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Quality Agreement

by and between

Supplier Name _____

Address: _____

and

Client Name: _____

Address: _____

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Supplier's & Client's Name

Supplier's Name ("Supplier") and *Client's Name* ("Client") wish to define the individual responsibilities of the parties as to the quality aspects of manufacturing and release of Product as defined in Appendix 1 to ensure compliance with the approved Product application and/or Client requirements.

In order to do so, this Quality Agreement ("Quality Agreement") takes the form, in part, of a detailed listing of activities associated with manufacture, supply, production, analysis, and release of Product. Unless otherwise indicated, responsibility for each activity is assigned to either Client, Supplier, or is assigned to both Supplier and Client.

In consideration of the parties' agreement to perform the activities provided in this Quality Agreement and for other valuable consideration the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, Supplier and Client agree as provided in this Quality Agreement as follows:

Client	**Supplier**
Signature	Signature
Name	Name
Title	Title
Signed the day of in the year 20 .	**Signed the day of in the year 20 .**

Manufacturer's Quality Agreement Template

1. Effective Date

The Effective Date of this Quality Agreement shall be the date of last signature (the "Effective Date").

2. Scope

This Quality Agreement outlines the responsibilities of Supplier and Client with respect to the quality assurance of the Product manufactured and/or supplied by Supplier for Client.

3. Other Agreements

This Quality Agreement is in addition to all other agreements between the parties, if any, (the "Supply Agreement") regarding the subject matter hereof. If there are any direct conflicts between the terms of this Quality Agreement and the Supply Agreement, the following will prevail:

☐ Quality Agreement

☐ Supply Agreement

4. Amendments to Quality Agreement

This Quality Agreement may be amended by the written consent of both parties.

The parties agree to amend terms of this Quality Agreement that must be amended in order that the Product continue to meet regulatory requirements of applicable regulatory agencies, as may exist from time to time.

If an amendment to this Quality Agreement is proposed, the proposing party will circulate the proposed amendment to the appropriate contact person at Supplier and Client for review and internal approval. The appropriate contact person at Supplier and Client is listed in **Appendix 2** (Contacts and Responsibilities).

5. Term of Quality Agreement

This Quality Agreement shall commence on the Effective Date and shall remain in effect for as long as the Supplier supplies Product to Client unless the Quality Agreement is terminated earlier in accordance with the terms of this Quality Agreement.

Either party may terminate this Quality Agreement upon thirty (30) days written notice to the other party.

6. Use of Third-Parties

Supplier shall not allow a third party to manufacture, package, label, inspect, test and release Product unless Supplier has disclosed in writing to Client the Supplier's use of a third party and in what capacity to which the third party is used. If Supplier employs a third party to perform any or part of the manufacturing, packaging, labelling, inspection, testing, release and/or handling of Product that is supplied to Client, Supplier shall assure that the third party has been fully qualified via the Supplier's third party qualification process prior to performing such activity(ies). Supplier shall have entered into a written confidentiality agreement with any third party providing for confidentiality of all Client information under obligations of confidentiality similar to and requiring the same protection or greater protection of confidential information as the obligations of confidentiality between Supplier and Client. Supplier shall, however, retain all obligations under this Agreement whether or not a third party manufactures, packages, labels, inspects, tests, releases and/or handles Product. If a third party is used by Supplier to manufacture, package, label, inspect, test, release and/or handle Products, Client may, upon request, review the list of such third party(ies) during an on-site visit and/or audit pursuant to the Right To Audit section of this Agreement. Client agrees to treat such information as Confidential Information of Supplier and agrees not to contact any such parties in connection with this Agreement without Supplier's prior consent**.**

7. Survival Clause

All regulatory obligations contained herein that are required of either party or both parties by an applicable regulatory authority shall survive termination of this Quality Agreement.

8. Assignment

Supplier shall not assign any or all of its rights or obligations under this Quality Agreement without Client's prior written consent. Client's consent shall not be required in connection with a merger, consolidation, or a sale of all or substantially all of Supplier's assets or the subject matter of this Quality Agreement to another party (an "Assignment Transaction"). In the event of an Assignment Transaction, Supplier shall provide written notice to Client to the appropriate contact person indicated in **Appendix**

2 (Contacts and Responsibilities). Client shall have the right to assign any or all of its rights or obligations under this Quality Agreement without the consent of Supplier. In the event of an assignment, the assigning party shall continue to be bound by all pre-existing obligations under this Quality Agreement including all obligations of confidentiality and non-disclosure.

