



Testing. Advising. Assuring.

## Welcome to Exova!

For submitting samples

**Analytical Request Form**  
Interactive PDF

**Analytical Request Form**  
PDF

**Analytical Request Form**  
Word

### Setting up an Account

**Terms & Conditions** Will need to be signed before starting work.

**Credit Application** Complete and sign if you intend to send in over \$1,500 over the next 6 months and use a purchase order. We do accept company checks, bank transfers, and credit cards.

**Accounting Information** Complete information for your accounting department including our W-9.

**Client Services Information** Complete information including contacts and services offered.

Before we can commence with work, our **Terms & Conditions** need to be signed by the company paying for the testing and both pages returned. If you intend to spend more than \$1,500 over the next 6 months and would like to use a purchase order, then please complete, sign, and return our **Credit Application**, along with the signed Terms & Conditions, either by email or fax. We will review your business information and get back to you within 5 to 10 working days. Payment can also be made by check, cash, bank transfer, or credit card. Please see our **Accounting Information** sheet for information such as tax ID, bill to addresses, W-9, etc.

### Confidentiality

**Confidentiality Agreement** You can either use ours or we would be happy to review yours.

Although we handle all client information under strict confidentiality, we prefer to enter into a **Confidentiality Agreement**. Feel free to use ours or submit your own for approval. We always highly suggest that these agreements be mutual as our SOPs are our work product and, as such, we are not able to share them with your company unless a confidentiality agreement is in place. Please note that we will only discuss confidential information with the individual who submitted the samples. If a co-worker or supervisor calls requesting information we will have to get approval from the original requestor. Feel free to identify on your paperwork other individuals who are approved to receive confidential information.

### Quality Assurance

**Quality Agreement** Required for all cGMP clients.

**FDA Scope of Work Definitions** Information on FDA definitions.

**Data/Sample Storage Information** Our policies.

**Quality Assurance Information** Complete information for your QA department.

For clients that are regulated by the FDA or similar agencies, we request that a **Quality Agreement** be completed between our two firms. Feel free to use our Quality Agreement or submit your own for review. As the scope of work is a critical issue to both firms, as well as the FDA, we offer our **FDA Scope of Work Definitions** sheet to more fully explain this issue. As per our **Data/Sample Storage Information** sheet we store all raw data for 7 years and samples for 30 days past invoicing. Our **Quality Assurance Information** sheet will provide you with all our permits, as well as other important regulatory information. Visit [www.exovachemist.com](http://www.exovachemist.com) for information on QA audits.

#### Client Services

Name: Louis Albanese  
Title: Client Services Director  
Phone: 562-948-2225, ext. 303  
Email: [louis.albanese@exova.com](mailto:louis.albanese@exova.com)

#### Business Development

Name: Christine Rowen  
Title: Account Executive  
Phone: 562.536.9869 (cell)  
Email: [christine.rowen@exova.com](mailto:christine.rowen@exova.com)

#### Accounting and Human Resources

Name: Helen Briggs  
Title: Office Manager  
Phone: 562-948-2225, ext. 224  
Email: [helen.briggs@exova.com](mailto:helen.briggs@exova.com)

#### Technical Director - Mike Shelton

Phone: 562-948-2225, ext. 602  
Email: [mike.shelton@exova.com](mailto:mike.shelton@exova.com)

#### QA Officer - Lorraine Shelton

Phone: 562-948-2225, ext. 107  
Email: [lorraine.shelton@exova.com](mailto:lorraine.shelton@exova.com)

#### General Manager - Eric Lindsay

Phone: 562-948-2225, ext. 300  
Email: [eric.lindsay@exova.com](mailto:eric.lindsay@exova.com)

Home web page - [www.exovachemist.com](http://www.exovachemist.com)

General Fax Number: 562-948-5850



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## Client Services Information

### Summary

This information is being supplied due to our change in name and ownership. We also have Information Sheets for Quality Assurance and Accounting. With over 130 laboratories, Exova provides services to wide range of industries including pharmaceuticals, supplements, environmental, aerospace, energy, metallurgy and engineering, plastics and polymer, transportation, utilities, telecom and electronics, food and consumer products. You can always contact us, or our corporate offices, to get more information on the breadth of services Exova provides. Below is a summary of the markets served and testing provided from this location. This is not a complete list; if you do not see a service you need, please give us a call or email your request.

**New Company Name:** Exova Inc

**Formerly Known As (FKA):** Bodycote Testing Group  
Bodycote Materials Testing  
Bodycote PLC  
West Coast Analytical Service  
WCAS

**Facility/Mailing Address:** 9240 Santa Fe Springs Road  
(no change) Santa Fe Springs, CA 90670

**Web Sites:** www.exovachemist.com www.wcas.com

**Markets Served:** Pharmaceutical, Supplements, Medical Devices, Environmental, Industrial Problem Solving, Product Testing such as CA Prop 65, RoHS, CPSC, and REACH, etc.

**Sample Types:** Raw materials, finished goods, food, tissue, blood, other body fluids, soil, sea sediment, water, waste, solvents, paints, low level radioactive, foreign soils, insects, plants, etc.

**Instrumentation:** ICPMS, ICP, XRF, Laser-Ablation ICPMS, LC-ICPMS, GC-ICPMS, GCMS/MS, LCMS/MS, GC, LC, IC, FTIR, NMR, Karl-Fischer, UV/Vis, Elemental, and others.

**Services Provided:** Trace organic and inorganic compounds, compound characterization by NMR, assays, impurities, CHN, identification by FTIR, pesticide residues, residual solvents, elemental speciation, product compliance, titrations, and more.

**Methods:** USP, EP, JP, EPA, ASTM, ACS, CARB, SCAQMD, NIOSH, AOAC, client specific methods, as well as in-house developed proprietary methods.

**For Accounting, Quality Assurance, and other information sheets please call Eric Lindsay at 562-948-2225, ext 300.**

### History

Exova Inc. is a privately held company consisting of over 130 testing laboratories located in over 25 countries. In October of 2008, Clayton, Dubilier, and Rice, Inc. (CD&R) purchased these laboratories from Bodycote PLC. This testing division was formerly known as Bodycote Testing Group. The specific location at 9240 Santa Fe Springs Road, Santa Fe Springs, California, was founded as West Coast Analytical Service, Inc. (WCAS) in 1984 and was purchased on February 1, 2006 by Bodycote PLC.

On June 16<sup>th</sup> 2009 the name was formally changed to Exova Inc.

