**QUALITY ASSURANCE AGREEMENT**

**THIS QUALITY ASSURANCE AGREEMENT** (this “**Quality Agreement**”) is entered into as of the \_\_\_1st\_ day of [MONTH], 2021\_ (the “Effective Date”) by and between AVANTOR FUNDING, INC., a Delaware corporation with a principal place of business at Radnor Corporate Center, Building One, Suite 200, 100 Matsonford Road, Radnor, PA 19087 (for itself and on behalf of its Affiliates, collectively “**Avantor**”) and [COUNTERPARTY COMPANY FULL NAME (with Inc/LLC, etc.)], a [State of Incorporation/Country] [type of corporation], having offices at [Insert Counterparty Full Address] (for itself and on behalf of its Affiliates, collectively “**Supplier**”). As used herein, “Affiliate” in relation to Avantor shall mean any firm, person or entity that is directly or indirectly controlled by Avantor Funding, Inc. As used herein, “Affiliate” in relation to Supplier shall mean any firm, person or entity controlling, controlled by or under common control with Supplier. For the purpose of this Agreement, “control” shall mean the ownership or control, whether directly or indirectly, of more than fifty percent (50%) of the outstanding shares or securities of an entity (representing the right to vote for the election of directors or other managing authority), or otherwise has the power to control, whether directly or indirectly, the management of such entity. Avantor and Supplier may hereafter be referred to collectively as the “Parties” and individually as a “Party”.

**WHEREAS**, Avantor and Supplier have entered into a Supply Agreement dated [DATE] (the “Supply Agreement”) pursuant to which Avantor intends to purchase one or more products supplied by Supplier (the “**Products**”)

[or if no Supply Agreement, use: **WHEREAS**, Avantor and Supplier have entered into a series of commercial transactions, each governed by Avantor’s Terms and Conditions of Purchase (the “TCP”) pursuant to which Avantor intends to purchase one or more products supplied by Supplier (the “Products”); and]; and

**WHEREAS**, Avantor and Supplier desire to enter into this Quality Agreement to define the roles and responsibilities of each Party with respect to quality assurance issues related to the Supplier’s supply of Products to Avantor.

**NOW, THEREFORE**, in consideration of the premises set forth above, the respective covenants of the Parties hereto, and for other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, and the Parties intending to be legally bound hereto agree as follows:

1. **PRECEDENCE, TERM and TERMINATION.** This Agreement is supplemental to the Supply Agreement [or TCP]; and in the event of any conflict or inconsistency between the terms of this Agreement and the Supply Agreement [or TCP], this Agreement shall prevail with respect to quality matters and the Supply Agreement [or TCP] shall prevail with regards to any other matters. This Agreement shall become effective and binding upon the date of first indicated above and shall be coterminous with the term of the Supply Agreement [or if no Supply Agreement: shall be effective for three (3) years] unless the Parties specifically agree to an extension of this Agreement by written Amendment. Either Party may terminate this Agreement by giving six (6) months written notice to the other Party.
2. **DEBARMENT.** Supplier certifies by entering into this Quality Agreement that neither it nor its principals nor any of its subcontractors are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from supplying the Products covered by, or from entering into, this Quality Agreement or the Supply Agreement [or the TCP] by any federal, state or supranational government or by any department, agency or political subdivision of any federal, state or supranational government or notified body. More specifically, Supplier certifies that, after due inquiry, neither it, nor any of its employees, nor any party it my retain in connection with the supply of Products for Avantor, are debarred under subsection 306 (a) or (b) of the United States Federal Food, Drug and Cosmetic Act, and that it has not and will not use in any capacity the services of any such person debarred under such law with respect to material to be provided under this agreement. Supplier shall, within ten (10) business days of a request from Avantor, provide Avantor with a written confirmation that it complies with the foregoing statement. The Supplier shall immediately notify Avantor if Supplier or any subcontractor becomes debarred or suspended, and shall, at the Avantor's request, take all steps required by Avantor to terminate its contractual relationship with the subcontractor for work to be performed under this Quality Agreement.
3. **QUALITY SYSTEMS/RECORDS.** Supplier has a documented and effective quality system that ensures the consistent supply of products. The Supplier’s Quality unit shall operate independently from the Supplier’s manufacturing or operations unit for the Products supplied to Avantor. The Supplier has a system in place compliant with IPEC-PQG and/or USP General Chapter <1078> to control documents and establish retention periods for such documents consistent with the requirements herein and/or those under applicable laws, regulations and industry standards (“Applicable Laws”). Supplier has established an internal Standard Operating Procedure that defines the retention period for all QA controlled files which has been assigned a retention period of 20 years minimum - including receipt and release of raw materials, batch records, specifications, test results, Quality Control documentation, test methods, standard operating procedures (“SOPs”), investigative reports (Out of specifications (“OOS”), manufacturing investigations, deviations, change controls, protocols, Certificates of Analysis and others, as appropriate. This data can be viewed on-site during the course of a scheduled visit.
4. **MANUFACTURING.**
   1. Supplier will supply, test, repackage and release the Products(s) in accordance with the following quality criteria, *as applicable to Products being supplied*:
      1. ICH Q7 GMP Guidelines
      2. Standards established by the United States Pharmacopeia (USP) as specified in the current version of USP General Chapter <1078> and/or the Joint IPEC-PQG GMP Guide
      3. EXCiPACT cGMP and cGDP Standards:2017
      4. EU MDR
      5. United States FD&C Act Misbranding and Adulteration Provisions
      6. Other regional certification required by laws or regulations
   2. Supplier shall supply, manufacture, package, label, store, test and release Products in accordance with those Products specifications and operating procedures as agreed to by the Parties, and Applicable Laws. Where the Products specifications and/or operating procedures are not designated within the Supply Agreement [or TCP], then the following parameters shall be used in primary order: (a) those Avantor Products specifications and/or operating procedures as agreed to by Supplier; or (b) those Products specifications and/or operating procedures of the Supplier.
   3. Supplier shall notify Avantor of any proposed material changes to the facility or process related to the supply of the Products(s) that could adversely impact the quality of the Products no less than one hundred and eighty (180) days in advance of the proposed change in accordance with the Change Control process outlined within **Appendix 1** (Quality Agreement Responsibility Table).The appropriate contact person for each Party is listed in **Appendix 2** (Key Contacts).
5. **USE OF THIRD PARTIES.** Supplier shall have the ability to use in any capacity the services of any third party to perform services and responsibilities ancillary to Supplier’s obligations described in this Agreement. Where use of a third party provider would represent a change in Products manufacturing or performance, Supplier shall provide Avantor with the necessary notifications in accordance with IPEC Significant Change Guide. Notwithstanding the foregoing, Supplier shall be responsible for all of its obligations under this Agreement, whether or not a third party manufactures, supplies, packages, repackages, labels, re-labels, and inspects, tests, re-tests, stores, releases, handles and or processes the Products for the Supplier.
6. **RAW AND SOURCE MATERIALS.** Supplier, in accordance with its standard operating procedures, shall qualify its raw and source material suppliers and inspect and test said raw and source materials that are used in the production of the Products and/or supplied as Products. An assessment of the quality systems of the raw material suppliers or source manufacturers (a Quality Assessment Report or on-site supplier audit) will be conducted on a routine basis by the Supplier to demonstrate that they can consistently meet those specifications and requirements for the supply of said raw or source materials as specified by the Supplier or as agreed to between the Parties. Such Quality Assessment Report or on-site audit reports and any other back-up detail of the third party supplier quality assessments shall be maintained by Supplier in accordance with Supplier’s record retention policy and be made available for Avantor review upon reasonable request.
7. **CHANGE CONTROL.** Change Control for the Products will be administered through the Supplier’s change control system and in accordance with IPEC Significant Change Guide and Applicable Laws. Supplier shall complete Avantor’s Supplier Change Notification form. As used herein, “Change Control” means the procedure for making changes to the manufacturing of the Products, including, without limitation, changes to the specifications, changes to sub-suppliers, changes to manufacturing process that affect the product performance, and changes to the location of manufacturing. Supplier shall include in its change Control System a process and criteria for Avantor notification and approval in accordance with the IPEC Significant Change Guide.
8. **STABILITY STUDIES AND SHELF LIFE.** Supplier will conduct stability studies related to the Products in accordance with industry standards or agreed to operating procedures and Applicable Laws. Products supplied by Supplier with an expiration date of twenty-four (24) months or less shall have a Shelf-Life of at least seventy percent (70%). Products supplied by Supplier with an expiration date of greater than twenty-four (24) months shall have a shelf life of at least fifty percent (50%). Any Product that are delivered with a Shelf-Life at date of delivery that is less than set forth in this Section 8 shall be deemed Non-Conforming Product. For Shelf-Life Non-Conforming Products, Avantor shall notify Supplier in writing within ten (10) business days of inspection that the shipment includes Non-Conforming Product.
9. **REGULATORY COMPLIANCE.** With respect to the Products, Supplier will be responsible for all contact with regulatory authorities and all necessary regulatory filings and registrations. Avantor will assist Supplier as reasonably necessary with any issues with regulatory authorities concerning the Products. In accordance with its standard operating procedures and Applicable Laws, Supplier shall retain samples and documentation.
10. **QUALITY AUDITS.** 
    1. Avantor, at its expense, during normal business hours and at a mutually convenient time, may inspect that portion of the Supplier’s facility used in the raw material receipt, supply, packaging, testing and warehousing of Products, as well as the records of Supplier related to the packaging or distribution of Products, for the sole purpose of determining Supplier’s compliance with the terms of this Agreement.
    2. In addition, Avantor shall have the right to conduct an Audit of the Supplier’s facility and documentation pertaining to the supply of Products at any time (a) Products is received failing to routinely meet Products specification requirements, or (b) Avantor is made aware of any failure by Supplier to meet applicable operational or regulatory requirements, or (c) a change requiring application of the Change Control process is needed or (d) at a minimum of once every third calendar year.
    3. Those attending any audit on Avantor’s behalf shall abide by all of Supplier’s visitor regulations and safety rules. Such inspections shall be conducted in such a manner as to minimize disruption of Supplier’s operations. Such audits may be performed by Avantor’s representatives provided the same agree to adhere to the same confidentiality requirements as applicable to Avantor under the Supply Agreement [or TCP].
11. **SUPPLIER AUDITS.** Supplier shall have a robust third party supplier auditing and qualification program in place covering those third party suppliers of materials or services to Supplier for the Products to be delivered to Avantor. At a minimum, all process critical suppliers, primary packaging component suppliers, contract testing laboratories and toll manufacturers are to be audited. All such Supplier audits will be performed at the site of chemical/packaging manufacture and/or testing and are to be conducted in accordance with the current GMP standards*.* Records of such Supplier performed audits of its third party providers shall be made available for Avantor review upon request or, where no such audit has been performed or the Supplier audit identifies material deviations from applicable standards, Supplier shall work with Avantor to assist Avantor in being granted access to audit said third party provider facilities and records as are applicable to the Products(s). Such Supplier performed audits shall be maintained consistent with Supplier’s applicable record retention policy.