9. Product Specifications

Product specifications are listed in **Appendix 3**.

Changes to the agreed upon specifications must be mutually agreed upon and communicated in writing between the parties to this Quality Agreement, except for compendial changes which can be implemented without mutual agreement. Compendial changes must be implemented by the compendial implementation date.

10. Resolution of Quality Issues

Quality related disagreements between Supplier and Client that are not resolved in the normal course of business shall be brought to the attention of the appropriate contact person for notices at the Supplier and Client, in writing, as listed in **Appendix 2** (Contacts and Responsibilities). If both parties agree that a resolution of the disagreement is reasonably possible, then both Supplier and Client shall agree to work jointly to develop a strategy for such resolution. Supplier and Client further agree to record such resolution in writing.

11. Debarment

Supplier warrants and represents that it is not debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. 335[a] (the "Generic Drug Enforcement Act"), and that it has not been convicted of a crime for which it could be debarred under the Generic Drug Enforcement Act. In connection with the Product, the Supplier further warrants and represents, in that it shall not use in any capacity the services of any person debarred under the Generic Drug Enforcement Act, or convicted of a crime for which a person can be debarred under the Generic Drug Enforcement Act.

12. Choice of Law: Jurisdiction/Miscellaneous

This Quality Agreement shall be construed and the relationship between the parties determined in accordance with the laws in the State of , United States of America, without regard to the conflicts of law principals thereof. Any and all disputes between the parties arising out of or related to this Quality Agreement shall be heard in the state and federal courts located in the State of , and the parties hereby consent and submit to the jurisdiction of such courts.

All appendices to this Quality Agreement are attached hereto and incorporated herein by reference. In this Quality Agreement, unless the contrary intention appears: (a) the words "including" and "include" mean "including, but not limited to";(b) the singular includes the plural and vice versa; (c) a reference to a person or entity (including Supplier or Client) includes a reference to the person's executors, administrators, successors, substitutes and assigns; and (d) headings are for reference only and do not form part of this contract.

13. Manufacturing and Testing Locations

Product will be manufactured and tested at the following location:

Address:

14. Quality Responsibilities Table

§	Responsibilities	Not Applicable	Client	Supplier
1.	**Compliance Requirements**			
1.01	Implement procedures and/or documented training to meet obligations under this Agreement.	☐	☐	☑
1.02	Follow applicable current Good Manufacturing Practices (cGMPs), including International Conference on Harmonization (ICH) Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (API)) and locally imposed requirements.	☐	☐	☑
1.03	Manufacture, package, ship, store and test the Product and materials in an environment meeting the applicable GMP regulations, which is designed, constructed and maintained in a manner that a) permits the operation therein to be performed under clean, sanitary and orderly conditions; b) permits the effective cleaning of pertinent surfaces; and c) prevents the contamination of the Product and the addition of extraneous material to the Product.	☐	☐	☑
1.04	Manufacture the Product in adherence to applicable regulatory submissions, such as Drug Master File (DMF), if applicable.	☐	☐	☑
1.05	Operate in compliance with applicable environmental, occupational health and safety laws and regulations.	☐	☐	☑
1.06	Maintain a quality unit that is independent of production that fulfills both quality assurance and quality control responsibilities.	☐	☐	☑
1.07	Involve the quality unit in all quality related matters and have them review and approve all quality critical related documents.	☐	☐	☑
1.08	As it relates to this Quality Agreement, notify the other party of name change, corporate reorganization, consolidation, merger or acquisition or sale of the party's company. Notify other party of key personnel changes.	☐	☑	☑
1.09	Maintain internal GMP audit program.	☐	☐	☑
1.10	Maintain external GMP audit program for suppliers of raw materials and components, or other suitable qualification program.	☐	☐	☑
2.	**Right to Audit**			
2.01	Client has the right to audit Supplier's facilities and systems and review documents as they relate to the manufacture of Product. Such inspections and document review shall be conducted by Client at a time, date and duration mutually agreeable to the Supplier and Client and subject to Client signature of a separate confidentiality agreement with the Supplier entity owning the production site.	☐	☑	☑
2.02	Client retains the right to conduct reasonable "for cause" audits. Specific goals/scope of the audit, proposed dates and names of the auditors will be agreed upon mutually by the Client and the Supplier.	☐	☑	☑
2.03	Issue Supplier a confidential audit report summarizing audit observations.	☐	☑	☐

