

EXCIPIENT GMP EVALUATION AND COMPLIANCE CERTIFICATION
AGREEMENT

This Excipient GMP Evaluation Compliance Certification Agreement (this “Agreement”) is made as of [date] (the “Effective Date”), by and between [Applicant name], a [type of entity] (the “Applicant”), and International Pharmaceutical Excipients Auditing, Inc., a Delaware corporation (“IPEA”) for the evaluation of quality system standards (the “Quality System”) used in manufacturing [excipient names] (the “Excipients”).

RECITALS

WHEREAS, the Applicant is engaged in the business of manufacturing chemicals and excipient materials; and

WHEREAS, the International Pharmaceutical Excipient Council (“IPEC”) and the Pharmaceutical Quality Group (“PGQ”) have published the Joint IPEC-PQG Good Manufacturing Practices for Pharmaceutical Excipients at www.ipecamericas.org (“GMP”), which are guidelines of good manufacturing practices, including implementation of certain quality system standards; and

[**WHEREAS**, IPEA is an organization in the process of being certified by the American National Standards Institute to certify excipient manufacturer’s compliance with the quality system standard guidelines contained in the GMP (the “Standards”); and (NOTE: Use this Whereas clause prior to ANSI certification. Remove NOTE, brackets and the next Whereas clause.)]

[**WHEREAS**, IPEA is an organization certified by the American National Standards Institute to certify excipient manufacturer’s compliance with the quality system standard guidelines contained in the GMP (the “Standards”); and (NOTE: use this Whereas clause after IPEA receives ANSI Certification. Remove NOTE, brackets and the above whereas clause.)]

WHEREAS, Applicant submitted an application, in the form attached hereto as **Exhibit A** (the “Application”), whereby Applicant has requested that IPEA audit and evaluate the Quality System used to manufacture the Excipients at the Applicant’s facility located at [full address of the site; include addresses contract laboratory, packaging facility, or warehouses where related quality system activities are conducted] (the “Site”) [NOTE: change (the “Site”) to (collectively, the “Site”) if the quality system activities are conducted at multiple addresses]; and

WHEREAS, IPEA shall conduct an audit and evaluate the Site to determine if it is being operated in compliance with the Standards and if the Excipients are being manufactured in accordance with the Standards (the audit and evaluation process shall be referred to herein as the “Audit”); and

WHEREAS, at the completion of the Audit, IPEA shall provide the Applicant with the Audit Report, which shall set forth all of the Auditor’s (as defined below) findings (the “Audit Report”); and

WHEREAS, at the completion of the Audit, IPEA shall provide the Applicant with a Certification Report, which shall set forth whether or not IPEA certifies that the Applicant is in compliance with the Standards (the “Certification Report”); and

WHEREAS, if the Applicant’s Quality System complies with the Standards then IPEA shall issue a certificate (the “Certificate”) that certifies that the Applicant’s Quality System comply with the Standards (the “Certification”).

NOW THEREFORE, in consideration of the premises and the mutual covenants contained herein, the parties, intending to be legally bound hereby, agree as follows:

I. Audit

A. The Applicant retains IPEA, and IPEA agrees, to perform all services related to the Audit of the Applicant’s Quality System, in order to evaluate the Site’s compliance with the Standards as more specifically described on the Evaluation and Certification for Excipient GMP Compliance, as attached hereto **Exhibit B**. IPEA has no obligation to issue Certification to the Applicant unless such Applicant complies with the Standards.

II. Applicant’s Obligations.

A. Applicant shall ensure that all officers, directors, employees, independent contractors, or agents with any direct or indirect responsibility for the implementation of the Quality System with respect to the Excipients (the “Quality Unit”) shall give IPEA their full cooperation in conducting the Audit.

B. At any time after the date of the Application, Applicant agrees to immediately notify IPEA in the event of:

1. The receipt of any adverse regulatory actions by the US or any foreign government agency (e.g., U.S. Food and Drug Administration’s Form 483 or Warning Letter);
2. Any change in the ownership of the Site (including by merger, consolidation or by operation of law). The Applicant will provide IPEA with a description of the relationship between the original owner and the new owner;
3. Any change in Quality Unit reporting relationship whether at the Site or another location;
4. Any change in the management or organizational structure affecting the Site related to any department with responsibility for Excipient compliance with the Standards; or
5. Any other modification or addition to any information provided in the Application.

C. Applicant agrees to comply with the procedures as set forth in the following documents:

1. **Exhibit C** - Requirements for Certification
2. **Exhibit D** - Applicants Rights and Duties
3. All other existing IPEA Standard Operating Procedures issued by IPEA (the “SOPs”) relating to the application process, the audit process or any other related matter as discussed herein, which shall be available on IPEA’s website at www.ipeainc.com.

