

NOTE TO USERS

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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__

Custom Manufacturer's Quality Agreement Template

Effective Date

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

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.

Other Agreement

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

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).

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.

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 the Client has provided written approval for the specific third party use. 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) unless the Client is providing the qualification of the third party. In this case, the Client will provide the Supplier written qualification documentation. A list of approved subcontractors is contained in **Appendix 4**. The party employing the subcontractor should have a quality agreement in place consistent with this agreement. 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.

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.

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.

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 and communicated between the Supplier and Client.

Shipping Under Quarantine

Shipping of batches/lots which have not been released.

If Client requests the shipment of quarantined or non-conforming material, Client will comply with Supplier's policy by signing a "waiver" attesting that Client is aware of the status of the material and is responsible for controlling its use which includes ensuring the lots/batch under quarantine do not enter into the marketplace until released.

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.

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.

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.

Manufacturing and Testing Location(s)

Product will be manufactured and tested at the following location:

Address(es):

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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.02	Follow applicable current Good Manufacturing Practices (cGMPs), including ICH Q7: International Conference on Harmonization Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (API) and locally imposed requirements.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.04	Manufacture the Product in adherence to applicable regulatory submissions, such as Drug Master File (DMF) if applicable.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.05	Operate in compliance with applicable environmental, occupational health and safety laws and regulations.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.06	Maintain a quality unit that is independent of production that fulfils both quality assurance and quality control responsibilities.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.07	Involve the quality unit in all quality related matters and have them review and approve all quality critical related documents.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
1.09	Maintain internal GMP audit program.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.10	Maintain external GMP audit program for suppliers of raw materials and components, or other suitable qualification program. *Client may qualify a supplier and take this responsibility but must be clearly defined for each material	<input type="checkbox"/>	<input checked="" type="checkbox"/> *	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

§	Responsibilities	Not Applicable	Client	Supplier
2.03	Issue Supplier a confidential audit report summarizing audit observations.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Regulatory Inspections and Exchanges				
3.01	Notify Client as soon as the inspection directly involves the Product. Client may be allowed to observe the inspection and contribute input into the discussion. Supplier is responsible for managing the inspection and determining appropriate Client interaction. 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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3.02	As they relate directly to either Product or the facilities used to produce, test, or warehouse, the Product sold to client, Supplier shall provide copies or a summary of the inspection report, deficiency letter or written regulatory compliance observation within 5 business days. These shall be edited to exclude Supplier or other client's proprietary information.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. Regulatory Filings and Regulatory Status*				
4.01	Client is responsible for determining the regulatory filing requirements and process. Supplier shall provide information and documentation to facilitate regulatory filings. Financial considerations for this shall be contained within a Supply Agreement.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

§	Responsibilities	Not Applicable	Client	Supplier
4.02	<i>(select one approach, if one is not selected then it is Not Applicable)</i> DMF filing/amendments NDA/ANDA CMC filing/changes	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
4.03	Responsible for communicating to the other party approvals, deficiencies or rejections by agencies regarding submissions, amendments or updates.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4.04	Responsible for submission and maintenance of registrations as follows: Drug substance listing Site establishment registration Or Labeler code as required.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4.06	Notify Supplier if Supplier will be named in any governmental filing prior to such filing being made.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4.07	Coordinate the activities necessary to ensure readiness prior to Regulatory Agency Pre-Approval Inspection (PAI).	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5.	Complaints and Recalls			
5.01	Have written procedures in place to document, investigate, and respond to all quality related complaints.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.02	Assist in investigations as reasonably requested by Client for complaints associated with Product.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.03	Retain complaint investigation records and evaluate trends and severity. Implement corrective and preventive actions as necessary.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.04	Suppliers will have procedures in place to facilitate the recall of an API as necessary. Suppliers will provide assistance to the client for the recall of drug product incorporating the supplier's API.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

§	Responsibilities	Not Applicable	Client	Supplier
7.	Validation/Qualification			
7.01	Determine according to Product lifecycle and guidance documents when process validation is required.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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. Client may provide validated methods, process validation, and in-process controls. Written copies to be provided to Supplier.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
7.03	Responsible for developing, preparing and maintaining validation documentation approved by the quality unit, including protocols, reports and associated documentation.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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)).	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.05	Allow viewing of the validation documentation for the Product during an onsite audit.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.02	Supplier shall generate the master batch production record, labeling and packaging procedures for the manufacture of the Product based on the information supplied by Client. Both parties may approve the master batch production record. Any changes to the master batch production record, labeling and packaging procedures for the manufacture of the Product shall go through Supplier's change control system and may be approved by Client. Supplier's change control system will include maintenance of a revision history file and justification for changes initiated by both parties. Client shall provide justification for changes initiated by Client.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

