Healthcare

Life Sciences Renewal Application

Instructions

This is an application for a CLAIMS MADE POLICY. Should this application be accepted by the Company, coverage will apply to claims first made against the insured during the policy period. No coverage will apply for claims first made against the insured after the end of the policy period unless the extended reporting period applies. No coverage will apply for claims first made prior to the retroactive date shown in the declarations page of the policy. The completion and submission of this application to the Company does not constitute a binder of insurance.

All questions must be answered. If a question is not applicable, please answer "N/A." If the answer to a question is none, state "None" or "0". If more space is required to answer a question completely, please provide a separate attachment and identify the question it responds to.

SECTION 1 – GENERAL INFORMATION

1. Name of Applicant (Please print): _____

   Mailing Address: _____

   City/Town: _____ Province: _____ Postal Code: _____

   Phone: _____ Email: _____

   Website: _____

   Location(s) other than that listed above: _____

2. List any subsidiary or affiliate (e.g., research organization) controlled by the Applicant that requires insurance coverage. Please note that separate applications may be required for additional entities to be insured.

Name of Entity	Relationship to Applicant	Description of Operations	Country of Domicile

3. Does the Applicant provide professional services over the internet? ◯ Yes ◯ No

   If yes, please provide a description of the services: _____

4. Please state sources and amounts of gross annual revenue for the following years (in CAD):

	Last Complete Financial Year	Estimate for Current Financial Year	Estimate for Next Financial Year
Canadian Revenue:			
U.S. Revenue:			
Other (please name country):			
Other (please name country):			
Total revenue:			

5. Percentage of revenue generated from:

Source of Revenue	Current Year	Projected Year
Royalties		
Cooperation-Collaboration Agreements		
Licensing Agreements		
Milestones		
Sales		
Total:		

6. Are there any intended substantial changes to your business or major new developments likely within the next 12 months? ☐ Yes ☐ No
If yes, please provide full details: _____

Please provide promotional materials on your products and services.

SECTION 2 – PRODUCTS AND SERVICES

1. Product/Service Profile
For the next 12 months, indicate all revenue sources that apply and the percentage of total gross revenues for the service:

Source/Potential Source of Revenues	% Total Revenue
Blood/Plasma/Tissue Banks	
Manufacturing – Pharmaceuticals	
Manufacturing – Medical Devices	
Contract Manufacturing – Pharmaceuticals	
Contract Manufacturing – Medical Devices	
Contract Research Organization	
Distributor – Pharmaceuticals	
Distributor – Medical Devices	
Diagnostic Laboratory	
Equipment Rentals/Leasing	
Research	
Repair/Installation/Service	
Other (specify)	

2. Product/Service Types
For the next 12 months, indicate all revenue sources that apply and the percentage of total gross revenues for the service:

Pharmaceuticals	Relative % of Revenue
Pharmaceuticals	
Pharmaceuticals Generic	
Pharmaceuticals Clinical	
Research	
Imaging/Diagnostic Agents	
Nutraceuticals	
Diet Aids	
Vaccines	
Infusions	

Medical Devices	Relative % of Revenue	Medical Devices	Relative % of Revenue
Cardiac Devices		Therapy/Rehabilitation	
Anesthesia/Respiratory		Dialysis Equipment	
Implants (Active)		Drug Delivery Systems	
Implants (Non-active)		Non-Cardiac Catheters	
Lasers		Analytical Instruments	
Surgical Devices		Diagnostic Kits	
Dental Instruments		Durable Medical Equipment	
Monitoring Devices		Hospital Products/ Supplies	
Imaging Devices			
Other (specify)			

Please provide a breakdown of your revenues by class of device (as defined by Health Canada, the FDA or any other pertinent regulatory authority:

	Last 12 Months			Next 12 Months		
	Canada	U.S.	Other	Canada	U.S.	Other
Class 1						
Class 2						
Class 3						
Class 4						
Other:						
Total:						

