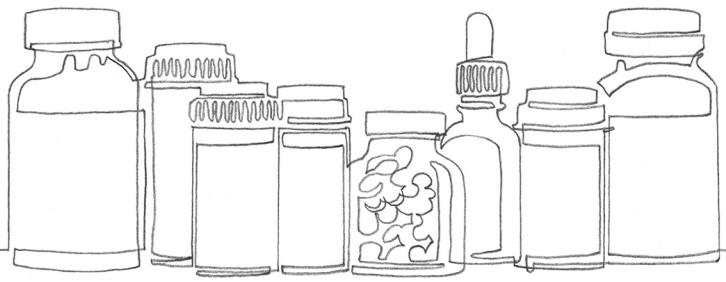
Application form

Beazley | Life Sciences Singapore/Hong Kong



Beazley Life Sciences Application

- This Application is for a claims made policy. A claims made policy only responds to claims made against the insured and notified to insurers during the policy period arising from activities or services provided on or after the policy retroactive date. This Application can be completed electronically or by hand and must be signed and dated by an authorised representative of the insured organisation. All hand written notes must be clearly legible and all questions should be answered fully, stating "Nil" or "None" as applicable. Incomplete answers may delay quotation.
- Please attach all supporting documents and include as much detail as possible, using the additional sheets as required.
- What you need to tell insurers:
- Statement pursuant to Section 25 (5) of the Insurance Act (Cap. 142) (or any subsequent amendments thereof) – You are to disclose in this Proposal Form fully and faithfully all facts which you know or ought to know, otherwise the policy issued hereunder may be void.
- A circumstance or representation is material if it would influence the judgement of a prudent insurer in determining whether to take the risk and, if so, on what terms.
- Please ensure you have signed and dated the declaration statement at the end of this Application.

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/483's and RESPONSES equivalent regulatory body
6. Most recent regulatory accreditation reports.
7. Any marketing brochures or literature detailing services provided.

Section 1 – Applicant/Broker Information

1. Name of insured:

2. Address of the named insured:

3. Website address:

4. Mailing address (if different from above):

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

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

7. Type of entity:

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

   e. Joint Venture ☐ f. Limited Liability Company ☐

   g. Other (please describe):

8. Parent company (name and address):

9. Additional insureds (please list):

   a.

   b.

   c.

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

    a.

    b.

    c.

11. Brief description of company operations:

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

13. 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 ☐

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

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

If answered 'Yes', to any questions 13 - 15, please explain here:

Section 2 – Previous insurance history

16. Please provide full details of your previous and current medical professional liability cover

Year	Insurer	Period of cover	Limit of indemnity	Excess	Premium

17. Has any application for this type of insurance cover ever been:

Declined Cancelled Required any special terms None

If any of the above are applicable, please provide detailed explanation and additional information on the supplementary sheet(s).

18. Policy limits/Retention/Retroactive dates request

	Limits ($)	Retention ($)	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			

19. Revenue History

		Domestic Revenue	Exports	Total
Projected	$			
Last year	$			
1st Prior	$			
2nd Prior	$			
3rd Prior	$			

20. 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, tick box and complete the Clinical Trials section in the application. ☐

Medical Devices	**%**
Analytical instruments	
Cosmetics/Topicals/Vitamins/Minerals/Herbs/Botanicals/Hand Sanitizers	
Clinical Trails (Phases I – II)	
Clinical Trails (Phases III +)	
Drug Delivery Systems (except for those that are used to deliver pain medications)	
Drug Delivery Systems (used to deliver pain medications)	
Dental Instruments/Equipment (Class I & II Devices)	
Dental Instruments/Equipment (Class III + Devices)	
Diagnostic Kits (excluding those catering to public health concerns – Pandemics (Covid-19), HIV, Hepatitis, Etc.)	
Diagnostic Kits (those catering to public health concerns – Pandemics (Covid-19), HIV, Hepatitis, Etc.)	
General Anaesthesia Equipment	
Hospital Equipment (please advise details)	
Hospital Products/Supplies (please advise details)	
Monitoring devices	
Personal Protective Equipment (face masks, shields, gowns, gloves, etc.)	
Pre-Packaged Sterile Products	
Surgical Equipment	
Rehabilitation Equipment (excluding for Mobility Devices)	
Rehabilitation Equipment (for Mobility Devices)	
Respiratory Accessories (excluding Ventilators)	
Respiratory Accessories (Ventilators only)	
Other (specify):	
Diagnostic and Testing	
Pre-Clinical Testing	
Drug Development	
Other (specify):	
Total %	**100%**

