(Your Company Name)

Contract Manufacturer Quality Agreement

PREFACE

The purpose of the (Your Company Name) Contract Manufacturer Quality Agreement is to establish a defined quality standard in which (Your Company Name) will hold the contract manufacturer responsible for maintaining compliance with its requirements regarding (Your Company Name) products. This document will serve as a reference for the contract manufacturer to implement the various clauses in their current quality assurance programs, if not already present.

The (Your Company Name) Contract Manufacturer Quality Agreement should be feasible and agreed upon mutually for both (Your Company Name) and the contract manufacturer. The Agreement is intended to address aspects of product safety and quality through the entire manufacturing process of (Your Company Name) products. However, every possible scenario that may be seen is not included in the agreement. Additional revisions to the Agreement must be agreed upon and signed by both (Your Company Name) and the contract manufacturer to be considered valid.

( ) CONTRACT MANUFACTURING AGREEMENT

1. Applicable Current Good Manufacturing Practices (cGMP) Standard

(Your Company Name) shall manufacture PRODUCT(s) in compliance with cGMP. Other products may be added to this list for (Contract Manufacturer Name) to manufacture. These PRODUCT(s) will fall under the same agreement unless deemed otherwise by (Your Company Name).

1.1 "Current Good Manufacturing Practices" (cGMP) means all applicable standards relating to the manufacture of PRODUCT(s) listed in the FDA, USDA, MDA, MDH or other guidelines as applicable to your PRODUCT(s)

1.2 For the purposes of this agreement, cGMP shall mean the principles described in the FDA, USDA, MDA, MDH or other guidelines as applicable to your PRODUCT(s), in the form of laws or guidance documents, where the guidance documents are to be implemented within the manufacturing industry for PRODUCT(s).

2. Change Control

(Contract Manufacturer Name) shall have a documented and effective change control system in place and is required to provide advanced notification to (Your Company Name) of any changes to the process, product formulation, specifications and analytical methods (PRODUCT, intermediates and raw materials), storage, labeling and primary packaging, and equipment, which may have an impact on the quality of PRODUCT, and/or on any regulatory applications related to PRODUCT to allow (Your Company Name) to assess the impact of the change upon PRODUCT supplied or its use by (Your Company Name). PRODUCT produced by the new process shall not be accepted unless the process change has first been reviewed and delivery of PRODUCT approved by (Your Company Name).

2.1 Change requests should be supported by appropriate documentation to support the change and to confirm that performance has not been altered.

2.2 Modifications relating to PRODUCT formulation and specifications should only take place by a mutual consent between the two parties.

2.3 For those changes required to comply with applicable laws and regulatory agency requirements, (Contract Manufacturer Name) shall notify (Your Company Name) of such requirements after (Contract Manufacturer Name) becomes aware of the need for such change.

2.4 (Your Company Name) shall assess any change request received from (Contract Manufacturer Name) in a timely manner. Unless there are justified scientific reasons to reject the change request, or regulatory implications why (Your Company Name) may not want to pursue the proposed change, (Your Company Name) will not unreasonably withhold its approval of the request.

2.5 (Your Company Name) will inform (Contract Manufacturer Name) of approval of the change or if any adjustments are required.

3. Right to Audit

(Contract Manufacturer Name) shall allow (Your Company Name) or its representatives to carry out on-site audits by appointment. (Contract Manufacturer Name) shall permit all reasonable access to the manufacturing, packaging, warehousing, and laboratory areas related to the manufacture of PRODUCT(s), including pertinent documentation. Any such audit shall take place during normal business hours and must not interfere with (Contract Manufacturer Name)'s manufacturing operations.

3.1 The results of the audit and the observation(s) shall be sent to (Contract Manufacturer Name) by means of a written report. This report may be simply a list of all the non-conformances observed during the audit, or a follow-up to a Form 483 from an FDA audit. (Contract Manufacturer Name) must

ensure a satisfactory follow up to the observations made during the audit performed by (Your Company Name), and take corrective actions mutually agreed upon by the parties.

3.2 The audit frequency shall depend upon the quality performance of (Contract Manufacturer Name). In the absence of critical quality incidents, the frequency shall be not more than once every year. If quality issues arise (Your Company Name) shall have the right to audit more frequently.

