LIFE SCIENCES LIABILITY APPLICATION

This is an application for a life sciences liability policy and the purpose of this application is for us to find out more about your company. All material information should be declared to us but note that completion of this application does not oblige either party to enter into a contract of insurance.

Please be aware that certain coverage under this policy operates on a claims-made basis. This means that for a claim to be covered, it must be made against the Insured and reported to us during the policy period. Additionally, claims related to any actual or alleged wrongful act that occurred before the Retroactive Date will not be covered.

WHO SHOULD COMPELTE THIS APPLICATION?

The person completing this application should be a senior staff member at the company. They must verify that they have consulted with other senior managers and colleagues responsible for arranging the insurance to ensure that all questions are answered accurately and thoroughly. Once finished, return the completed application to your insurance broker.

HOW TO COMPLETE THIS APPLICATION

Please complete all questions. If additional space is required for any response, please continue your response in the Additional Information section on the last page of the application.
In addition to completing this application, we may require additional documentation to be submitted which may include but is not limited to marketing materials, product lists, sample contracts, indemnification agreements, financial statements and/or clinical trial protocols & informed consent forms.

Please note that the application must be signed and dated to be considered complete.

SECTION 1 - APPLICANT INFORMATION

1. Applicant's name: _____

2. Applicant's address: _____

3. Phone: _____ Email: _____

4. Website: _____

5. Location address (if different from mailing address above):
_____

6. List of additional locations (if applicable)

Location #	Full address

7. Named insured is: ☐ A corporation ☐ A joint venture ☐ A partnership ☐ An individual ☐ Other, please provide additional details.
_____

8. Date entity was established (mm/dd/yyyy): _____

9. Have you acquired any companies in the last 3 years where you have a 50% or greater ownership interest? ☐ Yes ☐ No
If Yes, please identify each company, including date of acquisition and a brief description of their operations.

Company	Date of acquisition (mm/dd/yyy)	Description of operations

10. Are you a subsidiary of a parent company? ☐ Yes ☐ No
If Yes, please provide additional details:
_____

11. Have you ever operated under another name? ☐ Yes ☐ No
If Yes, please provide additional details:
_____

12. Do you require any other entity other than those listed above to be shown on the policy as additional insureds? ☐ Yes ☐ No
If Yes, please provide additional details:
_____

13. Please briefly describe the nature of your business operations:
_____
_____
_____

14. Are there any intended substantial changes to your business or major new developments likely within the next 12 months? This can include but is not limited to launching a new product line, expanding business practices, planned mergers and/or acquisitions, etc. ☐ Yes ☐ No
If Yes, please provide additional details on last page of application.

SECTION 2 - COVERAGE REQUESTED

Coverage	Limit of liability	Deductible	Alternative limits	Alternative deductible
Products-completed operations				
Clinical Trials				
Errors & Omissions (professional liability)				
Premises & Operations				
Advertising & personal injury				
Other, please describe				

SECTION 3 - REVENUE INFORMATION

** Please state all revenues in Canadian dollars ($).*

Country	Revenue ($) previous 12 months	Revenue ($) anticipated for next 12 months
Canada		
United States		
Rest of world		
Total:		

Revenue by operation	% of total revenue
Retail store	
Service provider (contract research organization, contract manufacturer, etc.)	
Manufacturing/sale of your own product	
Wholesale/distribution of other products	
Other	
If Other, please provide additional details	

Revenue by product	% Canada	% USA	% Rest of world	% Total
Cosmetics				
Dietary supplements/food/vitamins				
Proprietary pharmaceuticals				
Generic pharmaceuticals				
Imaging/diagnostics				
Medical devices				
Natural health products				
Vaccines				
Veterinary				
Other, please provide additional details				

Revenue by service	% Canada	% USA	% Rest of world	% Total
Contract manufacturing				
Contract research				
Importer				
Installation/repair/maintenance				
Lab services				
Protocol design				
Regulatory consulting				
Research & development				
Site management				
Information				
Business services (sales, marketing, distribution, packaging/re-packaging, labelling, labeling)				
Other, please provide additional detail				

