

# HDA PCSC GDP CERTIFICATION PROGRAM AGREEMENT

This HDA PCSC GDP Program Agreement (this "**Agreement**") is entered into as of the last date of signature set forth on the signature page below (the "**Effective Date**") by and between Healthcare Distribution Alliance, Inc. ("**HDA**") and the entity set forth in the signature block below ("**Applicant**"). HDA and Applicant are individually referred to as a "**Party**" and collectively as the "**Parties**."

# RECITALS

**A.** HDA maintains the HDA Pharmaceutical Cargo Security Coalition ("**PCSC**") Good Distribution Practice Accreditation Program (the "**Program**"), which is a comprehensive initiative designed to uphold and enhance the standards of Good Distribution Practices ("**GDPs**") within the pharmaceutical and life sciences industries.

**B.** The entity(ies) identified in <u>Schedule A</u> have been authorized by HDA to administer the Program (each, a "**Certification Entity**"). Collectively, HDA and the Certification Entities are referred to in this Agreement as the "**Administrators**."

**C.** Applicant wishes to participate in the Program and, as a pre-requisite for its participation in the Program, agrees to be bound by the terms and conditions of this Agreement.

# **AGREEMENT**

**NOW, THEREFORE**, in consideration of the promises and the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties agree as follows:

**1.** <u>Accreditation Process</u>. Applicant acknowledges and agrees that the Program's accreditation process will consist of 4 phases, each of which is described below:

1.1 <u>Phase 1 (Definition)</u>:

(a) Applicant shall complete the pre-assessment questionnaire (the "**Questionnaire**") provided by the Administrators and provide any other information reasonably requested by the Administrators.

(b) The Parties may enter into a Statement of Work ("**SOW**") that will further detail Applicant's accreditation process. If there is any conflict between such SOW and this Agreement, the terms of this Agreement will govern, unless the conflicting term(s) of the SOW explicitly override the conflicting term(s) of this Agreement.

1.2 <u>Phase 2 (Assessment #1)</u>: Following the Administrators' receipt of the Questionnaire and the Parties' completion of any SOW, the Administrators will assess Applicant's current pharmaceutical and life science product distribution services (the "**Distribution Services**") against (a) the EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use

(2013/C 343/01), and (b) the PIC/S Guide to Good Distribution Practice for Medicinal Products (items (a) and (b) are collectively referred to as the "**Specifications**"). The Administrators will measure Applicant's Distribution Services by conducting an off-site review of Applicant's documentation and an on-site review of Applicant's business practices.

1.3 <u>Phase 3 (Analyze)</u>: Following the Administrators' initial assessment of Applicant's Distribution Services, the Administrators will prepare and provide Applicant with a gap analysis report that details the findings of the evaluation conducted in Phase 2, including the components of Applicant's Distribution Services that are not consistent with the Specifications, and provides a list of recommendations for improving Applicant's Distribution Services such that they comply with the Specifications (the "**Gap Analysis Report**").

1.4 <u>Phase 4 (Assessment #2)</u>: Following Applicant's receipt of the Gap Analysis Report, Applicant will take steps to implement the recommendations in the Gap Analysis Report. On a mutually agreed upon date, the Administrators will re-assess Applicant's Distribution Services and prepare a second report detailing the findings of its evaluation (the "**Re-Assessment Findings Report**").

1.5 <u>Phase 5 (Control)</u>: Following the Administrators' preparation of the Re-Assessment Findings Report and Applicant's completion of all tasks and/or deliverables set forth in any SOWs entered into hereunder, the Administrators may, in their sole and absolute discretion, elect to issue Applicant an accreditation certificate (the "**Certificate**"). Upon receipt of the Certificate, Applicant will be deemed to have completed the Program and may hold itself out as accredited under the Program.

# 2. <u>Term of Accreditation; Renewal</u>.

2.1 <u>Term</u>. The Certificate received by Applicant pursuant to the accreditation process set forth in <u>Section 1</u> will be valid for a period of 2 years, unless earlier revoked or terminated under the terms of this Agreement (the "**Initial Term**").

2.2 <u>Renewal</u>. If Applicant desires to renew the Certificate, then it shall provide the Administrators with written notice of its desire to renew the Certificate by no later than 90 days prior to the expiration of the Initial Term or a Renewal Term (as defined below), as applicable. Upon receipt of such written notice from Applicant, the Administrators will re-assess Applicant's Distribution Services to determine if they remain in compliance with the Specifications.