4. Authority Inspections

(Contract Manufacturer Name) shall notify (Your Company Name) of all regulatory authority inspections that are related to PRODUCT, and those that take place at the facility where PRODUCT is manufactured or the testing laboratory where any of the associated testing is performed. If areas of concern exist, which specifically involve PRODUCT, (Your Company Name) should be notified prior to the inspection. In all other cases, information on the results of the inspection is appropriate. Such notification will include:

4.1 Written notification of any observation, if any, that may impact the manufacture of PRODUCT,
4.2 Written notification of all related corrective actions and planned completion dates,
4.3 Any further correspondence with the regulatory authority if the manufacture of PRODUCT is concerned.

5. Sub-Contracting

(Contract Manufacturer Name) agrees not to sub -contract to a third party or manufactured by a third party any of the work entrusted to them under this Quality Agreement without (Your Company Name)'s prior written approval. If such an agreement is given, (Contract Manufacturer Name) shall nonetheless remain fully responsible for the quality of the materials or services provided by sub-contractors and for all commitments as agreed upon with this Quality Agreement. This must be assured through quality agreements with the respective sub-contractors and technical delivery specifications.

6. Retention Samples

(Contract Manufacturer Name) will store PRODUCT(S) retention samples for each batch/lot manufactured, sufficient to perform at least two (2) full specification analyses, in containers that are equivalent to or more protective than the commercial packaging. Samples are to be retained for one (1) year after the date of manufacture.

6.1 Samples should be labeled, at least, with the following information:
- 6.1.1 PRODUCT,
- 6.1.2 (Contract Manufacturer Name) batch/lot number,
- 6.1.3 Date of manufacture

6.2 All retention samples must be stored in frozen storage for the duration of the retention time

6.3(Contract Manufacturer Name) will make PRODUCT retention samples available to (Your Company Name) upon request.

6.4 (Contract Manufacturer Name) shall keep available any retention samples relevant to assessing the quality of PRODUCT(s) in the event of complaints and/or recall procedures. This requirement shall continue even in case of termination of the supply of PRODUCT(s). In such a case, the (Contract Manufacturer) Name may choose to deliver all samples to (Your Company Name) instead of keeping them for the required period.

7. Retention of Records and Documentation

(Contract Manufacturer Name) will store the original master batch records, the executed batch records, and all other original documentation that is related to the manufacture of PRODUCT and that is required to be maintained under cGMPs for two (2) years after the batch is completely distributed by (Contract Manufacturer Name).

7.1 (Contract Manufacturer Name) will retain the original manufacturing records for any test batches for the entire term of the contract manufacturing agreement. Upon termination of the contract manufacturing agreement, (Contract Manufacturer Name) will provide (Your Company Name) with the original manufacturing records for all test batches.

7.2 Upon (Your Company Name) request, (Contract Manufacturer Name) will promptly make copies of the original records available for (Your Company Name).

7.3 (Contract Manufacturer Name) will offer (Your Company Name) the option to take over the documents before destruction after two (2) years.

7.4 (Contract Manufacturer Name) shall keep available any records relevant to assessing the quality of PRODUCT(s) in the event of complaints and/or recall procedures. This requirement shall continue even in case of termination of the supply of PRODUCT(s). In such a case, (Contract Manufacturer Name) may choose to deliver all documents to (Your Company Name) instead of keeping them for the required period.

8. Product Shelf Life/Stability

(Your Company Name) will perform shelf life/stability studies for PRODUCT(s).

8.1 (Your Company Name) is responsible for assigning re-evaluation dates to PRODUCT(s) and for determining suitable storage and shipping conditions, based upon shelf life/stability studies.

8.2 (Your Company Name) is responsible for generating and approving shelf life/stability protocols, methods, and specifications.

8.3 (Your Company Name) will upon request provide updated data from the shelf life/stability program (initial or on-going studies) to (Contract Manufacturer Name).

8.4 (Your Company Name) will inform (Contract Manufacturer Name) if there are any adverse trends.

9. Complaints

All complaints related to PRODUCT(s) reported, regardless of source will be handled by (Your Company Name Contract Manufacturer Name) and communicated to (Contract Manufacturer Name).

