valves, pumps, and sampling systems.
- Cleaning solution handling and disposal must comply with local environmental and regulatory requirements.
- Water source selection (potable versus well-water) and treatment strategy should be defined early, as water quality requirements vary by application and directly impact system design and maintenance.

Storage and Sampling

Storage design must support segregation, environmental control, and material traceability.

- Multiproduct facilities should provide segregated storage for AO and AOF materials, with sufficient capacity for raw materials and finished goods.

- Animal-derived materials may require specific temperature-controlled storage with significant space considerations.
- Facilities handling organic chemicals must account for permitting thresholds based on stored volumes.
- Specialized storage requirements (e.g., flammables, biologics, acids, bases) should be incorporated into the design program.
- Dedicated sampling areas are required where raw material identity testing is performed prior to release.

Compliance Alignment

Facility design must align with applicable regulatory, environmental, and local authority requirements.

- Applicable regulations and standards should be assessed and documented during design, including 21 CFR Parts 210/211 and 820, ISO 13485, EU GMP, WHO, and ICH guidance.
- Design Requirements documentation should capture regulatory assessments and compliance rationale.
- Construction materials and finishes must be cleanable and suitable for environmental monitoring.
- Air quality monitoring, air change rates, and pressure cascades must be designed to support cleanroom classification and ongoing compliance.

Quality System Essentials

Operation of an ancillary materials manufacturing facility requires a robust, inspection-ready quality system. Although ancillary materials are not administered directly to patients, their manufacture can directly impact the safety, quality, and regulatory acceptability of downstream pharmaceutical and biologic products. Regulatory agencies, including the FDA and EMA, therefore expect these activities to be governed by cGMP principles and Quality Risk Management.

The quality system for such a facility should be built upon the following foundational pillars:

Site Master Plan & Documentation

A structured and controlled documentation framework is essential to compliance.

Key Risk if Absent:

Lack of structured documentation increases the likelihood of inspection delays, reduced transparency, and quality unit observations under 21 CFR 211.22

- **Site Master Plan (SMP):** A high-level description of facility design, organizational structure, quality systems, material and personnel flows, and control strategies. The SMP serves as the primary reference during regulatory inspections.
- **Inspection-Ready Documentation:** SOPs, validation protocols, equipment and critical utility records, and quality manuals must be clearly written, version-controlled, and maintained within an integrated Quality Management System (QMS).
- **Data Integrity:** All records, paper and electronic, must comply with ALCOA+ principles to ensure accuracy, traceability, and availability of data.

Vendor Qualification & Change Control

Supplier oversight is a critical element of ancillary material quality assurance.

- **Risk-Based Vendor Qualification:** Suppliers of raw materials, disposables, packaging, and critical utilities must be qualified according to risk to product quality and patient safety. Higher-risk suppliers require enhanced due diligence; lower-risk suppliers may be qualified through documented assessments.

Key Risk if Absent:

Inadequate supplier oversight and change control are common sources of FDA observations, including findings under 21 CFR 211.84.

- **Change Control:** Vendor-initiated changes to materials, specifications, processes, or manufacturing sites must be formally communicated, assessed, approved, and documented prior to implementation.
- **Traceability:** Full material traceability from supplier through final ancillary material batch is required to support deviation management, recalls, and regulatory inquiries.
- **Contingency Planning:** Critical or high-risk materials must be supported by contingency plans addressing supply disruptions and geographic risk factors.

External Testing & Contingency Planning

Specialized testing may require the use of qualified external laboratories.

- **External Laboratory Oversight:** Third-party testing laboratories must be qualified and governed by Quality Agreements defining responsibilities for testing, deviations, reporting, and data retention.

Key Risk if Absent:

Over reliance on single suppliers or laboratories without contingency planning may result in supply interruptions, delayed testing, and regulatory or programmatic delays.

- **Business Continuity:** Contingency plans should address alternative qualified laboratories and suppliers, redundant storage or production options, and emergency response to facility or utility failures.
- **Periodic Review:** External partners should be reassessed and, where appropriate, audited at defined intervals to ensure continued compliance.

Quality System Culture

An effective quality system must be embedded as a core operational function, not treated as a procedural formality. Leadership commitment to quality as a strategic enabler is essential for sustained compliance, business continuity, and regulatory confidence.

