Supplier Quality Agreement

Responsibility Matrix Template

Item #	Description of Responsibilities	Biopharma Company	Supplier
1.	Regulatory Compliance		
1.1	Ensure all necessary licenses, registrations, and authorizations to do business and operate a cGMP manufacturing facility under the applicable laws and regulations of the applicable regulatory authority (RA).		X
1.2	Ensure that all facilities used for manufacturing, testing, packaging, shipping, and distribution maintain all licenses, registrations, and authorizations as are required to do business and operate a cGMP manufacturing facility under the applicable laws.		X
1.3	Maintain and operate the manufacturing facility in compliance with the cGMPs, applicable laws, and all other material-specific requirements as agreed to by the parties.		X
1.4	Manufacture, test, package, store, release, and ship the material under the cGMPs, applicable laws, regulatory submissions, and/or filings (e.g., IND, NDA, BLA, etc.), and all other material-specific instructions and requirements agreed to by both parties.		X
1.5	Prepare, maintain, and update the INDs, CTAs, and marketing authorizations under the industry guidance documents from applicable regulatory agencies, cGMPs, applicable laws, and all other material-specific instructions and requirements agreed to by the parties.	X	
1.6	Provide copies of the marketing applications that are associated with the manufacturing, testing, packaging, and shipping of the material prior to submission of the marketing applications to the regulatory authorities.	X	
1.7	Prepare and submit annual material quality review (PQR) reports to the relevant RA by the requirements as specified by the industry guidance documents from applicable regulatory agencies, cGMPs, applicable laws, and all other material-specific instructions and requirements agreed to by the parties.	X	X

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1.8	Develop the PQR schedule based on the RA approval for the material, and request information for the preparation of the annual PQR 120 days in advance of the scheduled submission date.	X	
1.9	Submit the annual PQR to the relevant RA.	X	
1.10	Operate as point of contact with the necessary RA regarding the approval, maintenance, and sale of the material.	X	
2.	Audits & Regulatory Inspections		
2.1	Conduct one annual cGMP audit, at a mutually agreed upon time, of all relevant areas of the supplier's facilities, procedures, and documentation related to the material and services provided by the supplier.	X	
2.2	Conduct a for cause audit, in addition to the annual cGMP audit, if an event or series of events arise which cause a justifiable concern over the quality of the material.	X	
2.3	Provide a written response to all audit findings that require corrective action within 30 business days of receipt of the audit report.		X
2.4	Conduct internal audits of all departments associated with the manufacturing, testing, and storage of the material.		X
2.5	Audit vendors and subcontractors that are used by the supplier associated with the material.		X
2.6	Coordinate the activities necessary to ensure readiness prior to the RA pre-approval inspection (PAI) and maintain inspection readiness for all subsequent inspections.	X	X
2.7	Notify the biopharma company of any RA notice related to an inspection, investigation, requests of information, notices, and violations of a cGMP manufacturing facility that is related to the material within one business day of receiving the notice.		X
2.8	Provide copies of any inspection findings (e.g., FDA Form 483, etc.), warning letters, consent decrees, and official communications related to the material from the associated RA within one business day of receipt.		X
2.9	Review and approve inspection responses to material specific observations prior to submission of the response to the RA.	X	X

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2.10	Ensure post-marketing commitments made to the relevant RA are fulfilled within committed or RA imposed time frames.	X	X
3.	Quality & Medical Complaints		
3.1	Maintain a system for receiving, communicating, investigating, and resolving material complaints.	X	X
3.2	Reply to the complainant according to applicable procedures, GMPs, and applicable laws.	X	
3.3	Supply any available complaint and retain samples for investigation.	X	X
3.4	Investigate all material complaints and adverse drug events.	X	X
3.5	Provide any information relating to the manufacturing of the material which is necessary or useful to address the material complaint or adverse drug event.		X
3.6	Provide the biopharma company with an interim investigation summary report within five days of being notified of the complaint.		X
3.7	Provide the biopharma company with a complete investigation summary report within 25 days of being notified of the complaint.		X
3.8	Reply to the complainant according to applicable procedures, GMPs, and applicable laws.	X	
4.	Recalls, Field Alerts, & Biologics Product Deviation Reports		
4.1	Inform the quality assurance contact from the other party if any issues are observed that might compromise the quality requirements of the material that is in production or already shipped.	X	X
4.2	Inform the quality assurance contact from the other party of any decisions to initiate or receipt of a material recall, Field Alert Report (FAR), or Biologics Product Deviation Report (BPDR).	X	X
4.3	Communicate with the appropriate RA of any material recall, FAR, or BPDR.	X	
4.4	Upon notification, immediately investigate to identify the possible causes for the material recall or material withdrawal and send the results to the biopharma company. Until the final report is issued, send interim report updates every 30 business days.		X