(a) If the Administrators determine, in their sole discretion, that Applicant's Distribution Services remain in compliance with the Specifications, then the Administrators will renew Applicant's Certificate for an additional 2-year term (a "**Renewal Term**" and together with the Initial Term, collectively, the "**Term**").

(b) If the Administrators determine, in their sole discretion, that Applicant's Distribution Services are not in compliance with the Specifications upon the expiration of the Initial Term or any Renewal Term, then they will prepare and deliver to Applicant a gap analysis report setting forth any deficiencies in Applicant's Distribution Services. Applicant's Certificate will not be renewed, and Applicant may not hold itself out as accredited under the Program, until Applicant has cured all such deficiencies to the Administrators' satisfaction, in their sole discretion.

3. <u>License Agreement</u>. Applicant acknowledges and agrees that its use of the Certificate and all intellectual property rights associated therewith is subject to the Licensing Agreement for the HDA PCSC GDP Certification Trademarks, to be entered into by the Parties prior to Applicant's receipt of the Certificate (the "License Agreement"), a copy of which is attached as <u>Exhibit A</u>.

4. **<u>Payment</u>**. Applicant shall pay to HDA the amounts set forth at <u>Schedule A</u> to this Agreement (the "**Fees**"). Applicant shall pay the Fees at the times and in the manner set forth at <u>Schedule A</u> to this Agreement.

5. <u>Recordkeeping Requirements</u>. Applicant shall maintain complete and accurate records of all activities and transactions relating to its Distribution Services during the Term. Applicant shall promptly provide the Administrators with access to such records upon the Administrators' request and shall grant the Administrators all permissions and access necessary for the Administrators to conduct their evaluations of Applicant's Distribution Services.

# 6. <u>Termination; Effect of Termination or Expiration</u>.

6.1 HDA may terminate this Agreement and revoke the Certificate upon the occurrence of any of the following:

(a) If the Administrators determine, in their sole discretion at any time during the Term, that Applicant's Distribution Services fail to comply with the Specifications, and Applicant fails to cure such failure, if capable of cure, within 30 days after written notice of such failure;

(b) If Applicant materially breaches this Agreement and such breach is incapable of cure or, with respect to a material breach capable of cure, if Applicant fails to cure such breach within 10 days after receipt of written notice of such breach;

(c) If Applicant materially breaches any provision of the License Agreement or if the License Agreement terminates or expires for any reason; or

(d) If Applicant (i) becomes insolvent or admits its inability to pay its debts generally as they become due; (ii) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully stayed within 10 business days or is not dismissed or vacated within 10 days after filing; (iii) is dissolved or liquidated or takes any corporate action for such purpose; (iv) makes a general assignment for the benefit of creditors; or (v) has a receiver, trustee, custodian, or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

6.2 Upon termination or expiration of this Agreement:

(a) The Certificate will expire, and Applicant shall not hold itself out as accredited under the Program; and

(b) Each Party shall (i) return to the other Party all documents and tangible materials (and any copies) containing, reflecting, incorporating, or based on the other Party's Confidential Information, (ii) permanently delete all of the other Party's Confidential Information from

its computer systems, and (iii) certify in writing to the other Party that it has complied with the requirements of this Section.

6.3 Upon termination or expiration of this Agreement, all provisions that, by their nature, are intended to survive termination or expiration of this Agreement will so survive.

# 7. <u>Confidentiality</u>.

7.1 As used in this Agreement, the term "**Confidential Information**" means any data or information relating to the business of each Party which is not generally known to the public, whether in tangible or intangible form, whenever and however disclosed, including, but not limited to: any marketing strategies, plans, financial information, or projections, operations, sales estimates, business plans and performance results relating to the past, present or future business activities of each Party, its affiliates, subsidiaries and affiliated companies.

7.2 Each Party shall maintain all Confidential Information of the other Party in strict confidence. Each Party shall not disclose any Confidential Information to any third parties nor use any Confidential Information for any purpose other than for the performance of the rights and obligations under this Agreement during the Term and for a period of 5 years thereafter. Notwithstanding the foregoing, HDA may disclose Applicant's Confidential Information to the Certification Entity(ies) administering the Program on HDA's behalf, but only to the extent necessary for such Certification Entity(ies) to evaluate Applicant's Distribution Services in connection with the Program. HDA shall enter into an agreement with all Certification Entities that contains non-disclosure and non-use provisions at least as strict as this Agreement, under which each Certification Entity will be obligated to maintain the confidentiality of Applicant's Confidential Information.

