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 exclusively to samples submitted for testing that must be tested in compliance with cGMP guidelines. It is the responsibility of the Client to inform ARL, utilizing the ARL sample submission form, and by contacting ARL's Business Development group, if the requested testing is to be conducted per cGMP guidelines. When samples are submitted to ARL and designated as cGMP and a quote is in place that indicates cGMP testing requirements, than the testing will be conducted under cGMP conditions. This Agreement shall remain in effect until cancelled with notice by either party.

ARL responsibility:

1. ARL will test cGMP samples in accordance with U.S. Current Good Manufacturing Practices (cGMP), accepted industry practices, and/or applicable USP guidelines. Testing activities will be fully documented in such a way to provide traceability.
2. ARL will maintain current FDA registration as an analytical laboratory.
3. ARL will maintain sufficient premises, equipment, processes, procedures and supplies to carry out testing of samples.
4. ARL will ensure that personnel performing and reviewing testing have the necessary education, experience and training.
5. ARL will perform testing as an independent contractor, and the Client will have no control over ARL's employees and agents. Any testing scheduled to be subcontracted to another testing facility shall be approved in advance by the Client.
6. ARL will perform testing, per the method and specifications agreed upon with the Client.
7. ARL will validate non-compendial methods and utilize USP standards or equivalent when available for cGMP testing.
8. ARL agrees to notify the Client of any Regulatory Authority request for specific test results relating to Client sample(s).
9. ARL shall notify the Client of any confirmed Out-of-Specification (OOS) results in a timely manner and perform an investigation in accordance with ARL's internal procedure(s).
10. ARL shall notify the Client of any non-conformance or deviation identified that will impact the Quality of the data generated by ARL for the Client.
11. ARL shall maintain a change management system. If a change has an impact on cGMP compliance, including changes to validated test methods with respect to the Client's Sample, the Client shall receive advance notification of such change in a timely manner. ARL shall obtain approval from the Client prior to implementation of such changes.
12. ARL shall maintain all test-related documents generated by ARL. 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. ARL 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 ARL 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 ARL on an annual basis. ARL 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. ARL will provide a written response to all findings provided to ARL 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. ARL'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 ARL'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 ARL 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 ARL 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 ARL in and of itself is not sufficient to make a decision on release of pharmaceutical products for distribution. ARL 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 ARL of any knowledge concerning sample instability and/or prior test results that might impact the storage, handling and/or testing of Client Samples.

Note: By submitting samples to ARL you certify that (1) all information provided is true and correct; (2) you have reviewed the Terms and Conditions located on ARL's website @ http://www.arlok.com/arl-forms; (3) you agree to be bound by the Terms and Conditions; and (4) if you are submitting samples on behalf of a company or other entity, you have the authority to bind that company or entity to the 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.

ARL Bio Pharma, Inc.	Client: _____
Name / Date: _____	Name / Date: _____
Signature: _____	Signature: _____