### Client Services Contacts

#### Louis Albanese

Title: Client Services Director  
Phone: 562-948-2225, ext. 303  
Fax: 562-948-5850  
Email: louis.albanese@exova.com  
Address: 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670

#### Ann Hobbs

Title: Project Manager  
Phone: 562-948-2225, ext. 307  
Fax: 562-948-5850  
Email: ann.hobbs@exova.com  
Address: 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670

#### Eric Lindsay

Title: General Manager  
Phone: 562-948-2225, ext. 300  
Fax: 562-948-5850  
Email: eric.lindsay@exova.com  
Address: 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670

**Exova Call Center:** 866-263-9268  
sales@exova.com



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## Accounting Information

### Summary

This information is supplied due to our name/ownership change in 2008. Please contact us if the information you need is not listed as this information is specifically for the location listed below. We would like to emphasize that there may be other Exova locations that you do business with. If you have any questions about this transition we would be happy to help you. Rest assured that this change has no impact on our Quality Systems.

**Company Name:** Exova Inc

**Formerly Known As (FKA):** Bodycote Testing Group  
Bodycote Materials Testing  
Bodycote PLC  
West Coast Analytical Service Inc.  
WCAS

**Facility/Mailing Address:** 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670

**Remit to Address:** Exova Inc  
- US Mail ONLY -  
*(call for FedEx, UPS address)* Lockbox # 774214  
4214 Solutions Center  
Chicago, IL 60677-4002

**Wire Transfer Information:** Exova Inc  
**(EFT and ACH)** Account # 4121487573  
Wells Fargo Bank, NA  
San Francisco, CA  
*Please email* ABA-121000248  
*helen.briggs@exova.com* SWIFT - WFBIUS6S  
*when sent.*

**Payment:** Check, cash, bank trsfr, credit card  
**Terms:** Net 30 days  
**Tax Identification No.:** 04-3322068  
**Date Incorporated:** June 10, 1996  
**State Incorporated In:** Delaware  
**Dun & Bradstreet No.:** 12-660-1801  
**SIC Code:** 8734, Testing Laboratories  
**NAICS Code:** 541380, Laboratory Testing Services  
**CAGE Code:** OUGPO  
**NTIS Customer ID No:** 145033

Exova is a large business. We are not veteran, woman, or service-disabled veteran owned. Not small disadvantaged and not in a HUBZone.

### History

Exova Inc. is a privately held company consisting of over 130 testing laboratories located in over 25 countries. In October of 2008, Clayton, Dubilier, and Rice, Inc. (CD&R) purchased these laboratories from Bodycote PLC. This testing division was formerly known as Bodycote Testing Group. The specific location at 9240 Santa Fe Springs Road, Santa Fe Springs, California, was founded as West Coast Analytical Service, Inc. (WCAS) in 1984 and was purchased on February 1, 2006 by Bodycote PLC.

On June 16<sup>th</sup> 2009 the name was formally changed to Exova Inc.

### Accounting Contacts

#### Helen Briggs

**Title:** Office Manager  
**Phone:** 562-948-2225, ext. 224  
**Fax:** 562-948-5850  
**Email:** helen.briggs@exova.com  
**Address:** 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670

#### Suzanne Lizaso

**Title:** Administrative Assistant  
**Phone:** 562-948-2225, ext. 302  
**Fax:** 562-948-5850  
**Email:** suzanne.lizaso@exova.com  
**Address:** 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670

#### Eric Lindsay

**Title:** General Manager  
**Phone:** 562-948-2225, ext. 300  
**Fax:** 562-948-5850  
**Email:** eric.lindsay@exova.com  
**Address:** 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670

## Request for Taxpayer Identification Number and Certification

**Give Form to the  
requester. Do not  
send to the IRS.**

Print or type See Specific Instructions on page 2.	Name (as shown on your income tax return) <b>Exova, Inc.</b>	
	Business name/disregarded entity name, if different from above	
	Check appropriate box for federal tax classification (required): <input type="checkbox"/> Individual/sole proprietor <input checked="" type="checkbox"/> C Corporation <input type="checkbox"/> S Corporation <input type="checkbox"/> Partnership <input type="checkbox"/> Trust/estate  <input type="checkbox"/> Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=partnership) ▶ _____ <input type="checkbox"/> Exempt payee  <input type="checkbox"/> Other (see instructions) ▶ _____	
	Address (number, street, and apt. or suite no.) <b>194 Internationale Boulevard</b>	Requester's name and address (optional)
City, state, and ZIP code <b>Glendale Heights, IL 60139</b>		
List account number(s) here (optional)		

<b>Part I Taxpayer Identification Number (TIN)</b>																				
Enter your TIN in the appropriate box. The TIN provided must match the name given on the "Name" line to avoid backup withholding. For individuals, this is your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the Part I instructions on page 3. For other entities, it is your employer identification number (EIN). If you do not have a number, see <i>How to get a TIN</i> on page 3.																				
	<table border="1" style="margin: auto;"> <tr><th colspan="9">Social security number</th></tr> <tr><td> </td><td> </td><td> </td><td>-</td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </table>	Social security number												-						
Social security number																				
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<b>Note.</b> If the account is in more than one name, see the chart on page 4 for guidelines on whose number to enter.	<table border="1" style="margin: auto;"> <tr><th colspan="9">Employer identification number</th></tr> <tr><td>0</td><td>4</td><td>-</td><td>3</td><td>3</td><td>2</td><td>2</td><td>0</td><td>6</td><td>8</td></tr> </table>	Employer identification number									0	4	-	3	3	2	2	0	6	8
Employer identification number																				
0	4	-	3	3	2	2	0	6	8											

<b>Part II Certification</b>	
Under penalties of perjury, I certify that:	
1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me), and 2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding, and 3. I am a U.S. citizen or other U.S. person (defined below).	
<b>Certification instructions.</b> You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions on page 4.	
<b>Sign Here</b>	Signature of U.S. person ▶
	Date ▶ <u>March 02, 2011</u>

**General Instructions**  
Section references are to the Internal Revenue Code unless otherwise noted.

**Purpose of Form**  
A person who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) to report, for example, income paid to you, real estate transactions, mortgage interest you paid, acquisition or abandonment of secured property, cancellation of debt, or contributions you made to an IRA.

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN to the person requesting it (the requester) and, when applicable, to:

1. Certify that the TIN you are giving is correct (or you are waiting for a number to be issued),
2. Certify that you are not subject to backup withholding, or
3. Claim exemption from backup withholding if you are a U.S. exempt payee. If applicable, you are also certifying that as a U.S. person, your allocable share of any partnership income from a U.S. trade or business is not subject to the withholding tax on foreign partners' share of effectively connected income.

