# Schedule M quality-system checklist

For small and mid-size Indian pharmaceutical plants. Use this to see whether Part I quality-system records are current — not assembled the week before inspection. This is not gazette text and not a certificate of Premises or Plant compliance.

**Scope.** Schedule M still requires suitable Premises, Plant, utilities, and equipment in the physical facility. This checklist covers the pharmaceutical quality system inspectors ask to see in records: documents, events, reviews, signatures, and evidence. QualiGxP does not certify a facility as Schedule M compliant. The site remains responsible for validated intended use and for the building.

## Plant

| | |
|---|---|
| LEGAL ENTITY / PLANT NAME | SITE TYPE (FORMULATION / API / BOTH) |
| OWN MANUFACTURING / CONTRACT / LOAN-LICENCE | INSPECTION TYPE (CDSCO / STATE / WHO / CUSTOMER) |
| ASSESSOR | DATE |

## How to mark each topic

☐ In place — procedure and current records ☐ Partial — SOP exists, records lag ☐ Gap — cannot show it this week

☐ N/A — justified in the Site Master File

Tick a box only if you can retrieve the record without rebuilding it. “We have an SOP” is not the same as “we can show the last three signed events.”

## Part I quality-system topics

*Topic codes I.1–I.22 match QualiGxP’s Schedule M gap-assessment checklist (key Part I subjects, not a substitute for the official Schedule).*

### I.1 Pharmaceutical Quality System (PQS)

☐ In place ☐ Partial ☐ Gap ☐ N/A

- A current description of the PQS exists (quality manual or equivalent) and names the quality unit’s independence.
- Management review of PQS performance happens on a defined cycle, with minutes and actions — not only an SOP that says it should.
- Open quality-event counts, overdue work, and inspection findings feed that review.

*QualiGxP: management review, quality metrics, Schedule M readiness view (QMS).*

| Evidence / location | Owner | Due |
|---|---|---|
| | | |

### I.2 Quality Risk Management (QRM)

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Risk assessments are used for changes, deviations, complaints, audit findings, investigations, and computerised systems — not a standalone binder.
- Initial and residual risk are scored, with a named owner and a reason for acceptance.
- Major and critical changes cannot be approved without residual-risk review where your procedure requires it.

*QualiGxP: QRM linked to change, deviation, CAPA, complaint, audit finding, investigation, and CSV.*

Evidence / location | Owner | Due

### I.3 Product Quality Review (PQR)

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Each product (or justified group) has a PQR for the defined period.
- Inputs include complaints, deviations, changes, recalls, laboratory events, and process performance — not a narrative written from memory.
- Completion is signed. Where the review requires it, CAPA or change control is raised and traced.

*QualiGxP: Product Quality Reviews with signed completion and spawn to CAPA or change control.*

Evidence / location | Owner | Due

### I.4 Change Control

☐ In place ☐ Partial ☐ Gap ☐ N/A

- GMP-relevant changes are logged and assessed before they are made.
- Impact on controlled documents, validation, training, and equipment is recorded.
- Implementation and effectiveness review are signed. Affected SOPs are revised through document control, not a side copy.

*QualiGxP: Change Control with document-impact tracing into DMS revisions.*

Evidence / location | Owner | Due

### I.5 Deviation Management

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Unplanned departures are recorded contemporaneously, with facts, product/batch where relevant, and a named owner.
- Investigation and root cause are completed before closure. Critical events have linked risk assessment where required.
- You can retrieve the last three closed deviations and show who signed each gate.

*QualiGxP: Deviations with linked investigations, signatures, and private evidence.*

Evidence / location | Owner | Due

### I.6 Corrective and Preventive Action (CAPA)

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Corrective and preventive actions are planned, owned, and dated — not a sentence at the bottom of a deviation.
- Effectiveness is checked before close. Failed checks reopen the plan; they are not overwritten.
- Overdue CAPAs are visible to QA without opening every spreadsheet.

*QualiGxP: CAPA lifecycle with effectiveness milestones linked to deviations and investigations.*

Evidence / location | Owner | Due

### I.7 Validation and Qualification

☐ In place ☐ Partial ☐ Gap ☐ N/A

- A Validation Master Plan is current and lists GxP equipment, processes, and computerised systems in scope.
- DQ / IQ / OQ / PQ (or equivalent) and process / cleaning qualification exist for assets your procedures require.
- Failed or incomplete qualification is visible; it is not filed as “done” without a signed close.