Quality System Readiness – Key Considerations

Site Master Plan & Documentation

- Is there a current, approved SMP describing facility design, flows, and controls?
- Are SOPs and validation records inspection-ready and periodically reviewed?
- How is ALCOA+ data integrity ensured for paper and electronic records?

Vendor Qualification & Change Control

- How are supplier risks assessed and managed?
- Are vendor-driven changes evaluated and approved prior to implementation?
- Can all ancillary material lots be traced to their source?

External Testing & Contingency Planning

- Are external laboratories qualified under formal Quality Agreements?
- Are backup laboratories or suppliers identified?
- Does the business continuity plan address facility, utility, and supply chain disruptions?

Quality Culture

- Is the quality system demonstrably fit-for-purpose?
- Is quality viewed by leadership as a driver of compliance and continuity rather than a cost center?

Commissioning, Qualification, and Validation Framework

Commissioning, qualification, and validation are essential to demonstrating scientific control, regulatory compliance, and operational readiness for ancillary material manufacturing facilities. Global regulatory authorities—including FDA, EMA, MHRA, WHO, ANVISA, and NMPA—expect a structured, lifecycle-based validation framework to ensure facilities, utilities, equipment, and processes consistently perform as intended.

A compliant program is built upon a defined Validation Master Plan (VMP), execution of IQ/OQ/PQ (and PPQ, where applicable), and robust Cleaning Validation and Environmental Monitoring Program Qualification (EMPQ). Together, these elements transition a facility from installation to sustained inspection readiness. Failure to adequately scope or execute these activities increases the risk of regulatory delay, rejected submissions, and potential impact to patient safety.

Validation Master Plan (VMP)

The VMP serves as the governing document for all commissioning, qualification, validation, and requalification activities. It defines scope, responsibilities, validation strategy, acceptance criteria, and lifecycle management. An effective VMP does not need to be all-inclusive or overloaded with technical detail. Its true value lies in serving as a core governance document that clearly outlines the strategy and links to supporting SOPs, technical reports, and regulatory guidance. By using the VMP as a hub that references other controlled documents, organizations avoid redundancy, maintain agility in updates, and ensure alignment with evolving regulatory expectations without recreating every detail inside a single document.

Core elements of the VMP include:

- Scope and applicability across facilities, utilities, equipment, systems, and processes
- Roles and responsibilities (QA, validation, engineering, operations, vendors)
- Risk-based validation approach aligned with ICH Q9/Q10

Key Deliverables:

Approved VMP, master validation schedule, and standardized qualification templates.

- Validation lifecycle (IQ/OQ/PQ), document hierarchy, and standard templates
- Master validation schedule with prioritization of critical systems
- Applicable regulatory standards and internal procedures
- Testing strategies, acceptance criteria, and deviation handling
- Data integrity controls (ALCOA+, Part 11 where applicable)
- Change control and requalification triggers
- Post-validation monitoring and continuous improvement

Qualification Lifecycle: IQ, OQ, PQ/PPQ

The qualification lifecycle demonstrates that systems are installed correctly, operate within defined limits, and perform consistently under routine and worst-case conditions.

- **Installation Qualification (IQ):** Verifies installation, materials of construction, utilities, calibration status, and documentation against design and vendor specifications.
- **Operational Qualification (OQ):** Confirms functional performance across operating ranges, including controls, alarms, interlocks, software functions, and cleaning cycles.
- **Performance Qualification (PQ/PPQ):** Demonstrates consistent process performance using representative materials, operators, and conditions, with defined acceptance criteria and post-qualification monitoring.

Requalification intervals and triggers (e.g., major changes, extended downtime) must be defined and managed through change control. Computerized systems used within validated processes must follow CSV expectations, including Part 11 compliance where applicable.