7.3 The obligations set forth in this Section will not apply to any information that: (a) is in the public domain at the time disclosed; (b) enters the public domain through no fault of the recipient; (c) is rightfully communicated to the recipient by persons not bound by confidentiality obligations with respect thereto; (d) is already in the recipient's possession free of any confidentiality obligations with respect thereto at the time of disclosure; (e) is independently developed by the recipient; or (f) is approved for release or disclosure by the disclosing Party without restriction.

# 8. <u>Representations and Warranties</u>.

8.1 Each Party represents and warrants to the other Party that:

(a) It is duly organized, validly existing and in good standing as a corporation or other entity as represented herein under the laws and regulations of its jurisdiction of incorporation, organization, or chartering;

(b) It has the full right, power, and authority to enter into this Agreement, to grant the rights and licenses granted hereunder, and to perform its obligations hereunder;

(c) The execution of this Agreement by its representative whose signature is set forth at the end hereof has been duly authorized by all necessary corporate action of the Party; and

(d) When executed and delivered by such party, this Agreement will constitute the legal, valid, and binding obligation of such Party, enforceable against such Party in accordance with its terms.

8.2 Without limiting the foregoing, Applicant further represents and warrants to HDA that:

(a) The information provided to the Administrators related to its Distribution Services is and will be complete and accurate in all material respects;

(b) The information provided to the Administrators related to its Distribution Services does not and will not infringe upon any third party's intellectual property rights, privacy rights, or other legal rights; and

(c) There are no legal proceedings or claims pending or threatened against it that could interfere with its ability to fulfill its obligations under this Agreement.

8.3 EXCEPT FOR THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT, HDA HEREBY DISCLAIMS ALL WARRANTIES, EITHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE WITH RESPECT TO THE PROGRAM AND THE CERTIFICATE. WITHOUT LIMITING THE FOREGOING, HDA SPECIFICALLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, AND NON-INFRINGEMENT WITH RESPECT TO THE PROGRAM AND THE CERTIFICATE.

# 9. **Indemnification**.

9.1 Applicant shall indemnify, defend, and hold harmless HDA and the Certification Entity(ies) administering the Program on HDA's behalf and each entity's officers, directors, agents, affiliates, successors, and permitted assigns (collectively, the "Administrator Indemnitees") from and against any and all losses, damages, liabilities, deficiencies, claims, actions, judgments, settlements, interest, awards, penalties, fines, costs, or expenses of any kind, including reasonable attorneys' fees, and the cost of pursuing any insurance providers (collectively, "Losses"), incurred by the Administrator Indemnitees in connection with any third-party claim, suit, action, or proceeding arising out of or resulting from:

in this Agreement;

(a) The breach or inaccuracy of any representation, warranty, or covenant

(b) Applicant's gross negligence or willful misconduct in the performance of its obligations or exercise of its rights under this Agreement;

(c) Applicant's violation of any applicable law, regulation, or ordinance in the performance of its obligations under this Agreement; or

(d) The infringement of any third party's intellectual property rights, privacy rights or other legal rights in the performance of Applicant's obligations or exercise of Applicant's rights under this Agreement.

9.2 HDA shall indemnify, defend, and hold harmless Applicant and Applicant's officers, directors, agents, affiliates, successors, and permitted assigns (collectively, the **'Applicant** 

**Indemnitees**") from and against any and all Losses incurred by the Applicant Indemnitees in connection with any third-party claim, suit, action, or proceeding arising out of or resulting from:

(a) The breach or inaccuracy of any representation, warranty, or covenant in this Agreement;

(b) HDA's gross negligence or willful misconduct in the performance of its obligations or exercise of its rights under this Agreement;

(c) HDA's violation of any applicable law, regulation, or ordinance in the performance of its obligations under this Agreement; or

(d) The infringement of any third party's intellectual property rights, privacy rights or other legal rights in the performance of HDA's obligations or exercise of HDA's rights under this Agreement.

# 10. Limitation of Liability.

10.1 EXCEPT AS SET FORTH IN <u>SECTION 10.3</u>, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY (NOR SHALL THE CERTIFICATION ENTITY(IES) ADMINISTERING THE PROGRAM ON HDA'S BEHALF BE LIABLE TO APPLICANT) FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL OR PUNITIVE DAMAGES, INCLUDING ANY DAMAGES FOR BUSINESS INTERRUPTION, LOSS OF USE, LOSS OF REVENUE, OR LOSS OF PROFIT, WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE AND WHETHER OR NOT THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

10.2 EXCEPT AS SET FORTH IN <u>SECTION 10.3</u>, IN NO EVENT SHALL EITHER PARTY'S TOTAL LIABILITY TO THE OTHER PARTY (NOR SHALL THE LIABILITY OF THE CERTIFICATION ENTITY(IES) ADMINISTERING THE PROGRAM ON HDA'S BEHALF TO APPLICANT) FOR ANY DAMAGES UNDER THIS AGREEMENT EXCEED THE TOTAL AMOUNT OF FEES PAID OR PAYABLE BY THE APPLICANT UNDER THIS AGREEMENT.

