PHARMUNI PRACTICAL GUIDE

EU GMP Requirements and Compliance Checklist

HOW TO USE THIS GUIDE

Purpose, Scope and Compliance Method

Use the checklist as a structured gap-assessment aid. It does not replace the legally applicable text, the marketing authorisation, site procedures, or competent-authority expectations.

EU Good Manufacturing Practice is not one isolated rule. It is a connected control system covering pharmaceutical quality systems, people, facilities, equipment, documentation, production, quality control, outsourced activities, complaints, recalls, self-inspection, qualification, validation and product-specific annexes.

Recommended use

- Define the products, processes, dosage forms and sites covered by the assessment.
- Map each process to the applicable EudraLex Volume 4 chapters and annexes.
- For every requirement, identify objective evidence: procedure, record, trend, validation output or management decision.
- Classify gaps by patient risk, product-quality risk, data-integrity risk and regulatory significance.
- Assign an owner and target date. Verify effectiveness rather than closing actions administratively.
- Re-run the checklist before inspections, major changes, new product introduction and periodic management review.

Evidence principle

A control is not inspection-ready merely because an SOP exists. Inspectors normally expect the written system to match actual practice, records to be complete and contemporaneous, responsibilities to be clear, and deviations from the intended state to be investigated and managed through the Pharmaceutical Quality System (PQS).

Document convention

Items marked [ ] are review points. “Evidence” means retrievable, approved and traceable records. “Risk-based” means the rationale is documented and proportionate to product quality, patient safety and data integrity.

ORIENTATION

Contents and 2026 Regulatory Snapshot

This edition reflects public EU/PIC/S material available in August 2026. Draft texts are clearly identified as drafts, not current binding GMP requirements.

Contents

CHAPTER 1

EU GMP Framework & Governance

Build the compliance map before you build the checklist.

Biopharmaceutical production environment. Photo: Asemi / Wikimedia Commons, CC BY-SA 4.0.

What this chapter helps you do

- Distinguish legal requirements, GMP guidance and company procedures.
- Understand how Part I, Part II, Part III, Part IV and annexes fit together.
- Connect ICH Q9 quality risk management with ICH Q10/PQS principles.
- Clarify senior management, Quality Unit, QP and MAH responsibilities.

CHAPTER 1.1

EU GMP Regulatory Architecture

A strong GMP program starts by identifying what is legally applicable, what is interpretive guidance, and what is an internal control standard.

EudraLex Volume 4 contains EU guidance for interpreting GMP principles and guidelines for medicinal products. Manufacturers should read it together with applicable EU legislation, national implementation, marketing authorisation commitments, manufacturing authorisation conditions and product-specific obligations.

Four layers to map

- Legal basis — EU directives, regulations and national law define enforceable obligations.
- GMP guide — EudraLex Volume 4 translates those principles into expected GMP systems and controls.
- Product commitments — the marketing authorisation, clinical-trial dossier or technical package may contain process, testing and control commitments.
- Site system — SOPs, specifications, master records, validation protocols and quality agreements operationalise the requirements.

Why the hierarchy matters

A site can be procedurally compliant yet still be regulatory non-compliant if its SOP conflicts with approved product commitments or omits an applicable annex. Conversely, an internal standard may deliberately be stricter than the minimum regulatory expectation. The gap assessment should therefore trace each critical control back to the governing source and the local implementation document.

Compliance question

Can the site explain, for each high-risk process, which regulatory requirement applies, where the requirement is implemented, who owns it, what evidence demonstrates performance and how changes to the requirement are monitored?

CHAPTER 1.2

How Volume 4 Is Structured

Use the structure to avoid “generic GMP” assessments that miss product- or technology-specific requirements.

Part I — Medicinal products

Part I contains the core GMP chapters for finished medicinal products, including the Pharmaceutical Quality System, personnel, premises and equipment, documentation, production, quality control, outsourced activities, complaints/recalls and self-inspection.

Part II — Active substances

Part II addresses GMP for active substances used as starting materials. Sites handling APIs should assess the applicability of Part II independently from finished-product controls because responsibilities, material flows, impurity risks and change management can differ.