9.1 In the case of all product complaints, both (Contract Manufacturer Name) and (Your Company Name) should work together to both define the root cause and establish a corrective action plan.

9.2 (Contract Manufacturer Name) is responsible for recording and investigating all quality-related complaints on PRODUCT and will maintain the complete complaint database and complaint files.

9.3 A formal written report on the complaint detailing identifiable root causes and corrective and preventive actions with timing where applicable shall be prepared by (Contract Manufacturer Name) in collaboration with (Your Company Name) and sent to (Your Company Name).

9.4 In the case of a formal FDA Audit resulting in Form 483 comments, (Contract Manufacturer Name) will complete their investigation and respond (Your Company Name) in writing to all complaints within 20 business days of receipt. In case the investigation could not be finalized within 20 business days, (

Contract Manufacturer Name) will work closely with (Your Company Name) to establish timing for completion of corrective actions. (Your Company Name) is responsible for reporting this delay to the FDA

9.5 (Contract Manufacturer Name) is responsible for implementing a corrective action plan to correct any deficiencies identified during an investigation.

9.6 (Your Company Name) will make relevant information and samples, if available, of the affected PRODUCT(s) available to assist in the investigation of (Contract Manufacturer Name).

10. Recall

In the event that (Contract Manufacturer Name) believes that a recall of PRODUCT(s) may be necessary or appropriate, (Contract Manufacturer Name) shall immediately notify (Your Company Name). The two parties will take joint decisions on the disposition of PRODUCT.

10.1 (Your Company Name) is responsible for the final decision and the coordination of any recalls or field alert activities.

10.2 (Contract Manufacturer Name) shall provide any information required by (Your Company Name) relating to recall or field alert activities within two (2) business days of the request, if such information is readily available by (Contract Manufacturer Name).

10.3 (Contract Manufacturer Name) will not initiate any notifications to health authorities concerning a (potential) non-conformance without notifying (Your Company Name) prior to initiating that contact.

10.4 (Contract Manufacturer Name) will collaborate, if needed, in any recall of a defective batch/lot of PRODUCT(s).

11. Management Quality Review

(Contract Manufacturer Name) shall conduct an annual management quality review for PRODUCT(s), per the requirements of current FDA, USDA, MDA, MDH or other guidelines as applicable to your PRODUCT(s) and any additional requirements mutually agreed between the parties.

11.1 (Your Company Name) shall provide the template to be used by (Contract Manufacturer Name) for the annual management quality review.

11.2 (Contract Manufacturer Name) shall provide (Your Company Name) with copies of the relevant information for the management quality review of the previous annual period, within any timeframe mutually agreed between the parties.

12. Storage and Distribution

(Contract Manufacturer Name) shall make reasonable efforts to exclude, during packaging, storage, and shipping of PRODUCT(s), the possibility of deterioration, contamination, or mix-ups with any other material.

12.1 (Contract Manufacturer Name) shall comply with the following requirements in relation to distribution of PRODUCT(s):

12.1.1 Distribution of product using the FIFO (First In, First Out) method.

12.1.2 Distribution in accordance with storage conditions stated on the labels,

12.1.3 Ability to recall PRODUCT from distribution network,

12.1.4 Quarantine PRODUCT with questionable quality,

12.1.5 (Your Company Name) will arrange shipping and hauling agents used to transport PRODUCT(s).

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BRAND OWNER INITIALS _____

12.2 (Contract Manufacturer Name) will provide an up-to-date Safety Data Sheet (SDS) and specification sheets for all raw materials to (Your Company Name) on an annual basis.

13. Cross Contamination, Cleaning, & Sanitizing

(Contract Manufacturer Name) shall ensure that its facilities are used in line with any authorizations for cGMPs granted by the competent regulatory authority.

13.1 (Contract Manufacturer Name) shall not conduct production and handling of materials in the equipment being used for PRODUCT(s) without a documented cleaning and sanitizing procedure in place.

13.2 In the case (Contract Manufacturer Name) intends to conduct production of any other products in the same equipment used for PRODUCT(s), it shall provide (Your Company Name) with the necessary information to allow (Your Company Name) a proper risk assessment. This includes, but not limited to; allergens, non-food products, specific cleaning/sanitizing solutions not approved for use with food, etc. (Your Company Name) will then approve or reject (Contract Manufacturer Name)'s request on a scientific basis.

