Beazley | Life Sciences

Beazley Life Sciences Form

NOTICE: PART OR ALL OF THE POLICY FOR WHICH THIS APPLICATION IS MADE IS WRITTEN ON A CLAIMS MADE BASIS, WHICH MEANS THAT THE POLICY APPLIES ONLY TO ANY CLAIM FIRST MADE AGAINST THE INSURED DURING THE POLICY PERIOD OR THE OPTIONAL EXTENDED REPORTING PERIOD, IF APPLICABLE. AMOUNTS INCURRED AS CLAIMS EXPENSES SHALL REDUCE AND MAY EXHAUST THE LIMIT OF LIABILITY AND ARE SUBJECT TO THE DEDUCTIBLE. PLEASE READ THE POLICY CAREFULLY. ANSWER ALL QUESTIONS COMPLETELY. UNANSWERED QUESTIONS WILL BE INTERPRETED AS HAVING BEEN MARKED "NOT APPLICABLE" BY APPLICANT. IF ADDITIONAL SPACE IS NEEDED TO ANSWER ANY QUESTION FULLY, PLEASE ATTACH A SEPARATE PAGE. THIS APPLICATION WILL BE ATTACHED TO AND MADE PART OF ANY POLICY ISSUED.

Please provide the following information:

1. Detailed Loss History for the last FIVE years. The loss runs should be updated within the last 30 days, and include a breakdown of total incurred losses (paid and reserves for both indemnity and expense), and a description of all losses, whether paid or outstanding.
2. Most recent AUDITED financial statements.
3. Copy of CONTRACTUAL AGREEMENT(S) in place with whom you enter into a service for a fee agreement.
4. Copy of Human Clinical Trial PROTOCOL(S) and INFORMED CONSENT FORM(S)
5. Copy of recently issued WARNING LETTERS/and RESPONSES
6. Most recent local and/or provincial/territorial accreditation agency reports.
7. Any marketing brochures or literature detailing services provided.

Section 1 – Applicant/Broker Information

1. First named insured:

2. Address (street, city, state, postal code):

3. Website address:

4. Mailing address (if different from above):

5. Company years in business: (mm/dd/yyyy) / /

6. Contact (name, phone number, email):

7. Broker firm (street, city, state, postal code):

8. Broker contact (name, phone number, email):

9. Type of entity:

   a. Corporation ☐ b. Partnership ☐ c. Non-profit ☐ d. Individual ☐

   e. Joint Venture ☐ f. Limited Liability Company ☐

   g. Other (please describe):

10. Parent company (name and address):

11. Additional insureds (please list):

    a.

    b.

    c.

12. Additional named insureds (ownership % must be >50%):

    a.

    b.

    c.

13. Brief description of company operations:

14. Has the company filed for bankruptcy in the last 7 years? Yes ☐ No ☐ N/A ☐

15. Has the company had any mergers/acquisitions in the last 6 years and/or have any plans in the next 12 months? Yes ☐ No ☐ N/A ☐

16. Is the company/shareholders/directors/officers/partners/members thereof under any investigation for alleged criminal violations relating to business? Yes ☐ No ☐ N/A ☐

17. Has the company ever operated under a different name? Yes ☐ No ☐ N/A ☐

If answered 'Yes', to any questions 15 - 17, please explain here:

Section 2 – Coverage Information

18. Coverage effective dates: From: (mm/dd/yyyy) ☐ / ☐ / ☐ To: (mm/dd/yyyy) ☐ / ☐ / ☐

19. Prior insurance history: Check here if no prior coverage: New ☐

Year	Coverage	Carrier	Limits	Deductible	Premium

20. Policy limits/Deductible/Retroactive dates request

	Limits	Deductible	Retroactive date
Errors and omissions liability			
Healthcare professional services			
Products/completed operations liability			
General liability			
Clinical trial medical expenses			
Clinical trials medical monitoring expenses			
Products medical expenses			
Products medical monitoring expenses			

21. Revenue History

	Canada	U.S.	Rest of World	Total
Projected				
Last year				
1st Prior				
2nd Prior				
3rd Prior				

22. Please provide a breakdown of revenue by product/service for the current financial year as follows:

Please provide a full listing of Services and/or Products offered, and the percentage of Total Gross Revenue. The total must equal 100%.
If these are Human Clinical Trials, check box and complete the Clinical Trials section in the application. ☐

