QUALITY AGREEMENT

The following Agreement has been concluded between

QUALITY COMPLIANCE LABORATORIES

The **contract laboratory and service provider**

11-145 Konrad Crescent
Markham, Ontario
Canada L3R 9T9

Hereinafter referred to as **QCL**

and

"INSERT COMPANY NAME"

The **Client**

"INSERT COMPANY ADDRESS"

Hereinafter referred to as **"INSERT COMPANY NAME"**

1. INTRODUCTION

QCL Quality Compliance Laboratories Inc. has its principle purpose of generating high quality data, utilizing analytical measurements that are accurate, reliable and meeting or exceeding client expectations. QCL will operate in full compliance with current GMP requirements to meet its client's needs for quality analytical testing.

1.1 This Quality Agreement defines the expectations and responsibilities between QCL as contract laboratory and service provider and “INSERT COMPANY NAME” as service requestor.

1.2 Both QCL and “INSERT COMPANY NAME” wish to ensure by this agreement that all services performed by QCL are up to acceptable GMP standards set forth by the Health Canada Therapeutics Programme Directorate, through the current GMP Guidelines as defined under Division 1A, Part C of the Food and Drug Regulations; and by FDA, through 21 CFR Parts 210, 211 and 11.

1.3 On agreement to the expectations and responsibilities defined in this Agreement, this Agreement is considered as binding to all parties named in this Agreement and in effect at the time upon final signature approval, and thereafter, as may be amended in writing.

1.4 QCL is currently approved by Health Canada (Establishment Licence No. 101432-A) and registered with and inspected by U.S. Food and Drug Administration (Facility Establishment Identifier 3005630028) to test drug, nutraceutical and device products. QCL will maintain an Establishment License as per the Canadian Food and Drug regulations as a licensed testing laboratory. A current copy of Establishment Licence will be made available to “INSERT COMPANY NAME” upon written request. QCL is responsible for informing “INSERT COMPANY NAME” without delay of any restriction to the regulatory licence for the products covered by the Agreement.

1.5 It is the responsibility of both QCL and “INSERT COMPANY NAME” to maintain this Agreement in a current state and to ensure that this Agreement continues to cover the responsibilities and obligations of the parties as stated under Canadian GMP regulations. Any modifications to this agreement must be communicated and agreed to in writing prior to implementation.

1.6 Should , due to any change of the legal situation, the basis of this agreement be modified to such an extend that the part affected thereby cannot be reasonably expected to continue to perform under this Agreement, then the document will be modified accordingly and signed by both parties. The parties shall amicably try to find new rules.

1.7 “INSERT COMPANY NAME” shall ensure that QCL is provided with the current testing procedures, columns (if unique or dedicated), and reference standards for all drug/device products to be tested by QCL. In addition, “INSERT COMPANY NAME” shall be responsible for providing QCL with the correct and current specifications and list of test methods for each lot of material to be tested.

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2. BASIS FOR THE QUALITY AGREEMENT

2.1 This agreement addresses the technical and quality aspects relating to the product(s) which form(s) the basis of this agreement. It shall specify the respective responsibilities of QCL and "INSERT COMPANY NAME" as generated by an appropriate and technically competent person(s) suitably knowledgeable in pharmaceutical technology, analysis and GMP.

2.2 QCL is responsible for the testing of the product (s) and "INSERT COMPANY NAME" is responsible for release of the product (s).

2.3 QCL (in the testing of all materials) and "INSERT COMPANY NAME" (in the release of all materials) must comply with the current regulatory requirements of Division 2, Part C of the Canadian Food and Drug Regulations (HPFB Inspectorate Good Manufacturing Practices Guidelines).

2.4 If "INSERT COMPANY NAME" wishes special provisions or guidelines to be followed that are not yet generally known or recognized, QCL must be informed of that fact and agreement obtained in writing.

2.5 "INSERT COMPANY NAME" and QCL are to designate responsible contacts to ensure responsible individuals are contacted for all technical matters. Attachment (I) is a listing of the persons named in the Company Contacts.