Part III — GMP-related documents

Part III contains GMP-related documents that support interpretation and implementation. They can be particularly useful for risk management, supply-chain understanding and quality-system design, even where a specific document is not structured as an annex.

Part IV — ATMP GMP

Advanced Therapy Medicinal Products are addressed through specific GMP guidance in Part IV. Do not automatically apply a standard finished-product checklist without assessing the product platform, manufacturing model and ATMP-specific expectations.

Annexes

Annexes add requirements for specific technologies or activities such as sterile manufacture, computerised systems, qualification and validation, certification/batch release and importation. Applicability should be documented rather than assumed.

CHAPTER 1.3

PQS and Quality Risk Management

The Pharmaceutical Quality System is the mechanism that keeps a validated, controlled process in a state of control.

The PQS should integrate management responsibility, process performance, product-quality monitoring, change management, CAPA, knowledge management and continual improvement. Quality risk management should support decisions without becoming a substitute for scientific understanding or basic GMP compliance.

Risk-based does not mean reduced evidence

- Define the question or decision before selecting a risk tool.
- Use current process knowledge, product data and historical performance.
- Separate severity from detectability and probability rather than collapsing concerns into one score.
- Document uncertainty, assumptions and the basis for risk acceptance.
- Escalate decisions where residual risk could affect patient safety, product quality or data integrity.
- Review risk assessments when deviations, trends, changes or new knowledge invalidate assumptions.

Management review evidence

Senior management should receive meaningful quality information, not only metrics. The review should identify adverse trends, overdue CAPAs, recurring deviations, supplier concerns, validation status, inspection findings, resource constraints and effectiveness of prior actions. Decisions should be documented with accountable owners and due dates.

CHAPTER 1.4

Roles, QP, MAH and Senior Management

GMP responsibilities may be delegated operationally, but accountability must remain explicit and traceable.

Senior management

Senior management is expected to support an effective PQS through governance, resources, escalation routes and quality culture. A repeated deficiency with no resource response can indicate a governance failure rather than an isolated operational problem.

Quality Unit / QA

QA commonly owns or oversees document control, deviation/CAPA systems, change control, qualification status, supplier quality, training governance, self-inspection and batch-disposition support. Independence should be sufficient to make quality decisions without inappropriate production pressure.

Qualified Person (QP)

For EU batch certification, the QP must be able to rely on complete and reliable evidence that the batch complies with applicable GMP and relevant authorisation requirements. Quality agreements and technical arrangements should support, not obscure, QP responsibilities.

Marketing Authorisation Holder (MAH)

The MAH can hold GMP-related responsibilities that require effective interfaces with manufacturers, contractors and supply-chain partners. Changes, product-quality reviews, complaints, shortages, recalls and regulatory commitments can require coordinated information exchange.

Inspection test

For any critical decision, can the site show who was authorised to decide, what information they reviewed, why the decision was justified and how conflicts or escalations were handled?

CHAPTER 1 — WORKING TABLE

Table 1. Regulatory Framework Mapping

Use this table to map a site's compliance architecture before detailed inspection preparation.

Framework element	Primary purpose	Typical owner	Expected evidence	Common gap
EU legal basis	Defines enforceable obligations	Regulatory / Legal	Applicable legislation register; licences	Requirements tracked only in SOPs
EudraLex Volume 4 Part I	Finished-product GMP system	QA / Operations	GMP gap assessment; SOP map	Generic checklist misses chapters
Part II	API GMP controls	API QA / Supply	Supplier/API controls; audits	API risks treated like excipients
Part III / IV	Supporting or specialised GMP guidance	QA / SMEs	Applicability rationale	Specialised product model overlooked
Applicable Annexes	Technology/activity-specific GMP	QA / Validation / QC	Annex matrix; evidence map	Annex applicability assumed
Marketing authorisation / dossier	Product-specific commitments	RA / QP / QA	Commitment register; change assessment	Site changes not checked vs dossier
Site PQS	Operationalises control	Senior Mgmt / QA	Procedures, records, metrics, reviews	System exists but is ineffective

How to use

Complete one mapping table per site or legal entity. Add product-specific rows where different dosage forms, sterile operations, importation models or contract-manufacturing networks create materially different requirements. Review the map whenever a regulation, licence, annex, manufacturing step or supply-chain responsibility changes.

