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INSURANCE FOR MEDICAL PRODUCTS AND BIOPHARMA APPLICATION FORM

INSTRUCTIONS

- Please complete all questions. If a question is not applicable please answer "N/A".
- If additional space is required for any response, please continue your response in the ADDITIONAL INFORMATION section at the back of this Application Form.
- Please make certain the application is currently dated and signed by a principal, partner or director of the company and should make all the necessary enquiries of their fellow partners, directors and employees to enable all the questions to be answered.
- **In order to utilize the Submit button to directly submit your application, please download the application first.**

Coverage:	Limit Required	Deductible Required:
Products Liability	CAD \$	CAD \$
Clinical Trials Testing	CAD \$	CAD \$
Errors & Omissions	CAD \$	CAD \$
General Liability	CAD \$	CAD \$
Commercial Property	CAD \$	CAD \$

Policy Effective Date: _____

SECTION 1: COMPANY DETAILS

1.1 Please provide the following details:

Applicant name: _____

Address: _____

Website: _____

Additional Names/ Locations: _____

1.2 Date the Applicant was established: _____

1.3 Names of Predecessor Firms: _____

1.4 Please provide the number of employees:

1.5 Please provide details of partners, active directors / sole practitioners:

Name:	University:	Degree:	Years of Experience	Additional Qualifications

1.6 Please provide fees received in the following years:

Fees emanating from:	Last complete financial year:	Estimate for current financial year	Estimate for next financial year:
Canada:	\$	\$	\$:
United States:	\$	\$	\$
Other Countries:	\$	\$	\$
Total:	\$	\$	\$

SECTION 2: NATURE OF SERVICES

2.1 Please briefly describe the nature of your business activities:

2.2 Please indicate the percentage of total revenue derived by activity: *(The total of all activities listed should equal 100%)*

Discipline Breakdown:	%	Discipline Breakdown:	%
Own Manufacturing	%	Service Provider (contract manufacturer, contract research organization, etc.)	%
Wholesale distribution	%	Retail	%
Research	%	Other (Please specify below)	%

Description of any other work:

2.3 Does the Applicant belong to any association related to these activities: Yes No

If "Yes," please list the associations below:

2.4 Does the Applicant expect any significant changes in services or products to occur in the next year? Yes No
If "Yes," please explain in the ADDITIONAL INFORMATION section at the end of this application form.

2.5 Have there been any changes in senior management within the last 12 months? Yes No
If "Yes," please explain in the ADDITIONAL INFORMATION section at the end of this application form.

2.6 In the event the Applicant's product or service failed or delivery was delayed, please describe the worst case scenario. Consider loss of life, injury to people, damage to buildings or other tangible property, or financial loss (consequential or otherwise) for

the Applicant's clients.

SECTION 3: CONTRACT INFORMATION

3.1 Please give details of the three largest contracts the Applicant has carried out in the past three years:

Name of client	Business of client	Nature of work undertaken for this contract	Total contract value

3.2 Approximately how many clients does the Applicant have?

3.3 Does the Applicant have written contracts signed by every client? Yes No

If "no", please explain the circumstances and why.

3.4 Does the Applicant ever accept contracts with clients in which the Applicant accepts liability for consequential loss or financial damages greater than the value of the contract? Yes No

If "yes", explain what percentage of the Applicant's contracts this applies to and what these are capped at.

3.5 What approximate percentage of fees, in current financial year, will be paid to sub-consultants?

3.6 Does the Applicant ensure that sub-contractors carry their own general liability and errors and omissions insurance? Yes No

SECTION 4: PRODUCTS-COMPLETED OPERATIONS INFORMATION

4.1 Please complete the following income projections:

Product	Canada	USA	Other (please specify)
Controlled Drugs			
Supplements			
Prescriptions			
Over-the-counter			
Cosmetics			
Other: Please Specify			

4.2 If you import products, please provide the name of the countries the products are imported from and what the approximate percentage of total revenues for each country.

Country	% of Total Revenue
	%
	%
	%

4.3 For all products where you are a distributor, do you retain rights of recourse against the manufacturer? Yes No

- 4.4 Have any of your products been on the market for 3 years or less? Yes No
If "Yes," please explain in the ADDITIONAL INFORMATION section at the end of this application form.
- 4.5 Does the Applicant follow Good Manufacturing Practices (GMP) Yes No
If "No," please explain in the ADDITIONAL INFORMATION section at the end of this application form.
- 4.6 Is the Applicant ISO registered? Yes No
- 4.7 Are all of your products approved by Health Canada, the FDA, or any other equivalent regulatory agency governing any country in which product is sold? Yes No
- 4.8 Do you maintain samples of your products? Yes No
If yes, for how long?
- 4.9 Does your company have a written quality control program? Yes No
If "yes", please advise last updated.
- 4.10 Does your company have a formal product recall procedure in place? Yes No
If "yes", please advise last updated.
- 4.11 Does the Applicant maintain a written record of incident reports and/or complaints? Yes No
If "yes", please list persons responsible for handling of complaints.

SECTION 5: CYBER AND PRIVACY

Only complete this section if the Applicant requires this coverage

- 5.1 Does the Applicant have procedures and protocols in place covering compliance with all applicable privacy regulations? Yes No
- 5.2 Does the Applicant have IT security procedures and protocols in place that govern the handling and storage of sensitive information? Yes No
- 5.3 Does the Applicant ensure that all sensitive personally identifiable data (including credit and debit card information) is encrypted while standing and during transmission? Yes No
- 5.4 Does the Applicant have anti-virus software installed and enabled on all desktops, laptops, and servers (excluding database servers) and is it updated on a regular basis? Yes No
- 5.5 Does the Applicant have firewalls installed on all external gateways? Yes No
- 5.6 Does the Applicant make regular back-ups (at minimum weekly) of all critical data and store the same offsite or in a fire-proof safe or can the Applicant confirm that their outsourced service provider meets this requirement? Yes No
- 5.7 If the Applicant accepts payment cards (debit or credit) as form of payment, is the Applicant compliant with the Payment Card Industry (PCI) Data Security Standard? Yes No

If there is any additional information with respect to the Applicant's IT security, please explain in the ADDITIONAL INFORMATION section at the end of this application form.

SECTION 6: CLAIMS INFORMATION

Regarding all types of insurance to which this application form relates:

- is the Applicant aware of any loss or damage, whether insured or not, that has occurred to any of the companies to be insured (or to any existing or previous business of the partners or directors of any of the companies to be insured) within the last five (5) years, or
- is the Applicant aware of any circumstances which may give rise to a claim against any of the companies to be insured or any partners or directors thereof, or
- have any claims or cease and desist orders been made against any of the companies to be insured, or partners or directors thereof, or
- have any partners or directors of the companies to be insured been found guilty of any criminal, dishonest or fraudulent activity or been investigated by any regulatory body?

With reference to questions a, b, c and d above:

Yes No

If the answer to the above is Yes, then please attach full details including an explanation of the background of events, the maximum amount involved/claimed, the status of the claim(s) or circumstance(s) and any reserve(s) or payment(s) made by the Applicant and/or by Insurers, and the dates of all developments and payments.

SECTION 7: DECLARATION

- I declare that after full enquiry the information provided in this application form is true and complete that I have not misstated or suppressed any material fact.
- I agree that this Application Form, together with any other material information supplied by me shall form the basis this contract of insurance.
- I undertake to inform Underwriters of any material alteration to these facts occurring before the inception of the policy.

Signed: _____	Full Name: _____
Position held: _____	Date: _____

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