Life Science Application
Pharmaceutical and Biotechnology

CNA
We can show you more.®

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.

Applicant Information

1. Applicant:

2. Address:

3. Mailing Address:

4. Locations: (if other than above)

5. All Named Insureds:

6. Additional Insureds: (explain relationships)

7. If you have acquired any subsidiaries within the last 5 years, identify:

Entity	Date Acquired

8. Named Insured is:

○ Individual ◉ Partnership ○ Corporation ○ Joint Venture ○ Other (Describe below)

9. How long has the Named Insured been in business?

10. Do you have a parent company?

11. Have you operated under another name? (please give full details)

Please complete and return this form to your insurance broker.

12. Projected U.S. revenues?

13. (a) Projected foreign revenues?

(b) Projected Canadian revenues?

14. Revenues for current year?

15. Revenues from previous year?

16. Product/Service Profile (percentage)

Source/Potential Source of Revenues	%	Product/Service Description
Medical Devices		
Diagnostics		
Proprietary Bio-Pharmaceuticals		
Generic Bio-Pharmaceuticals		
Contract Research		
Contract Manufacturing		
Distribution		
Equipment Rentals/Leasing		
Repair/Installation/Service		
Other (please explain)		

17. Product/Service Breakdown (percentage)

Preclinical Testing		Biostatistics	
Pharmacodynamics		Submission of Regulatory Filings	
Pharmacokinetics		Bioequivalency/Bioavailability Testing	
Protocol Design		Quality Control	
Study Selection or Monitoring		Manufacturing	
Clinical Investigations (indicate phases)		Repackaging/Assembly	
Clinical Staff Recruitment		Product/Equipment Sterilization	
Clinical Staff Training		Marketing	

Please complete and return this form to your insurance broker.

Case Report Form Design		Sales	
Data Entry/Database Management		Distribution	
Publications/Software Design		Other (please explain)	
Vaccines		Imaging/Diagnostic Agents	
Hormones & Steroids		Nutraceuticals	
Injectable/Oral Prescription		Vitamins/Food Supplements	
Topical Prescription		Diet Aids	
Drug Delivery		Other (please explain)	

18. List new products expected to be introduced:

19. List any discontinued products: (Please indicate reason)

20. Any distributed products manufactured outside U.S./Canada? If YES, is facility FDA/Health Canada approved?

21. Any product components imported? If yes, are they FDA/Health Canada approved?

22. Are any products manufactured sold under others' labels?

23. Are any products sold as components for other products? (Likely end product)

24. Do you require Certificates of Insurance from your suppliers? What limits do you require?

25. Do you contract out product development, manufacturing, sales, distribution services? (Please indicate activities contracted?

26. Do any of your products training/certification programs required FDA/Health Canada approval?

27. Are manufactured products UL listed and/or CSA certified?

28. Do you use a facility for reliability/design validation?

Please complete and return this form to your insurance broker.

29. Professional Services

Do any of your employees provide direct patient care?

Do they carry their own individual medical malpractice insurance?

Do you operate an in-patient facility?

Do any of your employees participate on an Institution Review Board?

Do you or any of your employees have a financial interest in the products of your clients?

List largest clients for current year:

30. Sponsored Clinical Trials

Product	# Active Subjects Over Next Policy Period	Indications	Country

* Please attach FDA/Health Canada approved protocols & informed consent documents for active clinical trials.

31. Regulatory

To the best of your knowledge are you in compliance with FDA and/or Health Canada Regulations or foreign agency equivalent?

Any product recalls in the past year? (if yes, please submit details & recall status)

Within past 12 months, has there been any Medical Device Reports's or Adverse Event Report's filed with FDA or any other country equivalent? (if yes, indicate the number of filings and the nature of each)

Please complete and return this form to your insurance broker.

Date & result of most recent FDA and/or Health Canada inspection(s).
(please submit a copy of Forms and your documented response)

Have any products or company practices been subject to an investigation by any government agency? (if yes, please explain)

Any clinical trials placed on a clinical hold? (if yes, provide details)

Do you audit Clinical Investigator performance?

Any warning letters issued against you in the last 3 years? (if yes please explain)

32. Risk Management

Loss Prevention/Control Program? (if yes please name person in charge of program)

Written Quality Control Program?

Written Product Recall Plan?

Written Records Retention Program?

Promotional materials, contracts, guarantees & labeling jointly reviewed by each applicable discipline?

Other (please explain)

33. Loss History

*** Total aggregate cost (losses from ground up including defense) for last five years**

Policy Period	Insurer	# of Claims	Total Incurred

*** Attach previous carrier loss runs**

Please complete and return this form to your insurance broker.

Please provide details on all incurred losses

Any known occurrence(s) not yet reported? (if yes, please submit details, attach sheet if necessary)

34. Coverage History

Policy Period	Primary & Excess Limits	Carriers	Retro Date

Has your insurance ever been cancelled or non-renewed by a carrier? (if yes, please explain)

What limit of liability are you seeking?

35. Please include the following with this application:

- Most recent Annual Report/Audited Financial Statement
- Clinical trial protocols & informed consent documents
- Senior staff curriculum vitae
- Outline of Quality Control Program
- Advertisements, brochures, descriptive literature
- Sample service contracts & indemnification agreements

Please complete and return this form to your insurance broker.

Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or "statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties, including but not limited to fines, denial of insurance benefits, civil damages, criminal prosecution and confinement in state prison.

Completing and signing this application does not bind coverage. Coverage will not be bound, nor will a policy be issued until the applicant signifies acceptance of the Company's premium quotation.

The undersigned authorized officer of the applicant knows of no other relevant facts which might affect the Company's judgment when considering this renewal application and warrants that the statements herein are true, and it is agreed that this renewal application shall be the basis of the renewal contract and shall be deemed incorporated therein should the Company evidence its acceptance of this renewal application by issuance of a renewal policy. It is agreed that this renewal application shall be on file with the Company and that it shall be deemed to be attached to and made part of the renewal policy, if issued, as if physically attached to the renewal policy.

Signature: _____ Title: _____

Print Name: _____ Date: _____

Please complete and return this form to your insurance broker.