D. Prior to the commencement of the Audit, the Applicant shall provide IPEA with the following written information:

1. a detailed description of the manufacturing process for the Excipients, including, but not limited to:
 - (i) name and location of manufacturer of the Excipient components;
 - (ii) process for acquiring Excipient components (including shipping details); and
 - (iii) component testing procedures; and
2. a process flow diagram with respect to the same;
3. an organizational chart showing the relationships and responsibilities of the key personnel responsible for the Quality System related to the Excipients; and
4. the name and contact information of the site representative who will serve as the contact person for the Audit.

E. The Auditors (as defined below) shall have full access to the Site, including other locations where related GMP quality system activities are conducted, such as a contract laboratory, packaging facility, or warehouse, with respect to the Excipients being audited.

F. The Applicant acknowledges and agrees that the Audit Report and the Certification, if provided, shall not be used to (i) assure the quality of the Excipient; (ii) establish that the Excipient has met the specified requirements of a compendial monograph; (iii) establish that the Excipient quality is as stated in the Certification of Analysis; or (iv) establish anything outside of the scope listed on the Certificate. If the Applicant violates any of the foregoing provisions, then the Certification shall be revoked.

III. IPEA’s Responsibility.

A. Prior to the commencement of the Audit, IPEA shall provide the Applicant with written notice identifying the name(s) of the IPEA personnel or IPEA independent contractor(s)

conducting the Audit (the “Auditors”). Such notification shall specifically identify the Auditor as an IPEA employee or an independent contractor.

B. The Audit only relates to the Excipients at the Site. Specifically, neither the Audit, the Audit Report nor the Certification (if provided) pertains to any other excipients or chemicals manufactured at the Site nor any Excipients, other excipients or chemicals manufactured at a location other than the Site.

C. The Auditors will perform the Audit in a professional manner.

D. The Auditors shall provide the Applicant with the following documents:

1. The Audit Report. Upon completion of the Audit, IPEA shall provide the Applicant with a draft copy of the Audit Report. The Applicant shall have an opportunity to comment on the Audit Report prior to it being finalized by the Auditors. After receiving comments from the Applicant, the Auditors will prepare a final Audit Report. IPEA will deliver the Audit Report to the Applicant. The Audit Report shall set forth the Auditor’s findings.

2. The Certification Report. Upon the completion of the Audit, IPEA shall provide the Applicant with a Certification Report, which shall set forth whether or not IPEA certifies that the Applicant complies with the Standards. If the Applicant’s Quality System complies with the Standards, then IPEA shall issue the Certification to the Applicant. If the Applicant’s Quality System does not comply with the Standards, then the Certification Report shall set forth (i) the deficiencies in the Quality System; and (ii) the cure period for compliance, if any. If the Applicant resolves all deficiencies within the cure period, then IPEA shall issue the Certification to the Applicant.

IV. Auditing Fees; Costs and Expenses

A. The Applicant will pay to IPEA as compensation for the Audit herein a service fee of [amount (\$_____)] (the “Service Fee”) payable as follows: (i) 50% of the Service Fee shall be due and payable upon the execution of this Agreement (the “Deposit”) which Deposit shall be nonrefundable in the event of cancellation under Section V; and (ii) 50% of the Service Fee shall be due and payable upon completion of the Audit. In addition to the Service Fee, the Applicant will reimburse IPEA for the costs and expenses IPEA incurs for any travel and living expenses incurred by the IPEA personnel and other representatives performing the Audit upon submission to the Applicant of invoices and/or receipts therefor.

B. The Applicant unconditionally agrees to pay IPEA within thirty (30) days of the date of any invoice. Neither the Audit Report (either in draft or final format) nor the Certification shall be provided to the Applicant until all invoices have been paid in full.

V. Cancellation

The Applicant reserves the right, upon no less than thirty (30) days written notice to IPEA, to cancel the Audit prior to its commencement and terminate this Agreement, and upon such cancellation and termination, the Applicant agrees that IPEA shall retain the Deposit and agrees to pay IPEA for any expenses and costs IPEA incurred in the preparation for the Audit

for that portion of the work or service then completed, including but not limited to non-refundable transportation, housing, and related expenses.

VI. Confidentiality

A. IPEA and the Applicant agree that, subject to this Section VI, all Applicant information, data, documents, records and other materials whether disclosed in writing, electronically or orally and whether marked or identified as confidential or proprietary relating to the Audit (collectively “Applicant Confidential Information”) shall be maintained as confidential and shall not be used or disclosed to any private third party other than in connection with the performance of this Agreement. IPEA shall have no obligation under this Agreement with respect to information which: (i) is or becomes public information through no breach by the IPEA, (ii) is in the possession of IPEA at the time of disclosure, (iii) is furnished to the IPEA by a third party without restriction on disclosure, (iv) is subject to Article VI, Sections D or E below; or (iv) is developed by the IPEA outside the scope of this Agreement.