Pharmaceuticals/ Biologics/Nutra	%	Medical Devices	%	Contracted Professionals	%
Injectable/Oral prescription		Analytical instruments		Contract research organization	
Benzodiazepine		Surgical instruments		Contract manufacturer	
SSRI's or SNRI's		Dental instruments		Academic medical institution	
Cannabinoids		Diagnostic kits		Site management organization	
Scheduled I or II Substance		Hospital Products/Supplies		Lab services	
Opioids		Mobility aides		Clinical staff recruitment/Training	
Fertility/Birth control		Monitoring devices		Database management/ Regulatory filings/Medical writing	
Hormone replacement		Imaging devices		Distribution	
Drug delivery/ Nanoparticles		Anesthesia/Respiratory		Assembly/Repackaging	
Generic Pharma		Pain pumps		Quality assurance/Control	
Imaging/Diagnostic agents		Implantable-Active		Sales/Marketing	
Nutri-parmaceuticals		Metal-on-Metal implants		Sterilisation	
Weight management		Breast implants			
Sexual enhancement		Impantable-Non active			
Topical prescription		Lasers			
Vaccines		Morcellators			
Food supplements/ vitamins		Dialysis			
Cosmetics		Surgical mesh			
		IVC Filters			
		Cold therapy			
		IUD devices			
Other (specify)		Other (specify)		Other (specify)	
Total %	**100%**	**Total %**	**100%**	**Total %**	**100%**

Section 3 – Products Completed Operations

23. Please list your Company's products and indicate whether you are the manufacturer or distributor. If you are the manufacturer, please indicate whether you manufacture the entire product or only a part of it. For distributed products, please indicate the product's country of origin.

Product	% of Total Revenue	Manufacturer or Distributor	Whole or Part	Country of origin (for distribution only)

(Attach list if necessary)

24. Please provide a breakdown of your revenues by class of device (as defined by Health Canada, the FDA in the U.S., or any other regulatory authority).

	Last Twelve (12) Months			Next Twelve (12) Months		
	Canada	U.S.	Other	Canada	U.S.	Other
Class 1:						
Class 2:						
Class 3:						
Class 4:						
Other:						
Total:						

25. Are products or parts manufactured outside Canada? Yes ☐ No ☐ N/A ☐

If 'Yes', what product(s) and where?

26. Are you aware of product(s) sold off-label? Yes ☐ No ☐ N/A ☐

a. If so, are off-label products tracked? Yes ☐ No ☐ N/A ☐

b. Do you have procedures in place for inhibiting employees from off label promotions? Yes ☐ No ☐ N/A ☐

27. Are any products repackaged or relabeled? Yes ☐ No ☐ N/A ☐
If 'Yes', what product(s)?

28. Do product(s) have a Black Box or other significant safety warning label(s)? Yes ☐ No ☐ N/A ☐
If 'Yes', what product(s)?

29. Are product(s) sold as components of other products? Yes ☐ No ☐ N/A ☐
If 'Yes', please explain:

30. Have product(s) ever been associated with death/permanent injury or hospitalization? Yes ☐ No ☐ N/A ☐
If 'Yes', please explain:

31. Has any product(s) been recalled in the past 5 years? Yes ☐ No ☐ N/A ☐

a. Are you considering recalling any known or suspected defective products from the market? Yes ☐ No ☐ N/A ☐
If 'Yes', please explain:

32. Are any products specifically approved for, and used by: minors, pregnant women, cognitively impaired and/or prisoners? Yes ☐ No ☐ N/A ☐
If 'Yes', what product(s):

33. Have you discontinued any products or services in the last 5 years? Yes ☐ No ☐ N/A ☐

a. Are you considering discontinuing any product or service? Yes ☐ No ☐ N/A ☐

If 'Yes', please explain:

34. Is applicant considering introducing any new products or services in the next 12 month? Yes No N/A
If 'Yes', please explain:

35. Do you rent/lease medical equipment? Yes No N/A
If so, what type:

36. Do you repair/install/or service medical equipment? Yes No N/A

If so, are you or your employees factory trained? Yes No N/A

37. Do you comply with the Health Canada's Good Manufacturing Practices (GMP) or equivalent manufacturing standards for your product(s)? Yes No N/A