1. **COMPLAINTS.** The Parties agree that each will notify the other Party upon becoming aware of any complaint concerning the Products. Supplier will process such complaint into its complaint system and Supplier will, as expeditiously as is reasonable, respond to Avantor with an acknowledgement letter. Supplier will then investigate and respond in writing to such complaint within twenty (20) business days, identifying the underlying cause of the complaint and those actions taken to prevent a reoccurrence of the same. If additional time is necessary to prepare a complete response, Supplier shall issue an interim response letter will be issued to the Avantor with a final response provided not less than ten (10) days from said interim response.
2. **SEIZURES, RECALLS, WITHDRAWALS OR FIELD CORRECTIONS.** Supplier shall be responsible for handling all complaints from Avantor relating to any recalls or similar actions with respect to the Products and will provide reasonable support to Avantor in responding to Avantor’s customers. Avantor will assist Supplier in investigating any such situation, if Supplier so requests.
3. **NOTICES.** All notices, consents, approvals or other notifications required to be sent by one Party to the other Party under this Agreement shall be in writing and shall be deemed served upon the other Party if delivered by hand or sent by United States registered or certified mail, postage prepaid, with return receipt requested, or by facsimile with a copy by registered or certified mail, or by a recognized overnight courier, addressed to the appropriate contact of the other Party at the appropriate address set out below, or the last address of such Party as shall have been communicated to the other party. Notice shall be deemed given on the day it is received**.** Appendix 2 (Key Contacts) sets forth the contact individuals and their respective areas of responsibility. If a Party changes its address or any of the individuals on Appendix 2, written notice shall be given promptly to the other Party of the new address or individual.
4. **CERTIFICATES of ANALYSIS.**  Suppler will provide Avantor with Certificates of Analysis (COA) upon request. The COA shall include but is not limited to:

* SUPPLIER Name and Address
* “Ship To” Address
* Supplier Products Name, Number and Description
* Supplier Lot and/or Batch Number
* Date of manufacture
* Name of test and specification limit
* Actual Test results
* Country of Origin
* Location of manufacture
* Name and Title of Approver of document or a statement (accompanied by an electronic signature from an authorized QS representative) that the lot in question was tested to determine compliance with all applicable specifications

1. **MISCELLANEOUS TERMS.**

(a) This Agreement shall be governed by and construed in accordance with the substantive and procedural laws of the State of Delaware, without application of the conflict of laws provisions of that state that may apply the law of another jurisdiction. The Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the state of Delaware, USA courts for any action, suit or proceeding arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding related thereto except in such courts.

(b) The failure by any Party to exercise any of its rights hereunder or to enforce any of the terms or conditions of this Agreement on any occasion shall not constitute or be deemed a waiver of that Party's rights thereafter to exercise any rights hereunder or to enforce each and every term and condition of this Agreement.

(c) This Agreement may not be amended or modified except by a writing specifically referring to this Agreement and executed by duly authorized representatives of both Parties.

1. Subject to Section 1 above, this Agreement and any exhibits attached hereto represent the entire agreement and understanding of the parties hereto with respect to this subject matter and supersede any and all prior agreements, understanding or discussions, whether written or oral, between the Parties.
2. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, successors and assigns.
3. Neither Party shall have the right to assign any or all of its rights or obligations under this Agreement without the other Party’s prior written consent, which shall not unreasonably be withheld. The foregoing notwithstanding, prior written consent shall not be required in connection with an assignment to any Affiliate or with any merger, consolidation, or a sale of all or substantially all of Party’s assets to a third party, except if such merger, consolidation or sale is with a competitor of the other Party.

