



Testing. Advising. Assuring.

## Quality Agreement for cGMP

The Purpose of this Quality Agreement is to establish, clarify, and communicate quality expectations for the chemical testing by Exova of drug substances, raw materials, in-process samples, and finished products for use in some Phase II, all Phase III and IV clinical trials, NDAs, or commercial distribution. It is the responsibility of Client to inform Exova through the Exova **Analytical Request Form** the regulatory scope of the testing being requested. All testing for R&D, Phase I, Phase II, and client internal use will not be cGMP unless Client specifically requests compliance.

1. Exova will test Samples in accordance with U.S. Current Good Manufacturing Practices (cGMP), accepted industry practices, and applicable USP and ICH guidelines. Testing activities will be fully documented.
2. Exova is responsible to register the facility with the FDA and to maintain the registration documents such that they are readily available for FDA or other regulatory inspection.
3. Exova will maintain sufficient premises, equipment, processes, procedures and supplies to carry out the analytical testing of Samples. Exova will ensure that it possesses ample, knowledgeable, experienced and trained staff to perform said testing. Exova will maintain and monitor appropriate records of training and competence in accordance with cGMP requirements.
4. Exova will perform testing as an independent contractor of Client and have complete and exclusive controls over its employees and agents. Any testing scheduled to be subcontracted to another testing facility, including other Exova sites, shall be approved in advance by Client.
5. Exova will perform testing, per the method and specifications agreed upon with Client. Exova will document and notify Client of all significant changes to or deviations from standard or validated/compendial testing methods and the investigation thereof as soon as the change or deviation has been identified. Documentation of changes or deviations will become part of the final report.
6. Validation or verification of non-compendial methods is a regulatory requirement for testing performed to support the release of product for some Phase II, Phase III clinical trials or approved products. Validation, verification, or method transfer services are available at an additional charge. Services performed using non-validated methods will be identified as such on the Laboratory Report for analytical testing requests identified by the client as being for a regulatory submission to the FDA or for a product or raw material regulated by the FDA.
7. Exova and Client shall advise each other of any events that, in their opinion, raise concerns about the testing processes, equipment, and/ or facility that may have an impact on the quality of the analytical testing. Exova shall notify Client within two (2) business days of any past or present non-conformance or deviation identified that could impact the Quality of the data generated by Exova for Client. Exova shall track and trend corrective and preventative actions in response to investigations and unplanned deviations.
8. Client will be responsible for shipping conditions intended to preserve Sample quality and integrity during transport. Sample shall be stored by Exova under controlled conditions (as indicated by the Client) in the container provided by the Client. Sample shall be maintained for a minimum of thirty (30) days following testing and then disposed of in accordance with Exova procedures, unless Client provides instructions for the return of Sample.
9. Client will be responsible for providing instructions to Exova regarding the disposal or dispatch of remaining unused Samples. Exova will be responsible for all other remaining waste associated with the testing operation.
10. Exova shall maintain all controlled documents. Original observations will be recorded in bound laboratory notebooks or on controlled, numbered worksheets. All documents relating to the Client samples shall be made available to Client for review upon request. Additional fees will apply for raw data copies provided to the Client.
11. Exova will keep complete, accurate, and authentic data records of all work performed by Exova, including complete and adequate records pertaining to the methods and facilities used for the testing of samples. Exova will make such records available for review upon request by Client.
12. Exova will provide Client a copy of the Exova standard analytical report, including analytical test results pertaining to the Samples. The report shall specify the identification of the Sample (as provided by the Client), specifications as provided by the Client, test method reference, and the signature of the person authorized to release the data.
13. Exova will retain, in accordance with cGMP, complete records for seven (7) years after the date of testing for each sample. If this retention time is deemed insufficient, Client is responsible for contacting Exova to arrange for the transfer of records, for a reasonable and customary fee, prior to the seven (7) year timepoint. If the records are to be transferred to the Client, Client will be responsible for transferring the records for archival per Client Standard Operating Procedures.
14. Exova shall notify Client of Out-of-Specification (OOS) results in a timely manner and perform an investigation in accordance with Exova SOP 2230. In the event of an OOS result, Exova will notify Client within two (2) business days of a confirmed OOS result. Trending of results is the responsibility of the client. Exova will investigate any out-of-trend results, upon notification of such by Client.
15. With notification and during normal business hours, Client may audit Exova on an annual basis not to exceed one day. Exova shall allow 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. Additional audits may occur if considered "for cause". Within 30 days of receipt of any audit report, Exova will provide a written response to all findings that describes the corrective action(s) it will implement and the time it will take to complete such action(s).
16. Exova agrees to notify Client within (2) business days upon receipt of notice and results of any Regulatory Authority visit (or requests for Client documentation) at Exova facility relating to the testing of any Sample. Exova will grant Client access to records and documentation relating to regulatory inspection citations pertaining to Samples and Client will have the opportunity to provide input prior to submission of the response to such investigations or requests.
17. Exova shall maintain a change management system that tracks and controls changes to documents (including test methods), analytical standards, qualified equipment, facilities and computer systems. If a change relates to or may have an impact on cGMP compliance, including changes to validated test methods with respect to Client's Sample, Client shall receive advance notification of such change in a timely manner and Exova must obtain approval from Client prior to implementation of such changes.

Company: \_\_\_\_\_

Exova Inc.

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

QA Officer - Lorraine Shelton ASQ, CQA

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_