CHAPTER 2

Core GMP System Controls

Convert the regulatory framework into routine, observable control.

Vials on a pharmaceutical production line. Photo: Sadegh Nikgostar / Wikimedia Commons, CC BY 4.0.

What this chapter helps you do

- Assess the operating health of the core Part I GMP systems.
- Connect procedures with records, training, monitoring and effectiveness.
- Identify evidence that an inspector can retrieve and challenge.
- Distinguish isolated record errors from weak system design.

CHAPTER 2.1

Personnel, Training and GMP Behaviour

Training is effective only when people can perform the controlled task correctly and understand when to stop or escalate.

- Maintain current organisation charts, job descriptions and delegated responsibilities for GMP-critical roles.
- Define initial, task-specific, periodic and remedial training requirements by role.
- Link training assignments to effective SOP versions and required completion dates.
- Evaluate practical competence for aseptic work, sampling, equipment operation, review activities and other high-risk tasks.
- Control temporary staff, contractors and visitors according to risk and access level.
- Ensure hygiene, gowning, health and behaviour rules are appropriate to the manufacturing area.
- Use deviation and audit trends to identify where “training completed” has not translated into reliable performance.

Inspection evidence

Inspectors may compare the training record with what the operator actually does. A useful readiness review therefore selects critical tasks, observes execution, checks the current procedure, confirms training/qualification status and verifies that the person knows the escalation route for abnormal conditions.

Red flag

Repeated “operator error” root causes can indicate weak procedure design, supervision, workload, ergonomics, equipment interface or quality culture. Human performance should be evaluated within the system, not used as an automatic CAPA endpoint.

CHAPTER 2.2

Premises, Equipment and Utilities

Facility and equipment controls should prevent mix-ups, contamination, cross-contamination and loss of process control.

- Maintain layouts and flows that support segregation of people, materials, waste and product states.
- Define cleaning, sanitation/disinfection and maintenance programs with justified frequencies.
- Control status labelling and prevent use of equipment that is unqualified, overdue or under maintenance.
- Identify critical utilities such as HVAC, water, gases, steam, compressed air and environmental systems.
- Trend alarms, excursions, maintenance history and repeated breakdowns for quality impact.
- Assess cross-contamination risk using product, process, facility and containment knowledge.
- Ensure measuring devices are calibrated and traceable; investigate out-of-tolerance conditions for prior impact.

Lifecycle expectation

Equipment control does not end at IQ/OQ/PQ. The site should maintain the qualified state through preventive maintenance, calibration, change control, periodic review, software/configuration control where relevant, and requalification triggered by risk or evidence.

CHAPTER 2.3

Documentation and Data Integrity

Good documentation should reconstruct what happened, when it happened, who performed it and what evidence supported the decision.

Records should be attributable, legible, contemporaneous, original or a controlled true copy, accurate, complete, consistent, enduring and available across the retention period. Data-integrity controls should cover paper, hybrid and electronic records rather than focusing only on laboratory systems.

Control points

- Approve, issue, revise and archive documents through controlled workflows.
- Prevent obsolete instructions from remaining available at points of use.
- Define good documentation practices for corrections, blank fields, dates, signatures and attachments.
- Identify critical data and metadata before setting review depth and frequency.
- Control user access, privileges, shared accounts, administrator activity and segregation of duties.
- Review audit trails where they are required to support data reliability and GMP decisions.
- Validate backup, restore, retention, archiving and record retrieval processes.

Inspection question

Can the organisation demonstrate not only that data exist, but that data were generated under controlled conditions and that the complete record — including relevant metadata and changes — supports the reported result or batch decision?

CHAPTER 2.4

Production and In-Process Controls

The batch record should demonstrate that the process remained within the approved and validated operating state.