10.3 THE LIMITATIONS OF LIABILITY SET FORTH ABOVE WILL NOT APPLY TO (A) EACH PARTY'S INDEMNIFICATION OBLIGATIONS HEREUNDER, (B) EACH PARTY'S CONFIDENTIALITY OBLIGATIONS HEREUNDER, OR (C) DAMAGES RESULTING FROM THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF EITHER PARTY.

# 11. Miscellaneous.

11.1 <u>Relationship</u>. The relationship between the Parties is that of independent contractors. Nothing contained in this Agreement shall be construed as creating any agency, partnership, joint venture, or other form of joint enterprise, employment, or fiduciary relationship between the Parties, and neither party shall have authority to contract for or bind the other Party in any manner whatsoever.

11.2 <u>Press Release</u>. Applicant shall not issue or release any announcement, statement, press release, or other publicity or marketing materials relating to this Agreement, the

Certificate, or the Program, or otherwise use HDA's trademarks, service marks, trade names, logos, symbols, or brand names, in each case, without the prior written consent of HDA.

11.3 <u>Notice</u>. All notices, requests, consents, claims, demands, waivers, and other communications hereunder shall be in writing and shall be deemed to have been given (a) when delivered by hand (with written confirmation of receipt); (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); (c) on the date sent by email if sent during normal business hours of the recipient, and on the next business day if sent after normal business hours of the recipient or (d) on the third day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. All communications intended for HDA must be sent to HDA at the addresses indicated below. All communications intended for Applicant must be sent to HDA at the addresses set forth on the signature page below.

Healthcare Distribution Alliance 1275 Pennsylvania Avenue NW Suite 600 Washington, DC 20004 Attn: Elizabeth Gallenagh, General Counsel Email: egallenagh@hda.org

11.4 <u>Entire Agreement</u>. This Agreement, together with all Schedules, Exhibits, and SOWs and any other documents incorporated herein by reference, constitutes the sole and entire agreement of the parties to this Agreement with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter.

11.5 <u>Third-Party Beneficiary</u>.

(a) Except as set forth in <u>Section 11.5(b)</u>, the Parties do not confer any rights or remedies upon any other person or entity other than the Parties and their respective successors and permitted assigns.

(b) The Parties hereby designate the Certification Entity(ies) set forth at <u>Schedule B</u> as a third-party beneficiary(ies) of <u>Sections 9.1</u>, <u>10.1</u>, and <u>10.2</u> having the right to enforce such Sections as if such Certification Entity(ies) were an original party hereto.

11.6 <u>Assignment</u>. Applicant may not assign, transfer, or delegate any or all of its rights or obligations under this Agreement, including by operation of law, change of control, or merger, without the prior written consent of HDA. No assignment shall relieve the assigning party of any of its obligations hereunder. Any attempted assignment, transfer, or other conveyance in violation of the foregoing shall be null and void. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns.

11.7 <u>Headings</u>. The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.

11.8 <u>Amendment; Waiver</u>. This Agreement may be amended, modified, or supplemented only by an agreement in writing signed by each Party. No waiver by any Party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the Party

so waiving. Except as otherwise set forth in this Agreement, no failure to exercise, or delay in exercising, any rights, remedy, power, or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power, or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power, or privilege.

11.9 Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the District of Columbia without giving effect to any choice or conflict of law provision or rule (whether of District of Columbia or any other jurisdiction) that would cause the application of laws of any jurisdiction other than those of District of Columbia. Any suit, action, or proceeding arising out of or relating to this Agreement may be exclusively and confidentially litigated through two-party (not class-based) arbitration administered by the American Arbitration Association (AAA) under its then-current rules for expedited commercial disputes (except that discovery may include no more than a single eight-hour deposition by each side and the exchange of documents that either side reasonably may use at the arbitration hearing), before a single arbitrator and with the hearing occurring in Washington, D.C., within 12 months of filing the arbitration demand, and the prevailing party entitled to recovery of its legal fees and costs, as determined by the arbitrator. Any injunctive relief may also be exclusively pursued through the AAA before the same arbitrator. Each party waives any right to file an action in court, or to join any class or consolidated action against the other, for claims arising out of or relating to this Agreement. The decisions of the arbitrator will be final and binding on all parties to the dispute, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction. The arbitrator has exclusive power to rule on their own jurisdiction, including the existence, scope, waiver, or validity of the arbitration agreement or to the arbitrability of any claim or counterclaim, and to determine the existence or validity of a contract of which an arbitration clause forms a part (for this purpose alone, an arbitration clause will be treated as an agreement independent of the validity of a contract or its other terms).