**Note.** If a requester gives you a form other than Form W-9 to request your TIN, you must use the requester's form if it is substantially similar to this Form W-9.

**Definition of a U.S. person.** For federal tax purposes, you are considered a U.S. person if you are:

- An individual who is a U.S. citizen or U.S. resident alien,
- A partnership, corporation, company, or association created or organized in the United States or under the laws of the United States,
- An estate (other than a foreign estate), or
- A domestic trust (as defined in Regulations section 301.7701-7).

**Special rules for partnerships.** Partnerships that conduct a trade or business in the United States are generally required to pay a withholding tax on any foreign partners' share of income from such business. Further, in certain cases where a Form W-9 has not been received, a partnership is required to presume that a partner is a foreign person, and pay the withholding tax. Therefore, if you are a U.S. person that is a partner in a partnership conducting a trade or business in the United States, provide Form W-9 to the partnership to establish your U.S. status and avoid withholding on your share of partnership income.

EXOVA CANADA INC. (and Subsidiaries) AND EXOVA INC., A DELAWARE CORPORATION (and Subsidiaries) STANDARD TERMS AND CONDITIONS OF CONTRACT ("the Conditions")

#### INTERPRETATION

1. In these Conditions the following expressions shall (unless the context requires) have the following meanings:

"Client" means the person, firm or company to whom a Quotation is addressed or for whom a Test or any Services is carried out;

"Company" means the member of Exova that is providing the Services, being any of Exova Canada Inc., Exova Inc. a Delaware corporation and/or any of their respective subsidiaries, as applicable;

"Contract" means these Conditions including the Quotation or Proposal which refer to these Conditions;

"Indemnified Persons" means the Company, its affiliates and subsidiaries, and its and their respective directors, officers, employees, agents, contractors and subcontractors;

"Price" means the price stated in the Quotation, or otherwise agreed with the Client in writing together with all other sums due pursuant to these Conditions;

"Proposal" means the Company's proposal of which these Conditions form a part and shall be deemed incorporated by reference as if fully set forth therein;

"Quotation" means the Company's quotation (whether written or oral) of which these Conditions form a part and shall be deemed incorporated by reference as if fully set forth therein ;

"Report" means any report, recommendation or the like issued by the Company in respect of the Services;

"Sample" means any material supplied by the Client to form the basis of a Test;

"Services" means the services specified in the Quotation or Proposal;

"Test" means any testing, analysis, assay or the like specified in a Quotation or Proposal;

"Test Certificate" means any test certificate, recommendation or the like issued by the Company in respect of a Test.

#### QUOTATION

2.1 The Quotation constitutes a revocable offer by the Company to provide Services and/or carry out a Test subject to the Conditions and is open for acceptance for ninety days only from the date thereof unless stated otherwise on the written Quotation or Proposal or unless revoked prior to acceptance. Acceptance by the Client must include written authorisation, including a Purchase Order, or advance payment.

2.2 Except in accordance with these Conditions no variation of the Contract will be accepted unless agreed in writing by the Company.

2.3 No condition, statement or representation contained in any advertisement or brochure or in any trade or promotional circular or other literature, nor the terms or conditions of any trade association or other body, or which would or might but for this sub-paragraph be implied or incorporated by custom or trade, usage, negotiations, course of dealing or otherwise shall be deemed to be incorporated in the Contract and all of the same are hereby expressly excluded from the Contract.

#### PRICE

3.1 The Price is based on information available to the Company at the date of the Quotation. If during the period of the Contract there shall be any variation in the cost of materials, labour or otherwise to the Company, the Price may, in the absolute discretion of the Company, be adjusted to take account of such variation.

3.2 In addition to the amount specified in the Quotation the following shall be in addition to the Price and payable if imposed on the Company or otherwise appropriate:

- (i) any applicable value added tax, excise tax, goods and services tax, sales tax, use tax or other applicable tax;
- (ii) all bank charges;
- (iii) package, insurance, freight and storage charges incurred on behalf of the Client, whether on the Company's premises or elsewhere, and to include storage charges on the Company's premises, if any Sample or materials supplied by the Client are not removed from the Company's premises within seven days of the date of notification to the Client that they are ready for collection;
- (iv) insurance incurred by the Company, in its absolute discretion, in respect of any property belonging to the Client in the possession of the Company;
- (v) the cost of all sub-contractors engaged by the Company unless included in the Quotation; and
- (vi) any additional costs incurred by the Company in accordance with these Conditions.

#### PAYMENT

4.1 The Price shall be paid to the Company in full without any deduction, set-off or counterclaim within thirty days of the date of the Company's invoice and in default of payment within the thirty days the Company may suspend any further Services and/or Tests being carried out for the Client and the amount outstanding from time to time shall bear interest (both before and after any judgment) at a rate equal to the lesser of 24% per annum or the maximum rate permitted by law until payment in full is made (a part of a month being treated as a full month for the purpose of calculating interest to the extent permitted by law). Late fees shall be in addition to (and not in lieu of) other remedies for default available to the Company.

4.2 All payments due to the Company shall be payable within the specified time irrespective of whether or not the Client has recovered payment from a third party and, for the avoidance of doubt, but without prejudice to the generality of the foregoing, this includes payments of fees due to the Company acting as experts or as expert witnesses when instructed by solicitors/attorneys acting for a party in a dispute.

4.3 The Company reserves the right not to initiate work or perform Services or Tests until acceptable credit terms have been established. Credit terms may include, payment of outstanding invoices, prepayments outlined in the Quotation and/or submission of a completed credit application by the Client including a release to allow the Company to draw upon a third party credit checking agency.

#### EXECUTION OF TESTS

5.1 The Test shall be carried out singly unless prior written instructions from the Client are received for replicates or unless the Company considers replicates are necessary or desirable. The Company reserves the right to charge for replicates even if the original result is confirmed.

5.2 The Client shall supply as much information as possible about each Sample in order to assist in achieving an efficient Service. Where Samples are incorrectly

described and the Company is involved in additional work, the Company reserves the right to charge for such additional work.

5.3 Unless specific prior instructions in writing are received by the Company, the Test shall be carried out on the Sample in the state in which the Sample is received. The Company reserves the right to charge for any work required to be carried out to the Sample prior to the performance of any Test.

5.4 Methods of carrying out the Test shall be at the sole discretion of the Company unless specific prior instructions in writing are received by the Client specifying a particular procedure which are agreed to by the Company. Charges for such special procedures will be negotiated and agreed to between the Company and the Client prior to carrying out the Test.