SECTION 4 - PRODUCT/SERVICE PROFILE

1. Pharmaceuticals & biologics

Product category	% of total revenue	Product category	% of total revenue	Product category	% of total revenue
Blood & blood components		Branded pharmaceuticals		Cannabis	
Controlled drugs		Cosmetics & skin care		Diet aids	
Drug delivery		Generic pharmaceuticals		Hormones & steroids	
Imaging/diagnostic agents		Injectable (other than vaccines)		Oral prescription	
Orphan pharmaceuticals		Radiopharmaceuticals		Topical prescription	
Vaccines		Vitamins, food & dietary supplements		Other	

2. Medical devices & equipment

Product class	% of total revenue	Product class	% of total revenue
Analytical instruments		Cardiovascular	
Dental instruments		Diagnostic devices and/or kits	
Dialysis devices		Drug delivery systems	
Durable medical equipment		Hospital products/supplies	
Imaging devices		Implants (active)	
Implants (non-active)		Lasers	
Medical monitoring equipment		Rehabilitation/therapy	
Surgical devices		Ventilators	
Other, please provide additional details			

Medical device class	% of total revenue	Additional comments
Class 1		
Class 2		
Class 3		
Class 4		

3. Natural health products

Product class	% of total revenue	Additional comments
Cosmetics/Skincare		
Homeopathic medicine		
Natural products		
Supplements & food products		
Vitamins		
Other, please provide additional details		

4. Please select any products manufactured or distributed by the insured and provide further information if any past/present/future manufacturing or distribution is planned; please select "None of the above" if no categories apply.

☐	Acetaminophen	☐	Androstenedione	☐	Azidomethyl-biphenyl-tetrazole (AZBT)
☐	Benzene	☐	Bisphosphonates	☐	Bupropion
☐	Contraceptives	☐	Cox-2 Inhibitors	☐	Di-(2-ethylhexyl) phthalate (DEHP)
☐	Diethylstilbesterol (DES)	☐	Dioxins	☐	Ephedrine and pseudoephedrine including the natural plant
☐	Fibrates	☐	Formaldehyde and/or acetaldehyde	☐	Hydroquinone
☐	Isotretinoin	☐	Latex	☐	Implantable silicone
☐	Methylphenidate	☐	Metoclopramide	☐	Nitrosamine
☐	Opioids	☐	Phenylpropanolamine (PPA)	☐	Piper methysticum (Kava)
☐	Risperidone	☐	Selective serotonin reuptake inhibitors (SSRIs) and serotonin - norepinephrine reuptake inhibitors (SNRIs)	☐	Synthetic and/or biologic mesh implanted trans-vaginal
☐	Talcum powder	☐	Thiazolidinediones	☐	Thimerosal and/or thiomersal
☐	Tobacco, e-cigarettes and/or vaping products	☐	None of the above		

5. Services

Services	% of total revenue	Services	% of total revenue
Assembly/packaging/labelling		Bioequivalence testing	
Biostatistics		Clinical investigations	
Clinical participant recruitment		Clinical staff training/recruitment	
Database management		Lab services	
Preclinical testing		Pharmacodynamics	
Pharmacokinetics		Pharmacovigilance	
Protocol design		Quality control	
Research & development		Study section/study monitoring	
Other, please provide additional details			

6. If applicable to your organization, please complete the below table outlining the percentage of revenues per trial phase.

Percentage (%) of revenues	Phase 1	Phase 2	Phase 3	Phase 4	Bioequivalency
Next 12 month (anticipated)					
Current year					

7. Does your company recruit its own subjects/trial participants? ☐ Yes ☐ No

8. Are all participants required to sign an informed consent form? ☐ Yes ☐ No

9. Are all participants at least 18 years of age? ☐ Yes ☐ No

10. Do your employees provide medical advice or services related to a clinical trial? ☐ Yes ☐ No

SECTION 5 - PRODUCT COMPLETED OPERATIONS INFORMATION

1. Do you expect to be introducing any new products in the next 12 months? ☐ Yes ☐ No
If Yes, please complete the below table.