§	Responsibilities	Not Applicable	Client	Supplier
8.04	Will provide the following document for lot/batch produced: Complete Certificate of Analysis for the Product, containing "at minimum" the following information: <ul style="list-style-type: none"> • 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 Requested copies of: <ul style="list-style-type: none"> Batch Records <input type="checkbox"/> Significant Deviations <input type="checkbox"/> Analytical Data <input type="checkbox"/> Certificate of Origin <input type="checkbox"/> Certificate of Compliance <input type="checkbox"/> Others... <input type="checkbox"/> 	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.05	Where applicable, electronic signatures used on the certificate of analysis or other controlled documents should be authenticated and secure.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9. Annual Product Reviews				
9.01	Have procedures to conduct and document annual product reviews, if applicable.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.02	Allow viewing of the Annual Product Review (APR) for the Product during an on-site audit. Client approval is optional.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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. (If Client requires approval, list documents under Client approval here).	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.02	Notify and gain approval from 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*).	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.04	Jointly establish a strategy to secure regulatory approvals for significant changes, as necessary.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

§	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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
11.03	Evaluate deviations to determine impact on validation/qualification studies.		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
11.04	Notify Client of significant deviations within 3 business days	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
12.02	Will not blend Out of Specification batches with other batches for the purpose of meeting specifications.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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).	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
12.04	Receive written approval by Client for reprocessing and reworking outside of approved filed processes.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
12.05	Will not perform recovery of materials and/or solvents unless approved procedures and specifications are in place.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13.	Production and In Process Controls, Packaging and Labeling			
13.01	Procure, test as required, and release raw materials and packaging and labeling materials used in manufacture of Product. Client approval is optional.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13.02	Establish and document specifications for raw materials, Product labelling and packaging materials and other materials that would likely affect product quality. Client approval is optional.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13.03	Prepare/develop master batch production records in accordance with applicable cGMP requirements or guidelines, as applicable for lifecycle of product. Client approval is optional.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

§	Responsibilities	Not Applicable	Client	Supplier
13.04	Inspect, weigh and measure raw materials used for Product manufacturing and verify critical weighing by a second individual or validated automated system.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13.05	Manufacture Product in a manner that prevents contamination by other materials including carryovers.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13.07	Review and approval of batch production records by quality unit prior to batch release.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13.08	Release Product by quality unit. Client release is an option.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
14.	Storage and Distribution			
14.01	Maintain storage facilities appropriate for conditions specified on the Product label. Maintain records of any critical storage conditions.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
14.02	Have systems for controlling quarantined, rejected or recalled materials.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
14.03	Provide Material Safety Data Sheets or equivalent. (select one)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.04	Notify client in a timely manner if Supplier finds a quality issue post Supplier release/shipment.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15.	Laboratory Controls			
15.01	Have written procedures for sample management, testing, approval, disposition, recording, storage, retention and disposal of laboratory data.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15.02	Retain samples as required by regulatory agencies.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15.03	Have written procedures and appropriately document the preparation, use and management of reagents, solutions, and standards.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15.04	Have appropriate specifications and test procedures for the Product which are consistent with the applicable approved filing and/or compendial monograph.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
15.05	Test Product in accordance with approved validated or qualified methods and specifications using calibrated equipment.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15.06	Have a program for qualification, calibration, and preventive maintenance of all analytical equipment.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15.07	Responsible for analytical method development, qualification and or validation as appropriate. If provided by the Client, Client will provide written copies to the Supplier.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
15.08	Responsible for transferring any developed methods to Supplier.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
15.09	If commercially available reference standards are not available, reference standards for the Product will be provided.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

§	Responsibilities	Not Applicable	Client	Supplier
16.	Stability (must decide Client or Supplier or NA)* if supplied by Client, Client will provide all necessary information to the supplier.			
16.01	Maintain a documented, ongoing stability program to monitor the stability of the Product using stability indicating procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.02	Data analysis and trending reporting will be performed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.03	OOS notification to other party will be provided in a timely manner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.04	Use data to confirm appropriateness of storage conditions and retest or expiry date.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.05	Store stability samples in commercial size and/or simulated market containers under ICH storage conditions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

APPENDIX 1: Definition of Product

“Product” shall mean the following Products:

APPENDIX 2: Contacts and Responsibilities

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

APPENDIX 3: Product Specifications

APPENDIX 4: List of Approved Subcontractors