Supplier Qualification Questionnaire/QMS Compliance

Code: QUAL-FOR-024	Edition:02	Implementation date: 01/04/2025

General Supplier Information	Company Name
	Contact Person
	Address
	Telephone
	Email
	Website
	Years in Operation
	Domestic/International
	Services Provided

#	Section	Criteria / Information		Comments
1	**Compliance and Certifications**	Valid Licenses and Registrations (ISO1705, WHO, MOPH)	☐ Yes ☐ No	
		Valid accreditation / Certificates	☐ Yes ☐ No	
2	**Quality Assurance**	Quality Management System (QMS) in place	☐ Yes ☐ No	
		Organizational structure and job descriptions	☐ Yes ☐ No	
		Deviations/non-conformities documented	☐ Yes ☐ No	
		Change control process in place	☐ Yes ☐ No	
		Regular internal audits conducted	☐ Yes ☐ No	
4	**Personnel**	Regular staff training provided	☐ Yes ☐ No	
		Annual training plan available	☐ Yes ☐ No	
5	**Facilities & Equipment**	Cleaning schedule for storage areas	☐ Yes ☐ No	
		Temperature data loggers calibrated regularly	☐ Yes ☐ No	
		Equipment regularly maintained	☐ Yes ☐ No	
		Storage room and refrigerator/freezer temperature monitored	☐ Yes ☐ No	
		Access rights to the pharmaceutical warehouse defined	☐ Yes ☐ No	

#	Section	Criteria / Information		Comments
		Measures to prevent contamination and mix-ups	☐ Yes ☐ No	
		Differentiated storage rules followed	☐ Yes ☐ No	
		Designated area for quarantined goods	☐ Yes ☐ No	
6	**Distribution & Transport**	Availability of qualified personnel (drivers, coordinators, etc.)	☐ Yes ☐ No	
		Temperature-controlled transport ensured	☐ Yes ☐ No	
7	**Complaints & Recalls**	Defined procedure for complaint management	☐ Yes ☐ No	
		Batch recall SOP in place	☐ Yes ☐ No	
8	**Returns**	Defined procedure for returns	☐ Yes ☐ No	
		Responsibilities for return handling established	☐ Yes ☐ No	

Evaluation Summary: *The following evaluation summary section is to be completed exclusively by LRC BTS Quality Department.*

Supplier Approval Status Record

Supplier Name	Qualification Status	Review Date	Next Review Date	Comments
	☐ Approved ☐ Conditional ☐ Rejected			

Corrective Action Plan (CAP) Form

#	Issue Identified	Corrective Action Required	Deadline	Responsible Party	Status
1					
2					

Completed by the supplier representative:	**LRC BTS Approval:**
Name: _____	Name: _____
Position: _____	Position: _____
Date: _____	Date: _____
Signature: _____	Signature: _____