Cleaning Validation and EMPQ

Cleaning Validation and Environmental Monitoring Program Qualification collectively ensure contamination control and environmental suitability. **Cleaning Validation** demonstrates effective removal of product residues, cleaning agents, and microbiological contaminants through:

- Risk-based worst-case assessments
- Defined cleaning parameters and acceptance limits
- Validated analytical methods
- Swab and/or rinse sampling strategies
- Ongoing verification and revalidation triggers

EMPQ and Cleanroom Qualification confirm that cleanroom environments consistently meet classification requirements (ISO 5/7/8 or equivalent) through:

- HVAC and HEPA system IQ/OQ/PQ
- Airflow visualization, particle monitoring, and viable sampling
- Personnel qualification and monitoring
- Defined EM sampling plans, limits, trending, and CAPA integration
- Periodic requalification managed within the QMS

Common Pitfalls to Avoid

- Fragmented ownership of the VMP
- Insufficient data integrity integration
- Inadequate worst-case challenge conditions
- Poor risk-based sampling design
- Treating validation as a one-time activity rather than a lifecycle process

Minimum Readiness Before Commissioning

- Approved VMP and validation schedule
- Completed IQ documentation
- Executed OQ with verified controls and alarms
- Defined PQ/PPQ strategy and acceptance criteria
- Approved cleaning validation and EMPQ programs
- Data integrity and change control mechanisms in place

Facility Maintenance and Monitoring

Following construction and qualification, facilities must be maintained to ensure continued conformance with design intent, regulatory requirements, and environmental specifications. An effective maintenance and monitoring program is essential to sustaining a state of control.

Cleaning

A routine, documented cleaning program shall be established to maintain environmental conditions consistent with facility design and cleanroom classification.

- **Daily:** Post-production cleaning following line clearance and monitoring activities using surface-appropriate cleaning agents (e.g., 70% IPA for stainless steel; quaternary ammonium compounds for durable surfaces such as epoxy floors and walls).
- **Weekly:** Comprehensive surface cleaning with approved disinfectants to maintain facility readiness.
- **Monthly:** Periodic application of a sporicidal agent to control mold and spore-forming microorganisms.

Cleaning frequencies, agents, and methods should be defined in SOPs and supported by validation where applicable.

Environmental Monitoring

A robust environmental monitoring (EM) program is required to demonstrate ongoing facility performance.

- Monitoring shall encompass facilities, personnel, utilities, and processes, with defined investigation and escalation procedures for excursions.
- Where water systems are used, routine monitoring at points of use is required to confirm water quality.
- Environmental monitoring data shall be reviewed as part of production area release to verify suitability of the environment prior to use.

Trending and Performance Review

Environmental and utility monitoring data shall be routinely trended to detect early indicators of system degradation. Trending enables proactive mitigation before specifications are exceeded, reducing the risk of production delays and compliance issues.

Preventive Maintenance, Certification, and Calibration

A preventive maintenance program is required to ensure continued equipment and facility performance.

- HVAC systems shall be routinely serviced, with prefilters cleaned or replaced to protect HEPA filter integrity and maintain pressure cascades.
- Water systems shall be maintained across all components (e.g., filtration, activated carbon, RO/DI, UV, sanitization) to prevent biofilm formation and quality excursions.
- Classified areas shall be periodically certified to their designated classification, with particulate testing performed following maintenance or system intervention.
- HEPA filters shall undergo routine integrity testing and airflow verification.
- All monitoring and measurement instruments (e.g., pressure sensors, particle counters, balances, meters) shall be calibrated at defined intervals.

Strategic Takeaway

Building a facility for the production of ancillary materials is a high-impact initiative that requires integration of regulatory foresight, GMP discipline, and operational scalability. Investing in the right infrastructure, systems, and culture positions your organization to support innovation while meeting global compliance expectations. By assessing key items and design requirements early, the potential for design modifications, construction delays due to change orders, cost overages and timelines are less likely to be impacted and the project is more likely to meet its operational goals.

Regulatory/Compliance References

1. 21 CFR Part 210 and Part 211 — Current Good Manufacturing Practice for Finished Pharmaceuticals.
2. FDA Guidance for Industry — Process Validation: General Principles and Practices (January 2011; updates commentary 2011–2023).
3. FDA Guidance — Aseptic Processing (Guidance for Industry).
4. EU GMP Annex 1 — Manufacture of Sterile Medicinal Products (2022 revision).
5. WHO Technical Report Series/Annex on sterile pharmaceutical products (WHO TRS, Annex 2/Annex 6 guidance).
6. ICH Q9 — Quality Risk Management and ICH Q10 — Pharmaceutical Quality System.
7. PIC/S guidance and WHO GMP guides (where country references align). (Use local PA/inspectorate versions for country specifics.)
8. Local regulator guidance as applicable: NMPA (China) GMP requirements; ANVISA (Brazil) cleaning and GMP guidance; MHRA (UK) GMP guidance and Annex interpretations.