11.10 <u>Counterparts</u>. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by email or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

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

By:

Signature:\_\_\_\_\_

Title:

Date:

Email:

# <u>HDA</u>

HEALTHCARE DISTRIBUTION ALLIANCE, INC.	
By:	
Signature:	
Title:	
Date:	
Email:	

# SCHEDULE A

## **Fee Structure**

The total cost of an accreditation process *for a business entity* is broken down into three categories:

- Fee for the accreditation assessment itself
- Fees for the required training
- Fee for revalidation after the two-year accreditation period

There is also an option for *individualized GDP training* (when a person, as opposed to a business) desires familiarization and training in the GDP discipline.

Fee For the Accreditation Assessment Itself – Business Entity:

A differentiating factor in the fee structure would be whether the assessment can be performed virtually or in person.

For example, a freight forwarding, freight broker, customs agent, or insurance entity wouldn't necessarily require a "site" inspection, as these companies are principally involved in administrative processes - rather than the actual handling of goods.

Entities such as transportation firms, warehousing/3 PL entities, a manufacturer, or a distributor may require a visual inspection during the accreditation process.

# Assessment Fee Structure – Business Entity:

Transportation company/trucking firm: **\$7,500.00** 

Freight Broker/Freight Forwarder/Customs Agent/Insurer: \$6,500.00

Warehousing/3PL: **\$14,000.00** 

Manufacturer/Distributor: \$18,000.00

If the applicant desired an independent assessment for an additional site(s), the additional assessments would be  $\frac{1}{2}$  of the overall fee (each) to obtain a unique accreditation for that particular location.

Payment of ½ of the Program fee is required in advance of the initiation of the necessary assessment. If the accreditation effort is successful, this would count as a first-year installment. The remainder of the fee is payable upon initiating the second year of the accreditation period. If the applicant is unsuccessful in attaining an accreditation (for whatever reason), they forfeit the first-year Program payment.

All stated fees do not include the cost of any travel expenses, which would be extra.

# Fees for Required Training- Business Entity:

There are three phases to the required training for a business entity to obtain accreditation. They are:

- GDP Introductory Training (1 Hour - conducted virtually)

- GDP Awareness Training (6 hours - conducted virtually over a one or two-day period)

- GDP Responsible Person Training (12 hours – conducted in person over a two-day period)

At least two individuals from each business entity that has applied for accreditation must be trained in all three phases of the program. More than two individuals should receive GDP introductory training.

Introductory and Awareness Training are conducted virtually, while Responsible Person Training, due to its intensity level, is conducted in person over a two-day period in groups preferably no larger than 10.

Responsible Person training will be offered quarterly - or four times per year - at a site of the HDA's choosing.

Due to the generic nature of the type of training, multiple companies can be trained in the same session.

## Training Fee Structure – Business Entity:

GDP Introductory Training: **\$100.00/person** 

GDP Awareness Training: **\$750.00/person** (2 person minimum)

GDP Responsible Person Training: **\$1,500.00/person** (2 person minimum)

Training fee compensation is due upon invoice.

Fees for Individualized GDP Familiarization & Awareness:

Individualized GDP familiarization & awareness training is offered at a flat rate of **\$800.00/person** and would include both GDP Introductory and GDP Awareness Training.

Such training could be performed either virtually or in person. However, the in-person training option would require a group of individuals no less than 20 in number.

If an individual were interested in GDP Responsible Person training, the fee would be the same as it would be for a business individual, and there would need to be space in one of the four quarterly RP training sessions during the calendar year.

Individualized training fee compensation is due upon invoice.

## **Revalidation Fee – Business**

Revalidation (or the process of renewing an accreditation after the two-year membership period) would cost the same as when the entity first entered the Program.

If the cost increased during the participation period, the entity could be allowed to renew their participation in the program at the last price they paid once.

Revalidation training (for the same people who had been originally trained in the program) would involve a **one-day refresher course** at the cost of **\$750.00/person**. Any new individuals to be trained would revert to the original training fee matrix.