B. IPEA and the Applicant agree that, subject to Section VI hereof, all IPEA information, data, documents, records, auditing methods, and other materials whether disclosed in writing, electronically or orally and whether marked or identified as confidential or proprietary relating to the Audit (collectively “IPEA Confidential Information”) shall be maintained as confidential and shall not be used or disclosed to any third party other than in connection with the performance of this Agreement. “IPEA Confidential Information” shall not include and the duty of confidentiality and nonuse hereunder shall not apply to any information which (i) is or becomes public information through no breach by the Applicant, (ii) is in the possession of Applicant at the time of disclosure, (iii) is furnished to the Applicant by a third party without restriction on disclosure, or (iv) is developed by the Applicant outside the scope of this Agreement.

C. This Section VI expressly survives the termination or expiration of this Agreement.

D. Notwithstanding any provision to the contrary contained herein, the parties acknowledge and agree that in the event that any of the Applicant’s Quality System: (i) violate any law rule or regulation, (ii) violate the Standards, (iii) pose a serious risk to human health, or (iv) involve fraud, or gross negligence then IPEA shall submit the Audit Report or the Certification to the U.S. Food and Drug Administration (“FDA”) or the appropriate foreign governmental agencies for review. Furthermore, in the event that either the FDA or a foreign governmental agency request a copy of the Audit Report or the Certification, then IPEA shall provide FDA or the foreign governmental agency with a copy of same.

E. The parties shall timely disclose, in writing, to FDA whenever, in connection with the Audit and preparation of the Audit Report, one or the other party has credible evidence that a principal, employee, agent, or subcontractor of the Applicant has committed: (i) a violation of Federal criminal law involving fraud under Title 18 of the United States Code; or (ii) a violation of the civil False Claims Act (32 USC 3729-3733). The parties are required to fully cooperate with any U.S. Government agencies responsible for audits, investigations, or corrective actions relating to same.

VII. Property Rights

A. IPEA Property Rights.

1. Certification Mark. The Certification is represented by the Certification Mark (the “Mark”). Upon granting Certification to the Applicant, IPEA hereby grants the Applicant a non-exclusive, worldwide, royalty free license to use the Mark on the Applicant’s brochures, stationary, literature, advertising and labels. In all instances, the Mark must be accompanied by the statement “See Certification Requirements” in a font size not smaller than 8 point.

2. No License Granted. Except as expressly set forth in Section VII.A.1. above, nothing in this Agreement is intended to grant any rights to Applicant under any patent, copyright, trade secret or other intellectual property rights currently owned or hereinafter acquired by IPEA.

3. Certification. The Certification, if issued, shall be valid for twenty-four (24) months from the date of issuance unless renewed, withdrawn, revoked or suspended in accordance with the terms and conditions of this Agreement (the “Certification Term”).

4. Certificate.

(i) The Applicant may use the Certificate in following manner:

- a. display the original Certificate;
- b. photocopy the Certificate (in its entirety) for display or
handout;
- c. reproduce the Certificate (in its entirety) for publicity,
newsletters, advertisements; and
- d. reproduce the Certificate (in its entirety) and post the
Certificate on the Applicant’s website.

(ii) The following uses by the Applicant of the Certificate are prohibited:

- a. displaying, photocopying or reproducing parts of the
Certificate, the Certificate must be displayed, photocopied or reproduced in its entirety; provided
that the Applicant may use the Mark as set forth in Section VII.A.1. above; and
- b. allowing a third party to display, photocopy or reproduce
the Certificate in any manner.

5. Right of Use. If the Certification is withdrawn, suspended or revoked, then IPEA shall notify the Applicant in writing of such withdrawal, suspension or revocation (the “Certification Notice”). The Applicant must within ten (10) business days of the date of the

Certification Notice, discontinue any and all uses (including displaying or reproducing) of the Certification, the Certificate and the Mark. If, after thirty (30) days from the date of the Certification Notice, the Applicant continues to use the Certification, the Certificate or the Mark, then IPEA may, in its sole discretion, notify the FDA of the Applicant's violation of this Agreement and infringement of IPEA's intellectual property rights. The remedies set forth in this Section are in addition to any other remedies that IPEA may have.

(i) If the scope of the Certification is modified, and IPEA issues a new Certificate, then the Applicant agrees to replace all displays and reproductions of the Certificate with the displays or reproductions of the newly issued Certificate.

6. Audit Report.

(i) All audit materials and auditor work product including, but not limited to, audit notes, draft audit reports, and the Audit Report shall remain the property of IPEA.