Section 3 – Products Completed Operations

21. Are products or parts manufactured outside the Domestic Country? Yes ☐ No ☐ N/A ☐
If 'Yes', what product(s) and where?

22. 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 ☐

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

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

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

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

27. 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 below.

28. 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).

29. 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 below.

30. Is applicant considering introducing any new products or services in the next 12 month? Yes ☐ No ☐ N/A ☐

If 'Yes', please explain below.

31. Do you rent/lease medical equipment? Yes ☐ No ☐ N/A ☐

If so, what type:

32. 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 ☐

33. Do you comply with the U.S. Food & Drug Administration's Current Good Manufacturing Practices (CGMP) or equivalent manufacturing standards for your product(s)? Yes ☐ No ☐ N/A ☐

34. 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 ☐

Section 4 – Human Clinical Trials

35. Test subjects enrollment history:

	Clinical trial participants (Domestic)	Clinical trial participants (Overseas)	Number of minor participants	Total
Projected				
Last year				
Prior				

36. Sponsored human clinical trial(s):

Please provide copy of Protocol and Informed Consent Form for each 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

37. 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 below.

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 below.

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 below.

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 below.

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

If 'Yes', please explain below.

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

If 'Yes', please explain below.

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

If so, please explain below.

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 below.

Section 5 – Healthcare Professional Services

38. Healthcare Professional Staff:

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

39. 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? Yes ☐ No ☐ N/A ☐

If 'Yes', please explain below.

40. 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 ☐

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

42. 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/State/National? Yes ☐ No ☐ N/A ☐

d. Driving record? Yes ☐ No ☐ N/A ☐

e. Drug Test? Yes ☐ No ☐ N/A ☐

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

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

44. 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 below.

Section 6 – Errors and Omissions

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

If 'Yes', please explain below.

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

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

48. 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 ☐

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

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

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

52. 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? $

53. What is the largest contract by revenue: $

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

55. 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)

56. To the best of your knowledge, are you in compliance with the relevant regulatory body? 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 below.

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 FDA approval for marketing? Yes ☐ No ☐ N/A ☐

If 'Yes', please below.

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

Were you issued a warning notice 483 or equivalent? Yes ☐ No ☐ N/A ☐

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 – Claims history

57. Please list all claims made against the proposer and all circumstances that could give rise to a complaint and/or claim during the last 10 years. If none, please state "None". For additional space please use the supplementary pages.

Claim/ complaint/ incident	Status open or closed	Incident date (dd/mm/yyyy)	Reserve ($)	Total value ($)	Description/ nature of allegations

Declaration

Please use the supplementary page(s) to add any pertinent information or additional information as may be required to fully answer the questions.

I/We declare that the statements and particulars contained in the application are true and that I/we have not mis-stated or suppressed any material facts.

I/we undertake to inform insurers of any material alteration to these facts occurring before the completion of the contract of insurance. However, the duty to disclose material facts continues after the completion of the Application and throughout any policy period (and any extension thereto).

Statement pursuant to Section 25 (5) of the Insurance Act (Cap. 142) (or any subsequent amendments thereof) - You are to disclose in this Proposal Form fully and faithfully all facts which you know or ought to know, otherwise the policy issued hereunder may be void.

Signing this Declaration does not bind the proposer to complete this insurance.

Signature:

Print name:

Position held (Owner, partner, authorised officer):

Title:

Date: / /

Supplementary information

Please use this space to record the answers to any questions for which you require additional space, noting the appropriate question number.