SUPPLIER QUALITY TOOL

Supplier Qualification Assessment Workbook

Convert supplier selection into documented confidence based on material risk, capability, evidence and ongoing performance.

USE THIS WORKBOOK TO

01	02	03	04
Classify supplier and material risk	Plan due diligence and audits	Approve with evidence and conditions	Monitor performance and changes

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SECTION 1

Supplier and material risk profile

Qualification depth should reflect what is supplied, how failure could affect patients and how readily defects can be detected.

Profile element	Assessment	Evidence / rationale
Supplier legal name, site and role		
Material / service and intended use		
Critical quality attributes / service controls		
Detectability before use or release		
Supply complexity and business continuity		
Regulatory / compendial expectations		

Overall risk classification
Low / medium / high with rationale

SECTION 2

Desktop due diligence

Verify identity, authorisation, quality capability and history before relying on declarations or certificates.

Evidence	Acceptable?	Finding / expiry
Licences, registrations and inspection history		
GMP / GDP or relevant certification		
Quality-system questionnaire		
Specifications, methods and sample CoA		
Manufacturing site and subcontractors		
Recall, warning, complaint and change history		
Financial and continuity considerations		

Information gaps and required follow-up

SECTION 3

Audit and technical assessment

Use a risk-based audit or justified alternative evidence to assess the actual controls at the supplying site.

Area	Evidence to examine	Finding / rating
Quality governance and data integrity	Procedures, records, oversight and electronic controls	
Materials and traceability	Starting materials, sampling, testing and release	
Production / service controls	Process, validation, deviations and change control	
Facilities and equipment	Suitability, cleaning, maintenance and environment	
Laboratory controls	Methods, standards, OOS and retained data	
CAPA and improvement	Investigation quality, recurrence and effectiveness	

Critical observations / CAPA required before approval

SECTION 4

Sample, trial and quality-agreement review

Evidence should demonstrate that supplied material or service can meet defined requirements under routine conditions.

Requirement	Status	Reference / condition
Samples / trial lots meet specification		
Analytical method / CoA expectations agreed		
Packaging, labelling, storage and transport defined		
Change-notification requirements defined		
Deviation, complaint, recall and investigation roles clear		
Subcontracting and site-change controls agreed		
Records, retention and audit rights established		

Conditional approval requirements

SECTION 5

Approval decision and supplier controls

Approval status must state what is approved, for which site and material, under which controls and for how long.

Decision	Select	Control expectation
Approved	[ ]	Routine controls and performance monitoring.
Conditionally approved	[ ]	Defined restrictions and time-bound evidence.
Not approved	[ ]	Do not purchase or use for GMP supply.
Suspended	[ ]	Contain current risk and investigate before reinstatement.

Approved scope, site and materials

Incoming controls, review frequency and requalification date

SECTION 6

Ongoing performance scorecard

Qualification continues after approval. Trend quality, delivery, responsiveness and change-management signals.

Period / metric	Target	Result	Trend / action
Incoming rejects / OOS			
CoA or documentation discrepancies			
Complaints / deviations / recalls			
On-time delivery / excursions			
Change notifications			
Investigation and CAPA quality			

Requalification trigger and decision

SECTION 7

Review, conclusion and approval

Close only when the evidence supports the decision and all unresolved risks have an accountable route forward.

Closeout confirmation	Yes / No / N/A	Reference
Scope and risk rationale are documented		
Required evidence is complete and traceable		
Exceptions were assessed and escalated appropriately		
Actions, owners and due dates are defined		
Residual risk is understood and accepted by Quality		
Review and approval are independent where required		

Overall conclusion and decision

Follow-up actions / monitoring / effectiveness checks

Final approval - name, role, signature and date
Quality Unit and responsible function