Quality Agreement for CGMP Testing Services

The Purpose of this Quality Agreement is to establish, clarify, and communicate quality expectations related to CGMP testing. This agreement shall apply to all samples submitted for testing. It is the responsibility of the Client to inform NJ LABS, utilizing the NJ LABS sample submission form, and by contacting NJ LABS's Business Development group, of any special testing requirements. When samples are submitted to NJ LABS, they are designated as CGMP. This Agreement shall remain in effect until cancelled with notice by either party.

NJ LABS responsibility:

1. NJ LABS will test samples in accordance with U.S. Current Good Manufacturing Practices (CGMP), and/or applicable USP guidelines. Testing activities will be fully documented in such a way to provide traceability.
2. NJ LABS will maintain current FDA registration as an analytical laboratory.
3. NJ LABS will maintain sufficient premises, equipment, processes, procedures and supplies to carry out testing of samples.
4. NJ LABS will ensure that personnel performing and reviewing testing have the necessary education, experience and training.
5. NJ LABS will perform testing as an independent contractor, and the Client will have no control over NJ LABS's employees and agents. Any testing scheduled to be subcontracted to another testing facility shall be approved in advance by the Client.
6. NJ LABS will perform testing, per the method and specifications agreed upon with the Client.
7. NJ LABS will utilize USP standards or equivalent when available for CGMP testing.
8. NJ LABS agrees to notify the Client of any Regulatory Authority request for specific test results relating to Client sample(s).
9. NJ LABS shall notify the Client of any confirmed Out-of-Specification (OOS) results in a timely manner and perform an investigation in accordance with NJ LABS's internal procedure(s).
10. NJ LABS shall notify the Client of any non-conformance or major deviations identified that will impact the Quality of the data generated by NJ LABS for the Client.
11. NJ LABS shall maintain a change control system.
12. NJ LABS shall maintain all test-related documents generated by NJ LABS. Original observations will be recorded in bound laboratory notebooks or on controlled data collection forms. All documents relating to the Client samples shall be made available to the Client for review upon request.
13. NJ LABS will retain records for five (5) years beyond the date of testing for each sample. If this retention time is deemed insufficient, the Client is responsible for contacting NJ LABS to arrange for the recovery of records, prior to the five (5) year time point.
14. With prior notification and during normal business hours, the Client may audit NJ LABS every two years. NJ LABS shall allow the Client, or an approved Client affiliate and/or agent, reasonable access to the facility, to appropriate personnel, and to relevant documents, including laboratory testing notebooks and raw data. NJ LABS will provide a written response to all findings provided to NJ LABS in writing.

Client responsibility:

1. The Client is responsible for selecting samples for analysis and to ensure that those sampling programs are based on current regulation. NJ LABS's analysis is based on the sample submitted. Results reported only relate to the sample that was tested.
2. The Client is responsible for completing NJ LABS's sample submission form and/or supplying a copy of the approved quote with the samples to be tested. The Client must provide accurate information concerning the samples to be tested.
3. The Client will be responsible for safe and secure shipment including shipping conditions intended to preserve Sample quality and integrity during transport.
4. The Client is responsible for Reserve Samples. Samples shall be stored by NJ LABS under controlled conditions (as indicated by the Client) in the container provided by the Client for thirty (30) days following testing and then disposed of in accordance with NJ LABS procedures, unless the Client provides instructions for the return of Sample.
5. The Client is responsible for final product release and related specifications. Test data supplied by NJ LABS in and of itself is not sufficient to make a decision on release of pharmaceutical products for distribution. NJ LABS makes no claim to serve as Client's internal Quality Unit.
6. The Client is responsible for receiving and evaluating customer complaints including but not limited to the manufacture, processing, packaging, labeling, holding and analysis of Client Samples.
7. The Client is responsible for trending of test results and for defining unacceptable trends.
8. The Client shall advise NJ LABS of any knowledge concerning sample instability and/or prior test results that might impact the storage, handling and/or testing of Client samples.

Note: All services provided will adhere to NJ LABS's Terms and Conditions. In the event a conflict arises between the Quality Agreement and Quotation, the Quotation will govern.
IN WITNESS WHEREOF, the parties hereto have executed this Agreement by authorized representatives as of the date written below.

APPROVAL

CLIENT:	NEW JERSEY LABORATORIES
PRINT NAME:	PRINT NAME:
TITLE:	TITLE:
SIGNATURE:	SIGNATURE:
DATE:	DATE: