# Maturity Model Framework

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# Quality Compliance & Audit: High-Level Assessment (*page 1*)

**DEFINITION:** Leads and manages compliance with GxP requirements and GxP audit activities

| | UNAWARE | DEVELOPING | MANAGING | OPTIMIZING | LEADING |
|---|---|---|---|---|---|
| **Document Management** | Do not manage and control documents | Some procedures and instructions exist but are not controlled | Have a basic document control system for review, approval, and update; may be paper based | Using an optimized EDMS with appropriate procedures, training, and control | State-of-the-art EDMS fully integrated with other QS technology for ease of compliance |
| **Training System** | Training is sporadic and not documented | Some skills training in place, as needed; not a comprehensive plan, may not be fully documented | Overall training program in place, including curriculum assignments and ongoing updates; may be linked to document mgmt. system | Analysis of training metrics in relation to quality events with appropriate action taken; training effectiveness measured and monitored; pro-active refresher training | Integrated training system, linked to other QMS modules for quality review; state-of-the-art training methods in use |
| **Perform Internal Audits** | No internal audits performed | Internal audits only for limited key areas, no overall audit program | Scheduled periodic internal audit program with clear documentation and follow-up corrective actions | Risk-based internal audit schedule; audit metrics included in mgmt. Review; CAPA are robust and extended beyond the actual audited area | Audit metrics are correlated to other quality metrics; lessons learned shared across quality areas and incorporated into future training |
| **Perform External Audits** | No external audits performed | May perform occasional external audits as specifically indicated for cause | External audit program schedule and procedures in place with appropriate follow up of remediation efforts | Risk-based external audit schedule; audit metrics included in mgmt. Review; CAPA implementation and effectiveness reported | Work with vendors/partners to help them prepare for audits |

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# Quality Compliance & Audit: High-Level Assessment (*page 2*)

**DEFINITION:** Leads and manages compliance with GxP requirements and GxP audit activities

| | UNAWARE | DEVELOPING | MANAGING | OPTIMIZING | LEADING |
|---|---|---|---|---|---|
| **Host Audits / Inspections** | No plan in place to host audits/inspections; mad scramble takes place when auditors arrive | Some procedures and instructions exist but are not controlled | Have a plan and trained team in place for hosting, with appropriate documentation and forms available for use | Regularly conduct mock audits to prepare and test the process to be ready for unannounced inspection at any time; use any lessons learned to enhance the process | Work with partners/ vendors to teach them the skills needed to host inspections/audits |
| **Inspection Prep** | No advance inspection prep done | Prep conducted for specific announced inspections/ audits; some participants identified | A defined inspection team is identified and properly trained, appropriate procedures in place | Periodic readiness testing with mock audits, using audit results to improve future prep | Have a defined team with responsibility for audit prep and share insights with other companies/partners |
| **Lead / Facilitate Quality Management Reviews (Should Be 2x/Year)** | No Quality Mgmt. Reviews conducted | Plans for periodic quality reviews in place, may be only a superficial review with no actions taken | Procedures for quality review in place; required input for reviews is identified along with evaluation criteria; some CAPA in place for issues identified | Corrective actions assessed for effectiveness; quality reviews integrated into periodic project reviews to provide continuous awareness of any potential issues | Metrics and results from quality mgmt. reviews are incorporated into continuous improvement plans and future development of new project/product/process |
| **Quality Review Of Software Validation Including Protocols Scripts & Reports** | No quality review of software validation | Awareness of the need for software validation but only superficial review conducted | Procedures and plans in place for appropriate quality review and corrective action as indicated | Corrective actions are assessed for effectiveness; results analyzed for trends and identification of preventive action | Metrics and results from quality reviews are incorporated into continuous improvement plans |

# Quality Operations: High-Level Assessment (*page 1*)

**DEFINITION:** Manages Quality Assurance for pre-commercial and commercial product operations

| | UNAWARE | DEVELOPING | MANAGING | OPTIMIZING | LEADING |
|---|---|---|---|---|---|
| **BATCH RECORD REVIEW** | Not keeping appropriate batch record or conducting any review | Have basic batch documentation; may not control updates; may have a superficial review process | Have a basic document control system for review, approval, and update; may be paper based | Good control of updates and changes to batch records with clear criteria for review and evidence of completion | Robust control of batch record development, use, and review with clear instructions and evidence of completion |
| **Quality Events** (deviations, investigations, CAPA, change control) | Do not document or investigate Quality Events | Document events, but may not investigate thoroughly or think about wider impact of event | Have good event documentation and investigation process with some corrective actions initiated | Events are documented in a QMS with connections identified for related events; full investigation, analysis, and impact assessment made for all events | Use of an electronic QMS, with linked modules for related events, robust investigation, and follow-up process, with trending of metrics for analysis |
| **CHANGE CONTROLS** | No documentation or structured review of proposed changes | Review document with some proposed changes without full impact assessment | Document and review all changes, including assessing impact of change and providing contingency plans | Robust process controls for planning, approving, documenting, and implementing changes; analysis of results and trends | Integrated process for review of changes with metrics and analysis of impact on future quality events |
| **Annual Product Reviews (APR)** | No annual product reviews done | Awareness of the need for APR, but limited sets of metrics and data reviewed | Clearly identified metrics to be reviewed and plan for escalation to mgmt. as needed | Following a schedule for comprehensive review and discussion of results with senior mgmt. to address any identified trends | Reviewing APR info over time to look for trends; full process of escalation of any potential issues |
| **Quality Agreements** | No Quality Agreement in place | Informal agreements with some partners/vendors | Quality Agreements in place with key partners and vendors with periodic review and evaluation | Quality Agreements in place with every partner/vendor as needed; have a template and defined process for review and approval of QAs | Risk-based assessments to determine need and depth for QA; all agreements in place prior to use; periodic evaluation to ensure agreements are being enforced |

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# Quality Operations: High-Level Assessment (*page 2*)

**DEFINITION:** Manages Quality Assurance for pre-commercial and commercial product operations

| | ○ UNAWARE | ◔ DEVELOPING | ◑ MANAGING | ◕ OPTIMIZING | ● LEADING |
|---|---|---|---|---|---|
| **Product Complaints** | Not receiving or dealing with Product Complaints | Awareness of need to address complaints; may not do a thorough investigation or corrections | Documented process for receipt and handling of complaints, including investigation, notifications, and some corrective actions | Full system in place to investigate, do risk analysis, determine corrective actions or there is a related AE | Expand investigation to similar products, look for trends, report as needed to mgmt., implement corrective and preventative measures |
| **Quality Review of: Product / Process specific validation** | Product/Process validation not done | Awareness of the need for validation; may not include all required testing and analysis | Validation activities completed and documented for key processes | All required processes fully validated; change control system includes re-validation as indicated | Understanding of risk-based validation process to increase effectivity; sharing of info with similar products and processes |
| **Lot Release** | All lots are released automatically | Basic Lot release process in place; may not be robust | Lot release criteria and release process defined; have contingency plans in place to deal with any issues | Lot release metrics are compiled and reviewed; CAPAs initiated for any issues /risks identified | Metrics used to identify areas of risk; release process optimized to focus on high-risk areas |

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