- Use approved master instructions and ensure executed records identify the correct product, batch, equipment and materials.
- Verify line clearance and status controls before start-up and after changeover.
- Control dispensing, reconciliation, yields and material identity to detect mix-ups or unexplained losses.
- Record critical process parameters and in-process controls at the time of performance.
- Define action for alarms, process interruptions, holds, reprocessing, rework and unplanned interventions.
- Assess deviations for product impact before the batch is released or further processed.
- Maintain traceability of printed components, labels, packaging materials and reconciliation where relevant.

Validated state

A process can drift while still producing passing test results. Production review should therefore look at process capability, critical parameters, intervention patterns, equipment performance, deviations, yields and trends — not only the final specification result.

CHAPTER 2.5

Quality Control, Sampling and Laboratory Decisions

QC results are only as reliable as the sampling plan, method control, instrument state, data review and investigation process behind them.

- Use approved specifications, methods and sampling plans linked to the correct material or product version.
- Control reference standards, reagents, solutions, columns, cultures and laboratory consumables as applicable.
- Maintain instrument qualification/calibration status and controlled analytical software configurations.
- Review calculations, integrations, sequences, audit trails and atypical events proportionate to criticality.
- Define scientifically sound OOS/OOT/atypical-result procedures and avoid testing into compliance.
- Ensure stability samples, chambers, pulls, testing windows and data reviews are controlled.
- Verify data transfer and certificate generation when results move between LIMS, CDS, ERP or manual records.

Release readiness

The laboratory package should allow an independent reviewer to reconstruct the test from sample receipt through calculation and final result. Any invalidated result should have a documented scientific basis, and the investigation should consider laboratory and manufacturing causes without premature closure.

CHAPTER 2.6

Outsourced Activities and Supplier Control

Outsourcing transfers work, not GMP responsibility.

- Qualify suppliers and service providers using risk-based criteria before GMP-critical use.
- Define responsibilities, communication routes, deviations, changes, complaints, records and audit rights in quality agreements.
- Approve and monitor material specifications, certificates, transport conditions and supplier changes.
- Use performance indicators that reveal recurring late changes, deviations, OOS results or documentation failures.
- Control contract laboratories, calibration vendors, IT/cloud providers and consultants according to GMP impact.
- Define when an on-site audit, remote assessment, questionnaire or reliance model is justified.
- Requalify using actual performance and risk, not calendar frequency alone.

Supply-chain challenge

A certificate of analysis or service report is not a substitute for supplier oversight. The regulated organisation should understand what evidence it relies on, where critical records are retained, how changes are communicated and how failures are escalated across organisational boundaries.

CHAPTER 2 — WORKING TABLE

Table 2. Core GMP System Control Matrix

Rate each system on design, execution, monitoring and effectiveness rather than procedure existence alone.

System	Key control question	Minimum evidence	Leading indicator	Typical risk
Training	Can staff perform the task?	Curricula; qualification; observation	Repeat errors by task	Human-performance failure
Equipment	Is qualified state maintained?	Qualification; PM; calibration	Overdue PM / alarms	Process drift
Documents	Is current instruction used?	Version control; issuance; archive	Obsolete-copy events	Execution inconsistency
Data integrity	Is the complete record reliable?	Access; audit trail; backup; review	Privileged-user anomalies	Unreliable decisions
Production	Is process state controlled?	Batch record; IPC; deviations	Intervention / yield trends	Batch impact
QC	Are results scientifically defensible?	Raw data; review; OOS/OOT	Invalidation / repeat-test rate	False release/reject
Suppliers	Is external performance controlled?	Qualification; agreement; metrics	Recurring supplier events	Supply / quality failure
CAPA / Change	Do actions preserve control?	Investigation; risk; effectiveness	Repeat recurrence	Systemic failure

Scoring suggestion

Score each system 0–3: 0 = missing/uncontrolled; 1 = defined but inconsistently executed; 2 = generally effective with manageable gaps; 3 = demonstrated, monitored and sustained. Any patient-safety, product-quality or data-integrity critical gap should override the numerical score and trigger immediate escalation.

CHAPTER 3

Annex-Specific Compliance

Apply annexes by activity, technology and product risk — not by habit.

Biotechnology cleanroom team. Photo: Chien Chih-Hung / Taiwan Presidential Office via Wikimedia Commons, CC BY 2.0.

What this chapter helps you do

- Create an annex applicability matrix for each site and product family.
- Focus on Annex 1, Annex 11, Annex 15, Annex 16 and Annex 21 where relevant.
- Prepare for the revised Annex 19 effective date in September 2026.
- Track draft Chapter 1/4, Annex 11 and Annex 22 developments without treating drafts as final law.

CHAPTER 3.1

Build an Annex Applicability Matrix

The correct question is not “Which annexes exist?” but “Which annexes apply to this specific product, process, system and supply-chain step?”

Applicability logic

- Product type — sterile, biological, radiopharmaceutical, investigational, herbal, medicinal gas or other specialised category.
- Manufacturing activity — production, packaging, importation, sampling, testing, certification or storage.
- Technology — computerised systems, automated processing, isolators, lyophilisation or single-use systems.
- Supply-chain role — contract giver, contract acceptor, importer, testing site, packaging site or certification site.
- Lifecycle state — development, technology transfer, commercial manufacture, change, validation or discontinuation.

Evidence to retain

For each potentially relevant annex, document the applicability decision, responsible SME, implementing procedures, validation/qualification evidence, review frequency and known gaps. When an annex is judged not applicable, record the rationale if the exclusion could reasonably be challenged during inspection.

Avoid checklist copying

Annex requirements should be translated into process-specific evidence. For example, Annex 11 should not become an IT-only checklist: QA, system owner, process owner, validation, security and data governance may all contribute to the evidence package.

CHAPTER 3.2

Annex 1: Sterile Manufacturing and CCS

Sterility assurance depends on a holistic contamination-control system, not only environmental monitoring results.

EU GMP Annex 1 is fully applicable, including the previously deferred lyophiliser loading/unloading provision. A central expectation is the Contamination Control Strategy (CCS), which should integrate facility, equipment, utilities, personnel, materials, process controls, cleaning/disinfection, monitoring, validation and improvement.

CCS review points

- Identify critical contamination hazards and control points across the facility.
- Justify cleanroom grades, pressure cascades, airflow concepts and barrier technology.
- Qualify cleaning/disinfection processes and establish appropriate sporicidal strategy.
- Control aseptic operator qualification, interventions and ongoing performance.
- Trend viable/non-viable monitoring and identify meaningful changes in flora or process behaviour.
- Connect media fills/APS, sterilisation, filter integrity and container-closure controls to process risk.
- Review CCS effectiveness after deviations, facility changes, recurring trends and new technology.

Inspection focus

The CCS should work as a living synthesis of controls and risk, not as a document created only to satisfy Annex 1. Inspectors may test whether the strategy explains why controls are designed as they are and whether monitoring data support the claimed state of contamination control.

CHAPTER 3.3

Annex 11: Computerised Systems and Data Integrity

Treat the current Annex 11 as the compliance baseline and the consulted revision as a forward-looking design signal.

- Maintain an inventory of GMP-relevant systems with owners, intended use, criticality and validation status.
- Define user requirements and verify functionality proportionate to risk and complexity.
- Control configuration, interfaces, master data, user access, administrator privileges and changes.
- Protect records through backup, restore testing, retention, archiving and business continuity.
- Review incidents and system failures for product, process and data-integrity impact.
- Ensure supplier/service-provider responsibilities are defined and evidence remains accessible.
- Establish periodic evaluation to confirm continued validated state and appropriate security.

2026 horizon watch

The European Commission/PIC/S consultation on revised Annex 11 increases emphasis on data integrity, lifecycle management, automation and modern system risks. A new draft Annex 22 addresses AI/ML models in critical GMP applications, including intended use, training/test data, validation, performance monitoring, change control and human oversight. Until finalised, these drafts should support gap forecasting rather than be cited as current binding requirements.