38. Do you maintain the following records:

a. When and where product was manufactured? Yes No N/A

b. To whom the product was sold and date of sale? Yes No N/A

c. Who supplied the materials for the product? Yes No N/A

d. Change in design/change in advertising? Yes No N/A

39. Do any of your products contain the following (including any derivative thereof): Yes No N/A

Aconite, Higenamine; Aegeline; Androstenedione; animal derived products, AMP Citrate, 1,3-dimethylbutylamine citrate,1,3-dimethylbutylamine HCL, methylpentanamine; Aristolochic Acid, BMPEA, B-Methylphenethylamine, Acacia rigidula; Butanediol, Chaparral, Comfrey (Pyrrolizidine alkaloids), Contraceptives or any other products intended to inhibit pregnancy or act as birth control; Chomper, Creatine, Dehydroepiandrosterone, Dendrobium; Dieter's Tea, Dienestrol, diethylstilbestrol, or DES, or which has the same chemical formulary, or which is a stilbene derivative, or any other product or substance having substantially similar formation, structure, or function by whatever name manufactured or marketed as DES; Diethylistbestrol, DMAA, 1,3-dimethylamylamine, dimethylamylamine, methylhexanamine; Ephedra, Ma huang, Ephedra sinica, Chinese Ephedra, ephedrine, ephedrine Alkaloids, pseudoephrine, norpseudoephredine, or any other product or substance having substantially similar formation, structure or function, by whatever name manufactured, grown or marketed; Ephedrine, Estazolam, Gamma Butyrolactone, Gamma Hydroxybutyric Acid, Germander, Germanium, Injectables and implants intended for cosmetic purposes, including but not limited to breast implants, bovine collagen based dermal fillers or implants, human collagen based dermal fillers or implants, hyaluronic acid based dermal fillers or implants, autologous fat transfer, cadaveric based products, and botulinum toxin injections; Isotretinoin, Accutane; Indinavire, Jin Bu huan; Kava, kava-kava and related derivatives; Lobelia; L-Tryptophan or products of any kind or nature which contain L-Tryptophan or any derivative thereof, regardless of whether the product is designated as L-Tryptophan or given any other appellation; Melatonin, oral contraceptives, Pennyroyal Oil; Phenolphthalein or NeoPrunex, or any derivative thereof; Phentermine, Phenylalanine, Phenylpropanolamine, Phenylpropanolamine Hydrochloride, PPA or any product or drug containing any of these substances; Picamilon, N-nicotinoyl-GABA, pycamilon, pikamilon; products that are know mutagens, products that are known teratogens, psychotropic products, SSRI (Selective Serotonin Reuptake Inhibitor) or SNRI (Selective Norepinephrine Reuptake Inhibitor); Stephania; St. John's Wort, Stephania or Magnolia, tobacco or any tobacco products (or ingredients of, or used in the manufacture or production of, such products); Thalidomide; Thimerosal,

Tiractricol, Trix Metabolic Accelerator, Vaccines, toxoids, sera and other immunizing agents; Vinpocetine, Cavinton, Intelectol, ethyl apovincaminate; weight reduction products, Willow Bark, and Yohimbe?

arising out of any product used for the treatment of obesity, weight loss and/or weight management, including but not limited to suppressants containing fenfluramine (Ponderal, Ponderal Pacaps, Pondimin) or dexfenfluramine (Redux) or as part of a combined therapy known as fenphen (fenfluramine and phentermine);

any product containing silicone or similar which is in any form implanted or injected in the body;

If 'YES', please explain.

Section 4 – Human Clinical Trials

40. Test subjects enrollment history:

	Canada participants	U.S. participants	Rest of World participants	Number of minor participants	Total
Projected					
Last year					
Prior					

41. Schedule of human clinical trial(s):

Please provide copy of Protocol and Informed Consent Form for each sponsored trial (use attachment if necessary)

Product/Protocol Name & Number	Number of Test Subjects encolled last year	Number of Test Subjects Newly Enrolled this Year	Phase of Trial and Indication/ Disease tested	Country of Trials	Ongoing/ Completed

42. Human clinical trials supplemental questions:

a. Are all of your clinical trials approved and subject to oversight by an Institutional Review Board? Yes ☐ No ☐ N/A ☐

If 'No', please explain:

b. Do you operate an in-patient facility? Yes ☐ No ☐ N/A ☐

If so, how many beds?

c. Do you or your employees ever act as both the Trial Sponsor and Clinical Investigator? Yes ☐ No ☐ N/A ☐

If so, please explain:

d. Do your employees participate on an Institutional Review Board? Yes ☐ No ☐ N/A ☐

e. Has any of your trials been suspended/place on hold because of safety concerns? Yes ☐ No ☐ N/A ☐

If so, please explain:

f. Are any of the following incentives provided to the Clinical Investigator: Yes ☐ No ☐ N/A ☐

Money ☐ Stock ☐ Position ☐ Other

g. Have any clinical investigators been cited for regulatory violations in connection with your trials? Yes ☐ No ☐ N/A ☐

If 'Yes', please explain:

h. In the past 12 months have there been any AER's or SAER's filed? Yes ☐ No ☐ N/A ☐