§	Responsibilities	Not Applicable	Client	Supplier
2.04	Issue responses to all observations documented in the issued audit report in writing to Client Quality Assurance within 30 days of receipt of the report.	☐	☐	☑
3.	**Regulatory Inspections and Exchanges**			
3.01	Notify Client within three business days of the receipt of a Regulatory Authority inspection report, deficiency letter or written regulatory compliance observation, which contains any significant adverse findings that relate to the Product or the facilities used to produce, test or warehouse the Product sold to Client. A significant adverse finding is herein defined as the following: conditions, practices, or processes that adversely affect or may potentially adversely affect product or service quality and/or the rights, safety or well being of subjects/patients and/or the quality and integrity of data, documentation, or other materials or information addressed in the inspection.	☐	☐	☑
3.02	Provide copies of the inspection report, deficiency letter or written regulatory compliance observation that relate to the Product or the facilities used to produce, test or warehouse the Product sold to Client. This shall be edited to exclude Supplier or other Client's proprietary information or a complete summary report containing the description of the adverse finding as stated in the inspection report, deficiency letter or regulatory compliance observation to Client by facsimile or electronically within five (5) business days of the receipt of the inspection report.	☐	☐	☑

§	Responsibilities	Not Applicable	Client	Supplier
4.	**Regulatory Filings and Regulatory Status**			
4.01	Responsible for submission, maintenance, approvals and updates/amendments to regulatory filings for Product (including API DMF). Client will be notified as per FDA requirements.	☐	☐	☑
4.02	Responsible for providing to the agencies all requested documentation/data required for regulatory filings.	☐	☑	☑
4.03	Responsible for communicating to the other party approvals, deficiencies or rejections by agencies regarding submissions, amendments or updates.	☐	☑	☑
4.04	Responsible for submission and maintenance of drug substance registration and current site registration and obtaining labeler code as required by regulatory agencies.	☐	☐	☑
4.05	Client shall provide Supplier with the following information regarding the use of the product: – Clinical phase of development of the drug product or drug substance that Product is used in and any change regarding this status – Intended use of the drug product or drug substance in which that Product is used – Regulatory agencies with which the drug product or drug substance is filed and if Product is included in the filing.	☐	☑	☐
4.06	Notify Supplier if Supplier will be named in any governmental filing prior to such filing being made.	☐	☑	☐
4.07	Coordinate the activities necessary to ensure readiness prior to Regulatory Agency Pre-Approval Inspection (PAI).	☐	☑	☑
4.08	Provide Letter of Authorization for Client to permit reference to Supplier's regulatory submissions in the registration of the Client's drug product.	☐	☐	☑
5.	**Complaints**			
5.01	Have written procedures in place to document, investigate, and respond to all quality related complaints.	☐	☐	☑
5.02	Assist in investigations as reasonably requested by Client for complaints associated with Product.	☐	☐	☑
5.03	Retain complaint investigation records and evaluate trends and severity. Implement corrective and preventive actions as necessary.	☐	☐	☑

§	Responsibilities	Not Applicable	Client	Supplier
6.	**Animal Derived Materials**			
6.01	Evaluate and control the risk of Transmissible Spongiform Encephalopathy (TSE) for raw materials and components. Maintain appropriate records for each lot of animal derived material to ensure traceability. Where required by local regulations, Supplier will assure that the country of origin or slaughtering information (either or both, which ever can be obtained from the manufacturer) will be documented and provided to Client.	☐	☐	☑
7.	**Validation/Qualification**			
7.01	Determine according to Product lifecycle and guidance documents when process validation is required.	☐	☐	☑
7.02	Have a written master validation/qualification plan for the facilities, equipment/instruments, manufacturing process, cleaning procedures, analytical procedures, in process control tests and computerized systems as appropriate. These to be approved by the quality unit.	☐	☐	☑
7.03	Responsible for developing, preparing and maintaining validation documentation approved by the quality unit, including protocols, reports and associated documentation.	☐	☐	☑
7.04	Qualify as necessary all critical systems and equipment used for the manufacture and control of Product (Installation Qualification (IQ), Operational Qualification (OQ), and/or Performance Qualification (PQ)).	☐	☐	☑
7.05	Allow viewing of the validation documentation for the Product during an onsite audit.	☐	☐	☑
8.	**Documentation and Records**			
8.01	Have a controlled system to initiate, review, revise, approve, obsolete and archive all Good Manufacturing Practices documentation. At a minimum, all production, control, and distribution records should be retained for at least 1 year after the expiry date of the batch. For APIs with retest dates, records should be retained for at least 3 years after the batch is completely distributed.	☐	☐	☑
8.02	Have written procedures for the review and approval of all batch documentation.	☐	☐	☑
8.03	Maintain a document control system for specifications and test methods, including: raw materials, Product labeling, packaging materials and other materials that would likely affect product quality.	☐	☐	☑

