Life Sciences Product Recall Application

SIGNAL UNDERWRITING

Please complete this application in its entirety, as the responses given are material to the provision of terms. There is space for more details in the Additional Information Section at the end of the application. Coverage(s) may be provided on a claims-made basis.

Named Insured: _____

Street Address: _____

City: _____ Province: _____ Postal Code: _____

Contact: _____ Email: _____ Phone: _____

Section 1: About Your Organization

1. What year was your organization established: _____
2. Is your organization incorporated? Yes O No O
3. Do you expect a material change in your operations in the next 12 months? If Yes, please provide details.* Yes O No O
4. Please list any subsidiaries or related entities of your organization that are controlled by or control your organization:

Entity Name	Description of Operations	Relationship to Named Insured

Section 2: Operations and Sales

1. Please provide a complete description of your operations:

2. Please provide your sales breakdown by product category and provide the geographical region:

Product	Percent (%) of Total Sales	Geographical Region
Brand Name Drugs		
Generic Drugs		
Homeopathic Medicines		
Medical Devices		
Nutraceuticals		
Over-the-Counter Drugs		
Topicals/Cosmetics		
Other:		

3. Please indicate your estimated sales: _____
4. What is your total number of manufacturing plants/facilities? _____
5. What is the estimated revenue of the largest plant/facility? _____
6. Have you agreed to indemnify or hold harmless or allow contractual restrictions to the liability of your suppliers of products, goods, or services, or contract manufacturers in respect of recall and replacement costs, brand rehabilitation costs, and/or business interruption costs? If Yes, please provide details.* Yes O No O
7. Have you had any plant closures, riots, strikers, or work stoppages in the last 3 years? If Yes, please provide details.* Yes O No O
8. Have you ever been a direct target of environmental, political, racial, or other extremist or special interest group? If Yes, please provide details.* Yes O No O
9. Do you import or export with any volatile country or undertake other activities which might make you a target of extremist or special interest groups? If Yes, please provide details.* Yes O No O
10. Do you pay for animal testing of any of your products? If Yes, please provide details.* Yes O No O

*Please provide further details in the space provided under the Additional Information Section.

Section 3: Product Information

1. Please list any new products that have either begun production or brought to market in the last 12 months:

2. What percentage of your products are made for a third party under a contract manufacturing agreement? _____
3. What percentage of your products are an ingredient and/or component of another product? _____
4. What percentage of your products are sold as a finished product but are contract packaged for a third party? _____
5. What percentage of your products are manufactured by a contract manufacturer? _____
6. Please provide the following information on your top 3 selling products:

Product Name:			
Product Type:			
Is it a Finished Product?			
Is it an Ingredient or Component?			
Is it an Ingredient of Another Product?			
Shelf Life (weeks, months, years):			
Packaging Type (please specify):			
Annual Sales Volume:			
Daily Production Volume in $CAD:			
Daily Production in Units:			
Plant Locations Where Produced:			
Number of Production Lines Used:			
Failure Rate (% of PPM):			
Value of Largest Batch in $CAD:			

Section 4: Quality Control and Quality Assurance

1. Do you have a documented and active Quality Control (QC) and Quality Assurance (QA) programs? Yes O No O
2. Do your QC and QA programs comply with Health Canada Good Manufacturing Practices (GMP)? Yes O No O
3. When was the date of your last GMP audit? _____
4. If you are selling into the U.S.A., do your QC and QA programs comply with the FDA cGMPs and incorporate FDA Guidance, Guidance for Industry, and Q9 Quality Risk Assessment for all products? Yes O No O
5. If Yes to 4., please provide date they were last updated: _____
6. Do you QC and QA programs incorporate a Quality Risk Management Process? Yes O No O
7. Do you use allergens as part of your QC and QA processes? If Yes, please provide details.* Yes O No O
8. Do you have an Allergen Management Program in place to prevent cross contamination? Yes O No O
9. Do you have a full-time QC and QA department(s)? Yes O No O
10. Who is responsible for overseeing and implementing your GMPs/cGMPs? _____
11. Is the person in 10., dedicated full time to overseeing and implementing GMP/cGMPs? If No, please provide details.* Yes O No O
12. Please indicate if you audited to confirm compliance of manufacturing or distribution with the regulatory requirements of:
    a. Health Canada: Yes O No O
    b. Food and Drug Administration: Yes O No O
    c. European Medicines Agency: Yes O No O
    d. Other: Please provide details.* Yes O No O
13. How often are audits performed? _____
14. Are audits performed at all of your sites? Yes O No O

*Please provide further details in the space provided under the Additional Information Section.

15. Have you had any critical and/or major recommendations that have not been implemented? If Yes, please provide details.* Yes O No O
16. Do you require your suppliers to follow QC and QA standards that include GMPs/cGMPs and Quality Risk Management? If No, please indicate what other steps are taken.* Yes O No O
17. Do you have a formal process to assess the QC and QA standards of your suppliers, including such things as audits, inspection reports, references, questionnaires? If No, please indicate what steps are taken.* Yes O No O
18. Do you receive certificates of product conformance or certificates of analysis from your suppliers? Yes O No O
19. What position within your company determines whether a supplier is approved?
20. Please indicate the type of testing that you conduct on the following:

Product Test Type	Raw Materials	In-Line	End of Line
Chemical			
Metal Detectors			
Microbiological			
Physical			
X-Ray			

21. Do you have an in-house testing laboratory? If Yes, please provide the tests that are conducted below: Yes O No O

22. Do you use an outside testing laboratory? Yes O No O
23. If Yes to 21., is it open 24 hours per day? Yes O No O
24. If Yes to 21., are they accredited to ISO EN 17025? Yes O No O
25. If Yes to 21., please provide their name and address:

26. Do you have a hold period prior to shipping your product? Yes O No O
27. Do you have a positive release procedure in place? Yes O No O
28. Do you have an incoming quarantine process in place? Yes O No O
29. Are all of your product labels inspected? Yes O No O
30. If Yes to 29., please indicated when they are inspected and who conducts the inspection:

31. Do you collect and monitor customer complaints? Yes O No O
32. If Yes to 31., please indicate how you collect these complaints:

Section 5: Product Recall Plan

1. Do you have a formal written and active product recall plan? Yes O No O
2. Do you have a formal product recall team in place? Yes O No O
3. Have you tested your product recall plan in the past 12 months? Yes O No O
4. Have all members of the product recall team be trained in the past 12 months? Yes O No O
5. Do you have a formal written and active malicious product tampering/product defense plan? Yes O No O
6. Do you have a formal malicious product tampering/product defense team in place? Yes O No O
7. Have all members of the malicious product tampering/product defense team been trained within the past 12 months? Yes O No O

*Please provide further details in the space provided under the Additional Information Section.

8. Have your products or any of your premises been the subject of comment or complaint by any government agency or department? If Yes, please complete the following: Yes ☐ No ☐

Which Agency or Department?	
Date and Nature of Comment or Complaint:	
Outcome of Comment or Complaint:	
Date Resolved:	

Section 6: Claims History

1. Have you ever had a claim against your organisation's product recall insurance policies? If Yes, please provide details including date of loss, amount paid or held in reserve, and description of allegation.* Yes ☐ No ☐
2. Are you aware of any incidents or circumstances that could potentially give rise to a claim? If Yes, please provide details.* Yes ☐ No ☐
3. Are you aware of any actual, threatened, or suspected product tampering involving any of your products in the past 12 months? Yes ☐ No ☐
4. Have any of your products been recalled due to an accidental contamination and/or malicious tampering in the last 10 years? If Yes, please provide details, including division, product, reason for recall, date of recall, recall method used, and cost of recall.* Yes ☐ No ☐
5. Have any of your contracts been cancelled, lost or discontinued as a result of a recall? If Yes, please provide details.* Yes ☐ No ☐

Section 7: Additional Information

1. Please provide the following with your application:
   a. Recall Plan
   b. Crisis Management Plan
   c. Quality Control and Quality Assurance Program Policy
   d. Malicious Tampering Plan / Product Defence Plan
   e. GMP/cGMP Audit Report

   Attached ☐

Section 8: Prior Insurance

2. Have you ever been declined coverage, cancelled or non-renewed for insurance requested in this application? Yes ☐ No ☐
3. Please provide details of your expiring insurance policy:

Coverage	Insurer	Limit	Aggregate	Deductible	Retroactive Date	Premium
Product Recall						

Section 9: Requested Insurance Coverage

1. Please indicate the coverage limit, aggregate, retroactive date, and deductible are requested:

Coverage	Limit	Aggregate	Deductible	Retroactive Date
Product Recall				

Privacy Policy

By signing this form, you are consenting to the collection, use, disclosure, and retention of your personal information for the purposes of underwriting and rating, policy issuance, processing and remitting premium, reporting claims, complying with applicable laws and governing bodies, reporting and monitoring results and fraud and criminal prevention. Please see www.signalunderwriting.com/privacy-statement for our External Privacy Policy.

Declarations

I/We, the undersigned, do declare and warrant that all statements and responses provided in this application and the attached addenda are to the best of my/our knowledge are true. Further, I/we warrant that no information has been withheld, suppressed or misstated any material facts that the underwriters may come to rely upon. I/We will notify the underwriters as soon as practicable if anything material is to change. I/We hereby agree and accept that this Declaration shall be the basis of such contract and will form part of the policy. Signing this application does not bind the underwriters or insurers to complete the insurance, nor does it bind the me/us to purchase the quoted coverage.

*Please provide further details in the space provided under the Additional Information Section.

For British Columbia residents: SIGNAL Underwriting Inc. operates as SIGNAL Underwriting Services in British Columbia.
For Quebec and New Brunswick residents: Signing this Declaration confirms your request that all documentation and correspondence pertaining to the insurance coverage be in the English language.

Name (please print)	Title	Date

Signature

Additional Information Section

Please use this space to provide any additional information from the questions above, from the addenda or anything you feel is material to your operations:

*Please provide further details in the space provided under the Additional Information Section.

Life Sciences Product Recall Application Addenda

Please complete the section(s) relevant to your operations.

Addendum: Medical Device Addendum

1. Please indicate your percentage of sales by class of medical device:

Class I	Class II	Class III	Class IV

2. Are any of your products permanently invasive or intended to be introduced into the human body for more than 6 months?	Yes	O	No	O
3. If Yes to 2., what proportion of your sales relates to these products?				
4. What percent of your products (by sales volume) do you have full design responsibility for?				
5. Do you conduct your design work in-house?	Yes	O	No	O
6. Do you contract out your design work to a third party? If Yes, please provide their name and details.*	Yes	O	No	O
7. If Yes to 6., do you hold them harmless or limit their liability?	Yes	O	No	O
8. Specific to medical devices, do you use contract manufacturers?	Yes	O	No	O
9. If Yes to 8., please indicate the what portion of your sales volume is produced by these third parties:				
10. If Yes to 8., do you hold these third parties harmless or limit their liability?	Yes	O	No	O
11. Are any of your contract manufacturers located in China or India?	Yes	O	No	O
12. Do you contract manufacturer for others?	Yes	O	No	O
13. If Yes to 12., please indicate the what portion of your sales volume is for these third parties				

*Please provide further details in the space provided under the Additional Information Section.