Healthcare

Life Sciences New Business 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. Are you a current policyholder or a new Applicant? ◯ Existing Holder ◯ New Applicant

3. What is the legal structure of the business? (check appropriate box)

◯ Sole Proprietorship ◯ Joint Venture ◯ Not-for-Profit

◯ Partnership ◯ Corporation

◯ Other (describe): _____

4. What is tax status of the business? ◯ For profit ◯ Not-for-Profit ◯ Government

5. Date of incorporation: _____

6. 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

7. Is the Applicant a subsidiary of a parent company? ◯ Yes ◯ No

If yes, give full details here:_____

8. Have you ever operated under another name? ◯ Yes ◯ No

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

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

10. 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:			

11. Percentage of revenue generated from:

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

12. 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 – Coverage History

1. Please provide details of your current and previous medical malpractice insurance:

Insurer	Term	Limit	Deductible	Premium

i. Basis of current insurance coverage: Claims-made ◯ Retroactive date (dd/mm/yyyy)_____ Occurrence ◯

2. Coverage Requested: _____

i. Effective date of coverage (dd/mm/yyyy) _____

ii.	Limit of liability	$1M	$2M	$5M	$10M	Other: $_____
iii.	Deductible	$1K	$2.5K	$5K	$10K	Other: $_____
iv.	Aggregate	$1M	$2M	$5M	$10M	Other: $_____

Section 3 – Products and Services

1. Product/Service Profile

For the previous 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 previous 12 months, indicate all revenue sources that apply and the percentage of total gross revenues for the service:

Pharmaceuticals	Relative % of Revenue
Proprietary Pharmaceuticals	
Generic Pharmaceuticals	
Clinical Research	
Imaging/Diagnostic Agents	
Nutraceuticals	
Diet Aids	
Vaccines	
Infusions	
Other (specify)	

Medical Devices	Relative % of Revenue
Cardiac Devices	
Anesthesia/Respiratory	
Implants (Active)	
Implants (Non-active)	
Lasers	
Surgical Devices	
Dental Instruments	
Monitoring Devices	
Imaging Devices	
Other (specify)	

Medical Devices	Relative % of Revenue
Therapy/Rehabilitation	
Dialysis Equipment	
Drug Delivery Systems	
Non-Cardiac Catheters	
Analytical Instruments	
Diagnostic Kits	
Durable Medical Equipment	
Hospital Products/ Supplies	

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
Preclinical Testing Services	
Pharmacodynamics	
Pharmacokinetics	
Protocol Design	
Study Participant Selection or Monitoring	
Clinical Investigations (indicate phases):	
Clinical Staff Recruitment	
Case Report Form Design	
Data Entry/Database	
Publications/Software Design	

Medical Devices	Relative % of Revenue
Biostatistics	
Submission of Regulatory Filings	
Bio-Equivalency/Bioavailability Testing	
Quality Control Monitoring	
Manufacturing	
Repackaging/Assembly	
Product/Equipment Sterilization	
Marketing	
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 4 – 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 a 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 license (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 correction 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:_____

10. Is there a written and implemented loss prevention/loss control program? ◯ Yes ◯ No

If yes, please note the name and title of the individual responsible for the program: _____

11. Is there a written and implemented quality control program? ◯ Yes ◯ No

12. Is there a written and implemented records retention program? ◯ Yes ◯ No

13. Is the applicant in compliance with all applicable Good Manufacturing Practices (GMP)/Good Laboratory Practices (GLP), Good Clinical Practices? ◯ Yes ◯ No

14. Is there a formal product recall program? ◯ Yes ◯ No

15. Are complete inventory records maintained? ◯ Yes ◯ No

16. Are promotional materials, contracts, guarantees and labelling reviewed by applicant's risk management and legal counsel? ◯ Yes ◯ No

Section 5 – Clinical Trials

1. Are clinical trials approved by the appropriate regulatory agency/authority? ◯ Yes ◯ No

2. Please state for whom clinical research projects are undertaken (trial sponsors including pharmaceutical company, research foundations, etc.):_____

3. Do you receive full indemnity from the clinical trial sponsors? ◯ Yes ◯ No

4. Please provide annual revenue derived from clinical trial activity: $_____

5. Please state the number of trials during the last 12 months, detailing the number of subjects in each trial:

Activity	Gross Receipts					
	Canada last 12 months	Canada next 12 months	U.S. last 12 months	U.S. next 12 months	Other last 12 months	Other next 12 months
Phase 1 Testing						
Phase 2 Testing						
Phase 3 Testing						
Phase 4 Testing						
Other (please explain)						
1.						
2.						
3.						
4.						
Totals:						

6. 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 Subjects	Trial Location (country)	Trial Date: Commencement/completion

7. How are subjects recruited for the clinical trial?_____

8. Is the informed consent form written at or below grade 8? ◯ Yes ◯ No

9. Does the applicant conduct any formal research, testing or experimental activities in the following categories?

Major Organ Surgery ◯ Yes ◯ No

Pregnant Women ◯ Yes ◯ No

Minors: ◯ Yes ◯ No

Genetic Engineering/Gene Therapy: ◯ Yes ◯ No

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

Group

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

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

Activity	Yes/No
Any Assisted or Altered Conception	
Any Method of Contraception	
Obesity Drugs	
Stem Cell Therapy	
Blood and Blood Products	
Dexfenfluramine	
Fenfluramine	
Phentermine Thalidomide	
Silicone Gel Used as an Injection or as Part of an Implantable Device	
Accutane	
Birth Control Devices and Medications	
Diethystilbestrol (DES)	
Swine Flu Vaccine	
Phenylpropanolamine	
Metoclopramide	

Any Intra-Articular Pain Pump or Continuous Infusion Device to Deliver Any Type of Medication to the Patient	
Implantable Mesh Products Used in Anterior or Posterior Pelvic Floor Repair	
Any Metal-on-Metal (Use of Femoral Head Articulating in Conjunction with a Metal Liner or Metal Cup) Hip Replacement Systems, Including Components Thereof	
Testosterone	
Depakine	
Opioid	
Cannabis	

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

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

14. Have any trials been discontinued or suspended, whether by you, Health Canada, FDA or any other regulatory authority?

◯ Yes ◯ No

15. 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

16. Are any foreign clinical trials planned in the future? ◯ Yes ◯ No

If yes, please describe: _____

(CNA cannot quote on trials located in Canadian-sanctioned countries or Cuba.)

Section 6 – Claims and Insurance History

1. Loss History (Provide total aggregate losses from ground up including defense expenses for last 5 years):

Policy Period	Insurer	Number of Claims	Total Incurred

* Attach previous carrier loss runs

2. Coverage History

Carrier	Policy Period	Primary and Excess Limits	Retro Date

i. Has any carrier declined, cancelled or non-renewed of the applicant's insurance coverages? ◯ Yes ◯ No

If yes, please explain: _____

ii. Have you ever been cancelled for non-payment? ◯ Yes ◯ No

iii. What limits of liability are being requested by the applicant?_____

_____

Please include the following with this application:

- Most recent annual report/audited financial statement
- Senior staff curriculum vitae
- Outline of quality control program
- Advertisements, brochures, descriptive literature
- Sample service contracts and indemnification agreements with CROs, CMOs
- Clinical trial informed consent forms and protocols

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.