**IN WITNESS WHEREOF**, the Parties hereto have caused this Agreement to be executed as of the Effective Date.

**AVANTOR FUNDING, INC. <SUPPLIER>**

By: By: Quality Coating Company

Name: Name: Eldon Entwhistle

Title: Title: President

Date: Date: 9/1/2021

**Appendix 1: QUALITY AGREEMENT RESPONSIBILITY TABLE**

| **No.** | **Responsibilities** | | | **Supplier** | | **Avantor** | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1.0** | **Compliance** | | |  | |  | | |
| 1.1 | Conform to the Joint IPEC-PQG GMP Guide and/or other quality criteria and systems as defined in Section 4 of this Agreement. Comply with all applicable laws, regulations and guidelines and with quality system requirements. | | | X |  | | | |
| 1.2 | Mutually agree upon specifications for the Products which are the subject of this Agreement.  Specifications in place at the time of this Agreement are attached or referenced herein. | | | X | X | | | |
| 1.3 | Changes to the specifications shall be mutually agreed upon and communicated in writing between the parties to this Agreement, except for compendial changes which can be implemented without mutual agreement. Compendial changes shall be implemented by the compendial implementation date. | | | X | X | | | |
| 1.4 | Ensure that the specifications for compendial Products are in compliance with the current compendia. | | | X |  | | | |
| 1.5 | Manufacture Products that conform to the mutually agreed upon specifications. | | | X |  | | | |
| 1.6 | Ensure Product is appropriate for its intended use. | | |  | X | | | |
| 1.7 | Upon request, disclose information to Avantor regarding any recent regulatory agency inspections and adverse findings pertaining to the Products. | | | X |  | | | |
| 1.8 | Notify promptly if, in the course of a regulatory inspection, findings are made related to the quality or safety of the Products already supplied. | | | X |  | | | |
| 1.9 | Supplier shall have a qualification, and approval process for management of third parties that includes periodic re-evaluation. Supplier shall retain related records. | | | X |  | | | |
| **2.0** | **Manufacturing, Packaging and Labeling** | | |  | |  | | |
| 2.1 | Document that manufacturing and packaging process meet agreed upon requirements and are fit for purpose and all equipment necessary for the supply of Products are operational and routinely maintained sufficiently to support Products delivery requirements. Demonstrate the commissioning of critical systems and equipment used in the supply and control of the Products. Demonstrate that cleaning procedures are appropriate and their effectiveness has been demonstrated. | | | X | |  | | |
| 2.2 | Samples will be retained for a period of one (1) year past the expiration date. | | | X | |  | | |
| 2.3 | Agree upon special labeling requirements. | | | X | | X | | |
| 2.4 | SUPPLIER will provide documentation supporting residual solvent, allergens, and BSE/TSE in the Products(s) regulatory datasheet, where applicable. | | | X | |  | | |
| 2.5 | Where required, equip the regulated Products with tamper evident seals for improved supply chain security. | | | X | |  | | |
| 2.6 | Have necessary and appropriate controls designed to prevent cross contamination of the raw materials and intermediates used in the supply of Products(s). | | | X | |  | | |
| **3.0** | **Documentation and Records** | | |  | |  | | |
| 3.1 | Certificate of Analysis will be supplied with each batch. | | | X | |  | | |
| 3.2 | Certificate of Analysis will be prepared according to Section 15. | | | X | |  | | |
| 3.3 | Agree upon special Certificate of Analysis requirements. | | | X | | X | | |
| 3.4 | Where applicable, electronic signatures used on the Certificates of Analysis must conform to the requirements as defined in this agreement. | | | X | |  | | |
| 3.5 | Records required by the agreed upon quality system will be maintained in accordance with Supplier’s record retention procedure, except as otherwise required by law. | | | X | |  | | |
| 3.6 | Maintain procedures designed to assure the accuracy and consistency of data. | | | X | |  | | |
| **4.0** | **Storage and Distribution** | | |  | |  | | |
| 4.1 | Maintain and supply upon request documentation that supports the recommended Products(s) storage and any required transportation conditions, plus re-evaluation or expiry dates. | | | X | |  | | |
| 4.2 | Maintain a Products inventory and tracking system to assure accurate records of Products maintained or stored for Avantor so that such Products is readily identifiable within the storage location. | | | X | |  | | |
| 4.3 | Ensure that Products are stored and shipped in accordance with Product manufacturer’s recommended conditions. | | | X | | X | | |
| 4.4 | Where applicable, agree upon requirements for reusable shipping containers. | | | X | | X | | |
| 4.5 | Perform incoming quality control testing within a reasonable timeframe after receipt of the Product.  Note: Parties may choose to define this timeline for example within this Agreement or a supply agreement/TCP. | | |  | | X | | |
| **5.0** | **Change Control** | | |  | |  | | |
| 5.1 | Changes will be evaluated and communicated based upon agreed criteria and timelines | | | X | |  | | |
| 5.2 | Supplier shall provide adequate notice based on the type of change. | | | X | |  | | |
| 5.3 | Provide up to date instructions detailing how to submit notification of a change (e.g., generic email address). | | |  | | X | | |
| **6.0** | **Non-Conformance** | | |  | |  | | |
| 6.1 | Investigation of non-conformance includes the identification of the root cause, a risk analysis (including the risk to other lots and the impact to other test results) of the actions taken for correction of the problem, prevention of future occurrence and the formal conclusion by Supplier’s Quality Assurance. If an investigation reveals that there is an impact to the quality of the Products(s) or other materials received by Avantor, Supplier shall inform Avantor without unreasonable delay. | | | X | |  | | |
| 6.2 | Deviations and out of specification results occurring during GMP activities (e.g., manufacture and testing of Products) shall be investigated by Supplier according to Supplier's documented procedures. Supplier shall document the investigation and implement appropriate corrective and preventive actions, in accordance with current Product GMPs as listed in Section 4 of the agreement. Impact to other batches shall be checked, where applicable. | | | X | |  | | |
| 6.3 | Impacted Products may only be released and shipped to Customer after investigation has been finalized and demonstrated Product's compliance to its agreed specification. | | | X | |  | | |