Contracted Professional Services	Relative % of Revenue	Medical Devices	Relative % of Revenue
Preclinical Testing Services		Biostatistics	
Pharmacodynamics		Submission of Regulatory Filings	
Pharmacokinetics		Bio-Equivalency/Bioavailability Testing	

Study Participant Selection or Monitoring		Quality Control Monitoring	
Clinical Investigations (indicate phases):		Manufacturing	
Clinical Staff Recruitment		Repackaging/Assembly	
Case Report Form Design		Product/Equipment Sterilization	
Data Entry/Database		Marketing	
Publications/Software Design		Sales Management	
		Distribution	
		Other (specify)	

3. Are any products manufactured and/or sold under others' labels? ◯ Yes ◯ No

4. Are any products sold as components for other products? (Indicate the likely end product.) ◯ Yes ◯ No
   End Product(s): _____

5. Do you subcontract/utilize independent contractors for product development, manufacturing, sales and/or distribution services? ◯ Yes ◯ No
   Activities contracted: _____

6. Are you planning to introduce any new products? ◯ Yes ◯ No
   If yes, please list: _____

7. List any discontinued products (Please indicate reasons): _____

8. List any product withdrawn from the market in the last 5 years:

Product	Reason for Withdrawal

9. List any raw materials imported from China, India or any other foreign countries:

Raw Material	Country of Origin	Regulatory Approval of Facility (Health Canada, FDA or equivalent)

10. Professional Services:
    i. Do any of the applicant's employees provide direct patient care? ◯ Yes ◯ No
    ii. Do they carry their own individual medical professional liability coverage? ◯ Yes ◯ No

iii. Does the applicant operate an inpatient facility? ◯ Yes ◯ No

iv. Do any of the applicant's employees participate on an institutional review board/research ethics board? ◯ Yes ◯ No

v. Does the applicant have a financial interest in the products of the applicant's clients? ◯ Yes ◯ No

vi. List the applicant's largest clients for the current year:

_____

_____

SECTION 3 – REGULATORY AND RISK MANAGEMENT INFORMATION

1. Do all Independent Contractors carry their own Professional Liability (Medical Malpractice) insurance? ◯ Yes ◯ No
2. Does the applicant hold an active license to manufacture its product(s) in Canada? ◯ Yes ◯ No

   Medical device establishment license number: _____

   Pharmaceutical product establishment license number: _____

   Natural health product site license number: _____
3. Do all medical devices hold active medical licenses (Class II – Class IV)? ◯ Yes ◯ No
4. Do all pharmaceutical/natural health products hold active licenses? ◯ Yes ◯ No
5. What was the date and result of your most recent on-site inspection by Health Canada/FDA: _____

   Were any deficiencies noted in this inspection? ◯ Yes ◯ No

   If yes, please provide details, including corrective action taken: _____
6. Has the applicant had any product recalls in the past year? ◯ Yes ◯ No

   If yes, please submit details and current recall status: _____
7. Have any medical device reports or adverse drug reaction reports been filed on product(s) in the past 12 months? ◯ Yes ◯ No

Product	Patient Outcome - product associated with death, permanent injury or hospitalization

8. Have you, any products or company practices been subject to an investigation by any government agency? ◯ Yes ◯ No

   If yes, please explain: _____
9. Have any clinical trials been placed on hold? ◯ Yes ◯ No

   If yes, provide details: _____

SECTION 4 – CLINICAL TRIALS

1. Please state the anticipated number of trials with which the Applicant will be involved in during the next 12 months detailing the number of new subjects in each trial:

Trial Name	Trial Phase	Number of New Subjects	Trial Location (country)	Trial Date: Commencement/ completion

