

STANDARD OPERATING PROCEDURE
International Pharmaceutical Excipients Auditing, Inc.

Title Conflict of Interest		Revision 2	SOP Number 11
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved Jan. 26, 2012	Page Page 1 of 2

PURPOSE:

This document details IPEA’s standard operating procedure (“SOP”) regarding conflicts of interest for Contract Consultants (as defined below).

SCOPE:

This SOP applies to all Contract Consultants, IPEA Board of Directors, and IPEA employees performing a service for IPEA under the Excipient GMP Conformance Certification Program where they can influence the assessment of excipient manufacturers, who have applied to IPEA’s Excipient GMP Conformance Certification Program (“Applicant”). Such activities include: conducting an audit, reviewing an audit report, participation on the Arbitration Board, or participating in the decision to certify the audited Applicant for substantial conformance to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.

RESPONSIBILITIES:

1. **Contract Consultant:** Provide information requested herein.
2. **IPEA Executive Management:** Evaluate the information provided by the Contract Consultant to identify potential conflict of interest.
3. **IPEA Management Committee:** Notify other members of the committee when they perceive a potential conflict of interest.

REFERENCES:

1. Independent Contractor Services Agreement

DEFINITIONS:

See Glossary

PROCEDURE:

1. This procedure relies on the cooperation of our Contract Consultants, IPEA Board of Directors, and IPEA employees to voluntarily disclose any relationship that can jeopardize their freedom from bias in the conduct of specified activities for IPEA.
2. The primary source of information concerning the relationship of a Contract Consultant to the Applicant is through the Contract Consultants Curriculum Vitae or resume (collectively referred to as CV) filed with IPEA. The CV should disclose all employers for whom the contractor has worked.
 - a. It is recognized that the CV may not list all clients with the necessary information for IPEA to determine if a conflict of interest exists.
 - b. IPEA requests that the Contract Consultant inform IPEA Executive Management if they are aware that they have a situation where a perceived conflict of interest or bias may exist. For consideration, such situations include but are not be limited to:
 - i. Contract Consultant has been employed by the Applicant or an affiliate thereof within the past 5 years.

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- ii. Contract Consultant has provided service to the Applicant or an affiliate thereof within the past 5 years.
- iii. Contract Consultant's immediate family member (spouse, parent, sibling, or child) has been employed by the Applicant or an affiliate thereof with the past 5 years.
- iv. Contract Consultant owns a financial interest in the Applicant that represents a significant percentage of the consultant's total assets.
- c. When informed by a Contract Consultant that there is a potential conflict of interest, IPEA Executive Management reviews the matter.
 - i. If the matter presents a conflict of interest or the perception that there is a conflict of interest, IPEA Executive Management will assign another contractor.
 - ii. IPEA Executive Management may choose in rare circumstances, to discuss the matter with the Applicant to waive any conflicts and permit the services to be performed by the Contract Consultant.
 - 1. If the decision is made to use the services of the contract consultant, IPEA Executive Management notifies the IPEA Management Committee.
 - 2. The full approval of the Management Committee and agreement of the customer is required to proceed with the use of the consultant..
- 3. IPEA's policy is that no contractor involved in the Excipient Certification Program performs or participates in any audit, reviews an audit report, or participates as a member of the Certification Board if they have any personal involvement as set forth in Section 2b above that might influence, or appear to influence, Contract Consultant's judgment or jeopardize Contract Consultant's objectivity.
- 4. No Contract Consultant can participate in the IPEA Excipient Certification Program unless they have signed the Independent Services Agreement which includes an acknowledgement that he/she agrees to comply with the terms and conditions of this SOP.

HISTORY OF REVISIONS

Revision No.	Effective Date	Description of Changes
0	Nov. 21, 2008	New Procedure
1	Aug. 26, 2009	Add Arbitration Board to Scope, define applicant and contract consultant, and improve various wording.
2	Jan. 26, 2012	Added to 2cii and 2cii1.