If 'Yes', please explain:

i. Have any warning letters been issued against you or your Investigators? Yes ☐ No ☐ N/A ☐

If 'Yes', please explain:

j. Have there been any clinical trial "For Cause Audits" conducted in the last 5 years? Yes No N/A

If so, please explain:

k. Do any clinical trials involve minors (under the age of 18)? Yes No N/A

l. Are any subjects approved for expanded access/compassionate use? Yes No N/A

If so, how many

m. Do you publish all clinical trial results? Yes No N/A

n. Do you ever provide material/product for another organization's clinical trial? Yes No N/A
If so, please explain:

Section 5 – Healthcare Professional Services

43. Healthcare Professional Staff:

Name	Specialty	Board certification	Hours worked	Full-time/ part time	Own malpractice Insurance? Limits

44. Has applicant or any of its staff's license to practice medicine or license to prescribe or dispense drugs ever been limited, suspended, revoked, placed on probation or been voluntarily surrendered in any province/territory? Yes No N/A

If 'Yes', please explain:

45. Are any of the above-listed physicians to be listed under applicant's policy? If 'Yes', please provide CV for each physician — Yes ☐ No ☐ N/A ☐

46. Do any of the physicians have direct patient care responsibilities? — Yes ☐ No ☐ N/A ☐

47. Prior to hiring any employee, do you verify the following:

    a. Education background/training? — Yes ☐ No ☐ N/A ☐

    b. Employment references with at least two previous employers? — Yes ☐ No ☐ N/A ☐

    c. Criminal record on Local/Provincial/Territorial/National? — Yes ☐ No ☐ N/A ☐

    d. Driving record? — Yes ☐ No ☐ N/A ☐

    e. Drug Test? — Yes ☐ No ☐ N/A ☐

48. Are all health professionals credentialed prior to hiring? — Yes ☐ No ☐ N/A ☐

    a. If 'Yes', how often are physicians re-credentialed?

49. Has the applicant or any staff ever been the subject of disciplinary/investigative proceedings or reprimand by a governmental/administrative agency, hospital, or professional association? — Yes ☐ No ☐ N/A ☐

    If 'Yes', please explain:

Section 6 – Errors and Omissions

50. Are any contracts past due, customers stopped payments or requested refunds? Yes ☐ No ☐ N/A ☐

If 'Yes', please explain:

51. Do you have formal written contracts/agreements in place with all clients/customers? Yes ☐ No ☐ N/A ☐

52. Do you ever assume liability of others in your contract? Yes ☐ No ☐ N/A ☐

53. Do the contracts include the following provisions:

a. all duties and responsibilities of each party Yes ☐ No ☐ N/A ☐

b. arbitration clause Yes ☐ No ☐ N/A ☐

c. choice of law or jurisdiction Yes ☐ No ☐ N/A ☐

d. force Majeure Yes ☐ No ☐ N/A ☐

e. guarantees/warranty disclaimers Yes ☐ No ☐ N/A ☐

f. hold harmless agreements/indemnification Yes ☐ No ☐ N/A ☐

g. limitation of consequential damages Yes ☐ No ☐ N/A ☐

h. limitation of liabilities/capping of limits Yes ☐ No ☐ N/A ☐

54. Does an attorney review all contracts or agreements including changes prior to use? Yes ☐ No ☐ N/A ☐

55. Do you contract out product development, manufacturing, packaging, sales, distribution, sterilization and/or validation? Yes ☐ No ☐ N/A ☐

56. Do you receive a hold harmless agreement from each contractor? Yes ☐ No ☐ N/A ☐

57. Do you obtain Certificate of Insurance from all manufacturers/suppliers evidencing Product Liability insurance? Yes ☐ No ☐ N/A ☐

If so, what are the minimum limits required? $

58. What is the largest contract by revenue: $

59. What is the longest contract by duration (month)

60. What is the average value and duration of contracts: $ month

Section 7 – Regulatory/Risk Management

(NOTE: UW may request to review copies of QC/QA, Product Recall, Contract Agreements as part of the submission)

61. To the best of your knowledge, are you in compliance with the Health Canada regulations and if applicable, the foreign agency equivalent? Yes No N/A

a. Have there been any incidents of non-compliance (including sales and marketing practices)in the past 5 years? Yes No N/A

If 'Yes', please explain:

b. Do you have a formal Quality Control program? Yes No N/A

c. Do you have a formal Loss Control/Risk Management program? Yes No N/A

d. Do you have a formal written Product Recall plan? Yes No N/A

e. Do you have a Records Retention Plan? Yes No N/A

f. Do you require all sales personnel to participate in a formal training program that instructs them on all applicable company policies and procedures? Yes No N/A

g. Do you have any products that do not have a formal Health Canada and if applicable, foreign agency equivalent approval for marketing? Yes No N/A

