

STANDARD OPERATING PROCEDURE
International Pharmaceutical Excipients Auditing, Inc.

Title IPEA Certification Board		Revision 2	SOP Number 7
Originator Irwin Silverstein	Approved By IPEA Management Committee	Effective Date Sept. 15, 2011	Page Page 1 of 5

PURPOSE:

This document governs the operation of and membership of the IPEA Certification Board. The Board convenes as necessary to review applications and audit information in support of Excipient GMP Conformance Certification of the quality system under which a specified excipient is manufactured to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.

SCOPE:

This procedure applies to all Certification Board meetings and to members approved to participate on the Certification Board. Certification Board activities are limited to the excipient certification program.

RESPONSIBILITIES:

1. **Certification Board Member:** To objectively review the application and audit information that establishes substantial conformance to excipient GMP expectations.
2. **IPEA Executive Management:** Management assures Board members are trained, designates members to the Board and assigns a chair, and periodically provides an evaluation of Board members for review by the Management Committee.
3. **IPEA Management Committee:** The Committee approves members to the Certification Board and reviews the performance of Board members as reported by the Executive Management for their continued participation on the Board.

REFERENCES:

1. ISO/IEC Guide 65:1996(E), "General requirements for bodies operating product certification systems".
2. SOP 8, IPEA Certification Criteria
3. SOP 9, Certificate of Excipient GMP Conformance
4. SOP 11, Conflict of Interest
5. SOP 16, Appeals, Complaints, and Disputes
6. SOP 24, Documenting the Certification Audit

DEFINITIONS:

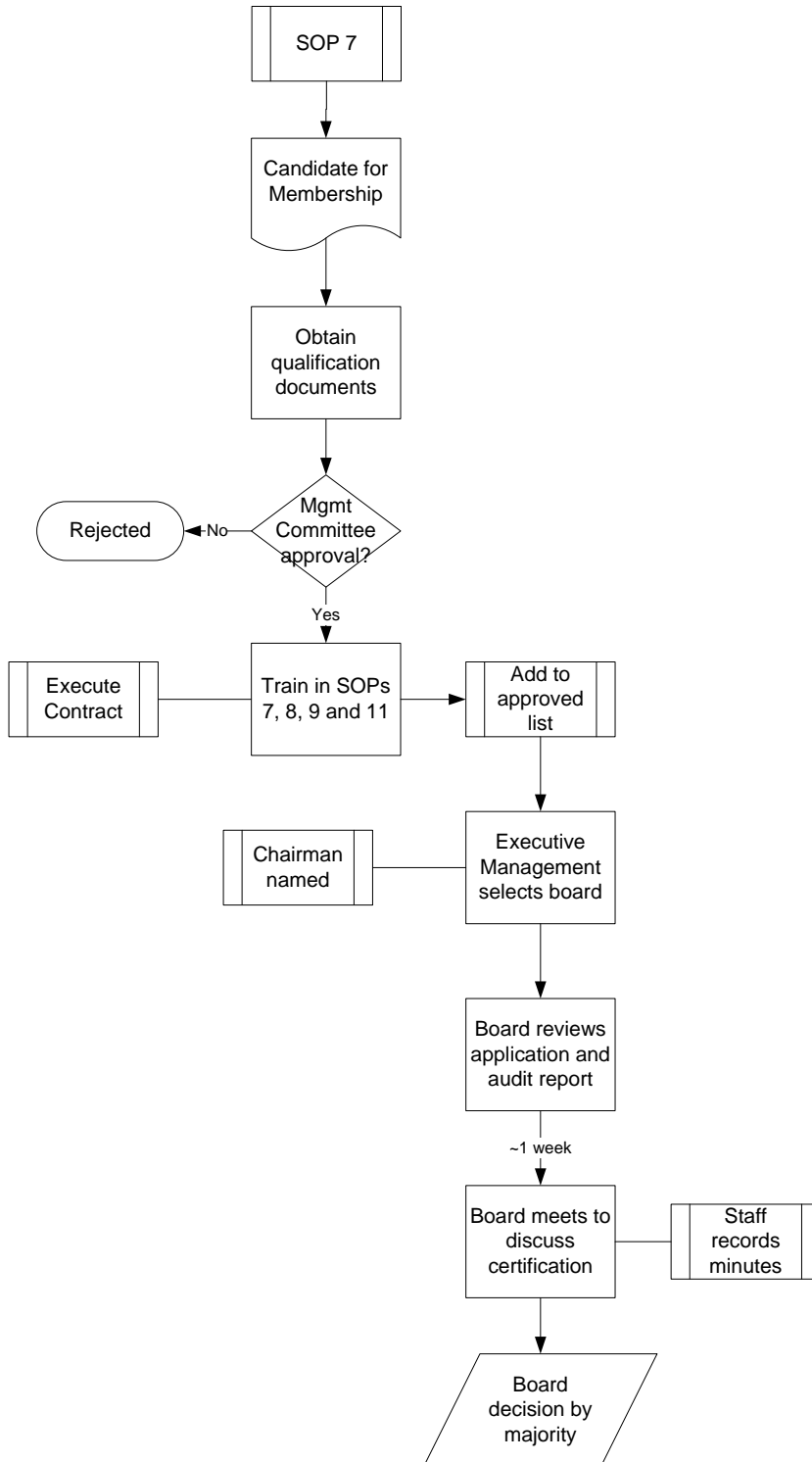
1. **See Glossary**

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Certification Board



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PROCEDURE:

1. Candidates for membership on the IPEA Certification Board are reviewed and approved by the IPEA Management Committee (MC). The MC will review the qualifications of the candidates looking for individuals who possess:
 - a. A Bachelor degree in a scientific discipline or other suitable education
 - b. Work experience in the pharmaceutical market at a pharmaceutical manufacturer, excipient manufacturer, appropriate regulatory authority, standard setting organization, or academic institution.
 - i. Work experience in a quality, regulatory, or manufacturing function is preferred.
 - ii. A minimum of 10 years work experience in this market is preferred.
2. Candidates for membership submit Curriculum Vitae (CV) that demonstrate they meet the qualifications stated in (1). The CV will list all employers along with the date of employment, job title and a brief description of duties and responsibilities. The CV should also note any areas of technical expertise that are related to excipient ingredients.
3. The MC reviews the candidate CV to determine if they meet the minimum expectations for education, training, technical knowledge, and experience to be a Board member. Acceptance as a Board member requires consensus of the MC.
4. Upon acceptance as a member of the IPEA Certification Board, IPEA trains the Board member in the operation of the Certification Board, their role in the deliberations (as noted in 9), an overview of the Certification Program (SOP 9), the evaluation and acceptance criteria for conformance to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients (SOP 8), and their responsibilities especially with regards to conflict of interest (SOP 11).
5. Upon completion of training, IPEA executes a contract with the member that includes their agreement to comply with the rules of the Certification Board as noted in item 6.
6. IPEA Certification Board rules require:
 - a. Confidentiality of applicant names until approved for certification,
 - b. Confidentiality of Certification Audit Report contents,
 - c. Independence from commercial or other potential conflicts of interest with the applicant, and
 - d. Declaration of any association with the applicant as an employee, consultant, or significant financial interest.
7. IPEA maintains a list of all approved Certification Board members that includes:
 - a. Name and address,
 - b. Organization affiliation and position, if appropriate,
 - c. Education and professional status,
 - d. Experience and training (including under (4.)),
 - e. Date of last updated record, and
 - f. IPEA Performance appraisal.

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8. The IPEA Certification Board meets as required to review the certification application and Audit Report. Each Board meeting is comprised of members with qualifications primarily in the pharmaceutical industry and in the excipient supplier industry. Independent members such as regulators, academics, or members from standards setting organizations (i.e., USP) may substitute for either pharmaceutical or excipient industry member as long as there is one member with pharmaceutical and excipient industry experience. Board members whose qualifications are from a regulatory authority can substitute for either category. In addition, the auditor(s) who conducted the audit is present to answer questions concerning their report, but does not take part in the certification decision.

Membership of a Certification Board is determined by IPEA Executive Management. In addition to selecting participants with appropriate qualifications and who have not been involved with the audit, Board members must not have a conflict of interest with the party whose application is to be reviewed. The IPEA Executive assures, and the Board member affirms they:

- a. Have not been an employee of the applicant for at least five years,
 - b. Have not provided any consulting services to the applicant related to excipient GMP conformance for at least three years,
 - c. Did not perform or participate in the certification audit, and
 - d. Do not have a substantial financial interest in the applicant company.
9. The IPEA Certification Board members:
- a. Evaluate the application for excipient certification to verify it has been properly executed and states the scope of the certification.
 - b. Evaluate the audit report and corrective action plan if applicable in conjunction with the application to confirm:
 - i. The scope of the certification noted on the application is supported by the audit report,
 - ii. The applicant meets the standards for certification, and
 - iii. The audit report supports the site is in substantial conformance to excipient GMP.
 - c. Participate in discussion of the application and other information as provided for under 10c,
 - d. Recommend the applicant for certification or identify improvements needed to achieve substantial excipient GMP conformance, and
 - e. Affirm their evaluation is without any conflict of interest.
10. The IPEA Certification Board operates as follows:
- a. IPEA Executive Management designates ad hoc membership of the Board.
 - b. IPEA makes arrangements for the Board meeting, which is ordinarily conducted using appropriate telecommunications tools.
 - c. IPEA provides to each Board member at least 1 week prior to the meeting:
 - i. The Certification Audit Report
 - ii. Corrective Plan if applicable

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- iii. The application
 - iv. The excipient monograph and/or specification
 - v. Agenda for the meeting
 - d. IPEA assigns a staff member to attend the Board meeting for the purpose of assuring the meeting is conducted in an appropriate manner and to take the minutes.
 - e. The presence of four Board members and the Lead Auditor is required to conduct the meeting.
 - f. Board members discuss the application and the Certification Audit Report. Each member expresses their concerns with the adequacy of conformance of the site to excipient GMP. These concerns are based upon actionable observations and are documented in the meeting minutes.
 - g. Board members discuss their concerns. After the concerns have been discussed the application for certification is called to a vote. Members consider whether the site is in substantial conformance to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients for manufacture of the excipient(s) listed on the application. Approval requires a majority of the Board members present at the meeting. The votes are recorded in the minutes.
11. The Certification Board does not delegate authority to grant, maintain, extend, suspend, or withdraw certification.
12. The performance of IPEA Certification Board Members is reviewed by the IPEA Management Committee every three years to assure they are meeting their duties and responsibilities as stipulated in this SOP.

HISTORY OF REVISIONS

Revision No.	Effective Date	Description of Changes
0	Nov. 21, 2008	New Procedure
1	Sept. 18, 2009	Added flow diagram, modified Board membership, added independent party as candidate for Board membership and updated SOP reference from 5 to 24.
2	Sept. 15, 2011	Minor correction to sections 9 and 10 and reduce frequency of Board member review to 3 years.