14. Raw Materials

(Contract Manufacturer Name) shall be responsible for the purchase, storage, handling, sampling, testing and approval or rejection of materials used in manufacturing PRODUCT(s) pursuant to this agreement.

14.1 (Contract Manufacturer Name) shall implement a vendor qualification program for evaluating the vendors of critical materials, with the only exception of materials supplied by (Your Company Name).

14.2 (Contract Manufacturer Name) shall only purchase materials from qualified vendors.

14.3 (Contract Manufacturer Name) must utilize documented material inspection plan procedures. The results of this inspection must be in accordance with material specifications filed by (Your Company Name).

14.4 (Contract Manufacturer Name) will inspect all materials on a batch-by-batch basis. Raw materials supplied by qualified vendors and those supplied by (Your Company Name) must be placed on quarantine until a minimum of identity verification and/or testing is completed.

14.5 (Contract Manufacturer Name) shall store and handle materials used in manufacturing PRODUCT(s) under appropriate conditions, consistent with cGMPs, all applicable laws, rules and regulations, and industry standards. (Your Company Name) shall inform (Contract Manufacturer Name) on the storage conditions of any material supplied to (Contract Manufacturer Name).

14.6 (Contract Manufacturer Name) shall have all necessary and appropriate controls in place to prevent cross-contamination of the raw materials and intermediates used in the manufacture of PRODUCT(s) from other raw materials and products stored, used, or manufactured by (Contract Manufacturer Name).

14.7 If intermediates are to be supplied by (Your Company Name), (Your Company Name) shall supply (Contract Manufacturer Name) with enough amount of intermediate to manufacture the quantities of batches ordered.

14.7.1 (Your Company Name) warrants that any intermediate supplied to (Contract Manufacturer Name) shall comply with the agreed specifications. The specification for the intermediate will be supplied and updated by (Your Company Name).

14.7.2 (Your Company Name) shall be responsible for the maintenance and storage of appropriate retain samples of any material supplied to (Contract Manufacturer Name).

14.7.3 If (Contract Manufacturer Name) believes that any shipment of intermediate does not meet specification, they will notify it to (Your Company Name) in writing, including a detailed explanation of the non-conformity. (Your Company Name) shall investigate such alleged non-conformity and, if agrees, such intermediate is non-conformance and (Your Company Name) will replace the material.

15. Deviations / Out of Specification (OOS)

(Contract Manufacturer Name) will notify (Your Company Name) promptly in the event of any critical deviation(s) that can potentially affect the integrity of PRODUCT(s). Any advice by (Your Company Name) on the handling of the deviation or the affected material (e.g., on root cause analysis or corrective actions) shall be given promptly so that further production is not unreasonably hindered.

15.1 (Contract Manufacturer Name) will forward a copy of the completed report on any full-scale OOS (Out Of Specification) investigation to (Your Company Name) within a reasonable period of time.

15.2 For all confirmed OOS stability test results that indicate that PRODUCT(s) has (have) failed to remain within specifications, (Your Company Name) will notify (Contract Manufacturer Name) and provide the stability data.

15.3 (Your Company Name) may participate in any full-scale investigation concerning OOS results.

15.4 (Contract Manufacturer Name) will implement any agreed actions arising out of the completed investigation report in order to avoid the recurrence of similar issues in the future.

16. Reworking/Reprocessing

Reworking/reprocessing batches shall be performed only after prior approval by (Your Company Name). Reasons for reworking/reprocessing must be investigated, and the results shall be communicated with (Your Company Name). Additional analytical testing or inspections of reworked/reprocessed batches may be required.

17. Packaging

(Contract Manufacturer Name) shall package PRODUCT(s) using the components, closures, and secondary packaging as agreed upon by both (Contract Manufacturer Name) and (Your Company Name).

17.1 (Contract Manufacturer Name) shall apply suitable traceability to primary packaging materials such that the manufacturer's batch can be traced from the batch of PRODUCT(s) supplied.

18. Labeling

(Contract Manufacturer Name) shall comply with the following requirements:

18.1 Labeling operations shall be conducted to prevent mix ups.

18.2 All label information shall be checked for accuracy before application. This includes, but not limited to, stickers, print directly on the package, and printing during the manufacturing run (i.e., inkjet date coders, etc.)