(ii) The Applicant shall have right to provide copies of its Audit Report to industry experts for the sole purpose of assessing the Applicant's Quality System. Except as expressly provided in this Section, the Applicant shall not distribute the Audit Report to any third party or reproduce the Audit Report in any manner, without IPEA's prior written consent, which shall not be unreasonably withheld.

7. Violation. IPEA shall have the right, in its sole discretion, to revoke the Certification upon the Applicant's violation of any of the terms and conditions contained in this Article VII

B. Applicant Property Rights.

1. Applicant's Mark or Logo. Upon issuance of the Certification, shall list the Applicant's name and (in IPEA's sole discretion) the Applicant's logo on IPEA's website. In connection therewith, the Applicant grants IPEA a non-exclusive, worldwide, royalty free license to use Applicant's name, trade name, trademark, service mark and/or logo (the "Applicant IP License").

2. No License Granted. Except as expressly set forth in Section VII.B.1. above, nothing in this Agreement is intended to grant any rights to IPEA under any patent, copyright, trade secret or other intellectual property rights currently owned or hereinafter acquired by the Applicant.

3. Term. The Applicant IP License shall be for a term commencing on the date the Certification is issued and terminating on the later of: (i) the last day of the Certification Term; or (ii) [ninety (90)] days from the suspension or termination of the Certification (unless such Certification is reinstated then the Applicant IP License shall continue in full force and effect).

C. This Section VII expressly survives the termination or expiration of this Agreement.

VIII. Representations and Warranties.

A. The Applicant represents and warrants that all of the information provided on the Application or in connection with IPEA's conduct of the Audit and evaluation are true, accurate and complete.

B. Notwithstanding IPEA's review of the Applicant's data and products provided for audit and certification as specified elsewhere in this Agreement, it is expressly understood that the Applicant is completely responsible for the provision of accurate, current and complete information regarding the Applicant's subcontractors, suppliers, manufacturing, manufacturing processes, packaging, transportation, and component information provided to IPEA for the Audit and any reviews and approvals given by IPEA do not relieve the Applicant of any responsibility or liability for its products or the information provided to IPEA. Failure to fulfill any such commitment to provide current, accurate and complete information shall render the Applicant liable for any or all penalties or damages assessed against IPEA and any costs incurred by IPEA and/or the U.S. Government as a result of the Applicant's actions or inactions relating to its failure to provide IPEA and/or the U.S. Government current, accurate and complete data under the terms of this Agreement.

C. IPEA's audit is based upon the Applicant's provision of current, accurate and complete information. The provision of this information to IPEA is essential to and a material condition of IPEA's audit and certification. Any failure to provide current, accurate and complete information by the Applicant shall result in the automatic revocation of the Certification, if any, provided by IPEA regarding the Applicant's Quality System in the manufacturing of the Excipients and shall render the Audit Report null and void. In addition, IPEA shall notify the FDA and/or any foreign government agency of any false or misleading information. Furthermore, IPEA has the right, in its sole discretion, to publicly announce the revocation of the Certification via IPEA's website or through any other means.

D. The parties acknowledge and agree that the Audit Report and the Certification (if any) relates to the Excipients and the Site listed herein, and does not relate to any other chemicals or excipients that may be manufactured by the Applicant or to Excipients manufactured at any location other than the Site.

E. The Applicant represents and warrants that it will notify in writing any third party to whom Applicant wishes to distribute the Audit Report or the Certification that: (i) IPEA does not guarantee the findings set forth in the Audit Report; (ii) IPEA relied on statements made by and information provided by Applicant; and (iii) any false or misleading information provided, statements made or omissions of material information automatically revokes the Certification and renders the Audit Report null and void.

IX. Warranty; Disclaimer; Limitation of Liability; Applicant Acknowledgments

A. EXCEPT AS EXPRESSLY PROVIDED, NEITHER IPEA NOR ITS DIRECTORS, OFFICERS, AGENTS, AUDITORS, EMPLOYEES OR CONTRACTORS ASSUMES ANY LIABILITY OR RESPONSIBILITY FOR THE ACCURACY, COMPLETENESS OR

UTILITY OF ANY RESULTS OF ANY INFORMATION DISCLOSED OR PROVIDED IN THE SERVICES PERFORMED HEREUNDER OR THE AUDIT REPORT, THE CERTIFICATION (IF ANY) OR ANY OTHER DELIVERABLES PROVIDED BY IPEA HEREUNDER.