## SCHEDULE B

## **CERTIFICATION ENTITY(IES)**

# ASC Associates Ltd.Attn: Henry Moran

C/O Websters & Company 10 Wellington Street Cambridge, CB1 1HW

Email: <u>henrymoran@ascassociates.co.uk</u> Tel: +44(0) 7505 731299 / +44(0) 1954 780719

## <u>EXHIBIT A</u>

### LICENSING AGREEMENT FOR THE HDA PCSC GDP CERTIFICATION TRADEMARKS

This Licensing Agreement (the "License Agreement") is entered into as of the last date of signature set forth on the signature page below (the "Effective Date") by and between Healthcare Distribution Alliance ("HDA") and the entity set forth in the signature block below ("Applicant"). HDA and Applicant are individually referred to as a "Party" and collectively as the "Parties." "All capitalized terms used in this Agreement but not otherwise defined herein shall have the meanings ascribed to such terms in the HDA PCSC GDP Certification Program Agreement, which agreement is incorporated herein by reference.

#### RECITALS

A. HDA is the owner of the HDA PCSC GDP Certification Trademarks listed in <u>Appendix A</u> (the "**Marks**") and has the sole right to grant the license described herein.

B. The Applicant's pharmaceutical and life science product distribution services (the "**Distribution Services**") have been certified as complying with the Specifications by one of the Certification Entities in accordance with the HDA PCSC GDP Certification Program Agreement.

C. HDA desires and agrees to grant Applicant the right to use the Marks, pursuant to the terms of this License Agreement.

#### AGREEMENT

**NOW, THEREFORE,** in consideration of the promises and the mutual covenants contained in this License Agreement, and for other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties agree as follows:

#### 1. INITIAL TERM & RENEWAL TERM

- 1.1 This License Agreement will start on the Commencement Date and continue for a period of two (2) years ("**Initial Term**") unless terminated or extended in accordance with the terms of this Agreement and pending current, active certification.
- 1.2 Unless either Party terminates this Agreement by giving at least thirty (30) days written notice prior to the expiration of the Initial Term (or any Renewal Term), this Agreement will continue for additional two (2) year terms, each referred to as a "**Renewal Term**." Each Renewal Term shall commence upon the payment of the Renewal License Fee, which is described in <u>Section 4.3</u>.

#### 2. GRANT OF RIGHTS

2.1 **Rights.** Subject to the terms of this Agreement, HDA grants to Applicant a

limited, non-exclusive, non-sublicensable, non-transferrable, revocable license to use the Marks solely to communicate that Applicant's Distribution Services comply with the Specifications.

- 2.2 **HDA remains the owner.** Applicant acknowledges that HDA is the sole and exclusive owner of all rights, title and interest in the Marks and the goodwill associated therewith. Applicant further acknowledges that any and all use of the Marks shall inure to the sole benefit of HDA and that HDA may license use of the Marks to other entities.
- 2.3 **Protection of the Marks.** Applicant shall not at any time during or after the Term:
  - (a) register or attempt to register or use as a trademark the Marks, in whole or in part, or any trademark, design, or word that is confusingly similar to the Marks;
  - (b) oppose or contest the ownership or validity of the Marks, any application for registration, or registration of the Marks; or
  - (c) take any action inconsistent with HDA's rights in the Marks.

#### 3. APPLICANT'S OBLIGATIONS

- 3.1 Except as prohibited by law, Applicant shall comply with all requirements, directions and specifications of HDA and/or the Certification Entity for its use of the Marks, including the GDP Certification Mark Usage Guidelines shown in <u>Appendix</u> <u>B</u>, as well as any and all applicable laws and guidelines associated with the Services and/or the use of the Marks in connection with the Distribution Services.
- 3.2 HDA and the Certification Entity shall have the right to review and inspect Applicant's use of the Marks as well as the Distribution Services throughout the Term.
- 3.3 Applicant shall permanently cease all use of the Marks within 60 days of termination or expiration of this Agreement, including but not limited to, deletion or removal of the Marks from Applicant websites, social media pages, signage, invoices, packaging, and other Applicant materials or property, and/or destruction of such materials or property. Applicant shall comply with reasonable requests of HDA and the Certification Entity to demonstrate that it has complied with this section.
- 3.4 Applicant shall notify HDA of any circumstances of which Applicant becomes aware which may constitute an infringement of or challenge to the Marks and provide reasonable cooperation, in any enforcement or defense of HDA's rights against any unauthorized use of the Marks of which Applicant notifies HDA. The right to enforce any rights in the Marks rests entirely with HDA and shall be exercised in HDA's sole discretion. Applicant shall not commence any action or claim to enforce any rights in the Marks.