| 6.4 | Out-of-specification (OOS) test results should be investigated and documented according to a documented procedure. | | | X | |  | | |
| **7.0** | **Non-Conformances Detected by Supplier after Customer Receipt** | | | | | | | |
| 7.1 | When Supplier becomes aware that any batch of Product already shipped to Customer fails to conform to its specification or is considered to have negative impact on quality, Supplier shall notify Customer without unreasonable delay. (E.g., Product is in specification, but packaging container sheds foreign particles).  Additionally, an investigation report shall be provided to Customer as soon as possible. | | | X | |  | | |
| **8.0** | **Complaints** | | |  | |  | | |
| 8.1 | Customer shall inform Supplier of any complaint by written notice indicating at least the affected Product (name, article code, volume and batch number) and the complaint subject as soon as detected or confirmed. Notification can only be made within the Product's shelf life or retest date. Defects discovered during receipt of Product shall be recorded on the proof of delivery. | | |  | | X | | |
| 8.2 | Have a written procedure to investigate and document quality related complaints. A root cause analysis, actions taken for correction of the problem, prevention of future occurrence and the formal conclusion will be provided to the Avantor within a reasonable time after receipt of the complaint. Impact on other batches shall be checked, where applicable.  A rapid initial response and a final report shall be provided to Customer as soon as possible. | | | X | |  | | |
| 8.3 | Complaints made shall at least indicate the Supplier’s batch number of the Products and complaint subject. The complaint shall be communicated to the Supplier within twenty (20) business days after receipt of the Products by Avantor. Samples will be provided where appropriate and available. | | |  | | X | | |
| 8.4 | The Parties shall cooperate in the exchange of information required to effectively conduct an investigation. | | | X | | X | | |
| **9.0** | **Recalls** |  | | |  | | |
| 9.1 | In the case of a recall of the Products or any of its raw material components, SUPPLIER shall inform Avantor without unreasonable delay of the planned recall. | X | | |  | | |
| 9.2 | Have a written recall procedure. | X | | |  | | |
| 9.3 | Notify Avantor of any Products recall which has been investigated or is under investigation and has potential to be related to the quality of the Products(s), or other materials as soon as possible. | X | | |  | | |
| 9.4 | Customer shall notify Supplier as soon as possible of any finished product recall which has been investigated or is under investigation and has potential to be related to the quality of the Products. |  | | | X | | |
| 9.5 | The parties shall cooperate in the exchange of information required to effectively conduct a recall or recall investigation. | X | | | X | | |
| **10.0** | **Returned Products** |  | | |  | | |
| 10.1 | To prevent mix up with released Products, returned Products shall be identified as such by Supplier and handled, stored, tested or disposed according to written procedures. | X | | |  | | |
| **11.0** | **Auditing** |  | | |  | | |
| 11.1 | Have the right to audit Supplier’s facilities, systems and documentation, as they relate to the manufacture of Products, at mutually agreed upon time. |  | | | X | | |
| 11.2 | Have the right to perform non-routine (e.g. for-cause) audits of Supplier facilities, systems and documentation at short notice at mutually agreed upon times in the event of critical or major issues. |  | | | X | | |
| 11.3 | Issue a confidential written audit report to the Supplier, which will include audit observations, within 30 calendar days. |  | | | X | | |
| 11.4 | Supplier shall issue responses to all observations in writing to Customer Quality Assurance within 30 calendar days. Where the supplier commits to a corrective action, a description and timeframe for completion will be included in the written response. | X | | |  | | |
| **12.0** | **Sub-contracting** |  | | |  | | |
| 12.1 | Shall not sub-contract any activities without Customer’s written approval. | X | | |  | | |
| 12.2 | Notwithstanding Customer’s approval for Supplier to use a subcontractor the Supplier shall remain responsible and liable for all obligations under this Quality Agreement, whether or not a third party carries out such obligations per the section above. | X | | |  | | |
| 12.3 | Ensure a quality agreement with subcontractor(s) is implemented and such quality agreement is consistent with the contractual obligations as outlined in this Quality Agreement. | X | | |  | | |
| 12.4 | Supplier shall have a qualification, and approval process for management of third parties that includes periodic re-evaluation. Supplier shall retain related records. | X | | |  | | |
| **13.0** | **Annual Products Review** | |  | | | |  | |
| 13.1 | Maintain record of Products manufacturing on a quarterly basis tracking Products quality findings, delivery or manufacturing turnaround times, Products complaints and efforts to resolve the same | | X | | | |  | |
| 13.2 | Undertake a yearly meeting between the Parties to evaluate success of Products manufacturing and delivery requirements | | X | | | | X | |
| 13.3 | Provide CAPA analysis of identified issues including plan of resolution or improvement and timeline for proper implementation | | X | | | | X | |
| **14.0** | **Regulatory Inspections and Exchanges** | |  | | | |  | |
| 14.1 | Parties shall coordinate the activities necessary to ensure readiness prior to regulatory agency pre-approval inspections and maintain inspection readiness for all inspections. | | X | | | | X | |
| 14.2 | Supplier shall notify Avantor within one (1) business day of any pending or ongoing regulatory authority inspection or communication specific to the Product provided to Avantor. | | X | | | |  | |
| 14.3 | Provide a redacted copy of the regulatory inspection report, deficiency letter, or regulatory compliance observations, response and related correspondence related to products to Avantor. | | X | | | |  | |
| 14.4 | Allow Avantor time to review and comment on the response, relevant to products rendered, prior to submission of the response to the regulatory authority. Avantor must provide comments within three (3) business days. | | X | | | | X | |
| 14.5 | Notify Supplier of any regulatory compliance observation received by Avantor that pertains to operations performed by Supplier and requires Supplier information. Supplier will provide requested information within ten (10) business days or as required to meet regulatory obligations. | | X | | | | X | |