*QualiGxP: VMP, equipment assets, and qualification records — distinct from CSV of computerised systems. Facility Premises qualification remains a site engineering responsibility.*

Evidence / location | Owner | Due

### I.8 Self-inspection / Internal Audit

☐ In place ☐ Partial ☐ Gap ☐ N/A

- A defined internal-audit programme covers PQS processes on a cycle you can show.
- Findings are tracked. Actionable nonconformities spawn CAPA. An audit is not closed while findings remain open.
- Last audit report, findings, and CAPA status can be produced together.

*QualiGxP: self-inspection with findings and CAPA handoff.*

Evidence / location | Owner | Due

### I.9 Complaints Handling

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Every market complaint is logged with product and batch (or a justified reason they are unknown).
- Assessed product-quality complaints hand off to a deviation; recall-worthy complaints hand off to recall.
- Complaint trends appear in PQR and management review.

*QualiGxP: complaint intake with deviation and recall handoff.*

Evidence / location | Owner | Due

### I.10 Product Recalls

☐ In place ☐ Partial ☐ Gap ☐ N/A

- A current recall procedure exists. A mock recall has been run and the report is signed.
- Product recall is distinct from recalling a controlled document copy.
- Complaint linkage and reconciliation of returned packs can be shown.

*QualiGxP: product recall (including mock-recall) and returns with QA disposition.*

Evidence / location | Owner | Due

### I.11 Documentation and Document Control

☐ In place ☐ Partial ☐ Gap ☐ N/A

- There is one current master list of SOPs, BMR/BPR, logs, and forms. Effective is not the same as approved.
- Issued copies carry a number and watermark. Obsolete copies are recalled; they cannot still be printed or used on the line.
- Required training is complete before a document becomes operational. Retention, archival, and destruction are controlled states.

*QualiGxP DMS (required core): templates, masters, approval, training, issuance, execution copies, revision, retention.*

| Evidence / location | Owner | Due |
|---|---|---|
| | | |

### I.12 Computerized Systems

☐ In place ☐ Partial ☐ Gap ☐ N/A

- GxP computerised systems are inventoried with intended use.
- CSV exists: requirements, tests, executions, residual risk, independent QA release, periodic review.
- Access control, audit trails, and backup/restore are described and evidenced. Shared approval logins are not used.

*QualiGxP: CSV Validation Projects with signed decisions and printable ALCOA+ traceability.*

| Evidence / location | Owner | Due |
|---|---|---|
| | | |

### I.13 Personnel and Training

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Role curricula are tied to effective SOPs, not to a one-time induction pack.
- People do not execute or independently verify work they are not trained for. Requalification is defined.
- A training sample for a named role can be produced for an inspector pack.

*QualiGxP: competency matrix linked to effective SOPs; optional gates on execution and change-control approval.*

| Evidence / location | Owner | Due |
|---|---|---|
| | | |

### I.14 Premises and Equipment

☐ In place ☐ Partial ☐ Gap ☐ N/A

- **Records you should hold:** equipment list, qualification status, calibration and preventive-maintenance schedules, out-of-tolerance linked to a deviation, overdue calibration visible to QA.
- **Not a software certificate:** building layout, HVAC performance, utilities, and physical Plant suitability remain the site's responsibility.
- Critical assets cannot be treated as in-use when calibration is overdue, if your procedure says they cannot.

*QualiGxP: equipment, calibration, and PM records. QualiGxP does not certify Premises, HVAC, or plant layout.*

| Evidence / location | Owner | Due |
|---|---|---|
| | | |

### I.15 Materials Management

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Receipt, quarantine, sampling, and release procedures are controlled documents, and status is visible in the batch record.
- Critical material suppliers are qualified, with periodic review and signed decisions.
- Traceability from material lot to batch can be shown without reconstructing email.

*QualiGxP: controlled procedures and supplier qualification; warehouse execution remains a site process supported by issued records.*

Evidence / location | Owner | Due

### I.16 Production Operations

☐ In place ☐ Partial ☐ Gap ☐ N/A

- The copy on the line is an issued BMR/BPR or log, not a photocopy of the last batch.
- Independent verification and line clearance are captured where required. Incomplete steps block QA disposition.
- Yield, reconciliation, and contemporaneous entries match ALCOA+ expectations in your procedures.