2.6 "INSERT COMPANY NAME" and QCL agree to continually review the requirements of this Quality Agreement to ensure continued compliance with all such requirements.

2.7 Arrangements on prices and other commercial terms are reserved for a separate Commercial Agreement.

3. QUALITY SYSTEM

3.1 QCL will ensure that all activities are in compliance with current Canadian regulatory requirements, current Good Manufacturing Practice regulations and "INSERT COMPANY NAME" quality specifications and requirements as outlined in this document.

3.2 QCL shall have a written procedure for change control. Changes that may impact the testing of "INSERT COMPANY NAME" products will be done in consultation with "INSERT COMPANY NAME" prior to implementation of the change.

4. AUDITS and REGULATORY INSPECTION

4.1 QCL shall maintain an internal audit or self inspection program. A copy of the QCL self-inspection schedule shall be provided to "INSERT COMPANY NAME" or the Regulatory

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Authorities upon request. If applicable to "INSERT COMPANY NAME" products, QCL will notify immediately "INSERT COMPANY NAME" of any adverse finding.

4.2 QCL permits "INSERT COMPANY NAME" GMP audits of all relevant premises, procedures, documentation annually.

4.3 QCL shall permit Regulatory Authorities Inspections in relation to GMP certification and Establishment Licence renewal.

4.4 QCL shall notify "INSERT COMPANY NAME" within twenty-four (24) hours of all regulatory agency inspections that are potentially connected to "INSERT COMPANY NAME" materials. Additionally, the respective inspection reports or observations that impact "INSERT COMPANY NAME" shall be provided to "INSERT COMPANY NAME" within three working days.

4.5 A copy of the audit report from Health Canada or the current Establishment License from Health Canada shall be provided to "INSERT COMPANY NAME" upon request to verify GMP compliance.

4.6 QCL shall provide reasonable access to its premises, during normal working hours, at a time mutually agreed upon by "INSERT COMPANY NAME" and QCL, to permit audits of the relevant documents and facilities by "INSERT COMPANY NAME" or the Regulatory Authorities.

4.7 QCL will provide a copy of the most current local regulatory agency inspection reports along with the response to the report, if requested by "INSERT COMPANY NAME". This information provides evidence of GMP compliance as required by Health Canada.

4.8 For each audit conducted by "INSERT COMPANY NAME", QCL agrees to provide, within 30 calendar days after receipt the audit report, a written response for each observation, provide corrective action, and the timeline for implementation of such corrective action, if applicable.

4.9 QCL will be responsible for qualifying its supplier of services. The supplier qualification will be based on the latest Canadian GMP Guidelines and the frequency will be based on the CGMP's.

5. CHANGE CONTROL

5.1 QCL will follow its internal procedures for Change Control documentation and maintain a log of any changes made to its policies, procedures and practices.

5.2 Changes to the test method, product specification, or other applicable written procedures must follow a documented Change Control system.

5.3 A copy of QCL Change Control procedure will be provided to "INSERT COMPANY NAME" on QCL's site upon request.

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5.4 "INSERT COMPANY NAME" agrees to notify QCL of changes to test method, product specification, or other applicable written procedures if they are major or have an impact on a regulatory filing, prior to implementation.

5.5 QCL agrees that any testing methods provided to QCL by "INSERT COMPANY NAME" must be kept on file until "INSERT COMPANY NAME" provides QCL with new versions of such methods. Once new documentation is received, QCL agrees to archive or destroy the superseded documentation.

5.6 "INSERT COMPANY NAME" must authorize any changes to test method, product specification, or other applicable written procedures affecting "INSERT COMPANY NAME" products, prior to implementation.

6. DEVIATIONS, NON-CONFORMANCES OR INVESTIGATIONS OF OUT-OF-SPECIFICATION RESULTS (OOS)

6.1 When a test result falls outside the expected range, QCL shall conduct an initial internal investigation and, upon confirmation of non-conformance, deviation, or OOS, QCL shall notify "INSERT COMPANY NAME" within 24 hours.