B. IPEA'S TOTAL LIABILITY AND APPLICANT'S SOLE AND EXCLUSIVE REMEDY FOR ANY CLAIM WHATSOEVER, INCLUDING BUT NOT LIMITED TO CLAIMS BASED UPON CONTRACT, WARRANTY, NEGLIGENCE, OR STRICT LIABILITY IN TORT, THAT ARISES OUT OF OR IN CONNECTION WITH SERVICES PROVIDED HEREUNDER, SHALL BE LIMITED TO PROVEN DIRECT DAMAGES IN AN AMOUNT EQUAL TO THE SERVICE FEE. NEITHER PARTY SHALL HAVE LIABILITY TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT EXCEPT IN THE EVENT THAT ANY INFORMATION PROVIDED BY APPLICANT WAS FALSE OR MISLEADING, THEN APPLICANT CAN BE LIABLE FOR SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT AND THE MAKING OF SUCH FALSE OR MISLEADING STATEMENTS.

C. The Applicant expressly acknowledges and agrees that the Auditor shall be provided with access to all areas of the Site and that are necessary to complete the Audit. Latent and concealed defects and deficiencies are excluded from the Audit, the Audit Report, the Certification (if any) and any other deliverables provided by IPEA. The Applicant acknowledges that IPEA is not responsible for the accuracy of information the Applicant provides and further acknowledges that inaccurate information, omissions and/or any misrepresentations may adversely affect the outcome and recommendations made in the Audit Report, the Certification (if any) or any other deliverables provided by IPEA. The Applicant further expressly acknowledges and agrees that nothing in the Audit, the Audit Report, the Certification (if any) or any other deliverables provided by IPEA address or guarantees or is intended to address or guaranty and IPEA shall have no liability or responsibility for (i) the quality or function of the Excipients or any other products, nor (ii) any Applicant's compliance or certification for any past or present federal, state, local or other governmental statutes or regulations of any kind. Without limiting the generality of the foregoing, the Applicant expressly acknowledges and agrees that neither the Audit, the Audit Report, the Certification (if any) or any other deliverables performed or provided by IPEA are intended to assure or otherwise warrant that the FDA or other regulatory agency (domestic or foreign) will determine the Applicant to be in full compliance with its current good manufacturing practice rules and regulations.

D. This Section IX expressly survives the termination or expiration of this Agreement.

X. Indemnity

The Applicant shall indemnify, defend and hold harmless IPEA and IPEA's affiliates and subsidiaries and their respective successors, assigns, directors, officers, employees, independent contractors and agents from and against any and all liabilities, claims, demands, losses, costs and expenses (including attorneys' fees and court costs), damages, suits, actions, proceedings, obligations, judgments and liabilities ("Claims") of whatever character (including without limitation personal injury (fatal or nonfatal); property damage; economic damage or the like or

claims of any other nature) arising from or connected in any way with (i) the Audit or any other services provided hereunder, the Audit Report, the Certification (if any) any other deliverables provided by IPEA and/or performance or fulfillment of this Agreement by or on behalf of IPEA; (ii) any material breach of this Agreement by the Applicant (iii) Applicant's failure to provide IPEA with current, accurate and complete information as required by this Agreement; (iv) the use by the Applicant of the Audit Report and/or any Mark with or without IPEA's prior written consent; (v) the use of the Certification in any manner inconsistent or in violation of this Agreement; or (vi) any product, including the Excipient, manufactured or supplied by the Applicant, or any Applicant affiliate, subsidiary, successor or assign including without limitation, any Claims premised in whole or in part on the theory that such product was not manufactured or supplied in accordance with the Standards or the Food Drug and Cosmetics Act the past or current good manufacturing practice rules and regulations of the FDA or any other regulatory agency. This Article X expressly survives the termination or expiration of this Agreement.

XI. Notices

All notices or other communications required or permitted under this Agreement shall be made in writing and shall be deemed given upon delivery by hand, or overnight delivery to the parties at the following addresses, or by facsimile transmission, correctly transmitted, with original copy to follow by overnight delivery or first class postage prepaid and correctly addressed, all as follows:

If to Applicant:

If to IPEA: International Pharmaceutical Excipients Auditing, Inc.
1655 N. Ft. Myer Drive
Suite 700
Arlington, VA 22209
Attn: Irwin Silverstein
Chief Operating Officer
Telephone Number: (732) 463-8710
Facsimile Number:

With a copy to:

Buchanan Ingersoll & Rooney PC
1700 K Street, N.W.
Suite 300
Washington, DC 20006-3807
Attn: Robert G. Pinco
Telephone Number: (202) 452-7901
Facsimile Number:

or to such other address as any of the parties hereto may designate by notice to the others.

XII. Binding Effect; Governing Law

A. This Agreement shall be governed by and construed under the laws of the Commonwealth of Virginia without regard to principles of conflict of laws. The parties hereby irrevocably consent to the jurisdiction and venue of the state and federal courts located in Fairfax County, Virginia, in connection with any action relating to this Agreement.

B. By entering into this agreement, the Applicant consents to United States (U.S.) jurisdiction and agrees to be bound by the Food Drug and Cosmetics Act.