18.3 This agreement does not absolve (Contract Manufacturer Name) from complying with any legal requirements in relation to the transportation of PRODUCT(s).

18.4 (Contract Manufacturer Name) shall use the labeling convention (batch/lot number format) of their choosing but must communicate prior to initial production.

19. Regulatory Documents

(Your Company Name) shall, upon submission to any regulatory authority, provide (Contract Manufacturer Name) with current copies of portions of regulatory submissions, including amendments and supplement related to PRODUCT and (Contract Manufacturer Name)'s activities performed under this agreement.

19.1 (Contract Manufacturer Name) will provide, in mutually agreed timelines, all other information related to PRODUCT that (Your Company Name) may reasonably request for its regulatory submissions, including any data for annual reports.

19.2 When a change is known to require, or has the potential to require a regulatory submission, (Your Company Name) will develop a joint strategy to obtain the appropriate regulatory approvals prior to implementation of the change

19.3 (Your Company Name) will create and maintain Safety Data Sheets (SDS) for intermediate and finished products. These documents will be made available to (Contract Manufacturer Name) upon request.

20. Product Release

Contract Manufacturer Name) will not ship any PRODUCT to any destination, as identified by (Your Company Name) until PRODUCT is released for shipment, unless prior written approval has been received from (Contract Manufacturer Name) to perform such a shipment under quarantine.

20.1 Upon request, (Contract Manufacturer Name) will provide a pre-shipment sample to (Your Company Name). (Your Company Name) will test that sample, and if OK, will give its approval to (Contract Manufacturer Name) for shipment.

20.2 (Your Company Name) may delegate the final release authority for PRODUCT(s) to Co(ntract Manufacturer Name). (Your Company Name) reserves the right to withdraw the delegated final release authority from (Contract Manufacturer Name) at any time.

21. Gold Standards

(Your Company Name) shall provide and maintain Gold Standard product specifications for C(ontract Manufacturer Name) to compare for each batch or PRODUCT(s).

21.1 (Your Company Name) is responsible for maintaining and updating Gold Standard product specifications and providing(Contract Manufacturer Name)with new Gold Standard product specifications as necessary.

22. Product Analysis Specifications

Product analysis specifications to be used for testing PRODUCT(s) will be specified by (Your Company Name). In the event (Contract Manufacturer Name) does not have the appropriate equipment on hand for the testing the product analysis specifications, (Your Company Name) will work with (Contract Manufacturer Name) on an acceptable alternate method.

22.1 (Your Company Name) will supply a list of acceptable third-party labs for (Contract Manufacturer Name) to use.

22.1.1 In the event (Contract Manufacturer Name) desires to use a lab outside of the (Your Company Name) approved list, (Contract Manufacturer Name) must obtain written approval from (Your Company Name) prior to using that lab.

22.2 Any significant changes to these product analysis specifications must be approved by (Your Company Name) via a formal change control system.

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BRAND OWNER INITIALS _____

CONTRACT MANUFACTURER INITIALS _____

23. Manufacturing

(Contract Manufacturer Name) shall have appropriate control procedures in place to ensure that only authorized personnel have access to (Contract Manufacturer Name)'s manufacturing facilities.

( ) CONTRACT MANUFACTURER QUALITY AGREEMENT APPROVAL

I hereby declare I have read and understand the terms detailed in the (Your Company Name) Contract Manufacturer Quality Agreement. I have acknowledged the validity of the above-mentioned requirements and have determined the terms are feasible. I agree to the requirements listed in the (Your Company Name) Contract Manufacturer Quality Agreement and shall comply accordingly.

(Contract Manufacturer Name **) SIGNATURE:**

Name: _____ Position: _____

Signature: _____ Date: _____

(Your Company Name) **SIGNATURE:**

Name: _____ Position: _____

Signature: _____ Date: _____

(Your Company Name) shall retain the original copy of the (Your Company Name) Contract Manufacturer Quality Agreement. A copy of the signed Agreement shall be given to the contract manufacturer.

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BRAND OWNER INITIALS _____

CONTRACT MANUFACTURER INITIALS _____