6.2 "INSERT COMPANY NAME" is responsible to notify the appropriate authorities of a confirmed non-conformance by QCL (i.e. FDA field alert report under 21 C.F.R. § 314.81(b)(1)).

6.3 A confirmed non-conformance result from a stability sample stored under accelerated conditions at 40°C/75%RH will trigger QCL to remove a sample from the back-up condition (if present) and may result in "INSERT COMPANY NAME" requesting QCL to initiate testing at a back-up accelerated storage condition (e.g. 30°C/65%RH) as per ICH Q1(R2). QCL will only test sample from intermediate storage condition upon "INSERT COMPANY NAME" request.

6.4 Investigation of Out of Trend (OOT) results is "INSERT COMPANY NAME"'s responsibility unless otherwise specified in writing by "INSERT COMPANY NAME"

6.5 If the investigation findings results in laboratory error, QCL will re-test the sample at no additional cost.

6.6 If there is an Out Of Specification result from a received batch and "INSERT COMPANY NAME" instructs QCL to repeat the analysis using a different bottle of the same batch; passing the repeat testing does not lead to rejecting the initial result unless there is an assignable cause.

6.7 Unless otherwise instructed by "INSERT COMPANY NAME", QCL shall be responsible for conducting and documenting any investigation into non-conformance, deviation, or OOS according to QCL approved procedure (minimum requirement). Any investigation of non-conformance, deviation, or OOS shall not exceed 30 calendar days.

6.8 "INSERT COMPANY NAME" must review and approve any planned deviation that may have an impact on services for "INSERT COMPANY NAME", prior to implementation.

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7. DOCUMENTATION

7.1 "INSERT COMPANY NAME" is responsible for providing QCL with instructions on product testing, approved specifications, and method of analysis.

7.2 In circumstances where a "INSERT COMPANY NAME" test method is to be followed, the method will be provided in advance of the sample to allow QCL adequate preparation time.

7.3 QCL must review all documentation received and assure that it is thoroughly understood prior to implementation.

7.4 In the event that QCL believes that the documentation is inadequate and/or in error, it is the responsibility of QCL to communicate this to "INSERT COMPANY NAME".

7.5 If "INSERT COMPANY NAME" commissioned QCL for validation and/or specific project, QCL must ensure that the protocol of analysis is approved by "INSERT COMPANY NAME" prior to the execution of the protocol.

7.6 No changes can be made to the documentation without prior written notification and approval of the other party.

7.7 All documentation supplied to QCL by "INSERT COMPANY NAME" will be kept separate from documentation from other clients.

7.8 If methods, specifications or procedures are updated, it is the responsibility of "INSERT COMPANY NAME" to provide the most current copies of documentation to QCL.

8. TRAINING

8.1 QCL is responsible for assuring that all their personnel have an adequate combination of education, experience and training to perform the job functions.

8.2 Training shall be documented and GMP refresher training conducted annually at minimum.

9. SHIPPING, RECEIVING, STORAGE, AND DISPOSAL OF SAMPLES

9.1 "INSERT COMPANY NAME" is responsible for the sampling of all materials, and products sent to QCL and will ensure that sufficient quantities are provided for the purpose of the testing.

9.2 During transportation "INSERT COMPANY NAME" shall ensure that all samples are properly packaged, labeled and protected from adverse environmental exposure.

9.3 "INSERT COMPANY NAME" will ensure that the sample is clearly labelled with the product name, lot number, testing required and any storage conditions.

9.4 All received samples must be accompanied by documentation clearly indicating the sample name, lot number, test method, testing required and contact information.

9.5 "INSERT COMPANY NAME" must inform QCL of any potential risk to affect employee's health and any hazardous material.

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9.6 On receipt, integrity of the samples should be examined. QCL must immediately advise "INSERT COMPANY NAME" for any physical damage and/or identification problem and/or missing documentation.

9.7 On receipt of samples, QCL has the responsibility to keep the sample within required storage condition and to register sample immediately on receipt.