C. The Applicant's provision of inaccurate, incomplete, false or fraudulent information to IPEA in connection with the Audit will constitute a false or fraudulent statement under 18 USC Section 1001 and may subject the Applicant to criminal and/or civil prosecution under U.S. criminal laws, as well as the False Claims Act, 31 USC Sections 3729 -3733, as amended.

XIII. Independent Contractor

The relationship of IPEA and the Applicant is that of an independent contractor, and expressly not as employee-employer, partners or joint venturers. In addition, nothing contained in this Agreement shall be construed as imposing the method upon which IPEA is required to perform the work hereunder.

XIV. Force Majeure

No party shall be liable to the others for any delay or failure to perform its obligation under this Agreement (other than the payment of money) if such delay or failure to perform arises from any cause or causes beyond the reasonable control of such party, including but not limited to any act of God, fire, tempest, war or war-like operation, terrorism, civil war, rebellion, revolution, disorder, riot, strike, lockout, labor dispute, public health crisis, or action of any governmental entity.

XV. Entire Agreement; Amendments; Severability

This Agreement (including the recitals which are incorporated herein), the Exhibits hereto and the SOPs constitute the entire understanding between the parties superseding all previous agreements, representations and undertakings relating to the subject matter hereof, whether oral or written. In the event that any term or condition of any exhibit or SOP conflicts with the terms and conditions of this Agreement, then the terms and conditions of this Agreement shall govern.

No modification, amendment or waiver of this Agreement shall be effective unless in writing signed by both parties; provided, that IPEA may in its sole discretion amend or modify the SOPs without the Applicant's consent. If any provision of this Agreement shall be held illegal or unenforceable, such provision shall be deemed separable from, and shall in no way affect or impair the validity or enforceability of, the remaining provisions.

XVI. Counterparts

This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page to this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed counterpart of this Agreement.

**[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK;
SIGNATURE PAGE TO FOLLOW]**

WITNESS, the due execution hereof by the duly authorized representatives of the parties hereto, intending to be legally bound hereby, as of the day and year first above mentioned.

[INSERT Applicant's NAME]

**INTERNATIONAL PHARMACEUTICAL
EXCIPIENTS AUDITING, INC.**

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

EXHIBIT A
APPLICATION

See attached.

Evaluation and Certification for Excipient GMP Compliance

EXHIBIT B

IPEA grants certification of an excipient manufacturing site for substantial compliance to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients for excipients stated on the application. The duration of the certification is 24 months from the date of approval. This certification applies to the quality system and does not extend to the excipient and its compliance to monograph requirements or manufacturer's specifications.

Figure 1 illustrates the process for Excipient GMP Compliance Certification.

Manufacturers of excipients apply to IPEA for Excipient GMP Compliance Certification to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients. There are no pre-conditions prior to applying for certification other than to have an established GMP quality system with documents that describe its operation and records that show compliance. However, the manufacturer must:

- a. Allow IPEA to audit their site of manufacture including any site where related GMP quality system activities are conducted, such as a contract laboratory, packaging facility, or warehouse,
- b. Agree to notify IPEA of changes that may affect their quality system, and
- c. Agree to make payment of all fees related to the assessment.

The applicant submits the completed application to IPEA and upon acceptance a Certification Agreement is prepared.

After the applicant executes the Certification Agreement and remits the non-refundable deposit, IPEA assigns qualified auditors.

The applicant is informed by IPEA of the names of the audit team members and can request a replacement auditor if they perceive the auditor may have a bias or conflict of interest.

The audit is planned and conducted. The Lead Auditor submits the draft audit report to IPEA Executive Management for review and comment. IPEA then sends the draft audit report to the applicant for review and comment. If the report contains adverse findings, the applicant can submit a corrective or preventive action plan. Once comments from the manufacturer have been addressed by the Lead Auditor and/or IPEA Executive Management, the final report is submitted to the Certification Board.

The Certification Board reviews the application and report along with any corrective measures provided by the applicant. The Board considers certification based upon established criteria. If the Certification Board rejects the application for Certification, the applicant can appeal in accordance with IPEA SOP Number 16.

Upon certification, IPEA:

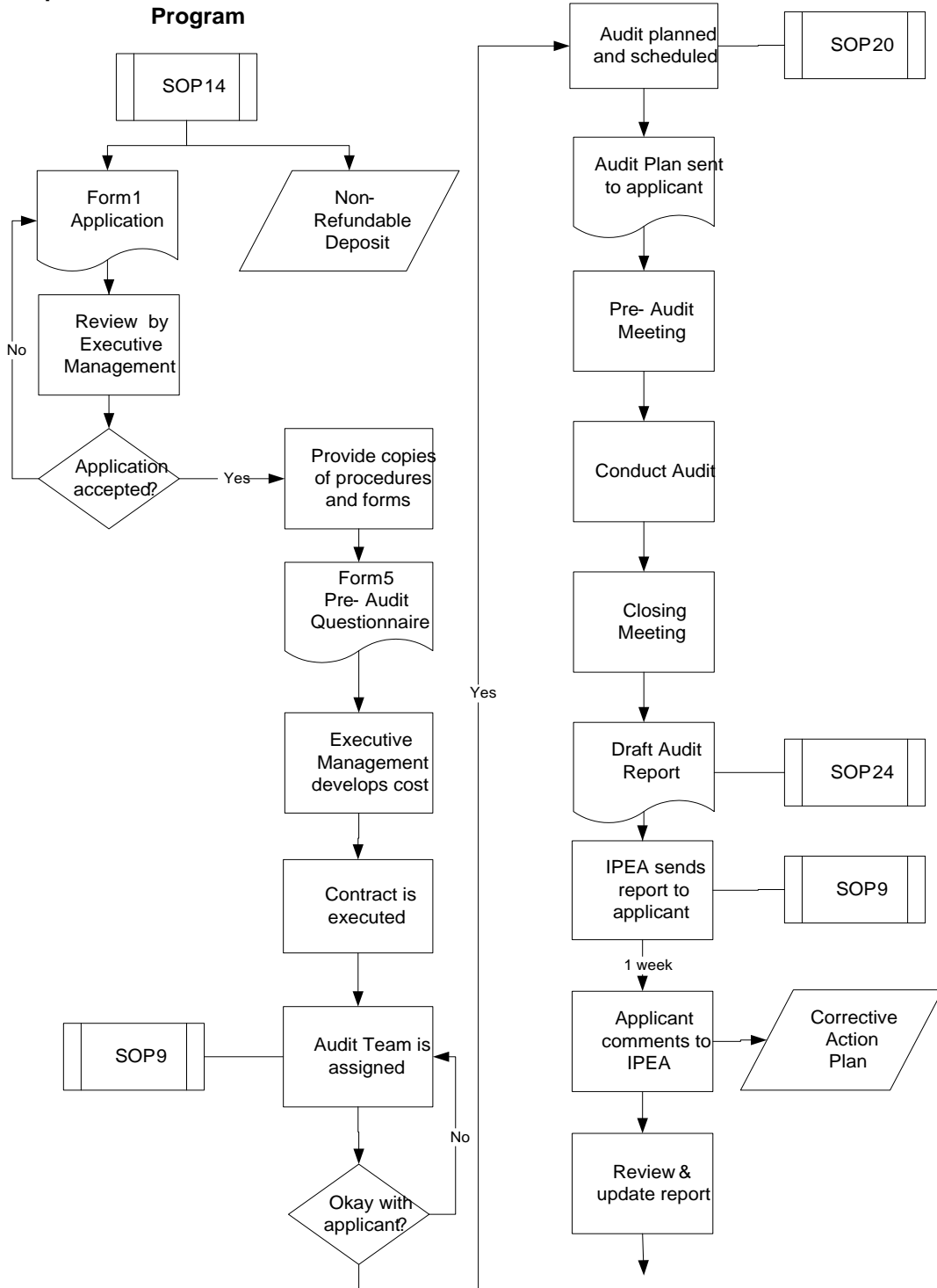
- a. Issues a certificate to the applicant.
- b. Adds the name of the company, manufacturing location, date of the last site audit, and list of excipients covered by the certification to the IPEA website.
- c. Makes available for purchase with the agreement of the applicant, the audit report with a portion of the proceeds credited to the applicant towards the annual certification fee.

