A Healthcare and Life Sciences MGA

COMMITTED TO BROKERS

MED THREE INSURANCE GROUP

21 Four Seasons Place - Suite 105, Toronto, ON M9B 6J8
Main: 416-477-2353 FAX: 416-477-2399

Canadian Pharmaceutical & Biotechnology Insurance Questionnaire

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.

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

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

GENERAL INFORMATION

Full Name(s) of all companies to be included:	
Address of Registered Office:	
Address(es) of any Overseas Offices to be Insured:	
Website Address:	
When established:	

Please provide copies of company literature if available

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						
Contract Manufacture (for others)						
Wholesale distribution						
Retail						
Research (for others)						
Other (please specify)						

GENERAL LIABILITY

Have all Manufacturing locations been inspected by the relevant regulatory body?	☐ Yes ☐ No
If 'YES', what was date of last inspection:	

Please indicate if the following coverages are required:

Extensions, Endorsements & Exclusions		*Extensions, Endorsements & Exclusions*	
Forest Fire Fighting Expense – Limit C$1,000,000 – Deductible CS$ 10,000	☐ Yes ☐ No	Non-owned Automobile Coverage	☐ Yes ☐ No
Worldwide Coverage	☐ Yes ☐ No	Employee Benefits Liability – Aggregate C$1,000,000 – Deductible C$1,000	☐ Yes ☐ No
S.E.F No.94 Legal Liability for Damages to Hired Automobiles – Limit C$ 75,000	☐ Yes ☐ No	Contingent Employers Liability	☐ Yes ☐ No

Incidental Medical Malpractice Liability	☐ Yes ☐ No	Voluntary Medical Payments – Limit C$50,000	☐ Yes ☐ No
Tenant's Legal Liability – Limit C$ 100,000	☐ Yes ☐ No	Employer's Liability Coverage Rider (note if required please provide details of payrolls)	☐ Yes ☐ No

Others (please specify):

CLINICAL TRIALS

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

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 CAN*
				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 CAN*

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

ERRORS AND OMMISSIONS

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

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

Please provide:

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

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

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

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?

PRODUCTS LIABILITY

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):			

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

For all products where you are a distributor, do you retain rights of recourse against the manufacturers?		☐ Yes ☐ No
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	%
Do you have a separate design team?		☐ Yes ☐ No

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

Is your Company in compliance with all applicable government regulations? ☐ Yes ☐ No

If No, please provides details.

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

If Yes, please advise date last updated:

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

If Yes, please advise date last updated:

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

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?

INSURANCE HISTORY

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

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*

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

If Yes, please provide details:

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				

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 Medthree Insurance Group, a customer provides Medthree 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 MedThree Insurance and any affiliated companies and service providers. Further information about Medthree Insurance personal information protection policy may be obtained by contacting their privacy officer at 416-477-2340.

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:	