5.5 A general description of the method used in the Test shall be given verbally on request. Where written descriptions of detailed procedures are requested, whether as part of the Test Certificate or issued separately, the Company reserves the right to make an additional charge. If the method needed in the Test represents the end product of development work carried out at the Company's expense, the method shall only be revealed at the discretion of the Company.

5.6 If special standards or equipment are used in the Test, they shall be invoiced in addition to the charge of the Test itself.

5.7 The Company may, at its sole discretion, undertake to give priority in carrying out a particular Test. A surcharge may be imposed by the Company for the carrying out of priority work. (Details of these arrangements will be issued by the Company on request.)

#### SAMPLES SUBJECT OF LEGAL PROCEEDINGS

6. The Client shall notify the Company in writing if the Services to be performed are in support of pending or contemplated litigation prior to the Company commencing the Services. If that fact is not disclosed to the Company, the Company shall not necessarily be prepared to provide expert testimony. Should the Company be legally compelled to perform other work such as giving of evidence under a summons to witness the Client shall pay a fee based on standard hourly rates in effect.

#### DISCLAIMER OF LIABILITY AND LIMITATION OF WARRANTY

7.1 The Company's total liability (if any) to the Client (excepting always liabilities in respect of personal injury or death caused by the gross negligence or willful misconduct of the Company's operations), whether in contract, tort, delict, quasi delict, or otherwise in respect of any loss, direct or indirect or consequential, or damage (howsoever caused) directly or indirectly arising from any breach of Contract, or from any negligent act or omission of any Indemnified Person, or from any breach by any Indemnified Person of any duty owed to the Client in connection with the Contract shall be limited to the Price.

7.2 All Services and/or Tests are undertaken in good faith, to a reasonable standard of care and on a confidential basis. Reports and Test Certificates are issued on the basis of information known to the Company at the time the Services and/or the Tests are carried out. Although the Company will use all reasonable endeavors to insure accuracy the Company's achievements depend, inter alia, on the effective co-operation of the Client, its staff, and on the information and materials submitted to the Company. Save as required by law, no representation or warranty, whether expressed or implied or otherwise as to the accuracy of a Test Certificate or a Report is given by the Company. In consequence, all Reports and Test Certificates are prepared on the basis that:

- (i) there is no responsibility or liability to any person or body other than the Client;
- (ii) they are not carried out for any particular purpose and no statement is to be deemed, in any circumstances to be or give rise to a representation, undertaking, warranty or contractual condition unless specifically stated; and
- (iii) they are determined solely by the professional analysis undertaken by the Company's staff on each individual Contract and any forecasts by the Company of the results is an estimate only and the Company is entitled to be paid the Price irrespective of the results or conclusions reached.

7.3 All time limits, if any, are estimates and no undertaking is given to carry out the Services and/or Tests or to dispatch any Test Certification within any period of time.

7.4 The Company shall not be responsible or liable to the Client for the consequences of any delay in carrying out the Services and/or Tests or in delivering the Report and/or Test Certificate arising from any strike, lockout, trade dispute, accident, fire, inclement weather, flood, tempest, war, or act of God or any other matter or thing beyond its reasonable control.

7.5 No Indemnified Person shall be liable to the Client for any amount exceeding the Price arising from the inaccuracy of the results set out in a Test Certificate or Report hereunder.

#### OBLIGATIONS OF CLIENT

8.1 The Client shall not reveal or make available the details of any Report or Test Certificate to any third party (see also 10.2) without first obtaining the prior written consent of the Company, however the Company shall have the right to disclose all information it possesses regarding the Contract, the Services and the Test results if required by court order or valid subpoena and the Company shall incur no liability to the Client resulting from such disclosures.

8.2 The Client shall be bound to inform the Company in writing prior to the carrying out of any Test that a sample is of a dangerous or unstable nature and shall indemnify the Indemnified Persons from and against all loss or damage suffered by the Indemnified Persons, including, without limiting the generality of the foregoing, all damage to the Indemnified Persons' property and all claims in respect of injury to or deaths of any of the Indemnified Persons or of any third party, directly or indirectly arising from or in connection with the failure of the Client to inform the Company of the dangerous or unstable nature of a Sample.

8.3 The Client shall indemnify the Company from and against all loss or damage suffered or incurred by the Company, whether to or at the instance of the Client or its employees, sub-contractors or agents or third parties or otherwise directly or indirectly arising from or in connection with the carrying out of the Services and/or Tests except to the extent such loss or damage is caused by the gross negligence or willful misconduct of the Company.

8.4 Unless otherwise agreed the Client will be responsible for providing a safe system of work for the Company and its employees, agents and sub-contractors while providing Services and the Client shall be responsible for all costs necessarily required in discharging this obligation and shall indemnify the Indemnified Persons in respect of all claims, costs, damages, and loss suffered as a result of any breach by the Client hereof.

**RISK AND PROPERTY IN RELATION TO TESTS**

9.1 The risk of loss or damage to the Sample shall remain with the Client at all times.  
 9.2 Samples of a stable nature shall be retained for up to thirty days from the date of their receipt and then destroyed, or at the Company's option stored at the Client's expense unless otherwise agreed to in writing. Samples shall be returned to the Client only if prior instructions in writing in that regard are received by the Company and the Client shall be charged for all costs associated therewith (including carriage).  
 9.3 Where Samples are, in the sole opinion of the Company, too bulky or too unstable to allow long storage time, it will be at the absolute discretion of the Company as to the length of time such Samples are kept.  
 9.4 All copyright in chart records and other scientific, documentary or primary data produced during any Test and in all Reports or Test Certificates shall belong to and remain the property of the Company.  
 9.5 The Report or Test Certificate refers only to the particular Samples, units, materials, instruments and/or other subject used and referred to in it, and is limited by the Tests and/or analyses performed. Similar articles may not be of like quality, and other testing and/or analysis programs might be desirable and might give different results.  
 9.6 Client agrees to indemnify and hold the Indemnified Persons harmless from and against any liabilities or costs incurred by or threatened against any of the Indemnified Persons resulting from the Client's breach of its obligations in the Contract and for any disposal costs, fines or penalties incurred or imposed on any of the Indemnified Persons relating to the return or disposal of hazardous materials as defined by the law of the jurisdiction of the location of the Company's facility that is performing the Services. Client warrants that it will at all times comply with all applicable laws, including, without limitation, environmental laws, rules and regulations of appropriate governmental agencies and authorities in the jurisdiction of the location of the Company's facility that is performing the Services. If the Client intends to deliver a Sample that contains a hazardous substance, hazardous chemical, or the transmission, use or disposal of the same is regulated by the law ("Hazardous Material"), the Client agrees to notify the Company in advance of the delivery and agrees to comply with all applicable laws, rules and regulations respecting the delivery and handling of the same.