New product	Description of product	Is the new product within current scope of operations?
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No

2. Have any of your products been on the market for less than 3 years? ☐ Yes ☐ No

3. Are you in compliance with all applicable Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP)? ☐ Yes ☐ No

4. Are all your products approved by Health Canada, the FDA, or any other equivalent regulatory agency governing any country in which product is sold? ☐ Yes ☐ No

5. Are you ISO registered? ☐ Yes ☐ No
If Yes, please confirm ISO #: _____

6. Do you maintain samples of your products? ☐ Yes ☐ No

7. Are any of your products manufactured on your behalf by a third party? ☐ Yes ☐ No
If Yes, please provide additional details on the following.
Country of origin: _____
Is a contract in place with the manufacturer? ☐ Yes ☐ No
What parts of your product are manufactured by a third party?
_____

8. Are any of your product components/ingredients imported? ☐ Yes ☐ No
If Yes, please complete the below table.

Product, component and/or ingredient imported	Country of origin	Comply with CDSA and Canadian Food and Drugs Act regulations?	Is the product, component and/or ingredient testing in Canada prior to use?
		☐ Yes ☐ No	☐ Yes ☐ No
		☐ Yes ☐ No	☐ Yes ☐ No
		☐ Yes ☐ No	☐ Yes ☐ No
		☐ Yes ☐ No	☐ Yes ☐ No

10. Are any of your products sold under other labels or as components of other products? ☐ Yes ☐ No
If Yes, please provide additional information on last page of application.

11. Have you experienced any product recalls, product withdrawals or discontinued any products in the last 5 years? ☐ Yes ☐ No
If Yes, please complete the below table.

Product	Reason for removal from the market

SECTION 6 - CLINICAL TRIALS

**The below is only with respect to clinical trials involving human participants. If you require clinical trial coverage, please complete the supplemental clinical trial application.*

1. Are you presently involved in or will you be involved in clinical trials over the next policy period? ☐ Yes ☐ No

2. Have you been involved in clinical trials over the past 5 years? ☐ Yes ☐ No

3. To your knowledge, are any of your products being used in clinical trials? ☐ Yes ☐ No
If Yes, please complete the below table.

Title of clinical trial	Sponsor of clinical trial	Trial start date	Anticipated trial end date

SECTION 7 - REGULATORY & RISK MANAGEMENT INFORMATION

1. Is your company currently in compliance with all applicable government regulations? ☐ Yes ☐ No

2. Please provide your current Establishment License (EL) number: _____

3. In the past 5 years has your EL been deemed non-compliance or been suspended? ☐ Yes ☐ No

4. Has your site ever been inspected by a Health Canada inspector? ☐ Yes ☐ No
Please provide the date of the most recent inspection (mm/dd/yyyy): _____

Were any deviations noted from the most recent inspection? ☐ Yes ☐ No
If Yes, please provide additional information.
_____

5. Does your company have a formal quality control program? ☐ Yes ☐ No
If Yes, when was it last updated?
_____

6. Does your company have a formal product recall program in place? ☐ Yes ☐ No
If Yes, when was it last updated?
_____

7. Do you maintain a written record of incident reports and/or complaints? ☐ Yes ☐ No
If Yes, please list persons responsible for handling of complaints.

_____

8. Are your operating policies and procedures audited annually? ☐ Yes ☐ No

9. Do any employees have direct contact with patients? ☐ Yes ☐ No

10. Do you require certificates of insurance from all suppliers and sub-contractors? ☐ Yes ☐ No

11. Do you engage in direct-to-consumer advertising? ☐ Yes ☐ No
If Yes, please briefly describe the extent of your direct-to-consumer advertising on the section below and select all that apply.

