AllMed

Life Sciences Insurance Application

The form must be signed by an Authorized Signatory of the Firm. All questions must be answered.
If a question or section is not applicable then please answer "N/A". The completion and signature of this form does not bind the Proposer or Underwriter to complete a contract of insurance unless specific agreement is given by both parties.

GENERAL INFORMATION

Full Name(s) of all companies to be included:

Mailing Address:

Website Address:

Location Address:

Please provide copies of company literature; brochure; current product listing and sample service contracts and indemnification agreements if applicable.

COMPANY INFORMATION

Full Business Description:

Estimated Gross Revenue in Past 12 months: C$	Estimate Revenue in Next 12 months: C$

Operations	*Past 12 Months (in C$)*			*Next 12 Months (in C$)*		
	Canada	*U.S.A.*	*ROW*	*Canada*	*U.S.A.*	*ROW*
Own Manufacture (where you hold product license)						
Own Products but manufacture is contracted to third party						
Consulting						
Contract Manufacture (for others)						
Equipment Rental / Leasing						
Genetic Testing						
Wholesale distribution						
Repair/ Installation / Services						
Retail						
Research (for others)						
Other (please specify)						

GENERAL LIABILITY

1. Have all Manufacturing locations been inspected by the relevant regulatory body? ☐ Yes ☐ No

   If 'YES', what was date of last inspection:

2. Do you store any hazardous substance at your location? ☐ Yes ☐ No

   If yes please describe:

3. What is your highest biohazard rating? Please list the location of all laboratories with this rating.

4. Are laboratory animals kept on premises? ☐ Yes ☐ No

5. Do you have any live viruses on your premises? ☐ Yes ☐ No

   If yes please describe:

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PRODUCTS LIABILITY

Please complete the following Income projections for the next 12 months (in C$)

Product

A. **Pharmaceutical/ Biologics / Natural Health**			
Blood & Blood Components/Tissue	$	Nutraceuticals	$
Controlled drugs	$	Over-the-Counter Products	$
Cannabis	$	Prescriptions	$
Cosmetics	$	Psilocybin Products	$
Drug Delivery	$	Radiopharmaceuticals	$
Food & Dietary Supplements/Products	$	Vaccines	$
Homeopathic Medicine	$	Veterinary	$
Hormone / Steroids	$	Vitamins	$
Imaging / Diagnostic Agent	$	Other (please provide details):	$
Injectable	$	Other (please provide details):	$
Natural Products	$	Other (please provide details):	$
B. **Medical Devices / Equipment**			
Analytical Instruments	$	Hospital Products / Supplies	$
Anesthesia / Respiratory	$	Imaging Devices	$
Cardiovascular Cardiac devices	$	Laser Systems	$
Dental Instruments	$	Medical Monitoring Devices	$
Diagnostic Kits	$	Surgical Devices	$
Dialysis Equipment	$	Other (please provide details):	$
Drug Delivery System	$	Other (please provide details):	$
Durable Medical Equipment	$	Other (please provide details):	$
C. **Nanotechnologies**	$		

1. If you export products, please provide all products exported:

2.	Do you comply with the federal laws or government regulations laid down in countries to which products are exported?	☐ Yes ☐ No

3. If you import products, please state from which countries obtained and approximate percentage of total turnover against each.

4.	Do the imported product components/ ingredients meet the applicable regulations of the Controlled Drugs and Substances Act and the Canadian Food and Drug Act?		☐ Yes ☐ No
5.	For all products where you are a distributor, do you retain rights of recourse against the manufacturers?		☐ Yes ☐ No
6.	Please give full details and percentage of total turnover of products that are:	(i) manufactured/supplied to own design/specification/formulation:	%
		(ii) manufactured/supplied to a design/specification/formulation: laid down by a customer	%
7.	Do you have a separate design team?		☐ Yes ☐ No

8. Describe extent and type of tests and checks undertaken before Product goes into production.

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9. Is your Company in compliance with all applicable government regulations?	☐ Yes ☐ No
If No, please provides details.	

10. Does your Company have a written quality control programme?	☐ Yes ☐ No
If Yes, please advise date last updated:	
11. Are sampling inspections made on incoming raw materials?	☐ Yes ☐ No
12. Does your Company follow Good Manufacturing Practice (GMP)?	☐ Yes ☐ No
13. Does your Company have a formal product recall procedure in place?	☐ Yes ☐ No
If Yes, please advise date last updated:	
14. Do you have discontinued product lines because of incidence or injury or damage or where potential hazards have been identified?	☐ Yes ☐ No
If Yes, please provide detail including when manufacture or supply ceased.	