**OWNERSHIP, COPYRIGHT AND PATENTS IN RELATION TO SERVICES**

10.1 Ownership and copyright in the Report and any other Reports, results, or information established or collated by the Company in the course of the Services shall remain with the Company until the Client has discharged all its obligations under the Contract, including payment of the Price, whereupon the title, ownership and copyright shall pass to the Client unless the Company is forced to part with any such results, reports or information of any nature to any body exercising its statutory or judicial powers.

10.2 The Client hereby warrants that it will not use the Report or any other reports, results, or information supplied by the Company for the purposes of advertisement or publication to third parties. Any such issue of the Report or other reports, results or information is permitted under the Contract only with the prior written consent of the Company who shall have the right to increase the Price where it consents to such advertisement and/or publication. If consent is granted the Report or Test Certificate may be reproduced only in its entirety.

10.3 Unless otherwise indicated by the Client in writing, it is understood that electronic transfer (including fax, Email, etc.) of the Quotation, Report or Test Certificate by the Company is acceptable.

**SUB-CONTRACTING**

11. The Company shall be entitled, in its absolute discretion, to sub-contract the whole or any part of the Services and/or Test.

**TERMINATION**

12.1 The Client shall not terminate the Contract without the written consent of the Company which may be subject to such terms as in the Company's absolute discretion including compensating the Company for all loss it may suffer as a result of termination.

12.2 The Company may terminate the Contract and any other contract with the Client forthwith, without prejudice to any other right or remedy available to the Company and without the Company incurring any liability to the Client, in the following circumstances:

- (i) if the Client shall commit a breach of any terms of the Contract or any other contract with the Company unless such breach is capable of remedy and the Client has failed to comply with a notice regarding remedy within the period specified in the said notice;
- (ii) without prejudice to the foregoing, if the Client fails to make payment of the Price within the specified time;
- (iii) the Client makes any voluntary arrangement with its creditors or becomes subject to an administrator order or (being individual or firm) becomes bankrupt or insolvent or subject to any bankruptcy or insolvency law or proceedings or (being a company) goes into liquidation (otherwise than for the purposes of amalgamation or reconstruction);
- (iv) an encumbrancer takes possession, or a receiver is appointed, of any of the property or assets of the Client;
- (v) the Client ceases, or threatens to cease, to carry on business; or,
- (vi) the Company reasonably believes that any of the events mentioned at (iii), (iv), and (v) above is about to occur in relation to the Client and notifies the Client accordingly.

12.3 Other than as required by law, upon termination of the Contract by the Company pursuant to Section 12.2, the Company shall have no further obligations under the Contract including any obligation to perform the Services or any Test; provided, however, that, notwithstanding such termination: (i) the Client shall remain liable to the Company for all amounts payable to the Company under the Contract in respect of the period up to and including the effective date of such termination; and (ii) the provisions of Sections 1, 7.1, 7.2, 7.4, 7.5, 8.1, 8.2, 8.3, 8.4, 9.1, 9.4, 9.6, 10.1, 10.2, 12.1, 12.2, 12.3 and Sections 13 to 17 (inclusive) shall survive any such termination. In the event of termination of the Contract under Section 12.2, or in the event that the Company institutes legal proceedings for the enforcement or interpretation of the provisions of this Contract, the Client agrees to reimburse the Indemnified Persons for the Indemnified Persons' reasonable legal fees and court costs incurred in connection therewith.

**NOTICES**

13. All notices to be served by one party on the other shall be deemed duly delivered or served five business days after posting if posted by first class or airmail pre-paid

post to the address of the other party or on the same day as transmission if sent by facsimile.

**GENERAL**

14. In the event of one or more of the provisions of these Conditions being held by a competent authority to be invalid, illegal, or unenforceable, in whole or in part, the validity, legality or enforceability of the remaining provisions of these Conditions and the remainder of the provision in question shall not be affected thereby.

15. No waiver by the Company of any breach of the Contract by the Client shall be considered as a waiver of any subsequent breach of the same or any other provision.

16. The construction, validity, and performance of the Contract shall be governed by and enforced under the laws of the Province (or State if in the United States of America) in which the Company's facility issuing the Report or Test Certificate is located. Any claims made against the Company will only be heard in the jurisdiction in which the Company's facility issuing the Report or Test Certificate is located.

17. The Contract contains the entire agreement between the Company and the Client with respect to the subject matter hereof and supersedes all prior agreements, Quotations, Proposals and other communications relating to the subject matter hereof and there are no other understandings or agreements, verbal or otherwise, in relation hereto between the Company and the Client. This Contract will control over any contradictory or inconsistent provision contained in any document provided by the Client unless expressly referred to in the Contract.

**18. ADDITIONAL REQUIREMENTS ON COMPANY'S WEBSITE.**

(a) The Company's Internet website, <http://www.exova.ca>, may contain specific additional requirements for certain items covered by this Contract, including specifications, procedures, directions and/or instructions. Any such requirements are hereby incorporated by reference herein, shall be deemed to form part of this Contract and are binding on the Client and the Company. The Company may periodically update such requirements by posting revisions thereto on its Internet website and, in such event, the Company will notify the Client of such updates and revisions. In the event of any inconsistency between this Contract and the Company's Internet website, the terms of this Contract shall prevail, unless the requirements specified on such website expressly provide otherwise.

(b) The Company may modify these Conditions with respect to future Quotations, Proposals and purchase orders, at any time and from time to time, by posting revised terms and conditions to its Internet website, at <http://www.exova.ca> and such revised Conditions shall apply to all Quotations, Proposals and purchase orders issued thereafter.

