



Quality Agreement for non-cGMP Testing Services

The Purpose of this Quality Agreement is to establish, clarify, and communicate quality expectations related to non-cGMP testing such as Pharmacy Compounding and/or Research and Development. This agreement shall apply exclusively to samples submitted for testing in which the client does not delineate as GMP. This Agreement shall remain in effect until cancelled with notice by either party.

ARL responsibility:

1. ARL will maintain sufficient premises, equipment, processes, and supplies to carry out testing of samples.
2. ARL will ensure that personnel performing and reviewing testing have the necessary education, experience and training.
3. ARL will perform testing as an independent contractor, and the Client will have no control over ARL's employees and agents.
4. ARL will perform testing, per the method chosen on the sample submission form. For non-cGMP potency testing ARL relies on Good Chromatography Practices and verification of system suitability that we are capable of performing the analysis. Unless otherwise noted, potency methods are not validated for your specific formulation. Validated methods that are specific to your formulation can be developed by our laboratory.
5. ARL agrees to notify the Client of any Regulatory Authority request for specific test results relating to Client sample(s).
6. 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).
7. 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.
8. 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.
9. 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.
10. 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: All services provided will adhere to ARL'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.

ARL Bio Pharma

Client: _____

Name: _____

Name: _____

Date: _____

Date: _____