CHAPTER 3.4

Annex 15: Qualification and Validation

Validation should demonstrate that facilities, systems, equipment, processes and controls remain fit for intended use throughout the lifecycle.

Lifecycle controls

- Maintain a Validation Master Plan or equivalent governance describing scope, responsibilities and strategy.
- Translate process/product knowledge into user requirements, acceptance criteria and critical aspects.
- Use DQ/IQ/OQ/PQ or justified equivalent lifecycle evidence for facilities, equipment and systems.
- Validate manufacturing processes using a strategy appropriate to lifecycle stage and process understanding.
- Control cleaning validation, including worst-case rationale, limits, sampling, recovery and hold times.
- Validate transport where conditions can affect product quality.
- Use change control and periodic review to determine requalification or revalidation need.

Evidence quality

A protocol that passed all tests is not sufficient if acceptance criteria were weak, deviations were unexplained, data were excluded without rationale or the qualified configuration no longer matches the equipment in use. Validation review should connect requirements, executed evidence, deviations and released state.

Regulatory intelligence

PIC/S has published a concept paper on future revision of Annex 15. Maintain awareness, but use the current approved Annex 15 as the compliance baseline until revisions are final.

CHAPTER 3.5

Annex 16, Annex 21 and Annex 19 Update

Batch certification, importation and sample retention depend on reliable information across organisational and geographic boundaries.

Annex 16 — Certification and batch release

The QP should have access to the information needed to certify that the batch meets GMP and relevant authorisation requirements. Technical agreements, deviations, supply-chain data, testing, manufacturing records and change information should support the certification decision.

Annex 21 — Importation

Importers should understand the full supply chain and control responsibilities for imported medicinal products. The importer's systems should address documentation, testing/certification arrangements, transport and storage, information exchange, deviations, complaints, recalls and oversight of third-country operations.

Annex 19 — Reference and retention samples

The European Commission published a revised Annex 19 in June 2026, applicable from 24 September 2026. Sites should complete an implementation assessment covering sample type, quantity, location, access, retention period, responsibilities and arrangements across contract and importation models before the effective date.

Readiness action

Create one cross-functional batch-certification evidence map showing what information flows to the QP, where it originates, who verifies it and how late changes or unresolved events prevent certification.

CHAPTER 3 — WORKING TABLE

Table 3. Annex Applicability Matrix

Adapt this matrix to the actual product, process and site. “Yes” should always link to concrete implementation evidence.

Annex	Typical trigger	Core evidence	Primary owners	Readiness question
Annex 1	Sterile manufacture	CCS; EM; APS; sterilisation	QA / Sterility / Ops	Does CCS explain control effectiveness?
Annex 11	GMP computerised systems	URS; validation; access; review	QA / IT / System owner	Is validated state maintained?
Annex 15	Qualification / validation	VMP; protocols; reports; review	Validation / QA / Engineering	Is lifecycle evidence traceable?
Annex 16	EU batch certification	QP evidence package; agreements	QP / QA / RA	Can every certification reliance be defended?
Annex 19	Reference/retention samples	Sampling/retention arrangements	QC / QA / Supply	Ready for 24 Sep 2026 revision?
Annex 21	Importation	Supply-chain map; import controls	Importer / QA / QP	Are third-country dependencies controlled?
Other annex	Product/activity specific	Applicability assessment	QA / SME	Has “not applicable” been justified?

Governance

Review the annex matrix during new-product introduction, technology transfer, major facility/system change, new import route, contract-manufacturer change and annual regulatory-intelligence review. Document both new applicability and justified removal of applicability.

CHAPTER 4

Inspection Readiness & Master Checklist

Move from “we have procedures” to “we can prove control quickly.”

Controlled bioprocess manufacturing area. Photo: Tehran Times / Wikimedia Commons, CC BY 4.0.

What this chapter helps you do

- Run a risk-based readiness review against objective evidence.
- Challenge data, deviations, CAPA, validation and supplier controls like an inspector.
- Use the 60-point checklist to identify weak links across systems.
- Score readiness and establish immediate containment for critical gaps.