2. Please list the group(s) in which you conduct clinical trials:

Group					
Products			**Devices**		
Cardiovascular Pharmaceuticals	◯ Yes	◯ No	Implantable – Inactive	◯ Yes	◯ No
Oncology Pharmaceuticals	◯ Yes	◯ No	Implantable – Active	◯ Yes	◯ No
Prescription Injectable	◯ Yes	◯ No	Invasive – Non-Implantable	◯ Yes	◯ No
Vaccines – Live	◯ Yes	◯ No	Non-invasive/Non-Implantable	◯ Yes	◯ No
Vaccines – Killed	◯ Yes	◯ No	Other (non-device)	◯ Yes	◯ No

3. Do the clinical trials involve any of the following?

Activity		
Any Assisted or Altered Conception	◯ Yes	◯ No
Any Method of Contraception	◯ Yes	◯ No
Obesity Drugs	◯ Yes	◯ No
Stem Cell Therapy	◯ Yes	◯ No
Blood and Blood Products	◯ Yes	◯ No
Dexfenfluramine	◯ Yes	◯ No
Fenfluramine	◯ Yes	◯ No
Phentermine Thalidomide	◯ Yes	◯ No
Silicone Gel Used as an Injection or as Part of an Implantable Device	◯ Yes	◯ No
Accutane	◯ Yes	◯ No
Birth Control Devices and Medications	◯ Yes	◯ No
Diethystilbestrol (DES)	◯ Yes	◯ No
Swine Flu Vaccine	◯ Yes	◯ No
Phenylpropanolamine	◯ Yes	◯ No
Metoclopramide	◯ Yes	◯ No
Any Intra-Articular Pain Pump or Continuous Infusion Device to Deliver Any Type of Medication to the Patient	◯ Yes	◯ No
Implantable Mesh Products Used in Anterior or Posterior Pelvic Floor Repair	◯ Yes	◯ No
Any Metal-on-Metal (Use of Femoral Head Articulating in Conjunction with a Metal Liner or Metal Cup) Hip Replacement Systems, Including Components Thereof	◯ Yes	◯ No

Testosterone	☐ Yes	☐ No
Depakine	☐ Yes	☐ No
Opioid	☐ Yes	☐ No
Cannabis	☐ Yes	☐ No

4. Has a Research Ethics Board or equivalent reviewed the clinical trial(s)? ☐ Yes ☐ No

5. Is the clinical trial registered with Health Canada or other regulatory equivalent? ☐ Yes ☐ No

6. Have any trials been discontinued or suspended, whether by you, Health Canada, FDA or any other regulatory authority? ☐ Yes ☐ No

7. Have any subjects had a serious adverse event (such as hospitalization, death, malignancy, etc.) while participating in any of the applicant's clinical trials? ☐ Yes ☐ No

8. Are any foreign clinical trials planned in the future?
   If yes, please describe: _____
   (CNA cannot quote on trials located in Canadian-sanctioned countries or Cuba.)

SECTION 5 – CLAIMS

1. Are there any incidents that have yet to be reported? ☐ Yes ☐ No

WARRANTY STATEMENT

Applicant declares that the information provided in this Application, as well as any supplemental information attached to this Application, is true, accurate and complete, and that no material facts have been omitted. Applicant acknowledges a continuing obligation to report to the CNA Company to whom this Application is made ("CNA"), as soon as practicable, any material changes in all such information, after signing the Application and prior to issuance of the policy, and acknowledges that CNA shall have the right to withdraw or modify any outstanding quotations and/or authorization or agreement to bind the insurance based upon such changes. Whereas completion of this Application and signing it does not bind coverage, the Applicant acknowledges and agrees that this Application shall be the basis of the contract if a policy is issued, and that if a policy is issued, CNA will have relied upon, as representations, the Application and any supplemental information attached to this Application, all of which are incorporated by reference to this Application and made a part hereof. Applicant acknowledges that the misrepresentation or failure to disclose material information in the Application could result in a denial of coverage or the issued policy being voidable or void.

Applicant:

By: _____
Signature and Title, as well as Printed Name of Authorized Representative*

Date: _____

*** This Application must be signed by the Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, General Counsel or Risk Manager.**

Please complete and return this form to your insurance broker.