PQS GMP Readiness Checklist

Practical educational self-assessment for pharmaceutical GMP systems and inspection readiness

Site / Department:		Assessment date:	
Area / Process:		Assessor:	
Product / Scope:		Reference SOP(s):	

1. Pharmaceutical Quality System and management oversight

Check	Readiness question	Status / evidence
[ ]	Are responsibilities for quality decisions, escalation and oversight clearly defined?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are deviations, complaints, CAPA, changes and quality trends reviewed for recurrence/systemic risk?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are significant quality issues escalated to appropriate management/Quality Unit?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Can the site show how recurring issues are converted into corrective or preventive system improvements?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are resources, responsibilities and quality objectives sufficient for the activities performed?	[ ] Ready [ ] Gap [ ] N/A

2. Personnel, training and hygiene

Check	Readiness question	Status / evidence
[ ]	Are personnel qualified/trained for the tasks they actually perform?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Can operators explain the current procedure and critical steps rather than only show a training signature?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are responsibilities and supervision appropriate to the activity and risk?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are gowning, hygiene and access controls implemented where required?	[ ] Ready [ ] Gap [ ] N/A

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3. Premises and equipment

Check	Readiness question	Status / evidence
[ ]	Are facility flows/layout and controls appropriate to prevent contamination, cross-contamination and mix-ups?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Is equipment status obvious and supported by current cleaning, maintenance, calibration and qualification evidence where required?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are equipment logs complete and consistent with actual use?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are utilities/environmental controls monitored and maintained as appropriate to product/process risk?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are cleaning and maintenance activities controlled so they do not compromise product quality?	[ ] Ready [ ] Gap [ ] N/A

4. Raw materials and packaging materials

Check	Readiness question	Status / evidence
[ ]	Can each material be traced from receipt through status, sampling/testing or verification, storage and issuance?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are approved, quarantined and rejected materials clearly controlled and segregated as appropriate?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are labels, identity and quantities reconciled where required?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are storage conditions monitored and excursions assessed?	[ ] Ready [ ] Gap [ ] N/A

Walkthrough rule: If a material or piece of equipment has a status, the site should be able to show the objective evidence that supports that status.

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5. Documentation and record control

Check	Readiness question	Status / evidence
[ ]	Are only current approved procedures/forms available at the point of use?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Do records show what actually happened, when, by whom and under which instruction?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are corrections, late entries, blanks and attachments handled under approved procedures?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are obsolete copies withdrawn/controlled and retention/retrieval requirements met?	[ ] Ready [ ] Gap [ ] N/A

6. Manufacturing and in-process controls

Check	Readiness question	Status / evidence
[ ]	Are batches manufactured according to current approved instructions?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are critical process parameters/steps and IPCs controlled and documented in real time?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are line clearance, reconciliation, yield and status controls implemented where required?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are unexpected events documented and assessed rather than informally worked around?	[ ] Ready [ ] Gap [ ] N/A

7. QC and laboratory controls

Check	Readiness question	Status / evidence
[ ]	Are approved specifications and suitable analytical methods used?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are standards, reagents, instruments and calculations controlled and traceable?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Can complete raw data, processing history and relevant metadata be reconstructed for a reported result?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are OOS/atypical laboratory events investigated with evidence rather than repeated until passing?	[ ] Ready [ ] Gap [ ] N/A

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8. Qualification and validation

Check	Readiness question	Status / evidence
[ ]	Are critical facilities, utilities, equipment, processes, cleaning, computerized systems and analytical procedures qualified/validated as required?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are acceptance criteria and conclusions linked to intended use and scientific evidence?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are changes to validated/qualified systems assessed through change control?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Is requalification/revalidation or continued monitoring performed where required/justified?	[ ] Ready [ ] Gap [ ] N/A

9. Deviations, CAPA and change control

Check	Readiness question	Status / evidence
[ ]	Are deviations investigated to an appropriate depth based on risk and evidence?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are recurring events trended rather than repeatedly closed as isolated errors?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Do CAPAs address root/system causes and include effectiveness verification where appropriate?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are planned changes impact-assessed, approved, implemented and verified before closure?	[ ] Ready [ ] Gap [ ] N/A

10. Batch review, complaints, recalls and self-inspection

Check	Readiness question	Status / evidence
[ ]	Does batch disposition consider manufacturing, laboratory and relevant open quality events together?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Are complaints and quality defects investigated and trended appropriately?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Can the site execute a recall/traceability response according to approved procedures?	[ ] Ready [ ] Gap [ ] N/A
[ ]	Do self-inspections identify meaningful system weaknesses and track corrective actions?	[ ] Ready [ ] Gap [ ] N/A

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11. Inspection-style observation record

Observation:	
Area / record / equipment:	
What was expected:	
What was observed:	
Immediate risk / product impact:	
Evidence reviewed:	
Systemic scope / recurrence:	
Proposed action / escalation:	

12. Action plan

Gap / action	Owner	Due date	Effectiveness / closure evidence

Overall readiness:
[ ] No major gaps identified in assessed scope
[ ] Improvement actions required
[ ] Formal deviation / CAPA / change assessment required
[ ] Quality Unit / management escalation required

Educational resource: This checklist does not replace applicable GMP regulations, official guidance, site SOPs, product-specific requirements, formal inspection programs or Quality Unit decisions.