**Appendix 2: KEY CONTACTS**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
| **Supplier** | | **Customer** | | |
| **Contact #1** | <Name><function> | **Contact #1** | Jennifer Goodman, Senior Director of Quality, Global Operations |
| <Email> | [Jennifer.Goodman@avantorsciences.com](mailto:Jennifer.Goodman@avantorsciences.com) | | |
| <Location> | Tower 6, Suite 800  600 W. Hamilton Street  Allentown, PA 18101 |
| <Phone number> | 484-273-8855 |
| **Contact #2** | <Name><function> | **Contact #2** | Nancy Ling, Senior Director of Sourcing |
| <Email> | [nancy.ling@avantorsciences.com](mailto:nancy.ling@avantorsciences.com) |
| <Location> | Building One, Suite 200, 100 Matsonford Road, Radnor, PA 19087 |
| <Phone number> | (610) 306-7466 |
| **Other** |  | **General Change Notice Inbox** | [corporate.qa@avantorinc.com](mailto:corporate.qa@avantorinc.com) |

**Appendix 3: LIST OF DEFINITIONS**:

As used in this Agreement, the following terms shall be as defined below:

**Agreement –** The arrangement undertaken by and legally binding upon parties hereunder.

**Applicable Laws –** all laws, statutes and regulations of any Regulatory Authority having jurisdiction over the Products in the territory in which the Products are manufactured, marketed, sold and/or distributed,, as may be in effect from time to time during the Term of this Agreement.

**Batch Number (Lot Number) –** A unique combination of numbers, letters and/or symbols that identifies a batch and from which the production and distribution history can be determined.

**Certificate of Analysis** (COA) - shall mean a document signed by an authorized representative of Supplier, stating the test methods, specification and results of testing a representative sample from the batch to be delivered.

**cGMP and cGDP** – Current Good Manufacturing Practices and Current Good Distribution Practices as defined in USP General Chapters <1078>, Joint IPEC-PQG GMP Guide, and The Certification Standards for Pharmaceutical Product Suppliers: Good Manufacturing Practices and Good Distribution Practices, EXCiPACT 2017

**cGLP** - shall refer to standards established by the FDA for current Good Laboratory Practices

**Confidentiality Agreement** – a legal agreement between two or more companies providing boundaries for sharing confidential company information beyond the scope of the intended effort.