§	Responsibilities	Not Applicable	Client	Supplier
8.04	Provide a complete Certificate of Analysis for the Product, containing "at minimum" the following information: • Supplier Product number • Supplier lot/batch number • Name of Product • Name of the test • Specification limit • Expiration or retest date, if applicable • Test result (as a numerical value, unless designated Pass/Fail in the specification limit, statistical values can be used if data supports their use except for assays and impurity tests), including retest results if required • Quality Assurance approval and date. • Manufacturing Site (name and address) • Manufacturing Date	☐	☐	☑
8.05	Provide certification that the Product was manufactured in a cGMP compliant facility, and was tested in accordance with and meets specifications.	☐	☐	☑
8.06	Where applicable, electronic signatures used on the certificate of analysis or other controlled documents should be authenticated and secure.	☐	☐	☑
9.	**Annual Product Reviews**			
9.01	Have procedures to conduct and document annual product reviews, if applicable.	☐	☐	☑
9.02	Allow viewing of the Annual Product Review (APR) for the Product during an on-site audit.	☐	☐	☑
10.	**Change Control**			
10.01	Have established written procedures for control of changes impacting the Product including manufacturing components or process, computer hardware/software, Product specifications, test methods, vendors, and subcontractors, if applicable.	☐	☐	☑
10.02	Notify Client within a reasonable time of intent to make changes that could impact the identity, strength, safety, potency, stability, purity, or regulatory status prior to implementation of the change (called significant*).	☐	☐	☑
10.03	Issue to Client a written evaluation of the significant* change including change justification so that Client can determine the impact of use of Product in Client's finished product.	☐	☐	☑
10.04	Have significant* changes reviewed and approved by the Supplier's quality unit.	☐	☐	☑
10.05	Jointly establish a strategy to secure regulatory approvals for significant changes, as necessary.	☐	☑	☑

§	Responsibilities	Not Applicable	Client	Supplier
11.	**Deviations**			
11.01	Have procedures for the identification, investigation, and reporting of deviations and Out-of-Specification (OOS) results that occur during the manufacture and testing of the Product.	☐	☐	☑
11.02	Document and explain all deviations. Investigate OOS results and critical deviations. Extend the investigation to other lots that may have been associated with the failure as appropriate. Include preventive actions and track these to completion.	☐	☐	☑
11.03	Evaluate deviations to determine impact on validation/qualification studies.	☐	☐	☑
12.	**Reprocess and Batch Adjustments /Rework/Retest**			
12.01	Have procedures for batch adjustments and reprocessing, if applicable. Reprocessing is defined as introducing an intermediate or API, including one that does not conform to standards or specifications, back into the process and repeating a crystallization step or other appropriate chemical or physical manipulation steps (e.g. distillation, filtration, chromatography, and milling) that are part of the manufacturing process.	☐	☐	☑
12.02	Will not blend Out of Specification batches with other batches for the purpose of meeting specifications.	☐	☐	☑
12.03	Have a protocol for Product requiring rework describing the rationale and justification for rework for approved filed rework processes, if applicable. Rework is defined as subjecting an intermediate or API that does not conform to standards or specifications to one or more processing steps that are different from the established manufacturing process to obtain an acceptable quality intermediate or API (e.g. recrystallizing with a different solvent).	☐	☐	☑
12.04	Receive written approval by Client for rework outside of approved filed rework processes.	☐	☐	☑
12.05	Will not perform recovery of materials and/or solvents unless approved procedures and specifications are in place.	☐	☐	☑
13.	**Production and In Process Controls, Packaging and Labelling**			
13.01	Procure, test as required, and release raw materials and packaging and labeling materials used in manufacture of Product.	☐	☐	☑
13.02	Establish and document specifications for raw materials, Product labelling and packaging materials and other materials that would likely affect product quality.	☐	☐	☑