15. Does your Company maintain a written record of incident reports and/or complaints?	☐ Yes ☐ No
If Yes, who is responsible for recording and handling complaints?	
16. Are products labelled and supplied with clear instructions in the language of the country to which they are supplied?	☐ Yes ☐ No
17. Are product hazard warnings clearly shown on products, packaging and / or instruction manuals?	☐ Yes ☐ No
18. Are your Representatives warned against overstating usage or effectiveness of products?	☐ Yes ☐ No
19. Do you maintain an adequate system of records which would enable identification of: (indicate the periods the records are kept, if answer is "Yes")	
a) Source of product / raw materials/ component parts purchased:	☐ Yes ☐ No
b) Source of design of products manufactured:	☐ Yes ☐ No
c) Quality Control and testing procedures effective at the time of design and / or manufacture:	☐ Yes ☐ No
d) Research undertaken to minimize risk to health and safety:	☐ Yes ☐ No

SPECIFIED PRODUCTS

Unless it is specifically agreed with the Underwriters cover provided may exclude any liability arising out of the following:

Blood-Borne Pathogens	☐ Yes ☐ No	Lymerix	☐ Yes ☐ No
Bupropion	☐ Yes ☐ No	Metoclopramide	☐ Yes ☐ No
Contraceptives and /or Fertility Drugs	☐ Yes ☐ No	Pertussis Vaccine	☐ Yes ☐ No
Cox-2 Inhibitors	☐ Yes ☐ No	Phenylpropanolamine (PPA)	☐ Yes ☐ No
Diethylstilbestrol or Stilbestrol or DES	☐ Yes ☐ No	Phenytoin or Phenytoin Sodium	☐ Yes ☐ No
Ephedrine Ma Huang Pseudoephedrin Chinese Ephedra Mahuang Extract Ephedra Ephedra Sinica Ephedra Extract Ephedra Herb Powder or Epitonin	☐ Yes ☐ No	Selective Serotonin Re-Uptake Inhibitors	☐ Yes ☐ No
Fentanyl or Fentanyl Patches	☐ Yes ☐ No	Statins	☐ Yes ☐ No
Isotretinoin or Accutane	☐ Yes ☐ No	Thalidomide	☐ Yes ☐ No
Kava or Kava Kava	☐ Yes ☐ No	Thiazolidinedones	☐ Yes ☐ No
L-Tryptophan	☐ Yes ☐ No	Thimerosal or Thiomersal	☐ Yes ☐ No

Please complete the following if you have answered "Yes" to any of the above and in addition, please provide product details and information including safety data sheets where possible, estimated annual revenue per territory and details of how long have you been producing each products

1. Is the product manufactured by you?	☐ Yes ☐ No
If "No", whom?	
2. Are the products manufactured to your formula / specification?	☐ Yes ☐ No
If "No", why?	

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MEDICAL MALPRACTICE

1.	Do any of your employees provide direct patient care?	☐ Yes ☐ No
2.	Do they carry their own individual medical malpractice insurance?	☐ Yes ☐ No
3.	Do they operate an in-patient facility?	☐ Yes ☐ No
4.	Do any of your employees participate on an Institution Review Board?	☐ Yes ☐ No

ERRORS AND OMMISSIONS

1. Please provide a full and clear description of the activities of the Firm(s) for which E&O cover is required.

2.	Estimated Income for next 12 months derived from Services (as per Company Information)	$
3.	Please list these activities and state the approximate percentage of work carried out in each instance:	
		%
		%
		%
		100%

4. Please provide:

Names of all Directors, Partners or principals	*Qualifications*	*Date Qualified*	*No Years as Directors, partner or principal of the firm*

5. Please list the Firm's three largest contracts in the last three years:

Work Undertaken	*Country*	*Contract Income (in C$)*	*Date Commenced*	*Date Completed*

6. Do you operate to standard contract conditions? ☐ Yes ☐ No

If Yes, then please supply copy

If No, what reviews are undertaken on the contract conditions before signing?

CLINICAL TRIALS

1. Are all clinical trials conducted in accordance with:
   (i) The appropriate government authority(ies)? ☐
   (ii) Ethics Committee Approval? ☐
   (iii) I.C.H. Guidelines? ☐

DETAILS OF ACTIVE AND ANTICIPATED CLINICAL TRIALS (please complete on separate page if insufficient room)
If any trials are First-in-Human then please state 'FIH' under Phase

Date Commenced	*Date Completed*	*Study Title in Full*	*Phase*	*No of Subjects*		*Territory if not CAN*
				Estimated	*Enrolled to date*	

For each trial to be insured please attached a copy Protocol Document
(if Final version not available please submit Draft or Synopsis for quote) plus Informed Patient Consent Form

