



FREE RESOURCE · 2026 EDITION

GxP Inspection Readiness Checklist

A practical self-assessment for pharmaceutical and biotech teams preparing for an FDA, Health Canada, MHRA or EU inspection, a customer audit or partner due diligence.

How to use it

Work through each section with the relevant owners. Tick only what you can evidence with documents or records today.

Scoring

Any unticked item is a potential finding. Prioritise items that affect patient safety, product quality or data integrity.

When

Start at least 90 days before an expected inspection, then repeat 30 days out to confirm gaps are closed.

01 Quality System & Management Oversight

- ☐ Quality manual and quality policy are current, approved and reflect how the organisation actually operates.
- ☐ Organisation chart and job descriptions are current, with QA independence clearly defined.
- ☐ Management reviews are held at the defined frequency, with quality metrics, trends and follow-up actions documented.
- ☐ Quality risk management is applied and documented for key processes and decisions (ICH Q9(R1)).
- ☐ Internal audit programme is on schedule, with findings tracked to closure.

02 Documentation & Data Integrity

- ☐ All SOPs are approved, within their periodic review date and consistent with actual practice on the floor.
- ☐ Records meet ALCOA+ principles: attributable, legible, contemporaneous, original, accurate — and complete, consistent, enduring and available.
- ☐ Computerised systems are validated, with access controls, audit trails enabled and audit-trail review defined (21 CFR Part 11 / EU Annex 11).
- ☐ Controlled forms and logbooks are issued and reconciled; no uncontrolled copies or "shadow" records exist.
- ☐ Records can be retrieved quickly — ideally within minutes — for any batch, study or product in scope.

03 Deviations, CAPA & Change Control

- ☐ Open deviations and investigations are within defined timelines; any overdue items have documented justification.
 - ☐ Investigations identify genuine root causes, not only "human error" or retraining.
 - ☐ CAPAs are specific, owned, on time and verified for effectiveness.
 - ☐ Change controls include documented impact assessment (regulatory, validation, training) before implementation.
 - ☐ Recurring issues are trended and escalated through management review.
-

04 Training & Personnel

- ☐ Training matrix covers every role; all staff are trained on current SOP versions before performing tasks.
 - ☐ GxP, data integrity and good documentation practice training is current for all relevant staff.
 - ☐ Training effectiveness is assessed for critical procedures.
-

05 Facilities, Equipment & Validation (manufacturing & laboratory sites)

- ☐ Equipment and utilities are qualified; calibration and preventive maintenance are current with no overdue items.
 - ☐ Process, cleaning and analytical method validation status is current and documented.
 - ☐ Environmental monitoring and water system data are trended, with excursions investigated.
 - ☐ Laboratory out-of-specification (OOS) and out-of-trend results are investigated per procedure.
-

06 Suppliers & Outsourced Activities

- ☐ Approved supplier list is current, with qualification rationale for each critical supplier.
 - ☐ Quality agreements are in place and current with every CMO, CRO, laboratory and critical supplier.
 - ☐ Supplier audits are performed on a risk-based schedule, with findings followed up.
 - ☐ Oversight of outsourced activities is documented — not assumed.
-

07 Product Quality, Complaints & Clinical Oversight

- ☐ Annual product reviews / product quality reviews are complete and on time.
 - ☐ Complaints are logged, investigated, trended and linked to CAPA where needed.
 - ☐ Recall procedure is current and has been tested with a mock recall.
 - ☐ For clinical programmes: sponsor oversight of CROs and sites is documented, and the trial master file is complete and inspection-ready (ICH E6).
-

08 Inspection Logistics & People

- ☐ An inspection-management SOP defines roles, escalation and communication.
- ☐ Front room / back room set-up, document request log and runners are planned and rehearsed.
- ☐ Subject-matter experts are identified and coached on answering clearly, factually and within their expertise.
- ☐ Storyboards or summaries are prepared for high-risk topics (for example, significant deviations or recent changes).
- ☐ Commitments and observations from previous inspections and audits are closed and evidenced.
- ☐ A plan exists to respond to observations promptly — for FDA Form 483 observations, within 15 business days.

► Suggested Timeline

90 days out
Complete this checklist and a gap assessment. Agree a prioritised remediation plan.

60 days out
Close high-risk gaps. Update SOPs and training. Run a mock inspection.

30 days out
Re-check open items, finalise storyboards, coach SMEs and rehearse logistics.

► Action Plan

Record every unticked item, assign an owner and a due date, and review progress weekly.

Gap / action	Owner	Due date	Status

Want an independent view before the inspectors arrive?

Radical Pharma Consultancy provides gap assessments, mock inspections and hands-on remediation support across Canada, the US, the UK and the EU.

Book a free discovery call: [radicalpharmaconsultancy.com](https://www.radicalpharmaconsultancy.com) · umesh@radicalpharmaconsultancy.com · +1 (416) 804-4974

This checklist is general guidance to support internal self-assessment. It does not constitute regulatory or legal advice and is not a complete list of requirements for any specific product, site or jurisdiction. © 2026 Radical Pharma Consultancy Inc.