# 4. HDA'S OBLIGATIONS

- 4.1 HDA agrees to the following obligations:
  - (a) HDA confirms HDA's exclusive ownership of the Marks and HDA's authority to license such Marks;
  - (b) HDA will use its best efforts to maintain the integrity and validity of the Marks; and
  - (c) HDA will notify Applicant in accordance with <u>Section 8</u> in the event that HDA no longer owns or intends to sell, transfer or otherwise abandon ownership of any of the Marks.

## 5. INDEMNITY AND LIMITATION OF LIABILITY

- 5.1 Applicant indemnifies HDA, the Certification Entity(ies), and each of their respective officers, employees, agents, and representatives against any and all claims or damages that they may suffer or incur as a result of:
  - (a) a breach of this Agreement by Applicant;
  - (b) any negligent, willful, reckless or unlawful act or omission of Applicant or any of its personnel in connection with this Agreement; and
  - (c) any claim by a third party arising from any act or omission of Applicant, whether negligent or not (including any claim for loss of or damage to any property or injury to or death of any person).
- 5.2 The indemnity provided herein will not apply to the extent that the damages were caused directly by the negligent, willful, reckless or unlawful act or omission of HDA, the Certification Entity(ies), or by a breach of this Agreement by HDA.
- 5.3 Neither HDA nor the Certification Entity(ies) shall have any liability to Applicant or to any third party for consequential, exemplary, special, incidental, or punitive damages even if they have been advised of the possibility of such damages.

## 6. CONFIDENTIALITY

- 6.1 Applicant will maintain as confidential all documents and information designated by HDA as confidential, and will not release, distribute, or publish to any third party without prior permission from HDA, except as compelled by order of a court or regulatory body of competent jurisdiction. As used herein, the term "Confidential Information" means any technical, financial, or other business information that is deemed proprietary or confidential by the Parties, including but not limited to information about plans, specifications, trade secrets, client lists, employee and subcontractor lists, business process documents, and other information. The confidentiality obligations under this Section, shall not apply, or shall cease to apply to the extent that Confidential Information:
  - (a) is or hereafter becomes generally known or available to the public or

interested persons through no breach of this section by one of the Parties;

- (b) is rightfully known to a Party without restriction or disclosure at the time of its receipt from the respective owner of the Confidential Information;
- (c) is rightfully furnished to one of the Parties by a third party without breach of an obligation of confidentiality;
- (d) is independently developed by one of the Parties without use or reference to the Confidential Information; or
- (e) is required to be disclosed by applicable law or pursuant to order of the court, administrative agency, or other governmental body; provided the Party provides sufficient prior notice to the respective owner of the Confidential Information to contest such order.
- 6.2 Except as required by law or by any record retention requirements by or for the Certification Entity(ies), or upon the termination of this Agreement, all materials containing Confidential Information shall be returned to HDA.

#### 7. TERMINATION

#### 7.1 **Termination for cause**

Either Party may terminate this Agreement with immediate effect if:

- (a) the other Party breaches any provision of this Agreement, and fails to remedy the breach within thirty (30) days after receiving written notice requiring it to do so; or
- (b) the other Party breaches a material provision of this Agreement where that breach is not capable of remedy.
- 7.2 **Termination at will.** Either Party may terminate this Agreement at any time by giving ninety (90) days written notice to the other Party.
- 7.3 **Accrued rights and remedies.** Termination of this Agreement under this provision does not affect any accrued rights or remedies of either Party.

#### 8. NOTICES

- 8.1 A Party notifying or giving notice under this Agreement shall provide notice:
  - (a) in writing;
  - (b) addressed to the address of the recipient specified in this Agreement or as altered by notice given in accordance with this Section; and
  - (c) hand delivered or sent by pre-paid post to that address or sent by facsimile transmission and promptly confirmed by hand delivery or pre-

paid post.

- 8.2 A notice given in accordance with this Agreement will be deemed received:
  - (a) if hand delivered, on the date of delivery;
  - (b) if sent by email and an acknowledgement or response was received;
  - (c) if sent by pre-paid post, 5 days after the date of posting; or
  - (d) if sent by facsimile transmission, on the date the facsimile transmission is sent (as long as there exists a sender's confirmation report specifying the facsimile number of the recipient, the number of pages sent and the date of the transmission).