2.	Are all trials conducted in compliance with the applicable regulatory requirements including international regulatory requirements were applicable?	☐ Yes ☐ No
3.	Are all trials conducted in compliance with the protocol that receive approval by the Research Ethics Board?	☐ Yes ☐ No

4. Are informed consent forms handled in accordance with the standard operating procedures, including how to inform, obtain and maintain the informed consent of the subjects?	☐ Yes ☐ No
5. Are all documentation recorded, handled and stored in a manner that allows for complete and accurate reporting?	☐ Yes ☐ No
6. Are all the documentation and communication with Health Canada or equivalent government authority completed with respect to modification, amendment or deviation from protocol?	☐ Yes ☐ No
7. Are there procedures including internal communication in place regarding notification and reporting of adverse drug reactions?	☐ Yes ☐ No
8. Do senior management or legal counsel review all contracts, agreements or other written documentation with third parties, including research ethics board, investigators, contract research organizations, site management organization and other vendors/ service providers?	☐ Yes ☐ No
9. Have any trials been discontinued or suspended by you, Health Canada or any other regulatory authority?	☐ Yes ☐ No
10. Have any subjects had a serious adverse event while participating in any of the applicant's clinical trials?	☐ Yes ☐ No

COVERAGE REQUESTED

Coverage	*Limit Required*	*Deductible*
General Liability	C$	C$
Clinical Trials –Testing Liability	C$	C$
Clinical Trials – No Fault	C$	C$
Errors and Omissions	C$	C$
Products/Completed Operations	C$	C$

INSURANCE HISTORY

1. Has any Insurer ever:

(i) Declined your proposal for insurance?	☐ Yes ☐ No
(ii) Refused your renewal of any insurance policy?	☐ Yes ☐ No
(iii) Terminated your Insurance?	☐ Yes ☐ No
2. Has your Company ever had a written demand or civil proceeding for damages made against them?	☐ Yes ☐ No

If Yes, please supply details as follows:

Date	*Policy Type*	*Brief Details of Incident whether or not an insurance claim has been made*	*Paid Amount*	*Insurers Outstanding Reserve*

3. Are you aware of any circumstances that might give rise to a claim?	☐ Yes ☐ No

If Yes, please provide details:

4. Is your Company currently Insured?	☐ Yes ☐ No

If Yes, please provide details of current insurance placements:

Policy	*Insurer*	*Period of Insurance*	*Limit of Indemnity*	*Premium*
General Liability				
Products Liability				
Clinical Trials				
Errors and Omissions				

5. If any of the above policies are currently placed on a "Claims Made" basis, please advise Retroactive Dates applied:

NOTICE CONCERNING PERSONAL INFORMATION

By purchasing insurance from Trans Canada Insurance Marketing Inc. (TCIM), a customer provides TCIM Insurance with his or her consent to the collection, use and disclosure of personal information, including that previously collected, for the following purposes:

- the communication with underwriters;
- the evaluation of claims;
- the analysis of business results;
- the underwriting of policies;
- the detection and prevention of fraud;
- purposes required or authorized by law.

For the purposes identified above, personal information may be disclosed to TCIM and any affiliated companies and service providers. Further information about TCIM Insurance personal information protection policy may be obtained by contacting their privacy officer at 204-925-8268.

WARRANTY STATEMENT

The undersigned warrants that to the best of his or her knowledge, the statements set forth in this Application are true. The undersigned also warrants that they have not suppressed or misstated any material facts. It is further agreed by the undersigned that each policy or renewal thereof, if issued, is issued in reliance upon the truth of the representations and information in this Application.

If the information provided in this Application should change between the date of the Application and the effective date of the policy, the undersigned warrants he or she will immediately report such changes to the Insurer and the Insurer may modify or withdraw any quotation or agreement to bind or modify insurance.

Signing of this Application does not bind the undersigned to purchase this insurance, nor does it bind the Insurer to complete this insurance. However, should the Insurer bind and issue a policy, this Application shall serve as the basis of such contract and will be attached to and form part of the policy.

Any person who knowingly or with intent to defraud or to facilitate a fraud against any insurance company or other person submits an application or files a claim for insurance containing false, deceptive or misleading information may be guilty of insurance fraud.

IMPORTANT: **THE APPLICANT MUST SIGN THIS APPLICATION.** SIGNING THIS FORM DOES NOT BIND THE COMPANY TO COMPLETE THE INSURANCE.

QUEBEC AND NEW BRUNSWICK RESIDENTS ONLY:

I hereby confirm my request that the present document and any other document and correspondence pertaining to the present insurance be in the English language.

SIGNATURE

Signature:		Date (mm/dd/yyyy):	
	(Authorized Representative)		
Name (please print):		Title/Position:	