

STANDARD OPERATING PROCEDURE
International Pharmaceutical Excipients Auditing, Inc.

Title Appeals, Complaints, and Disputes		Revision 2	SOP Number 16
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved Oct. 19, 2009	Page Page 1 of 6

PURPOSE:

This document establishes the recourse an applicant has to dispute an audit item or Certification Board decision and provides for the report of complaints.

SCOPE:

This procedure is applicable to all aspects of the Excipient GMP Certification program.

RESPONSIBILITIES:

1. **IPEA Administrator:** Assures all applicant appeals, complaints, and disputes are entered into the appropriate log, tracked until the matter is closed, and assures all pertinent information is retained and retrievable.
2. **IPEA Vice President and Chief Operating Officer (COO):** The COO is responsible for administering the Excipient GMP Certification program.
3. **IPEA President and Chief Executive Officer (CEO):** The CEO assures appeals, complaints, and disputes are properly handled, and is the highest authority in IPEA to whom such matters are escalated prior to the Arbitration Board.

REFERENCES:

1. SOP 11, Conflict of Interest
2. SOP 17, Post Certification Review
3. SOP 20, Conducting the Certification Audit
4. SOP 21, Internal Audit and Management Review
5. SOP 25, Authorized Use of the Certificate and Mark

DEFINITIONS:

1. **Appeal:** A request by the applicant for review of a finding or its rating in the audit report or for review of a decision by IPEA Executive Management or the Certification Board.
2. **Applicant:** The excipient manufacturer or distributor requesting certification of a site for substantial conformance to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.
3. **Application Number:** The number assigned to the application filed by the applicant.
4. **Arbitration Board:** Members of the IPEA Board of Directors who meet the requirements of SOP 11, Conflict of Interest, and form an ad hoc committee to review an Appeal.
5. **Audit Team:** One or more auditors conducting an audit led by the Lead Auditor.
6. **Certification Board:** The organization that convenes to review the application and the qualification audit report in support of excipient certification or the surveillance audit report in support of ongoing excipient certification.
7. **Company Representative:** The individual in the applicant company who has approved the application for Excipient GMP Certification or who is representing the company in the appeal, complaint, or dispute.

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8. **Complaint:** A request to investigate nonconformance with an aspect of the Excipient GMP Certification program.
9. **Dispute:** A disagreement with the finding or its rating by the audit team during the audit or in the draft audit report.
10. **Draft Audit Report:** The version of the audit report submitted to the applicant for their review and comment prior to issuing the final report.
11. **IPEA Executive Management:** The IPEA Chief Executive Officer (CEO) or Chief Operating Officer (COO).
12. **IPEA Management Committee:** The IPEA Management Committee comprises: Chief Executive Officer (CEO), Chief Operating Officer (COO), Secretary-Treasurer, and Immediate Past Chair of IPEC-Americas.
13. **Lead Auditor:** A qualified auditor who is responsible for conducting the audit sometimes accompanied by other auditors. The Lead Auditor is responsible for assuring the audit is conducted according to SOP 20.
14. **Site Representative:** The individual assigned by the company to be the primary contact with IPEA. The site representative may also be the host for the audit.

PROCEDURE:

1. The applicant is provided with instructions for resolving a dispute, submitting an appeal, or filing a complaint either by contacting the IPEA office or consulting the website at www.ipeainc.com. The instructions for appeals and complaints are disclosed by electronic means such as e-mail or the IPEA website.
- I. Disputes**
2. IPEA encourages disputes to be discussed between the applicant and the audit team before they are escalated to an appeal. Disputes are handled informally with no requirement for formal documentation.
 - a. During the audit, disputes raised by the applicant or site escort are discussed with the auditor involved. Where the dispute is not resolved, the applicant Site Representative discusses the matter with the Lead Auditor.
 - b. Disputes with the content of the draft audit report are discussed between the Site Representative and the Lead Auditor.
- II. Appeals**
3. Where there is no resolution to the dispute, the applicant can appeal a finding or the rating of a finding in a draft audit report or the decision of the Certification Board by contacting the IPEA Administrator.
 - a. The IPEA Administrator opens an appeal by assigning an appeal number in the format AYY-XXX where YY are the last two digits of the year and XXX are sequential beginning with the first appeal of the year. Documents related to the appeal are filed by appeal number. The appeal file contains the:
 - i. Application Number,
 - ii. Corporate Name,
 - iii. Site name and location,

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- iv. Excipient(s) certified or being certified,
 - v. Description of the matter for which the appeal is made, and
 - vi. Why the applicant believes, with supporting information, the audit report, Executive Management, or Board decision was in error.
 - b. The IPEA Administrator:
 - i. Provides the applicant with the appeal number,
 - ii. Notifies the COO that an appeal has been filed,
 - 1. If the COO was involved in the matter under appeal, the CEO will designate an IPEA Board member as the substitute for the COO.
 - 2. If the CEO was also involved in the matter under appeal, the CEO nominates a designee who is approved by the IPEA Board of Directors.
 - iii. Assures the applicant is periodically informed of the status of the appeal, and
 - iv. Assures the applicant is informed of the final decision regarding the appeal.
- 4. The COO or designee investigates the appeal by:
 - a. Discussing the matter with the site representative.
 - b. Discussing the matter with the Lead Auditor, IPEA Executive Management or Certification Board member as appropriate.
 - c. Reviewing all documents pertinent to the appeal, including the auditor notes, audit report, Certification Board minutes, Excipient GMPs and audit standard, and conformity assessment standards such as ISO/IEC Guide 65 and ISO/IEC 17021.
- 5. The COO or designee discusses resolution to the appeal with both parties. If agreement is reached, the COO or designee issues a final report on the matter to the CEO for approval. Where agreement cannot be reached, the appeal is escalated to the CEO.
 - a. If the CEO was involved in the matter under appeal, the CEO names a designee who is approved by the IPEA Board as the substitute for the CEO.
- 6. Upon escalation of the appeal, the CEO or designee reviews the appeal file and discusses resolution of the appeal with the company representative and COO. Where agreement cannot be reached, the CEO or designee will render a decision.
- 7. If the applicant disagrees with the decision of the CEO, final escalation of the appeal is made to an Arbitration Board, comprising independent members of the IPEA Board of Directors.
 - a. Board members are asked to review SOP 11, Conflict of Interest, and acknowledge their impartiality to hear the appeal or else recuse themselves from the appeal. In addition, any business relationship between the Board member's employer and the applicant, such as that of the applicant being a supplier or competitor requires Board members to recuse themselves.