**Corrective Action -** A change implemented to address a weakness identified in a management system.

**Critical –** A process step, process condition, test requirement or other relevant parameter or item that must be controlled within predetermined criteria to ensure that the Product meets its specification.

**Deviation –** Departure from an approved instruction or established standard.

**Distributor –** All parties in the distribution/supply chain starting from the point at which a Product is transferred outside the control of the original manufacturer’s material management system including parties involved in trade and distribution, (re)processors, (re)packagers, transport and warehousing companies, forwarding agents, brokers, traders, and suppliers other than the original manufacturer.

**Facilities -** shall mean Supplier’s facility as listed in **Appendix 5**.

**Label** – The display of written, printed or graphic matter on the immediate container of the Product (inactive ingredient) product.

**Labeling –** All written, printed or graphic matter accompanying a Product at any time while it is in-transit to Avantor or being held for sale after shipment or delivery to Avantor.

**Lot** - a batch or a specific quantity of material produced in a process or series of processes so that it can be expected to be homogeneous. In the case of continuous processes, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.

**Lot Number** – See Batch Number

**Manufacturer** – A party who performs the final processing step.

**Non-Conforming Product –** Products that fail to comply with the Specifications.

**Original or Source Manufacturer –** Person or company manufacturing a material to the stage at which it is designated as a pharmaceutical starting material.

**Packaging –** The container and its components that hold the Product for storage and transport to the customer.

**Procedure –** Written, authorized instruction for performing specified operations.

**Products -** shall mean the items manufactured by Supplier listed in **Appendix 4**.

**Quality Agreements -** Legally binding agreements that are mutually negotiated between users and suppliers. A quality agreement is intended to be a formalized, joint agreement on quality responsibilities and activities defining both the user’s and supplier’s respective obligations as they relate to quality. They are intended to address quality commitments between the parties and are based on the quality procedures in place.

**Quality Assurance –** The sum total of the organized arrangements made with the object of ensuring all Products are of the quality required for their intended use and that quality systems are maintained.

**Quality Records** - batch records, laboratory notebooks, and quality control data, or any data related to the supply or testing of the raw material or product.

**Recalls –** A process for withdrawing or removing a pharmaceutical material from the distribution chain because of defects in the materials or complaints of a serious nature. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.

**Record –** Document stating results achieved and/or providing evidence of activities performed. The medium may be paper, magnetic, electronic or optical, photography etc. or a combination thereof.

**Retained Sample –** Representative sample of a batch/delivery that is sufficient quantity to perform at least 2 full quality control analyses and will be kept for a defined period of time.

**Site –** A location where the Product is manufactured. This may be within the facility but in a different operational area or at a remote facility including a contract manufacturer.

**Specification –** shall mean any requirement with which a Product, process, service or other activity must conform, as described in required or related compendia (e.g. USP, NF, ACS, etc.), and/or by agreed and signed purchase specifications, or in further detail in Exhibit A. The Specifications shall also include, but not be limited to, all necessary test protocols, packaging and labeling specifications and other documentation required to describe, control, and assure the quality of the manufacture of the Products.

**Supplier –** Person or company providing pharmaceutical starting materials on request. Suppliers may be distributors, manufacturers, traders, etc.

**Supply Agreement or TCP** – Business agreement for supply of goods or performance of work at a specified price.

**User –** A party who utilizes a Product in the manufacture of a drug product or another Product.

**Validation –** A documented program that provides a high degree of assurance that a specific process, method or system will consistently produce a result meeting predetermined acceptance criteria.

**Appendix 4: PRODUCTS COVERED BY THIS AGREEMENT**

This Agreement pertains to the following Product(s) list:

| **Supplier Product Number** | **Supplier Product Name** | **Customer Product Number** | **Customer Product Name** |
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**Appendix 5: LIST OF APPLICABLE FACILITIES WITH ADDRESSES**

| Facility Name | Facility Address | Products Supplied / Services Performed at Facility |
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