CHAPTER 4.1

Checklist: Governance, People and Facility Control

Start with the systems that establish accountability and the physical conditions for reliable GMP execution.

[ ] **1.** Applicable EU GMP chapters, annexes and legal obligations are mapped to site activities.
[ ] **2.** Manufacturing and import authorisations, licences and site details are current and consistent with operations.
[ ] **3.** Marketing-authorisation or dossier commitments relevant to manufacturing/testing are controlled and accessible.
[ ] **4.** PQS governance, responsibilities and escalation paths are documented and understood.
[ ] **5.** Senior management reviews quality performance, recurring issues and resource constraints.
[ ] **6.** Quality-risk assessments use current data, clear assumptions and documented risk acceptance.
[ ] **7.** Organisation charts and job descriptions reflect actual GMP responsibilities.
[ ] **8.** Critical roles have qualified deputies and defined decision authority.
[ ] **9.** Training curricula match tasks, procedures and role risk.
[ ] **10.** Practical competence is verified for high-risk activities, not inferred from attendance alone.
[ ] **11.** Personnel know how and when to stop work or escalate an abnormal condition.
[ ] **12.** Hygiene, gowning and health controls are appropriate to the manufacturing area.
[ ] **13.** Facility flows reduce mix-up, contamination and cross-contamination risk.
[ ] **14.** Equipment status, calibration and preventive maintenance are current and visible.
[ ] **15.** Critical utilities are qualified, monitored and trended for adverse performance.

Escalation rule

Any gap that can directly compromise sterile assurance, identity, strength, purity, traceability, batch-release reliability or data integrity should be contained immediately. Do not wait for the full readiness review to finish before controlling a critical risk.

CHAPTER 4.2

Checklist: Documentation, Systems and Data Integrity

Challenge whether the complete GMP record can be reconstructed and trusted.

[ ] **16.** Only current approved procedures and forms are available at points of use.
[ ] **17.** Executed records are attributable, legible, contemporaneous, complete and traceable.
[ ] **18.** Corrections and late entries preserve the original information and include rationale where required.
[ ] **19.** Critical data and metadata are defined for each GMP-relevant process/system.
[ ] **20.** Electronic user accounts are unique; shared accounts are eliminated or strictly justified/controlled.
[ ] **21.** Administrator privileges are restricted, approved and subject to oversight.
[ ] **22.** Audit-trail review scope and frequency are risk-based and documented.
[ ] **23.** Backup and restore processes are tested; archived records remain readable and retrievable.
[ ] **24.** Computerised-system inventory, ownership, intended use and validation status are current.
[ ] **25.** System changes, patches, interfaces and configuration changes follow controlled assessment.
[ ] **26.** Hybrid paper/electronic workflows have defined source data and reconciliation controls.
[ ] **27.** Deleted, invalidated, repeated or reprocessed data are visible and scientifically explained.
[ ] **28.** Data review confirms completeness, not only final reported values.
[ ] **29.** Record-retention periods and locations are defined and match applicable requirements.
[ ] **30.** Business-continuity plans protect access to critical GMP records and systems.

Challenge method

Select one high-risk batch or laboratory result and trace it end-to-end: source data, metadata, review, changes, calculations, system access, audit trails and final decision. A well-designed control should remain coherent across all records.

CHAPTER 4.3

Checklist: Production, QC and Validation

Inspection readiness depends on the scientific defensibility of the process and the evidence supporting each result.