§	Responsibilities	Not Applicable	Client	Supplier
13.03	Prepare/develop master batch production records in accordance with applicable cGMP requirements or guidelines, as applicable for lifecycle of product.	☐	☐	☑
13.04	Inspect, weigh and measure raw materials used for Product manufacturing and verify critical weighing by a second individual or validated automated system.	☐	☐	☑
13.05	Manufacture Product in a manner that prevents contamination by other materials including carryovers.	☐	☐	☑
13.06	Provide product label to include: name and address of the manufacturer, identifying code, batch number, quantity of contents, storage and special transport conditions if applicable, the retest or expiry date and any special requirements. Revise label per change control as necessary.	☐	☐	☑
13.07	Review and approval of batch production records by quality unit prior to batch release.	☐	☐	☑
13.08	Release Product by quality unit.	☐	☐	☑

14.	**Storage and Distribution**			
14.01	Maintain storage facilities appropriate for conditions specified on the Product label. Maintain records of any critical storage conditions.	☐	☑	☑
14.02	Have systems for controlling quarantined, rejected or recalled materials.	☐	☐	☑
14.03	Provide Material Safety Data Sheets or equivalent.	☐	☐	☑
14.04	Notify Client in a timely manner if Supplier finds a quality issue post Supplier release/shipment.	☐	☐	☑

15.	**Laboratory Controls**			
15.01	Have written procedures for sample management, testing, approval, disposition, recording, storage, retention and disposal of laboratory data.	☐	☐	☑
15.02	Retain samples as required by regulatory agencies.	☐	☐	☑
15.03	Have written procedures and appropriately document the preparation, use and management of reagents, solutions, and standards.	☐	☐	☑
15.04	Have appropriate specifications and test procedures for the Product which are consistent with the applicable approved filing and/or compendial monograph.	☐	☑	☑
15.05	Test Product in accordance with approved validated or qualified methods and specifications using calibrated equipment.	☐	☐	☑
15.06	Have a program for qualification, calibration, and preventive maintenance of all analytical equipment.	☐	☐	☑
15.07	Responsible for analytical method development, qualification and or validation as appropriate.	☐	☐	☑

§	Responsibilities	Not Applicable	Client	Supplier
15.08	Responsible for transferring any developed methods to Supplier.	☐	☑	☐
15.09	If commercially available reference standards are not available, reference standards for the Product will be provided.	☐	☑	☑
16.	**Stability**			
16.01	Maintain a documented, ongoing stability program to monitor the stability of the Product using stability indicating procedures.	☐	☐	☑
16.02	Data analysis and trending reporting will be performed.	☐	☐	☑
16.03	OOS notification to Client will be provided in a timely manner.	☐	☐	☑
16.04	Use data to confirm appropriateness of storage conditions and retest or expiry date.	☐	☐	☑
16.05	Store stability samples in commercial size and/or simulated market containers under ICH storage conditions.	☐	☐	☑
16.06	Place the first three commercial production batches and at least one batch per year (if a batch is produced in the year) on stability or as required by applicable regulatory agencies.	☐	☐	☑
17.	**Recalls**			
17.01	In the event that either Client or Supplier determines that an event or circumstance has occurred relating to the manufacture or stability of the Product which may result in the need for a recall, stock recovery or market withdrawal of Client's finished drug product, Supplier and Client shall consult with each other in a timely manner. The final decision to recall any of the Client's drug products shall be made by Client.	☐	☑	☑
17.02	Notification of the recall or similar action to the authorities, distributors and customers of the finished drug product shall be made by Client	☐	☑	☐
17.03	Supplier will have procedures in place to facilitate the recall of an API as necessary. Supplier will provide assistance to the Client for the recall of drug product incorporating the Supplier's API.	☐	☑	☑

APPENDIX 1: Definition of Product

"Product" shall mean the following Products:

APPENDIX 2: Contacts and Responsibilities

Contact Person for Notices *(including Notices of Amendment, Assignment,Termination, Resolution of Quality Issues)*		
	Supplier	**Client**
Name:		
Title:		
Phone/Fax:		
Address ***(mail/delivery):***		
E-mail Address:		
With a Copy to:		
Name:		
Title:		
Phone/Fax:		
Address ***(mail/delivery):***		
E-mail Address:		

APPENDIX 3: Product Specifications