9.8 QCL will maintain a system to assure proper identification and traceability of samples.

9.9 Any rejected/damaged drug/device product shall be segregated, clearly identified and returned to "INSERT COMPANY NAME" or destroyed if requested in writing by "INSERT COMPANY NAME".

9.10 After analysis and final approval of data by QCL, QCL agrees to keep remaining samples for thirty (30) days within storage condition or longer if so directed by "INSERT COMPANY NAME".

9.11 QCL is responsible for ensuring that all waste is disposed of in a manner consistent with local, governmental and other applicable requirements and regulations.

9.12 QCL will not receive samples on weekends and public holidays unless "INSERT COMPANY NAME" informs QCL in advance.

10. TESTING AND DOCUMENTATION

10.1 "INSERT COMPANY NAME" is responsible for providing to QCL instructions on product testing, approved specifications, and method of analysis.

10.2 If testing is to be carried out according to a pharmacopoeia such as; European Pharmacopoeia, the British Pharmacopoeia, the National Formulary, and/or the United States Pharmacopoeia, etc., only the most current edition will be used (including supplements), unless otherwise requested by "INSERT COMPANY NAME".

10.3 If testing is to be performed using a "INSERT COMPANY NAME" test procedure, the test procedure shall be provided by "INSERT COMPANY NAME".

10.4 QCL agrees to conduct all "INSERT COMPANY NAME" analysis according to current Good Manufacturing Practices.

10.5 It is the client's responsibility to initiate method transfer for non-compendial methods and method verification for compendial methods, as applicable. If "INSERT COMPANY NAME" commissioned QCL for validation, technology transfer and/or specific project, QCL must ensure that the protocol of analysis is approved by "INSERT COMPANY NAME" prior to execution.

10.6 Within 48 hours of sample receipt, QCL is responsible to notify "INSERT COMPANY NAME" if the test execution will be delayed due to lack of required method of analysis, reagents, columns, equipment, and/or any other reason.

10.7 QCL shall not sub-contract any analysis/test to another contract laboratory without "INSERT COMPANY Name"'s written agreement.

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10.8 In the event that "INSERT COMPANY NAME" provide their own methods, "INSERT COMPANY NAME" is responsible to provide the most current copies to QCL. "INSERT COMPANY NAME" is responsible to initiate any technological transfer of analytical methods. QCL and "INSERT COMPANY NAME" must come to an agreement on who will be responsible for the writing of protocol and the transfer report before proceeding. "INSERT COMPANY NAME" must approve the protocol. QCL is responsible for the execution of the technological transfer.

10.9 If the requested methods are not from official monographs, "INSERT COMPANY NAME" is responsible to provide to QCL the respective methods (with validation of suitability of use demonstrated previously and on file at "INSERT COMPANY NAME").

10.10 Any planned deviation from these procedures must be communicated to "INSERT COMPANY NAME" prior to execution of the method.

10.11 QCL will perform "INSERT COMPANY NAME" tests with validated and calibrated equipment according to current Canadian Good Manufacturing Practices (GMP).

10.12 If "INSERT COMPANY NAME" provides a standard, "INSERT COMPANY NAME" is responsible for the purity and expiry date of such items. QCL will not test or otherwise qualify such standards unless expressed in written request of "INSERT COMPANY NAME".

10.13 In the event that any standard, reagent, analytical column or other material required for analysis of "INSERT COMPANY NAME"'s samples is not routinely used by QCL, "INSERT COMPANY NAME" is required to provide such item/s to QCL or, alternatively, QCL will purchase the item and invoice "INSERT COMPANY NAME" for its cost plus additional administrative fees. In this event, the item so purchased will be used only for testing "INSERT COMPANY NAME"'s sample and not for any other purpose.

10.14 QCL shall ensure that they have the correct testing procedures and the latest revision on file, prior to initiating any testing on the drug or device product/s.

10.15 QCL shall ensure that they use the correct reference standard to perform the testing and that the reference standard is not expired prior to use in any testing process.

