

GxP GAP Assessment Readiness Checklist

Inspection-Focused Compliance Screening for Regulated Environments

Overview

This advisory checklist is designed to support structured readiness reviews in regulated pharmaceutical and life sciences environments. It provides a practical framework for identifying weaknesses impacting compliance, data integrity assurance, and inspection readiness.

Key Areas Covered

- | Governance and accountability |
 - | Risk-based assurance controls |
 - | Evidence expectations and traceability |
 - | Audit trail and access management readiness |
 - | Inspection defensibility principles |
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CSV | Data Integrity | Validation | Inspection Readiness

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Prepared By: RelyAlnt Advisory Services

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Purpose

This checklist is designed to support a structured readiness review of key compliance controls commonly evaluated during regulatory inspections. It enables organisations to identify areas of potential weakness and prioritise improvement initiatives.

This document is intended for advisory screening purposes and does not represent a compliance determination.

How to Use

For each checklist item, assess implementation maturity using the following scale:

Score	Meaning	Description
0	Not Implemented	Control does not exist or is absent in practice.
1	Partially Implemented	Control exists but is inconsistent, incomplete, or poorly governed.
2	Implemented	Control exists and is generally followed with evidence available.
3	Implemented and Effective	Control is embedded, routinely monitored, and inspection defensible.

1. Quality Governance & Oversight

- ☐ Quality policy is approved, current, and communicated
- ☐ Quality objectives are defined and monitored
- ☐ Defined governance structure exists (QA oversight and accountability)
- ☐ Management review is performed and documented
- ☐ Quality metrics and trending are monitored routinely
- ☐ Deviation system is implemented and consistently used
- ☐ CAPA system exists and demonstrates effectiveness
- ☐ Change control process exists and is enforced
- ☐ Quality Risk Management framework is established (risk-based decision making)
- ☐ Outsourced activity oversight is defined and documented

2. Documentation & Good Documentation Practice (GDP)

- ☐ Document control system is implemented and effective
 - ☐ SOPs are current, approved, and aligned with operational practice
 - ☐ Document lifecycle management exists (review, approval, revision, archival)
 - ☐ Controlled forms and templates are used consistently
 - ☐ Obsolete documents are prevented from unintended use
 - ☐ Record retention requirements are defined and followed
 - ☐ Archive and retrieval processes are effective and traceable
 - ☐ GDP expectations are formally trained and enforced
 - ☐ Logbooks are controlled, issued, and reconciled
 - ☐ Documentation errors and corrections follow GDP standards
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3. Training & Competency

- ☐ Role-based training matrix exists
 - ☐ GxP induction training is performed for all relevant personnel
 - ☐ Training is performed prior to task execution
 - ☐ Training records are complete, current, and retrievable
 - ☐ Training effectiveness is assessed (not only attendance)
 - ☐ Refresher training is performed periodically
 - ☐ Contractor and third-party training is controlled
 - ☐ Validation and data integrity training exists for system users
 - ☐ Competency assessments exist for critical roles
 - ☐ Training gaps are tracked and addressed through quality processes
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4. Validation Lifecycle & Qualification Controls

- ☐ Validation Master Plan (VMP) exists and is current
- ☐ Qualification strategy is defined (DQ / IQ / OQ / PQ)
- ☐ Validation deliverables are traceable, approved, and version controlled
- ☐ Equipment qualification is performed and documented
- ☐ Utility systems qualification exists (e.g., HVAC, purified water, compressed air)
- ☐ Cleaning validation is implemented where applicable
- ☐ Calibration program exists and is effective
- ☐ Preventive maintenance program exists and is documented
- ☐ Validation deviations are investigated and assessed for impact
- ☐ Requalification / periodic review approach is defined and implemented

5. Computerized Systems Assurance (CSV)

- ☐ Inventory of computerized systems exists and is current
 - ☐ GxP impact assessments are documented
 - ☐ System ownership and accountability are defined
 - ☐ Intended use and system boundaries are documented
 - ☐ Risk-based validation approach is implemented
 - ☐ Requirements documentation exists (URS / configuration / functional controls)
 - ☐ Testing evidence exists and is traceable to requirements
 - ☐ Backup and restore controls are implemented and tested
 - ☐ Change control is applied to validated systems and configurations
 - ☐ Periodic review is performed to confirm continued validated state
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6. Data Integrity (ALCOA+) Readiness

