Driving Quality
Innovation & Culture

AI Risk Management Readiness Checklist For QA/QC & GMP-Regulated Environments (Q2 2026)

Use this checklist to pressure-test whether your AI systems would withstand regulatory scrutiny under evolving FDA, EMA, and MHRA expectations.

1. Governance & Oversight

- ☐ AI systems are formally inventoried within the Pharmaceutical Quality System (PQS)
- ☐ Each AI system has a documented owner (business + technical)
- ☐ Roles and responsibilities are defined (including human oversight points)
- ☐ AI use cases are approved through a documented governance process
- ☐ There is a policy defining acceptable AI use in GMP environments

2. Risk Assessment (Aligned with ICH Q9)

- ☐ A documented Quality Risk Management (QRM) assessment exists for each AI system
- ☐ Risk assessment evaluates impact on:
  - Critical Quality Attributes (CQAs)
  - Critical Process Parameters (CPPs)
  - Batch release decisions
  - Data integrity
- ☐ Risk level determines validation depth and monitoring frequency
- ☐ Failure modes (e.g., incorrect prediction, model drift, data corruption) are identified
- ☐ Mitigation controls are clearly documented
- ☐ AI-related risks are included in site-level risk registers

3. Validation & Model Qualification

- ☐ Intended use is clearly defined and documented
- ☐ Training data sources are documented and assessed for quality and bias
- ☐ Validation dataset is independent from training data
- ☐ Performance metrics are predefined and justified
- ☐ Acceptance criteria are documented prior to validation
- ☐ Validation results are formally approved
- ☐ Worst-case and edge-case scenarios are tested (where applicable)

4. Change Control & Lifecycle Management

- ☐ AI models are under formal change control
- ☐ Retraining triggers are predefined (e.g., performance degradation thresholds)
- ☐ Model versioning is documented and traceable
- ☐ Updates require impact assessment before deployment
- ☐ Periodic review schedule is defined
- ☐ Decommissioning procedures exist

5. Ongoing Performance Monitoring

- ☐ Performance monitoring plan is documented
- ☐ Model drift detection mechanisms are in place
- ☐ Trending is performed on prediction accuracy
- ☐ Alerts are triggered when thresholds are exceeded
- ☐ Escalation procedures are defined
- ☐ Human override capability exists

6. Data Integrity & Documentation (ALCOA+ Ready)

- ☐ Full audit trail for:
  - Input data
  - Model version
  - Output results
- ☐ Access controls are defined and enforced
- ☐ Data lineage is traceable
- ☐ Documentation supports inspection readiness
- ☐ Outputs are reviewable and explainable (as appropriate to risk level)

7. Regulatory Disclosure Assessment

- ☐ Assessment completed on whether AI outputs:
  - Support regulatory submissions
  - Influence validated processes
  - Affect batch disposition decisions
- ☐ Documentation package prepared in case of inspection or regulatory query
- ☐ Clear rationale exists if AI use is considered "internal decision support only"

8. "Human-in-the-Loop" Controls

- ☐ Defined review points before critical decisions
- ☐ Clear override authority established
- ☐ Staff trained on AI system limitations
- ☐ Training includes bias awareness and model limitations

9. Inspection Readiness Test

Ask your team:

- Can we explain this AI system clearly to an FDA/EMA inspector?
- Can we show documented risk assessment aligned with ICH Q9?
- Can we demonstrate ongoing control of performance?
- Can we justify why this level of validation is sufficient?

If any answer is unclear, then remediation is likely needed.

⚠ Red Flags Regulators May Focus On

- Black-box tools influencing release decisions
- Undocumented retraining
- No drift monitoring
- Lack of change control
- No documented risk assessment
- Overreliance without human review