



# IPEA AUDITING SERVICES

PROGRAMS	 <b>Excipient GMP Conformance Certification</b>	<b>Excipient GMP Audit Service</b>
<b>SINGLE EXCIPIENT AUDIT</b>		
<b>Purpose</b>	Certify that the excipient is in substantial conformance to excipient GMP to customers and regulators	Issue audit report to be used by customers to assess acceptability of excipient manufacture. Primary purpose is to share audits and costs.
<b>Typical Price</b>	\$22,000 non members / \$20,000 members	\$6,000 non members / \$5,500 members
<b>Duration (on-site)</b>	2 days 2 auditors	1 day 1 auditor
<b>AUDIT REPORT</b>		
<b>Findings</b>	Rated by audit team	Assessed by purchaser of the report
<b>Corrective Action Plan</b>	All corrective action is followed. Response is assessed by Audit Team and reviewed by Certification Board.	Corrective action response is recommended but optional, and if provided is sent along with the final audit report
<b>Audit report review</b>	Audit report reviewed and recommendation to certify is approved by IPEA Certification Board	Audit report is reviewed by IPEA Executive Management and issued to sponsor and available for sale.
<b>Report content</b>	Conforms to ANSI expectations	As would be completed by customer audit
<b>Audit timeline</b>	Annual surveillance cost at ½ the price of certification	Report expires 2 years from issue. Re-audit cost is same price as initial audit
<b>CONFORMANCE TO EXCIPIENT GMP</b>		
<b>Status</b>	 <b>ANSI Accredited Certification for substantial conformance to excipient GMP</b>	Audit report reviewed by purchaser for conformance to excipient GMP