GESTIONNAIRES D'ASSURANCES | SUM | STRATEGIC UNDERWRITING MANAGERS INC

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LIFESCIENCES – **CANADIAN PHARMACEUTICAL & BIOTECHNOLOGY INSURANCE**

The form must be signed by a Partner or Director or Authorised 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.
All figures are in Canadian dollars unless otherwise stated.

COVERAGE REQUIRED	LIMIT REQUIRED
General Liability	$ _____
Clinical Trials –Testing Liability	$ _____
Clinical Trials – No Fault	$ _____
Errors and Omissions	$ _____
Products/Completed Operations	$ _____

For each head of cover required please complete the relevant sections attached.

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

_____

_____

Mailing Address of Registered Office: _____

_____

_____

Address(es) of any Overseas Offices to be Insured: _____

_____

_____

Website Address: _____

When established: _____

1. COMPANY INFORMATION (Please provide copies of company literature if available)

Full Business Description:

_____

_____

Estimated Gross Income in Past 12 months: $_____

Estimate Income in Next 12 months: $_____

OPERATIONS	PAST 12 MONTHS (IN C$)			NEXT 12 MONTHS (IN C$)		
	CANADA	U.S.A.	ROW	CANADA	U.S.A.	ROW
Own Manufacture	$	$	$	$	$	$
Contract Manufacture (for others)	$	$	$	$	$	$
Wholesale distribution	$	$	$	$	$	$
Retail	$	$	$	$	$	$
Research (for others)	$	$	$	$	$	$
Other (please specify) _____	$	$	$	$	$	$

2. GENERAL LIABILITY

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

If Yes, state regulator_____ and date of last inspection: _____

Please indicate which of the following coverage's are required:

EXTENSIONS, ENDORSEMENTS & EXCLUSIONS			
Forest Fire Fighting Expense	☐ Yes ☐ No	Non-owned Automobile Coverage	☐ Yes ☐ No
Worldwide Coverage	☐ Yes ☐ No	Employee Benefits Liability – Aggregate	☐ Yes ☐ No
S.E.F No.94 Legal Liability for Damages to Hired Automobiles	☐ Yes ☐ No	Contingent Employers Liability	☐ Yes ☐ No
Incidental Medical Malpractice Liability	☐ Yes ☐ No	Voluntary Medical Payments	☐ Yes ☐ No
Tenant's Legal Liability	☐ Yes ☐ No	Employer's Liability Coverage Rider (note if required please provide details of payrolls)	☐ Yes ☐ No
Others (please specify):			

3. CLINICAL TRIALS

Are all trials conducted in accordance with:

a) The appropriate government authority(ies) ☐ Yes ☐ No

b) Ethics Committee Approval? ☐ Yes ☐ No

c) I.C.H. Guidelines? ☐ Yes ☐ No

DETAILS OF TRIALS **PERFORMED** IN THE **LAST 12 MONTHS**

(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 CANADA
				Estimated	Enrolled to date	

SUMMARY OF TRIALS **PLANNED** FOR THE NEXT **12 MONTHS**

(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 CANADA
				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

Within the next 12 months, does your Company plan to sell any of its research conclusions to third parties? ☐ Yes ☐ No

4. ERRORS AND OMISSIONS

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

_____

_____

_____

b) Estimated Income for the next 12 months derived from Services (as per Company Information) $_____

c) Please list these activities and state the approximate percentage of work carried out in each instance:

	%
	%
	%
	%
	%
	%
	%
Total should be100%	0 %

d) Please provide:

NAMES OF ALL DIRECTORS, PARTNERS OR PRINCIPALS	QUALIFICATIONS	DATE QUALIFIED	NO YEARS AS DIRECTORS, PARTNER OR PRINCIPAL OF THE FIRM

e) Please list the Firm's three largest contracts in the last three years:

WORK UNDERTAKEN	COUNTRY	CONTRACT INCOME (IN C$)	DATE COMMENCED	DATE COMPLETED

f) 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:

_____

_____

5. PRODUCTS LIABILITY

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

PRODUCT	CANADA	U.S.A.	ROW
Controlled drugs			
Hormone / Steroids			
Prescriptions			
Vaccines			
Over-the-Counter			
Food Supplements/Vitamins			
Cosmetics			
Other (please provide details):			

b) If you import products please state from which countries obtained and approximate percentage of total turnover against each:

_____

_____

c) For all products where you are a distributor do you retain rights of recourse against the manufacturers? ☐Yes ☐No

d) 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: _____%

_____

e) Do you have a separate design team? ☐Yes ☐No

f) Describe extent and type of tests and checks undertaken before Product goes into production:

_____

_____

g) Is your Company in compliance with all applicable government regulations? ☐Yes ☐No If No, please provides details:

_____

_____

h) Do you and your suppliers/subcontractors only use Canadian approved chemicals and pesticides? ☐Yes ☐No

If No, please provides details: _____

_____

i) Does your Company have a written quality control programme? ☐Yes ☐No

If Yes, please advise date last updated: _____

j) Does your Company have a formal product recall procedure in place? ☐Yes ☐No

If Yes, please advise date last updated: _____

k) Does your Company follow Good Manufacturing Practice (GMP)? ☐Yes ☐No

l) 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?

_____

7. INSURANCE HISTORY

Has any Insurer ever:

a) Declined your proposal for insurance? ☐Yes ☐No

b) Refused your renewal of any insurance policy? ☐Yes ☐No

c) Terminated your Insurance? ☐ Yes ☐ No

d) 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				

e) 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

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

If Yes, please provide details: _____

_____

DECLARATION STATEMENT

I/We declare that to the best of my/our knowledge and belief the above statements are true and complete and will form part of the contract between me/us and the Underwriters.

Name and position of person completing this Questionnaire:

Name:_____ Position _____

Signed: _____ Date: _____

POUR LES RÉSIDENTS DU QUÉBEC SEULEMENT:

Je confirme que ma demande pour la présente assurance ainsi que la proposition et tout autre document et correspondance soient en anglais.

QUEBEC 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.

Nom/Name: _____

Signature : _____

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