**THE COMPANY MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, EXCEPT AS IS EXPRESSLY SET FORTH HEREIN, ALL SUCH OTHER WARRANTIES BEING HEREBY DISCLAIMED.**

\_\_\_\_\_  
 Company

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Name

\_\_\_\_\_  
 Title

\_\_\_\_\_  
 Date

*By signing Client agrees to the above Terms and Conditions.*



## Application for Credit

(Terms are NET 30)

**BILLING INFORMATION:**

Legal company name \_\_\_\_\_

Trade name (if any) \_\_\_\_\_

Parent company (if any) \_\_\_\_\_

GST number \_\_\_\_\_ Initial Order USD \$ \_\_\_\_\_

Bill to: Attention \_\_\_\_\_

Street address \_\_\_\_\_ City \_\_\_\_\_

State \_\_\_\_\_ Country \_\_\_\_\_

Zip Code \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

**PRINCIPALS AND OFFICERS:**

*Circle one:* Ownership of company is Private / Public Date Incorporated: \_\_\_\_\_

Name: President/Owner 1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

Controller \_\_\_\_\_

Accounts payable \_\_\_\_\_

**BUSINESS INFORMATION:**

Nature of business \_\_\_\_\_

*Circle one:* Building/Premises are Owned / Leased

**REFERENCES:**

Reference Trade name	Mailing Address, Postal code
1. _____	_____
Phone No: _____	Fax: _____ Acct. No. _____
2. _____	_____
Phone No: _____	Fax: _____ Acct. No. _____
3. _____	_____
Phone No: _____	Fax: _____ Acct. No. _____

**BANK:** Name \_\_\_\_\_ Contact \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_



**CREDIT AGREEMENT:**

In reliance on the statements and representations above and on the agreement set below. Exova Inc may from time to time and at the sole discretion of its Credit Department, extend credit to the firm named in this Agreement with regard to purchases by such firm, from or through Exova Inc of goods and services.

If credit is extended, the firm named in the Agreement agrees with Exova Inc as follows:

1. The firm will pay when due, according to the terms of all bills, statements, accounts and invoices from Exova, any such payment to be made to Exova at its office, or any such other place or places Exova may direct.
2. That all past-due accounts shall bear the maximum legal rate of interest.
3. That the firm agrees to pay any reasonable attorney fees and court costs incurred in any efforts to enforce payment of sums due by the company or to collect the same.
4. That Exova Inc at its sole discretion, at any time, cease further extensions of credit to the firm.
5. That any firm with returned or stop payment cheques will be placed on C.O.D. Cashiers Cheque only terms, indefinitely.

**THE ABOVE INFORMATION AS WELL AS THAT GIVEN ON THE ENTIRE CREDIT APPLICATION DOCUMENT IS FOR THE PURPOSE OF OBTAINING CREDIT AND IS WARRANTED TO BE TRUE UNDER PENALTY OF PERJURY. I/WE AUTHORIZE EXOVA INC TO INVESTIGATE THE REFERENCES LISTED AND PERFORM A GENERAL CREDIT CHECK AS IT PERTAINS TO THE APPLICANT'S CREDIT FINANCIAL RESPONSIBILITY.**

Company Name: \_\_\_\_\_ (required)

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

Print Name: \_\_\_\_\_ Date: \_\_\_\_\_

**When complete please fax both pages of credit application and both pages of the signed Terms & Conditions to 562-948-5850 or email to helen.briggs@exova.com**



### Confidentiality Agreement

\_\_\_\_\_ and Exova Inc. are prepared to exchange information to determine the feasibility of working together in the area of testing services, (the "Program") and it will be necessary for both parties to disclose to each other certain valuable business, technical and/or trade secret information relating to the above. Such valuable business, technical and trade secret information shall be marked as confidential, or if disclosed orally, shall be confirmed in writing as confidential within thirty (30) days of its disclosure to be considered as "Confidential Information". It is agreed that each disclosing party is willing to disclose such Confidential Information under the conditions specified below:

1. Each receiving party agrees to maintain in confidence for a period of ten (10) years from the date of this Agreement, all Confidential Information disclosed by the other party and not to publish or otherwise divulge said Confidential Information, in whole or in part, to any third party, and not to make use of said Confidential Information other than in relation to the Program without the written consent of the disclosing party. This obligation shall not apply to:
  - (a) Confidential Information which is now or hereafter becomes public through no action or omission of the receiving party;
  - (b) Confidential Information which the receiving party can show by written records was in its possession at the time of the disclosure, or was developed independently of any Confidential Information received from the disclosing party;
  - (c) Confidential Information which was disclosed to the receiving party by a third party having no obligation of confidentiality to the disclosing party with respect to such Confidential Information.

No aspect of the Confidential Information shall be deemed to be or to have been in the public domain or in the receiving party's possession because it is embraced by more general public information, or because unrelated parts may be found in the public domain or in the possession of the receiving party.

2. If either party learns that it is already in possession of all or any part of the Confidential Information disclosed concerning the Program, that party will arrange for evidence of this and its source to be given to the other party within fifteen (15) days to avoid any subsequent risk of dispute unless and to the extent that either party is prevented from doing so by any condition subject to which they received such information.
3. A receiving party may disclose Confidential Information to the extent required by law, however, prior to such disclosure the receiving party must give the disclosing party prompt notice of the request for disclosure to allow the disclosing party sufficient time to make a reasonable effort to obtain a protective order or other appropriate remedy to prevent such disclosure.
4. Each receiving party agrees that it shall restrict disclosure of the Confidential Information within its own organization to those persons having a need to know it for the purposes of this Program, and that such persons shall be bound by the obligations set forth in this Agreement.
5. Documents, drawings, prototypes, disks, tapes, and all other material bearing, containing, disclosing or relating to Confidential Information furnished by either party shall remain the property of the disclosing party, and shall be returned upon request of the disclosing party.
6. Nothing contained in this Agreement shall be construed as granting or conferring any rights, either express or implied, under any intellectual property rights, or any rights to use any Confidential Information made available hereunder other than for the limited purposes specified.
7. In providing Confidential Information, the disclosing party makes no representation or warranty, express or implied, as to its adequacy, sufficiency, fitness for any purpose or freedom from defect of any kind, including, without limitation, freedom from patent infringement that may result from use of the Confidential Information.
8. Nothing contained in this Agreement is intended to create any sponsored research, assignment, license, technology transfer, joint venture, partnership or agency relationship between the parties.
9. Nothing contained in this Agreement is intended to limit or preclude either party from dealing with others concerning the subject matter of this Agreement, provided that the terms of this Agreement are not breached.
10. Nothing contained in this Agreement shall obligate the parties either to negotiate or enter into any future business arrangement. If, as a result of the discussions contemplated under this Agreement, the parties decide to enter into a business arrangement, then such arrangement will be the subject of a separate negotiation between the parties.
11. This Agreement shall be construed, interpreted and applied in accordance with the laws of the State of California, USA.

**Exova Inc.**

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

\_\_\_\_\_  
Michael Hincks, V.P., Health Sciences

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

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

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

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



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## Quality Assurance Information

### Summary

For copies of our QA Manual, many of our SOPs, and certifications please visit [www.exovachemist.com](http://www.exovachemist.com). The information below is supplied to assist you in preparation for an audit or completing regulatory required documents. Please contact us if the information you need is not on our web site or listed below. This information is specifically for the location listed below as there may be other Exova locations that you do business with.