If 'Yes', please explain:

h. When was your last Health Canada inspection (if relevant)? (mm/dd/yyyy) / /

Were you issued a notice as part of this inspection? Yes No N/A
If 'Yes', please provide a copy along with your responses, if applicable

i. Do you audit foreign/domestic suppliers? Yes No N/A

If 'Yes', when was the last audit and result:

j. Do your product(s) require a Risk Evaluation & Mitigation Strategy (REMS)? Yes No N/A

If 'Yes', what product(s):

Section 8 – Loss Information

62. **Please provide details of applicant's total aggregate losses, from the 1st dollar, including expenses (and please also attach hard copy loss runs for the last 5 years): If None, check here** None ☐

Policy Period	Insurer	Number of Claims	Total Cost Incurred

a. Any claim(s)/known occurrence(s) not yet reported? Yes ☐ No ☐ N/A ☐

b. Does the applicant handle claims in-house or utilise the services of a third party administrator? Yes ☐ No ☐ N/A ☐

c. Has any claim or suit for an error, omission or malpractice ever been made against applicant or any employees/staff working on its behalf? Yes ☐ No ☐ N/A ☐

d. Any product or service has been/is involved with any certified/attempted class action or multi-national litigation? Yes ☐ No ☐ N/A ☐

e. Has your insurance ever been cancelled or non-renewed by a carrier? Yes ☐ No ☐ N/A ☐

If answered 'Yes', to any questions 62a - e, please explain below:

Declaration

The undersigned is authorized by the applicant and declares that the statements set forth herein and all written statements and materials furnished to the insurer in conjunction with this application are true. Signing of this application does not bind the applicant or the insurer to complete the insurance, but it is agreed that the statements contained in this application, any supplemental attachments, and the materials submitted herewith are the basis of the contract should a policy be issued and have been relied upon by the insurer in issuing any policy.

This application and materials submitted with it shall be retained on file with the insurer and shall be deemed attached to and become part of the policy if issued. The insurer is authorized to make any investigation and inquiry in connection with this application as it deems necessary.

The applicant agrees that if the information supplied on this application changes between the date of this application and the effective date of the insurance, the applicant will, in order for the information to be accurate on the effective date of the insurance, immediately notify the insurer of such changes, and the insurer may withdraw or modify any outstanding quotations or authorizations or agreements to bind the insurance

I have read the foregoing application of insurance and any attachment and represent that the responses provided on behalf of the applicant are true and correct.

Warning

Any person who, with intent to defraud or knowing that (s)he is facilitating a fraud against the insurer, submits an application or files a claim containing a false or deceptive statement may be guilty of insurance fraud.

Signature:

Print name:

Position held (Owner, partner, authorised officer):

Title:

Date: / /

Insurance Act 2015 – Duty of Fair Presentation

1. Before this insurance contract is entered into, the Insured must make a fair presentation of the risk to the Insurer, in accordance with Section 3 of the Insurance Act 2015. In summary, the Insured must:
   a. Disclose to the Insurer every material circumstance which the Insured knows or ought to know. Failing that, the Insured must give the Insurer sufficient information to put a prudent insurer on notice that it needs to make further enquiries in order to reveal material circumstances. A matter is material if it would influence the judgement of a prudent insurer as to whether to accept the risk, or the terms of the insurance (including premium);
   b. Make the disclosure in clause (1)(a) above in a reasonably clear and accessible way; and
   c. Ensure that every material representation of fact is substantially correct, and that every material representation of expectation or belief is made in good faith.
2. For the purposes of clause (1.)(a.) above, the Insured is expected to know the following:
   a. If the Insured is an individual, what is known to the individual and anybody who is responsible for arranging his or her insurance.
   b. If the Insured is not an individual, what is known to anybody who is part of the Insured's senior management; or anybody who is responsible for arranging the Insured's insurance.
   c. Whether the Insured is an individual or not, what should reasonably have been revealed by a reasonable search of information available to the Insured. The information may be held within the Insured's organisation, or by any third party (including but not limited to subsidiaries, affiliates, the broker, or any other person who will be covered under the insurance). If the Insured is insuring subsidiaries, affiliates or other parties, the Insurer expects that the Insured will have included them in its enquiries, and that the Insured will inform the Insurer if it has not done so. The reasonable search may be conducted by making enquiries or by any other means.

LMA9117

16 March 2016