10.16 QCL shall give "INSERT COMPANY NAME" one month prior notice of the expiry reference standards in order for "INSERT COMPANY NAME" to ensure reordering of standards in a timely manner.

10.17 QCL will complete testing and provide results to "INSERT COMPANY NAME" within 10 working days of receipt of the sample.

10.18 If QCL cannot complete the testing in 10 working days, they will inform "INSERT COMPANY NAME" immediately stating the reason for the delay and the expected date of completion

NOTE: Exceptions to the 10 day turn around include method development and validation, technology transfer, stability studies, and out of specification investigations.

10.19 QCL is responsible to review raw data generated and test results, and to issue a Certificate of Analysis (COA) approved by qualified personnel as stated in Canadian GMP.

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10.20 QCL will be responsible for faxing and/or e-mailing a completed Certificate of Analysis to "INSERT COMPANY NAME". QCL will ensure that the following documentation is provided to "INSERT COMPANY NAME" in a timely manner :

- The original copy of the Certificate of Analysis.
- Copies of all laboratory data recorded during testing.
- Copies of all records generated during testing (including chromatograms)
- Laboratory OOS investigation reports / non-conformance reports (if applicable).
- Any documentation and samples requested for return to "INSERT COMPANY NAME" (if applicable).
- Narcotic documentation and sample not consumed by testing (if applicable).

NOTE: Unless otherwise requested by "INSERT COMPANY NAME", all original raw data and results shall be stored at QCL archive for a period of seven (7) years.

10.21 If any discrepancies are identified upon receipt of the paper work, "INSERT COMPANY NAME" will immediately inform QCL and further action will be discussed and/or initiated.

10.22 QCL will ensure that these records are available to "INSERT COMPANY NAME" upon request.

10.23 Stability samples maintained and tested at QCL will be analyzed for "time zero" upon "INSERT COMPANY NAME"'s request or the results of time zero will be provided by "INSERT COMPANY NAME".

11. CONFIDENTIALITY

11.1 Except if required by law including regulatory authorities, information contained in specifications, procedures, test methods, testing data, COA, etc., relating to "INSERT COMPANY NAME"'s test products is confidential (see signed Confidentiality Agreement with "INSERT COMPANY NAME") and QCL shall, under no circumstances, disclose this information to any other party without the written approval of "INSERT COMPANY NAME" or use the information in any manner other than for the purpose of this Agreement.

11.2 No unspecified testing or evaluation of any type of "INSERT COMPANY NAME" products is to be conducted without prior written consent of "INSERT COMPANY NAME".

11.3 QCL may be requested to sign a confidentiality agreement.

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12. APPROVAL OF THE QUALITY AGREEMENT

We agree with the foregoing terms and conditions and, in testimony whereof, we have signed

QCL Quality Compliance Laboratories	**"INSERT COMPANY NAME"**
Date:	Date:
_____	_____
Ronald Turton Head of Technical Operations, CSO	
_____	_____
Esther Yip Head of Quality Assurance	

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ATTACHMENT I

LIST OF CONTACTS AND RESPONSIBLE PEOPLE

QCL

Title	Name	Phone / Fax / E-mail
President	Dr. Mehrdad Barghian	Phone: (905) 305-0998 ext.207 Fax: (905) 305-0996 E-mail: mbarghian@qctest.com
Head of Quality Assurance	Esther Yip	Phone: (905) 305-0998 ext.204 Fax: (905) 305-0996 E-mail: eyip@qctest.com
Head of Technical Operations, CSO	Ronald Turton	Phone: (905) 305-0998 ext. 202 Fax: (905) 305-0996 E-mail: rturton@qctest.com
Laboratory Manager	Behsheed Akhavan	Phone: (905) 305-0998 ext.211 Fax: (905) 305-0996 E-mail: bakhavan@qctest.com
Project Manager	Javaneh Javanbakht	Phone: (905) 305-0998 ext.228 Fax: (905) 305-0996 E-mail: jjavanbakht@qctest.com

"INSERT COMPANY NAME"

Title	Name	Phone / Fax / E-mail

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