<b>New Company Name:</b>	Exova Inc
<b>Formerly Known As (FKA):</b>	Bodycote Testing Group Bodycote Materials Testing Bodycote PLC West Coast Analytical Service WCAS
<b>Facility/Mailing Address:</b> <i>(no change)</i>	9240 Santa Fe Springs Road Santa Fe Springs, CA 90670
<b>FDA Registration No:</b> <i>(human and veterinary drugs and medical devices)</i>	2030726 / 3000203007 <i>Last inspected Dec. 2010, no Form 483 issued.</i>
<b>cGMP Compliant:</b>	Yes, upon request
<b>cGLP Compliant:</b>	Yes, upon request
<b>ISO 9001 Compliant:</b>	Quality systems are compliant
<b>ISO/IEC 17025 Compliant:</b>	with these standards.
<b>USDEA Regulated Drugs Lic:</b> <i>(Schedule 1,2,2N,3,3N,4,5)</i>	RB0366927
<b>Environmental Certifications:</b>	
<b>California ELAP No:</b>	2652
<b>Washington DOE No:</b>	C2051
<b>LACSD Wastewater ID No:</b>	10144
<b>Radioactive Materials Lic (CA):</b>	6119-19
<b>USDA Permit to Move Soils:</b>	S-55628
<b>USDHHS Permit No:</b> <i>(Import or Transfer of Etiological Agents or Vectors of Human Disease)</i>	2001-11-55

**For copies of above please visit [www.exovachemist.com](http://www.exovachemist.com) and select the specific links to the right of this web page.**

### History

Exova Inc. is a privately held company consisting of over 130 testing laboratories located in over 25 countries. In October of 2008, Clayton, Dubilier, and Rice, Inc. (CD&R) purchased these laboratories from Bodycote PLC. This testing division was formerly known as Bodycote Testing Group. The specific location at 9240 Santa Fe Springs Road, Santa Fe Springs, California, was founded as West Coast Analytical Service, Inc. (WCAS) in 1984 and was purchased on February 1, 2006 by Bodycote PLC.

On June 16<sup>th</sup> 2009 the name was formally changed to Exova Inc.

### QA Contacts

#### Lorraine Shelton, ASQ CQA

Title: QA Officer  
Phone: 562-948-2225, ext. 107  
Fax: 562-948-5850  
Email: [lorraine.shelton@exova.com](mailto:lorraine.shelton@exova.com)  
Address: 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670

#### Mike Shelton

Title: Technical Director  
Phone: 562-948-2225, ext. 602  
Fax: 562-948-5850  
Email: [mike.shelton@exova.com](mailto:mike.shelton@exova.com)  
Address: 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670

#### Eric Lindsay

Title: General Manager  
Phone: 562-948-2225, ext. 300  
Fax: 562-948-5850  
Email: [eric.lindsay@exova.com](mailto:eric.lindsay@exova.com)  
Address: 9240 Santa Fe Springs Road  
Santa Fe Springs, CA 90670



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## 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: \_\_\_\_\_



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## FDA Scope of Work Definitions

### Summary

The FDA has made it very clear to industry that any testing results obtained for cGMP regulated materials must be annotated when testing is not performed using a validated method, annually qualified instrument, or software that has not been challenged to meet the data integrity requirements of 21CFR/Part11. Data derived from a USP/NF/FCC monograph method is compliant if performed on an annually qualified instrument with software that has been challenged. Methods must be validated to the requirements of ICH Q2/R1 and must be matrix specific. It is also the testing facility's responsibility to obtain from the test requestor confirmation of whether the test article is a cGMP regulated material or not. This document is our understanding of the regulations so please check with your regulatory department on how you should proceed with your specific product or requirements.

### Test Articles within the Scope of cGMP

(Requires testing per compendial or validated methods performed on annually requalified instruments with software that has been challenged per 21CFR/Part11.)

Drug Products, API Substances, and Raw Materials as follows:

- Phase II Clinical Trials (depending on toxicity)
- Phase III Clinical Trials
- Phase IV Clinical Trials
- New Drug Application (NDA)
- Being sold on the open market

- Dietary Supplements for Consumption
- Human Blood Testing
- Cosmetics that are also a drug
- Soaps regulated as a drug

### Programs/Products that are not within the Scope of cGMP

(Does not require method validation but would recommend operational qualified instrumentation and software that has been challenged per 21CFR/Part11.)

The following activities may not be within the scope of cGMP regulations. We highly suggest that you confirm with either your Regulatory Affairs Department or the FDA whether or not your program/material is regulated by the FDA under cGMP regulations.

- Research & Development
- Cleaning Validations
- Manufacturing Process Development
- Drug Products, API, Substances, and Raw Materials as follows:
  - Pre-clinical Studies
  - Phase 0 Clinical Trials - IND
  - Phase I Clinical Trials
  - Phase II Clinical Trials (depending on toxicity)
  - Cosmetics that are not also a drug
  - Soaps, if regulated as a cosmetic and not a drug

### If you have a question, please contact one of the following

#### Louis Albanese

Title: Client Services Director  
Phone: 562-948-2225, ext. 303  
Email: louis.albanese@exova.com

#### Mike Shelton

Title: Technical Director  
Phone: 562-948-2225, ext. 602  
Email: mike.shelton@exova.com

#### Lorraine Shelton

Title: Quality Assurance Officer  
Phone: 562-948-2225, ext. 107  
Email: lorraine.shelton@exova.com



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## Data/Sample Storage Information

### Summary

Due to storage limitations, we are unable to store client data past 7 years and samples past 30 days after invoicing. We will also only be able to store data on-site for 3 years. Data over 3 years old will be transferred to an off-site facility and then disposed of after 7 years. The 7 year time frame was chosen after reviewing regulatory requirements. If you require your data to be archived past 7 years, we suggest that you order a complete raw data package at the time the testing is performed. This complete raw data package will provide you with copies of all pertinent documents, chromatograms, spectra, etc. so that you may archive them in accordance with your company's policies. Samples will be disposed of unless they are high hazard or you have requested them to be returned to you. Costs for data retrieval and sample return are listed below.

### Exceptions

The following data will be stored indefinitely: Method Transfers and Validations, Equipment Qualifications, Software Validations, Employee Training Records, Instrument Log Books, Standard Operating Procedures, and Electronic Instrument Data. In exceptional cases, samples may be stored past 30 days if requested in writing, space is available, and storage fees are paid six months in advance. In general storage fees are \$50 per sample per month.