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4.5	Manage material recalls or material withdrawals.	X	X
4.6	Issue the response to any RA field alerts or inquiries regarding safety.	X	
5.	Document Control		
5.1	Review and approve executed batch production records (BPRs) within five business days of receipt.	X	
5.2	Store the master production records (MPRs), BPRs, cGMP documentation, analytical and microbial documentation, and all other documentation associated with the manufacture and testing of the material (e.g., manufacturing facility operation records from the building management system, etc.) for a minimum of two years following the expiration date of manufacture of each batch.		X
5.3	Store records for the minimum time required by cGMPs and applicable laws.		X
5.4	Provide copies of all documentation necessary for biopharma company to respond to inquiries by regulatory authorities.		X
6.	Change Management		
6.1	Act as the primary party responsible for ensuring that all specifications and batch records that specifically relate to the cGMP manufacture and release of the material comply with relevant portions of the marketing applications and marketing authorizations.	X	
6.2	Maintain a change control system that complies with cGMPs and RA expectations and guidance.		X
6.3	Submit any proposed changes to the facilities, critical utilities, specifications, formulation processing, raw materials, container closure, packaging, and labeling specific to or impacting the material to the biopharma company for review, comment, and approval prior to the implementation of such changes.		X
6.4	Evaluate the proposed change controls and assign regulatory reporting category to such changes and proceed as defined per procedures and cGMPs. Minor: Change is not considered an Annual Reportable. Major: Change is considered an Annual Reportable.	X	X

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6.5	Provide any general operations document changes that might have regulatory impact for review and approval.		X
6.6	Notify the supplier of any relevant changes to the RA registrations or their statuses.	X	
6.7	Prepare regulatory applications for filing of documentation in support of the proposed facility, material manufacturing/processing/specification changes and receive regulatory approval for implementation of the changes in accordance with requirements of appropriate agency. Provide a copy of the relevant application to supplier.	X	
6.8	Support the preparation of regulatory applications by providing relevant technical data and other relevant documentation requests.		X
6.9	Act as the primary party in communication with RAs on all regulatory affairs matters.	X	
7.	Quality Operations		
7.1	Ensure the manufacturing facilities are designed, constructed, tested, and maintained in accordance with cleanliness and microbial standards as stated by applicable laws, cGMPs, and procedures.		X
7.2	Ensure the cGMP environment and utilities are designed, constructed, tested, and maintained in accordance with cleanliness and microbial standards as stated by applicable laws, cGMPs, and procedures.		X
7.3	Qualify and validate the facility, equipment, and processes associated with processing the material in accordance with applicable laws, cGMPs, and procedures.		X
7.4	Assure equipment and materials are sufficiently cleaned and stored in a fashion to prevent microbial contamination and cross-contamination.		X
7.5	Establish and approve material specifications.	X	X
7.6	Review material specifications annually for appropriateness by analyzing data generated during the manufacture and testing of the material.	X	X
7.7	Create, approve, and maintain MPRs for all manufacturing operations related material.		X
7.8	Create, review, and approve the initial MPRs and future revisions to the MPRs.	X	X

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7.9	Manufacture and test the material at the established manufacturing facility in accordance with the approved MPRs, analytical/microbial test methods, and specifications.		X
7.10	Document, investigate, and resolve deviations from the MPRs and any out of specification/out of trend (OOS/OOT) test results in accordance with cGMPs.		X
7.11	Provide the biopharma company with a listing of all investigation reports, upon request.		X
7.12	Provide the biopharma company with a copy of an investigation report, upon request.		X
7.13	Obtain QA approval of all investigations and corrective and preventive actions (CAPAs).		X
7.14	Ensure all computerized systems comply with 21 CFR Part 11 requirements.		X
7.15	Create a master validation plan (MVP) and process validation plan (PVP) for the manufacturing processes of the material.		X
7.16	Provide the biopharma company with process or analytical/microbial method validation plans, protocols, development reports, and summary reports related to the testing of the material prior to execution for the biopharma company's review and approval.		X
7.17	Prepare and approve all inserts, labeling, and packaging in connection with the material.	X	X
7.18	Label the material in accordance with the specifications.		X
7.19	Package the material in accordance with the specifications.		X
7.20	Maintain a batch numbering system designed to assure traceability of the material.		X
7.21	Assign a unique lot number to each batch of material to ensure appropriate identification and tracking of material so that it meets RA serialization requirements.		X
7.22	Calculate expiry date from the date of manufacture using the expiry period listed in the RA filing (e.g., IND, NDA, BLA, etc.) or as instructed, in writing, by the biopharma company.		X