- ☐ Unique user accounts are enforced (no shared accounts)
 - ☐ Access control is role-based and reviewed periodically
 - ☐ Audit trails are enabled for critical data and cannot be disabled by users
 - ☐ Audit trail review is performed routinely and documented
 - ☐ Metadata is retained and retrievable
 - ☐ Data review process includes completeness and abnormality checks
 - ☐ Raw data is retained (including failed, aborted, or repeat activities)
 - ☐ Data transcription is controlled and verified
 - ☐ Time synchronization is implemented across systems
 - ☐ Spreadsheet governance exists and is applied to critical spreadsheets
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7. Production & Operational Control Readiness

- ☐ Batch record process is controlled and complete
- ☐ Line clearance is defined and consistently performed
- ☐ Material status controls exist (approved, quarantined, rejected)
- ☐ Traceability exists for raw materials and finished product
- ☐ In-process controls are documented and performed
- ☐ Hold times are defined and justified where applicable
- ☐ Deviations in production are recorded and investigated
- ☐ Process validation lifecycle is documented (where applicable)

- ☐ Environmental monitoring controls exist (where applicable)
 - ☐ Cross-contamination and mix-up prevention controls exist
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8. Laboratory / QC Readiness (If Applicable)

- ☐ Laboratory instruments are qualified and calibrated
 - ☐ Analytical methods are validated or verified
 - ☐ Sample management and chain of custody are controlled
 - ☐ OOS / OOT processes exist and are followed
 - ☐ Chromatography systems are validated and controlled
 - ☐ Laboratory audit trail review controls exist
 - ☐ Data review and approval processes are documented
 - ☐ Reference standards are controlled and traceable
 - ☐ Stability program exists where applicable
 - ☐ Raw data is retained and inspection-ready
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9. Supplier & Outsourced Activity Oversight

- ☐ Supplier qualification program exists
 - ☐ Critical suppliers are risk-ranked
 - ☐ Supplier audits performed or justified
 - ☐ Quality agreements exist for outsourced activities
 - ☐ Incoming goods inspection process exists
 - ☐ Supplier change notification is monitored
 - ☐ Outsourced testing oversight exists
 - ☐ Supplier performance is reviewed periodically
 - ☐ Transport and storage conditions are controlled where required
 - ☐ Complaints linked to suppliers are investigated and trended
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10. Inspection Readiness & Evidence Availability

- ☐ Inspection readiness approach exists and is documented
- ☐ Key quality documents can be retrieved rapidly
- ☐ Validation documentation can be retrieved within defined timelines
- ☐ Training records are retrievable and complete
- ☐ CAPA, deviations, and change control logs are current and accessible
- ☐ System and equipment evidence is organised and inspection-ready

- ☐ SMEs can explain processes, controls, and system intended use
 - ☐ Site documentation reflects actual operational practices
 - ☐ Data integrity evidence is available (audit trail reviews, access reviews)
 - ☐ Mock inspection or readiness exercises performed periodically
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11. Critical Red Flags (Immediate Escalation Indicators)

If any of the following are observed, urgent remediation is recommended:

- ☐ Shared logins exist in GxP systems
 - ☐ Audit trails are disabled, missing, or not reviewed
 - ☐ Incomplete or missing batch records
 - ☐ Uncontrolled spreadsheets used for critical calculations or batch release
 - ☐ Weak segregation of duties (admins approving their own work)
 - ☐ Deviations and CAPAs remain open or repeatedly ineffective
 - ☐ Validation documentation missing for critical systems
 - ☐ Data is overwritten rather than retained
 - ☐ System backups exist but restore testing is not performed
 - ☐ SOPs exist but do not reflect actual practice
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12. Overall Readiness Rating

Suggested Scoring

Total Score: ____ / ____

Readiness Interpretation

- **0–40%** → High Risk (Significant Remediation Required)
- **41–70%** → Moderate Risk (Targeted Remediation Required)
- **71–100%** → Inspection Ready (Maintain and Improve)

Recommended Next Step

For organisations seeking inspection-defensible readiness evaluation, a structured GAP assessment is recommended to confirm applicability, evidence quality, and remediation priorities aligned with regulatory expectations.

Disclaimer

This checklist is intended as an advisory screening tool and does not constitute a compliance determination. Regulatory applicability, risk classifications, and compliance conclusions must be confirmed by qualified professionals.

RelyAlnt

Confidence in regulated environments.