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- b. Those remaining IPEA Board members, a minimum of three, now comprise an ad hoc Arbitration Board. The intent is for the Arbitration Board to have a balance of representation from the excipient manufacturers and pharmaceutical users.
 - c. The CEO, ore designated substitute, presents to the Arbitration Board the relevant information regarding the appeal and the applicant company representative is requested to present their reason the proposed resolution to the appeal is inadequate.
 - d. The Arbitration Board discusses the matter and, by consensus, determines the final resolution.
 - i. Where the decision is not unanimous, the matter is put before the full IPEA Board of Directors for confirmation of the Arbitration Board decision.
 - ii. The Arbitration Board decision is affirmed through majority vote.
8. If resolution of the appeal includes corrective measures by the applicant, the IPEA Administrator facilitates follow-up with the COO who assure the measures are implemented and effective. Depending upon the severity of the corrective measure required, the COO provides assurance through written confirmation from the applicant or site audit.

Where corrective measures are needed to the IPEA Excipient GMP Conformance program, the CEO is notified and works with the COO to assure correction is implemented in a timely manner.

- 9. Appeals are closed once the applicant has received a written statement of the decision and the basis for the decision and, where applicable, the proposed resolution and corrective measures proffered have been confirmed as implemented.

III. Complaints

- 10. Complaints involve such issues as inappropriate use of the IPEA Certificate or Mark, nonconformance by the applicant with Excipient GMP expectations, inspection observations from a customer or regulatory authority, etc.
 - a. The IPEA Administrator opens a complaint by assigning a complaint number in the format CYY-XXX where YY are the last two digits of the year and XXX are sequential beginning with the first appeal of the year. Documents related to the complaint are filed by complaint number. The complaint file contains the:
 - i. Application Number
 - ii. Corporate Name
 - iii. Site name and location
 - iv. Excipient(s) certified
 - v. Name of complainant and company name
 - vi. Description of the nonconformance.
 - b. The IPEA Administrator:

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- i. Acknowledges receipt of the complaint to the complainant,
 - ii. Notifies the COO that the complaint has been filed,
 - iii. Assures the complainant is periodically informed of the status of the complaint, and
 - iv. Assures the complainant and applicant, where appropriate, are notified of the final decision regarding the complaint.
- 11. If the investigation of the complaint has not involved the applicant, then IPEA informs the applicant of the complaint, and progress of the investigation.
- 12. IPEA maintains confidentiality of the complainant and the applicant as stipulated by either party.
- 13. The COO investigates the complaint by:
 - a. Reviewing all documentation related to the complaint,
 - b. Where appropriate, discussing the complaint with the applicant,
 - c. Reviewing, as appropriate, the audit report, Certification Board minutes, applicant literature and labeling, the Excipient GMPs and audit standard, and conformity assessment standards such as ISO/IEC Guide 65 and ISO/IEC 17021.
- 14. The COO proposes resolution of the complaint to the CEO. The COO and CEO assess the impact of the complaint finding on the applicant's certification or the IPEA Excipient GMP Conformance Certification program.
 - a. If there is an impact on the certification of the applicant, the applicant is informed and given an opportunity to appeal.
 - b. Where the complaint corrective action must involve the identification of the complainant, the complainant is informed that their identity should be disclosed and their concurrence is requested.
- 15. Complaints are closed once the applicant has accepted the proposed resolution and proposed corrective measures have been implemented.

IV. Appeals and Complaints

- 16. Corrective actions arising from either an appeal or complaint are documented in the file and tracked to confirm completion and to verify effectiveness.
- 17. Appeals and complaints are reported quarterly to the COO and CEO. The report indicates the:
 - a. Number of new appeals or complaints initiated,
 - b. Status of open appeals and complaints, and
 - c. Number of appeals and complaints closed.

Where an appeal or complaint impugns the confidentiality, objectivity or impartiality of the certification program, IPEA Executive Management promptly notifies the IPEA Board.
- 18. At each quarterly meeting of the IPEA Board of Directors, IPEA Executive Management presents a list of all appeals and complaints that were either opened or closed in the prior quarter. Appeals and complaints are reviewed as part of the management review of the effectiveness of the IPEA Excipient GMP Conformance Certification program (SOP 21). A summary of all appeals and

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complaints filed year to date is discussed at the last IPEA Board of Directors meeting of the year.

HISTORY OF REVISIONS

Revision No.	Effective Date	Description of Changes
0	Apr. 15, 2009	New Procedure
1	Aug. 28, 2009	Added provisions for appeals where both the CEO and COO must recuse themselves and added to Step 9 the requirement for written notification to the applicant of the decision of the appeal
2	Oct. 19, 2009	Added to step 7 provisions for Arbitration Board decisions where consensus is not achieved. Added requirement for prompt notification of important appeals or complaints.