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7.23	Store the active pharmaceutical ingredient (API) of the material in accordance with applicable laws, cGMPs, procedures, and specifications.		X
7.24	Store the material bulk in accordance with applicable laws, cGMPs, procedures, and specifications.		X
7.25	Store the finished material in accordance with applicable laws, cGMPs, procedures, and specifications.		X
7.26	Ship the finished material via a qualified courier.		X
8.	Raw Materials		
8.1	Maintain specifications for all raw materials used in the manufacture of the material.		X
8.2	Audit and qualify the suppliers of the API that is used in the manufacture of the material in accordance with applicable laws, cGMPs, and procedures.		X
8.3	Audit and qualify the suppliers of the raw materials used in the manufacture of the material in accordance with applicable laws, cGMPs, and procedures.		X
8.4	Retain reference samples of raw materials and API used in the manufacture of the material as mutually agreed upon by both parties and in accordance with applicable laws, cGMPs, and procedures.		X
8.5	Store raw materials and API and raw materials in accordance with applicable laws, cGMPs, and procedures.		X
8.6	Qualify all suppliers and maintain an approved supplier list in accordance with applicable laws, cGMPs, and procedures.		X
8.7	Dispose of raw material waste in accordance with applicable laws, cGMPs, and procedures.		X
8.8	Notify the biopharma company of any deviations or discrepancies that have (or may have) an impact on the quality of the raw materials used in the manufacture of the material.		X
8.9	Maintain records for each animal derived material in accordance with applicable laws, cGMPs, and procedures to ensure traceability.		X
8.10	Inform the biopharma company if the introduction of any animal derived material could potentially impact the quality of the material.		X

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9.	Samples & Testing		
9.1	Perform material sampling in accordance with applicable laws, cGMPs, procedures, specifications, and BPRs.		X
9.2	Retain material samples as mutually agreed upon by both parties and in accordance with applicable laws, cGMPs, and procedures.		X
9.3	Store stability samples as mutually agreed upon by both parties and in accordance with applicable laws, cGMPs, and procedures.		X
9.4	Test finished material and generate a Certificate of Analysis (COA) based on the material specification for each batch.		X
9.5	Test material stability samples according to as mutually agreed upon by both parties and in accordance with applicable laws, cGMPs, ICH guidelines, and procedures.		X
9.6	Manage the stability program by maintaining and executing the appropriate stability protocols.		X
9.7	Provide the biopharma company with new and revised stability protocols for review and approval.		X
9.8	Review and approve new or revised stability protocols.	X	X
9.9	Store stability samples in the packaging containers and under the conditions specified in the stability protocol.		X
9.10	Draft annual stability reports for the biopharma company to review and approve no less than 30 business days prior to the due date of the annual report.		X
9.11	Review and approve annual material stability reports.	X	X
9.12	Document, investigate, and resolve deviations and OOS/OOT results associated with the testing of the material in accordance with cGMPs.		X
9.13	Notify the biopharma company of all critical deviations associated with the testing of the of the material.		X
9.14	Critical testing deviations are instances that may impact the quality of the material.		X
9.15	Perform all laboratory testing, sample handling, and documentation in accordance with Good Documentation Practice (GDP), Good Laboratory Practice (GLP), and cGMP standards.		X

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9.16	Provide and execute the analytical method validation protocols and reports for review and approval to the biopharma company.		X
9.17	Review and approve all analytical method validation protocols and reports.	X	
9.18	Review and approve new and revised reference standard protocols and reports related to the material.	X	X
10.	Material Release		
10.1	Perform material release as a function of the quality unit, based on the registered material specifications, and as mutually agreed upon by both parties and in accordance with applicable laws, cGMPs, and procedures.		X
10.2	Perform the review and approval of the BPRs and all test documentation of each material batch manufactured and tested.		X
10.3	Document and provide the biopharma company with a COA for each material batch.		X
10.4	Document and provide the biopharma company with a Certificate of cGMP Compliance (COC) and statement that each material batch was manufactured according to cGMP standards.		X
10.4	Provide authorization for each batch of material designated to be shipped after determining the final disposition.	X	
10.5	Respond to material release documentation (i.e., batch review) inquiries within two business days.		X
10.6	Ship each batch with a copy of the COA and COC.		X
10.7	Monitor a qualified system to track the shipping status of each batch of material that is shipped from the facility.		X
11.	Employees & Subcontractors		
11.1	Confirm and ensure that no employees, authorized agents, or consultants are debarred because of the U.S. Drug Enforcement Act of 1992 and actions of any other RA.	X	X
11.2	Notify and receive approval from biopharma company prior to use of subcontractors/third parties (e.g., warehouses, laboratories, etc.) directly engaged in the manufacturing or testing of the material.		X

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12.	Quality Agreement Review		
12.1	Conduct an annual review to ensure that the quality agreement is up-to-date and identify any necessary revisions. Revisions to the quality agreement will be effective after being accepted by both parties.	X	X