IPEA Certification Agreement

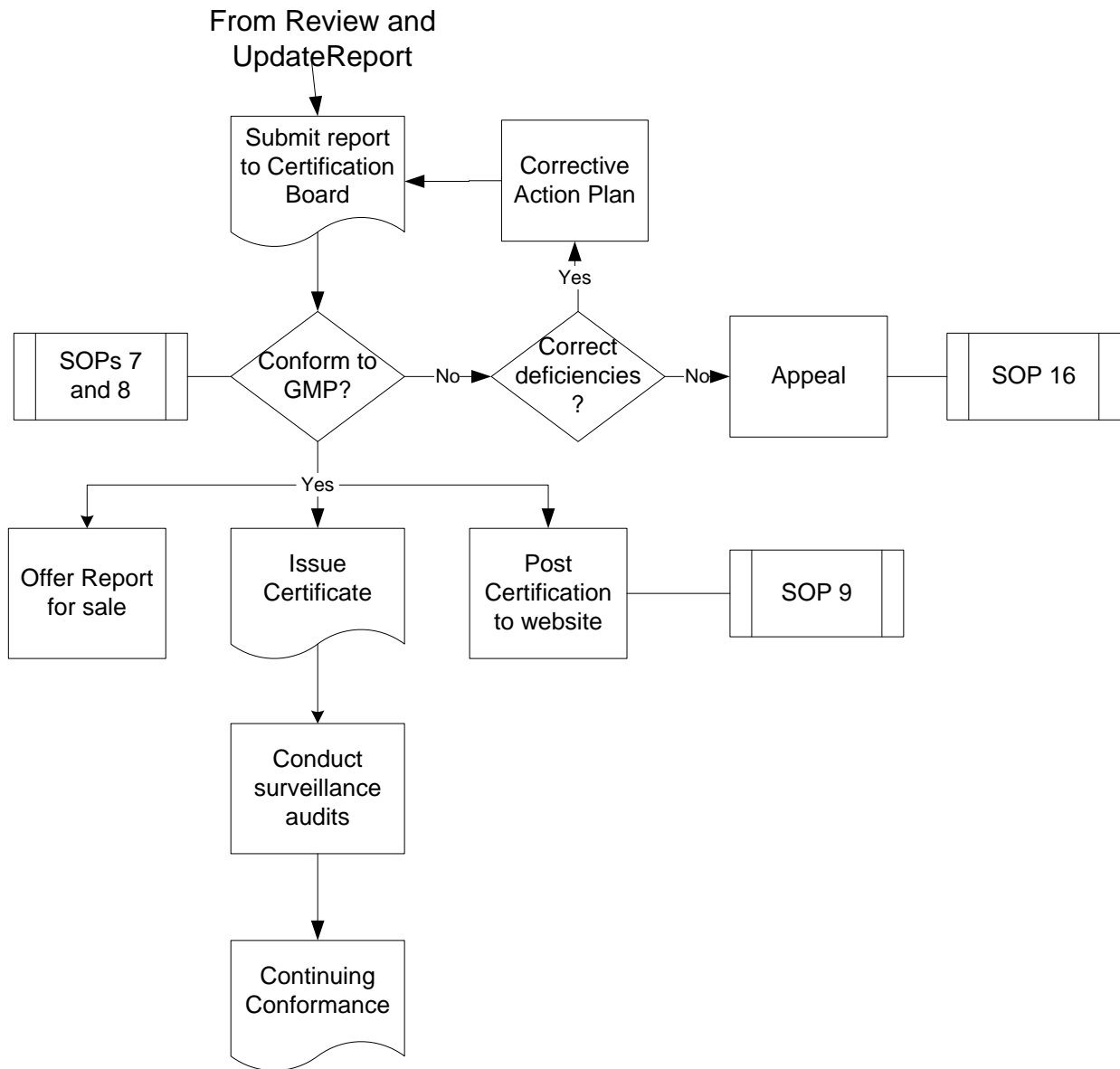
EXHIBIT B

FIGURE 1

Excipient GMP Conformance Certification Program



IPEA Certification Agreement
EXHIBIT B



IPEA Certification Agreement

EXHIBIT C

Requirements for Certification

Applicants must meet the following requirements for the Audit:

1. Have an established GMP quality system with documents that describe its operation and records that show compliance,
2. Assure the necessary arrangements for the conduct of the site audit, including the availability of documentation and access to all areas, records, and personnel for the purpose of evaluating the excipients and the site for compliance,
3. Agree to notify IPEA of changes that may affect their quality system,
4. Agree to use the IPEA Certification only in relation to the Quality System and not to infer the Certification extends to the quality of the excipient.
5. Agree to make payment of all fees related to the assessment as stipulated by the Excipient GMP Evaluation Compliance Certification Agreement.

IPEA Certification Agreement

EXHIBIT D

Applicants Rights and Duties

1. Rights of the Applicant

- a. The Applicant has the right to an Audit that is free from conflict of interest.
- b. Except as provided in the Excipient GMP Evaluation and Compliance Certification Agreement, confidential information provided or disclosed during the Audit is to be protected from disclosure.
- c. The Applicant can dispute a finding during the Audit and expect a fair hearing of their position.
- d. The Applicant can appeal the decision to refuse or withdraw Certification (in accordance with IPEA SOP Number 16) and has the right to expect a fair hearing on the matter.
- e. The Applicant can apply for expansion or reduction of the scope of the Certification and expect a prompt review of their application.

2. Duties of the Applicant

- a. The Applicant agrees to cooperate with the Auditors as they conduct the Audit. The Applicant agrees to make all documentation available for examination, provide access to all applicable areas of the facility, as well as all appropriate personnel.
- b. The Applicant shall not claim that the Certification extends to the quality of the excipient itself, other than that the quality system supports the manufacture and testing of the excipient in compliance with the Standards.
- c. The Applicant agrees to immediately discontinue all advertising that contains any reference to the Certification if the Certification is revoked for any reason.