- [ ] **31.** Master manufacturing instructions are approved and match the authorised/validated process.
- [ ] **32.** Executed batch records identify correct materials, equipment, steps, dates, times and performers.
- [ ] **33.** Line clearance and status controls prevent mix-ups and carryover.
- [ ] **34.** Critical process parameters and in-process controls are recorded and reviewed.
- [ ] **35.** Unplanned interventions, alarms, holds and process interruptions are assessed for batch impact.
- [ ] **36.** Process deviations are resolved or scientifically justified before disposition.
- [ ] **37.** Yield/reconciliation anomalies are investigated when outside justified expectations.
- [ ] **38.** QC methods, specifications and sampling plans are current and approved.
- [ ] **39.** Laboratory instruments and software are qualified/validated for intended use.
- [ ] **40.** OOS/OOT/atypical investigations follow scientifically sound, predefined processes.
- [ ] **41.** Retesting/resampling is controlled and cannot be used to test into compliance.
- [ ] **42.** Stability chambers, pulls, test windows and trend reviews are controlled.
- [ ] **43.** Validation/qualification protocols have meaningful acceptance criteria linked to requirements.
- [ ] **44.** Validation deviations are investigated before release of the validated state.
- [ ] **45.** Periodic review/change control confirms the validated state remains current.

Challenge method

Choose a process with recent changes or deviations. Compare the validated design, current operating parameters, executed records, investigation history and product-quality data. Look for silent drift, undocumented workarounds or acceptance criteria that no longer reflect actual process risk.

CHAPTER 4.4

Checklist and Readiness Scoring

Close the review by testing whether the PQS detects, corrects and prevents loss of control across organisational boundaries.

[ ] 46. Suppliers and contract service providers are qualified according to GMP risk.
[ ] 47. Quality agreements clearly define responsibilities, changes, deviations, records and communication.
[ ] 48. Supplier performance is monitored using actual quality and delivery data.
[ ] 49. Material/supplier changes are assessed before implementation.
[ ] 50. Deviations distinguish immediate correction from root-cause investigation and systemic CAPA.
[ ] 51. Root causes are supported by evidence and do not default to “human error.”
[ ] 52. CAPA actions address causal mechanisms and include effectiveness criteria.
[ ] 53. Recurring events are detected across products, departments, equipment and time periods.
[ ] 54. Change controls assess product, process, validation, regulatory and data-integrity impact.
[ ] 55. Changes are verified after implementation and closed only when intended outcomes are demonstrated.
[ ] 56. Complaints and quality defects are triaged for patient/product risk and possible recall impact.
[ ] 57. Recall/defect procedures include current contacts, traceability and periodic effectiveness testing.
[ ] 58. Self-inspection covers system effectiveness and verifies prior actions.
[ ] 59. Inspection commitments and prior findings are tracked to sustainable closure.
[ ] 60. The site can retrieve requested evidence quickly and explain the control in consistent language.

Table 4. Readiness Scoring

Score	State	Evidence profile	Action	Inspection stance
0	Uncontrolled	Missing or unreliable	Contain immediately	High exposure
1	Defined, weak execution	Procedure exists; records inconsistent	Correct system design/execution	Likely challenge
2	Generally controlled	Evidence present; limited gaps	Targeted remediation	Defensible with follow-up
3	Demonstrated control	Consistent evidence + trends + effectiveness	Maintain and monitor	Inspection-ready
Critical	Override	Patient/product/DI risk regardless of score	Escalate now	Do not average out

FINAL PAGE

10-Day Readiness Plan and Reference Library

Use the final ten working days before an inspection to improve evidence retrieval and control clarity — not to manufacture records retroactively.

10-day readiness sequence

- Days 10–9: confirm inspection scope, licences, product/site map, annex applicability and prior commitments.
- Days 8–7: run targeted record challenges for batches, deviations, CAPA, changes, OOS/OOT and validation.
- Days 6–5: review data-integrity controls, audit trails, privileged access, backups and critical system status.
- Days 4–3: verify supplier/contractor evidence, quality agreements, complaints/recalls and QP information flows.
- Day 2: conduct a mock inspection focused on retrieval speed, SME consistency and open high-risk issues.
- Day 1: confirm logistics, document-room controls, escalation routes and factual briefing of SMEs. Do not coach scripted answers.

Primary regulatory references

- European Commission — EudraLex Volume 4
- EMA — Good Manufacturing Practice
- EMA — GMP/GDP Questions & Answers
- PIC/S — Publications / PE 009-17 GMP Guide
- European Commission — revised Annex 19 notice
- European Commission — Chapter 4 / Annex 11 / Annex 22 consultation

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