9. United States Pharmacopeia (USP) <1043>, Ancillary Materials for Cell, Gene and Tissue Engineered Products

10. European Pharmacopeia (EP) 5.2.12, Raw Materials for the Production of cell-based and Gene Therapy Medicinal Products

11. International Pharmaceutical Regulators Programme (IPRP), General considerations for raw materials used in the production of human cell and gene therapy products

12. MHLW Notification No. 37, February 28, 2018 Standards for Biological Materials

13. ISO/TS 20399:1, -2, -3 Biotechnology- Ancillary materials present during the product of cellular therapeutic products

About GeminiBio

Founded in 1985, GeminiBio has two manufacturing facilities in West Sacramento, California. The company has a 25,000 square foot facility that is dedicated to Animal Origin Free (AOF) upstream and downstream media, buffer and water manufacturing, as well as a 32,000 square foot facility that includes a cGMP warehouse and classified manufacturing suites for Animal Origin (AO) and Xeno Free (XF) products. Both facilities are cGMP, ISO 13485:2016 certified and an FDA registered Class 1 Medical Device manufacturer.

GeminiBio's facility includes a range of ISO 7 processing suites with ISO 5 production areas, including suites with 500-liter and 1,000-liter single use mixing vessels. The manufacturing space contains 5,000-liter and 10,000-liter stainless-steel mixing vessels – allowing GeminiBio to support cGMP batch sizes spanning from 10-liters to 10,000-liters. Additional capabilities include aseptic filling into diverse containment types (rigid and flexible) and sizes (500 mL bottles to 1,000-liter pallet tanks). The company has segregated ISO 7 processing suites for Animal Origin Free, Animal Origin, as well as Xeno Free products – which includes validated processes for the movement and segregation of raw materials and finished goods.

The company has extensive cGMP warehousing capabilities, including temperature mapped and validated storage conditions at -20°C, 2°-8°C, and controlled room temperature (CRT) at 15°-25°C.

Specific to human serum in the support of cell therapy developers, GeminiBio has a market-leading portfolio of both Research Grade and Clinical Grade products, and capabilities to ensure cell therapy developers can successfully advance their technologies.

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What sets us apart is more than geography—it's mindset. We're not just compliance experts; we're problem-solvers, mentors, and strategic partners. When clients call us, it's because something critical needs to get done—right the first time, under scrutiny, and with confidence.

Our success is grounded in core values that define how we operate:

- **Integrity** – We speak the truth, even when it's uncomfortable, because patient safety and regulatory credibility demand it.
- **Excellence** – Every solution we offer is built for durability—not just inspection day, but for long-term operational strength.
- **Partnership** – We embed with our clients, listen before prescribing, and act like part of the team—because we've been the team.
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At Compliance Insight, our Regulatory Services are designed to support clients throughout the entire product lifecycle—from development through approval and beyond. We bring both strategic insight and tactical execution to help life science organizations navigate complex regulatory pathways with confidence and speed.

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- **FDA Meeting Support:** From pre-IND meetings to post-market interactions, we guide clients through formal and informal FDA communications, including meeting prep, briefing document development, and strategy for response to FDA queries or observations.
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Quality Services

Our Quality Services are built to embed operational excellence into your systems—so you're not just meeting compliance requirements, you're building a culture that sustains it.

Core Quality Capabilities Include:

- **Quality Management System (QMS) Development and Remediation:** We build, assess, and optimize QMS frameworks aligned with 21 CFR Parts 210/211, 820, ATMPs and applicable ICH and ISO standards. Whether designing from scratch or remediating findings, our systems are audit-proof and scalable.
- **Deviation, CAPA, and Change Control Systems:** Our team enhances the effectiveness of your deviation handling and CAPA processes, ensuring root causes are identified and sustainable corrections are implemented and tracked.
- **Internal and Supplier Audits:** We provide independent GMP, GCP, and GLP audits—of your internal systems or third-party suppliers—with risk-ranking and remediation recommendations that are inspection-grade.
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