Contract Lab Quality Agreement and Terms

Purpose

The purpose of this Quality Agreement is to establish, clarify and communicate quality expectations between Analytical Resource Laboratories, hereafter referred to as “ARL” and our clients, hereafter referred to as “the Client”.

Scope

This agreement is for all samples submitted to ARL related to the manufacture of products whether from a compounding facility, an outsource facility or a cGMP manufacturer. In the case where a separate quality agreement is signed between ARL and the Client, the Client specific quality agreement supersedes this general quality agreement. We recommend that clients generate their own quality agreement with ARL.

Terms

By submitting samples to Analytical Resource Laboratories the Client agrees to this Quality Agreement. The effective date of this agreement is the date the Client sends their first sample to ARL. This agreement is in affect throughout the duration of the business relationship between ARL and the Client.

Quality Unit Responsibilities

1. The client is responsible for assuring that the products they produce meet all applicable laws, regulations and standards.

2. The client is fully responsible for final product approval or rejection decisions. Test data supplied by ARL is not sufficient to make a decision on the release of products for distribution. The client is ultimately responsible for assuring the identity, strength, quality, purity and safety of their products. **ARL makes no claim to serve as the Client’s quality unit.**

3. The client is responsible for selecting appropriate samples and quantities for analysis and for ensuring that the sampling process is based on applicable laws, regulations and standards.

4. The client is responsible for determining sample and or product specifications.

5. The client is responsible for trending product test results and for defining unacceptable trends.

6. The client will advise ARL of any knowledge concerning sample instability and/or prior test results that might impact the storage, handling and/or testing of the Client's samples.

7. The client is responsible for the control and review of any services requested from ARL. With prior notification and during normal business hours, ARL shall allow the Client or an approved client affiliate, reasonable access to the facility, appropriate personnel (numbering up to three members) and relevant documents. ARL reserves the right to redact information and data containing other clients' information. The client may not publicly publish the results of the audit. ARL will respond to all concerns as the result of a client audit within sixty days.

Facilities and Equipment

1. ARL shall maintain all test data and records generated by ARL for a period no less than 7 years. Original observations will be recorded in bound laboratory notebooks or on controlled data collection forms. All data relating to the Client's samples shall be made available to the Client for review upon request, however information pertaining to other client data will be redacted. If this retention time is deemed insufficient, the Client is responsible for contacting ARL to arrange for the recovery of records prior to the 7 year time point. After 7 years, sample test records, and data may be destroyed.

2. ARL is not responsible for client's data retention. While records will be kept as per ARL Retention policies and made available, Clients are responsible for their own record retention obligations.

Change Control

ARL shall maintain a change management system including a work order system, deviation system, corrective/preventive action system and document control system.

Privacy

1. ARL will not divulge client's proprietary information such as formulations.

2. ARL will only release data to authorized agents within the Client's organization.

3. ARL may disclose client information to regulatory agencies as required by law.

Dispute Resolution

Any dispute regarding this quality agreement will be discussed between ARL and the Client.

Registrations and Audits

FDA Registered : FEI number 1421447326
ISO 17025:2017 Accreditation

Signature: _____

Date: _____

Company: _____

Name: _____

Title: _____

Signature: 

Agreement effective upon dated signature from client.

Analytical Resource Labs, LLC
Name: Jacob Teller
Title: Quality Director

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