_____

_____

☐ Instagram ☐ Facebook ☐ TikTok ☐ Twitter (X) ☐ Google ads ☐ Email

SECTION 8 - CONTRACT MANAGEMENT

1. Please describe your typical customer/end user:

_____

_____

2. List your 3 largest customers in the table below.

Customer	Revenue ($CAN)	Product/service

3. What is the average dollar value & length of contract?

_____

4. Do you always utilize contracts or agreements prior to the provision of services? ☐ Yes ☐ No

5. Do you accept customized or non-standard contracts? ☐ Yes ☐ No

6. Who in the company has the authority to sign contracts? ☐ Yes ☐ No

7. Are all contracts reviewed by legal counsel? ☐ Yes ☐ No
If No, please explain.

_____

_____

8. Do your written contracts ever contain Hold Harmless or Indemnification clauses in which you accept liability for loss of life, injury, property damage, or financial losses in circumstances other than where they are caused by your negligence? ☐ Yes ☐ No

9. In your written contracts, do you ever provide guarantees of products or services? ☐ Yes ☐ No

SECTION 9 - PREMISES INFORMATION

1. Do you store any hazardous substance at your location? ☐ Yes ☐ No
   If Yes, please provide additional information.

   _____
   _____

2. Are you in compliance with all federal & provincial laws regarding hazardous materials handling and disposal? ☐ Yes ☐ No

3. In the past 5 years, have you ever experienced a biohazard release? ☐ Yes ☐ No

4. What is your highest biohazard laboratory rating? _____

5. Are laboratory animals or live viruses kept on the premises? ☐ Yes ☐ No

6. Do you have personal property of others in your care custody, or control? ☐ Yes ☐ No
   If Yes, please describe the types of personal property at each location and the estimated value.

   _____
   _____

SECTION 10 - COVERAGE HISTORY

1. Please provide details of professional liability coverage purchased in the last 3 years.

Policy period	Limits of liability	Coverage type	Primary / excess	Carrier	Retroactive date

2. Please provide details of general liability coverage purchased in the last 3 years.

Policy period	Limits of liability	Coverage type	Primary / excess	Carrier	Retroactive date

3. Has any carrier declined, cancelled or non-renewed of the applicant's insurance coverages? ☐ Yes ☐ No
   If Yes, please provide additional information.

   _____
   _____

4. Have you ever been cancelled for non-payment? ☐ Yes ☐ No

5. Have you maintained continuous insurance since the retroactive date noted in the table above? ☐ Yes ☐ No

SECTION 11 - INSURANCE HISTORY & CLAIMS INFORMATION

1. Are you aware of any loss or damage, whether covered by insurance or not, that has occurred to any of the Companies to be insured (or to any existing or previous business of the partners or directors of the Companies) in the past 5 years? ☐ Yes ☐ No
   If Yes, please attach full details including an explanation of the background of events, the maximum amount involved/claimed, the status of the claim(s) or circumstance(s) and any reserve(s) or payment(s) made by the Applicant and/or by Insurers, and the dates of all developments and payments.

2. Are you aware of any circumstances that might lead to a claim against any of the companies to be insured or any of their partners or directors? ☐ Yes ☐ No

3. Have any claims or cease and desist orders been made against any of the companies to be insured, or their partners or directors? ☐ Yes ☐ No

4. Have any partners or directors of the Companies to be insured been found guilty of criminal, dishonest, or fraudulent activities, or been investigated by any regulatory body? ☐ Yes ☐ No

SECTION 12 - DECLARATIONS

I declare that after proper enquiry the statements and particulars given above are true and that I have not mis-stated or suppressed any material fact. I agree that this Application Form, together with any other material information supplied by me shall form the basis of any contract of insurance effected thereon. I undertake to inform the Insurer of any material alteration to these facts occurring before the completion of the contract.

The undersigned agrees that by signing below, they are affirming the conditions and statements set forth in the Life Sciences Liability Insurance Application.

Name of person completing this application: _____

Position: _____ Date: _____

Signature of the Insured: _____

Please send the completed, signed and dated application to underwriting@revau.com.

SECTION 13 - ADDITIONAL INFORMATION

1. Please declare all relevant information that are not mentioned in this application.