

## Applicants Rights and Duties

### 1. Rights of the Applicant

- a. The applicant has the right to a review of their application and GMP Quality System for conformance to excipient GMP requirements that is free from conflict of interest.
- b. Confidential information provided or disclosed during the review of their Quality System is to be protected from disclosure.
- c. The applicant can dispute a finding during the audit and expect a fair hearing of their position.
  - i. The applicant can elevate a dispute to an appeal.
- d. The applicant can appeal the decision to refuse or withdraw Certification 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 the change.

### 2. Duties of the Applicant

- a. The applicant agrees to cooperate in all audits that are specified in the IPEA Excipient GMP Conformance Certification program. 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. All claims made regarding the IPEA Excipient GMP Conformance Certification will be within the scope of the certification.
- c. No claims will be made 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 conformance with IPEC-PQG Excipient GMP requirements.
  - i. The IPEA Certification Mark may not be used on any excipient labeling; labels, or Certificate of Analysis, unless accompanied by the statement "Certified Quality System" in a font size no smaller than 8 point.
  - ii. The IPEA Certification Mark may be used on excipient specifications, brochures, and advertising.
- d. The applicant agrees to immediately discontinue all advertising that contains any reference to the Certification if IPEA has suspended or withdrawn the certification.