### Data Retrieval and Sample Return Charges

#### Data Retrieval:

Report only <sup>1</sup>	No charge
Raw Data, under 3 years old <sup>2</sup>	\$100 plus 25% of original testing charges
Raw Data, over 3 years old <sup>3</sup>	\$150 plus 25% of original testing charges
Raw Data, copy of previously supplied, under 3 years old <sup>1</sup>	\$150
Raw Data, copy of previously supplied, over 3 years old <sup>2</sup>	\$200

1 - Please allow 2 working days.      2 - Please allow 5 working days.      3 - Please allow 8 working days.

**Data retrieval will be expedited to the best of our ability for regulatory inspection requests.**

#### Sample Return:

< one pound, by UPS Ground, and within the United States	\$25
> one pound, by UPS Ground, and within the United States	\$25 plus UPS weight charges
Within the United States, using Client's shipping account	No charge unless special packaging required
Outside the United States	\$25 plus shipping charges
Outside the United States, using Client's shipping account	No charge unless special packaging required

**Samples are stored for 30 days past invoice and then disposed of, unless sample return is requested in the original documents submitted with the sample(s).**

### Data Storage and Sample Return Contacts

#### Louis Albanese

Title: Client Services Director  
Phone: 562-948-2225, ext. 303  
Email: louis.albanese@exova.com

#### Ann Hobbs

Title: Project Manager  
Phone: 562-948-2225, ext. 307  
Email: ann.hobbs@exova.com

#### Lorraine Shelton

Title: Quality Assurance Officer  
Phone: 562-948-2225, ext. 107  
Email: lorraine.shelton@exova.com



# ANALYTICAL REQUEST FORM

9240 Santa Fe Springs Road, Santa Fe Springs, CA 90670  
www.exovachemist.com

562.948.2225  
Fax 562.948.5850

Send Report To

Send Invoice To

Contact: \_\_\_\_\_

AP Contact: \_\_\_\_\_

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

Address: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Project: \_\_\_\_\_

Email: \_\_\_\_\_

Purchase Order: \_\_\_\_\_

Phone : \_\_\_\_\_ Fax: \_\_\_\_\_

Phone : \_\_\_\_\_ Fax: \_\_\_\_\_

**Turnaround Time (business days):**  
**Date Data Due:** \_\_\_\_\_

**Normal 10 days** (routine analysis)  
**Rush 5 days**  
**Rush 3 days**  
**Rush 1 day**

} rush fees  
will apply

**Pharmaceutical, Medical Device, or  
Supplements data to be used for:**  
Research & Dev (not submitted to FDA)  
Internal use only and/or Non FDA  
Regulatory Submission to FDA  
Product/Raw Material Regulated by FDA

**Storage  
Conditions**  
Room Temp  
2 to 8° C  
-10 to -25° C  
Other \_\_\_\_\_

**Raw Data Requested**  
(\* additional fees)  
Normal Report  
Raw Data\*  
GMP Data Package\*  
Other (list below)

**DEA Controlled Substance/Chem: Sched - \_\_\_\_\_**

**Radioactive Material \_\_\_\_\_ mCi** (license limit = 10 mCi, samples will be returned)

To ensure compliance with GMP requirements, non-compendial test methods must be transferred and/or validated. Method transfer and/or validation services are available on request and are the responsibility of the client. Where method transfer and/or validation have not occurred reports will indicate "method not validated for this matrix at this facility."

### Comments and Precautions (MSDS Must be included with all samples)

Sample Identification for Report	Matrix/Product	Analysis(es)

Relinquished by: _____	Company: _____	Date _____	Time _____	Received by: _____	Company: _____
Relinquished by: _____	Company: _____	Date _____	Time _____	Received by: _____	Company: _____

NOTES: Samples will be disposed of 30 days after invoicing, except for regulated substances and radioactive samples which will be returned at the client's expense. All services provided will adhere to Exova Inc Terms & Conditions.

Job No.: \_\_\_\_\_



# ANALYTICAL REQUEST FORM

9240 Santa Fe Springs Road, Santa Fe Springs, CA 90670  
www.exova.com www.exova.ca www.wcas.com

562.948.2225  
Fax 562.948.5850

Send Report To

Send Invoice To

Contact: \_\_\_\_\_ AP Contact: \_\_\_\_\_  
 Company: \_\_\_\_\_ Address: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 Email: \_\_\_\_\_ Purchase Order: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

<b>Turnaround Time (business days):</b> <b>Date Data Due:</b> _____ <input type="checkbox"/> <b>Normal 10 days</b> (routine analysis) <input type="checkbox"/> <b>Rush 5 days</b> <input type="checkbox"/> <b>Rush 3 days</b> <input type="checkbox"/> <b>Rush 1 day</b>	<b>Pharmaceutical, Medical Device, or Supplements data to be used for:</b> <input type="checkbox"/> Research & Dev (not submitted to FDA) <input type="checkbox"/> Internal use only and/or Non FDA <input type="checkbox"/> Regulatory Submission to FDA <input type="checkbox"/> Product/Raw Material Regulated by FDA	<b>Storage Conditions</b> <input type="checkbox"/> Room Temp <input type="checkbox"/> 2 to 8° C <input type="checkbox"/> -10 to -25° C <input type="checkbox"/> Other _____	<b>Raw Data Requested</b> (* additional fees) <input type="checkbox"/> Normal Report <input type="checkbox"/> Raw Data* <input type="checkbox"/> GMP Data Package* <input type="checkbox"/> Other (list below)
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**DEA Controlled Substance/Chem: Sched - \_\_\_\_\_**  **Radioactive Material \_\_\_\_\_ mCi** (license limit = 10 mCi, samples will be returned)

To ensure compliance with GMP requirements, non-compendial test methods must be transferred and/or validated. Method transfer and/or validation services are available on request and are the responsibility of the client. Where method transfer and/or validation have not occurred reports will indicate "method not validated for this matrix at this facility."

**Comments and Precautions (MSDS Must be included with all samples)**

Sample Identification for Report	Matrix/Product	Analysis(es)

Relinquished by: _____	Company: _____	Date: _____	Time: _____	Received by: _____	Company: _____
Relinquished by: _____	Company: _____	Date: _____	Time: _____	Received by: _____	Company: _____

NOTES: Samples will be disposed of 30 days after invoicing, except for regulated substances and radioactive samples which will be returned at the client's expense. All services provided will adhere to Exova Inc Terms & Conditions.

Job No.: \_\_\_\_\_