#### 9. GENERAL

#### 9.1 Assignment

Applicant shall not assign or attempt to assign any rights arising out of this Agreement without written consent from HDA.

#### 9.2 Waiver

The failure of a Party at any time to insist on performance of any obligation under this Agreement of the other Party is not a waiver of its right:

- (a) to insist on performance of, or claim damages or other remedy for breach of, that obligation unless that Party acknowledges in writing that the failure is a waiver; and
- (b) at any other time to insist on performance of that or any other obligation of the other Party under this Agreement.

#### 9.3 Severability

If part or all of any provision of this Agreement is illegal or unenforceable:

- (a) it will be severed from this Agreement and will not affect the continued operation of the remaining provisions of this Agreement; and
- (b) the Parties will attempt to replace that severed part with a legally acceptable alternative provision that meets the Parties' commercial objectives.

#### 9.4 **Governing law and jurisdiction**

Any legal action by either Party or any person or Party claiming any right or seeking to avoid any obligation under Agreement, or otherwise relating in any way to this Agreement, shall be brought and maintained exclusively in the District of Columbia. The Parties consent to personal jurisdiction and venue in the District of Columbia, and further agree not to seek to invoke the jurisdiction of any other state. This Contract shall be governed, interpreted, and construed in accordance with District of Columbia law, without regard to its conflicts of law provisions.

## 9.5 Entire Agreement and variation

This Agreement (including its Appendixes) constitutes the entire Agreement between the Parties as to its subject matter and supersedes all prior representations and agreements in connection with that subject matter and may only be amended in writing signed by both Parties.

[Signature Page Follows]

**IN WITNESS WHEREOF**, the Parties, by their duly authorized representatives, have executed this Agreement.

## APPLICANT:

By: Signature:\_\_\_\_\_ Title: Date: Email:

# <u>HDA</u>

# HEALTHCARE DISTRIBUTION ALLIANCE, INC.

By:

Signature:\_\_\_\_\_

Title:

Date:

[Signature Page to License Agreement]

# Appendix A

# HDA PCSC GDP CERTIFICATION TRADEMARKS



# Appendix B

# Mandatory HDA PCSC GDP Certification Trademarks **Usage Guidelines**

Updated April 25, 2024

# A. HDA PCSC GDP Certification Trademarks

The HDA owns the following certification trademarks:



## B. Permissible Uses of the Marks

The Marks may be used solely to indicate that its Services comply with the Specifications. They may be used on websites, social media, on signage or labels, and in other advertising, promotional, and sales materials, provided that such use complies with these Guidelines, all applicable federal and state laws and regulations, and does not mislead consumers as to the source of the Services or the Applicant's relationship with HDA.

# C. Prohibited Uses of the Marks

- 1. DO NOT use the Marks in advertising that is false or misleading.
- 2. DO NOT use the Marks on or in connection with any defamatory, scandalous, or other objectionable materials.
- DO NOT use the Marks to disparage HDA, a Certification Entity, or any related companies or their products or services.
- DO NOT use the Marks in a manner that violates the terms of the License Agreement or the HDA PCSC GDP Certification Program Agreement.
- D. Usage Guidelines

### 1. Appearance of the Marks

- a. The shape of the marks must look exactly as they are shown above. Embossing is permitted, but shadow effects, gradation, decorative patterns, or any decorative elements are not.
- b. The Marks should be presented consistently. The following general guidelines apply:
  - DO NOT distort the Marks for artistic purposes.
  - DO NOT enclose the Marks in a design that alters the look of the Marks.
  - DO NOT place photographs, lines, markings or artwork across or over the Marks.
  - DO NOT place copy over or too closely around the Marks to clutter it.

#### 2. Size of the Marks

The Marks may appear in any size, but must be noticeable and in the exact proportions as shown above.

### 3. Color of the Marks

The Marks may be represented in any single color, including a hologram effect. They must be clearly visible against their background.

#### 4. Third-Party Trademarks

Other than Applicant's trademark(s), the Marks must be displayed separately from, and cannot be co-joined, superimposed or combined with, any other trademarks.

#### 5. Trademark Notices

Users of the Marks must display the trademark symbol "™" or trademark registration symbol "®", as directed by HDA, on the right side of the mark (oriented to the top of the mark shown above). It must appear in a sufficiently visible size, but should be smaller than the trademark itself.

### 6. Attribution

For promotional materials, including websites, marketing literature, and advertisements, always include attribution within the credit notice section of materials with the following format: "The HDA PCSC GDP Certification Trademark(s) is/are trademarks of The Healthcare Distribution Alliance."