*QualiGxP DMS: issued writable execution copies for BMR, BPR, logs, forms, and checklists.*

Evidence / location | Owner | Due

### I.17 Quality Control Laboratory

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Specifications and methods are controlled documents. Unofficial printouts are not in use.
- OOS / OOT follow Phase I and Phase II rules. Confirmed events gate to investigation and deviation.
- You can show the last confirmed OOS through to deviation and CAPA without a gap in dates.

*QualiGxP: laboratory OOS/OOT with investigation and deviation gates.*

Evidence / location | Owner | Due

### I.18 Contract Manufacture and Analysis

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Quality agreements exist for contract manufacturers and laboratories, with defined PQS responsibilities.
- Oversight (audits, result review, deviation flow-back) is documented.
- Contract work appears in PQR and, where relevant, in change control and complaints.

*QualiGxP: supplier qualification and quality-event records that receive contract-site inputs. The agreement itself remains a site document.*

Evidence / location | Owner | Due

### I.19 Batch Release

☐ In place ☐ Partial ☐ Gap ☐ N/A

- QA / authorised-person release is a signed decision against a complete batch record.
- Open deviations, OOS, and missing issuance or verification are visible at the point of release.
- Release cannot be performed against an incomplete or recalled execution copy.

*QualiGxP: QA disposition on issued execution records; quality-event status remains in QMS.*

Evidence / location | Owner | Due

### I.20 Ongoing Stability Programme

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Marketed products have an ongoing stability programme described in a controlled procedure.
- Stability OOS / OOT are handled under laboratory and deviation rules.
- Stability conclusions feed PQR. Missing pulls are explained, not omitted.

*QualiGxP: controlled procedures, laboratory events, PQR inputs. Chamber mapping and pull execution remain site operations.*

Evidence / location | Owner | Due

### I.21 Retention Samples

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Quantity, storage conditions, identification, and retrieval are in a controlled procedure.
- Reconciliation of retention samples can be shown for recent batches.
- Use of a retention sample (complaint, investigation) is recorded and linked to the quality event.

*QualiGxP: controlled procedures and quality-event linkage. Physical sample stores remain a site responsibility.*

Evidence / location | Owner | Due

### I.22 Returns and Reprocessing

☐ In place ☐ Partial ☐ Gap ☐ N/A

- Returned product has QA disposition (release, reject, reprocess) with a reason and signature.
- Reprocessing or reworking runs only under change control or a justified deviation — not an undocumented line decision.
- Returns appear in recall, complaint, and PQR inputs where relevant.

*QualiGxP: product returns with QA disposition, linked to recall and complaints.*

Evidence / location | Owner | Due

## Inspector pack — can you produce this without a late-night binder?

**Documents**

- ☐ Effective SOP index and a sample of current masters
- ☐ Issued-copy register (who holds what)
- ☐ Signed Site Master File (current version)
- ☐ Training sample for one shop-floor role and one QA role

**Quality system**

- ☐ Open deviation, CAPA, and change-control counts
- ☐ Schedule M gap summary with clause status
- ☐ CSV project counts and release status
- ☐ Overdue calibration / critical findings

*QualiGxP QMS can export an entitlement-gated inspector evidence pack (SOP sample, open-event counts, gap summary, CSV counts, training sample). Use it as a start; your site still owns Premises evidence and physical walkthroughs.*

## After you score

- Anything marked **Gap** needs an owner and a date before the next inspection window — not a promise to "update the SOP."
- Anything marked **Partial** usually means the procedure exists and the last three records do not. Fix the records first.
- Start software with document control if issuance and obsolete copies are the finding. Add the quality-event workspace when CAPA and deviations live in spreadsheets.

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QualiGxP is pharmaceutical DMS and QMS software for small and mid-size Indian plants. Topic list I.1–I.22 is QualiGxP's Part I gap-assessment checklist (key subjects, not official gazette wording). This document does not certify Premises, Plant, HVAC, or Schedule M compliance. Request information: qualigxp.com/contact.html · Schedule M page: qualigxp.com/schedule-m.html · contact@qualigxp.com