Proposal form

Beazley | Life Sciences

beazley

beautifully designed insurance

Beazley Life Sciences proposal form

- 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:
- It is your duty to make a fair presentation of the risk to the insurers in accordance with Section 3 of the Insurance Act 2015 by disclosing to insurers all circumstances and representations material to the proposed insurance.
- For a summary, please refer to the LMA9117 at the back of this Application and Section 3 of the Insurance Act 2015 for a full explanation of the Duty of Fair Presentation.
- 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 Proposal.

Please provide the following information:

1. Detailed Loss History for the last FIVE years.
2. The loss runs should be updated within the last 30 days.
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.
6. If requesting medical malpractice: Schedule of employed physicians, actuarial reports if applicable, latest accreditation/licencing report if available.
7. Any marketing brochures or literature detailing services provided.

Section 1 – General details

1. Name of your organisation:

2. Registered address:

3. Trading name (if different from the above):

4. Website address:

5. Date established: (dd/mm/yyyy) / /

6 ERN:

7. Additional Insureds (please list):

   a.

   b.

   c.

8. Company is:

   a. Corporation ☐ b. Limited Liability Company ☐ c. Individual Partnership ☐ d. Joint Venture ☐

   e. Other (please describe):

9. Please provide below a full description of all your professional and business activities :

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

11. 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 ☐

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

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

    If answered 'Yes', to any questions 10 - 13, please explain here:

Coverage requested

Coverage	Limits	Deductible	Retroactive date
Products Liability			
Professional Indemnity (Bodily Injury)			
Professional Indemnity (Financial Loss)			
Public Liability			
Medical Malpractice			
Clinical Trials (No-Fault Compensation & Legal Liability)			

Section 2 – Product(s) service(s)

14. a. What is the total gross revenue from all activities for which you require cover?

	Estimate for current financial year	Actual last complete financial year	Prior year 2	Prior year 3
(dd/mm/yyyy)	/ /	/ /	/ /	/ /
UK				
EU				
EIRE				
USA/Canada				
Elsewhere (specify)				
Gross Revenue				

b. 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	%	Medical Devices	%	Contracted Professionals	%	Nutraceuticals	%
Injectable/Oral Prescription		Implantable-Active		Pre-Clinical Testing		Dietary supplements	
Generic Pharmaceuticals		Implantable-Non Active		Clinical Testing		Food & beverage	
Nutri-pharmaceuticals		Anaesthesia/ respiratory		Protocol Design		Personal care products	
Imaging/Diagnostic Agents		Lasers		Study Selection/ Monitoring		Cosmetics & skincare	
Topical Prescription		Surgical Devices		Clinical Staff Recruitment/Training			
Drug Delivery		Dental Instruments		Data Entry/Database Management/Regulatory Filings			
Vaccines		Monitoring Devices		Manufacturing			
Other (specify)		Imaging Devices		Assembly/Repackaging			
		Dialysis		Sales/Marketing			
		Analytical Instruments		Distribution			
		Diagnostic Kits		Quality Control			
		Durable Medical Equipment		Sterilisation			
		Hospital Products/ Supplies		Lab Services			
		Other (specify)		Other (specify)			
Total %	**100%**	**Total %**	**100%**	**Total %**	**100%**	**Total %**	**100%**

15. a. Does the Applicant manufacture/sell/distribute any of the following? Check if any apply.

Products	
Schedule I or II Substance	
Weight Management	
Sexual Enhancement	
Fertility / Birth Control	
Anti-Depressants	
Cold Therapy	
Opioids	
None	

Devices	
Metal-on-Metal Hip Implants	
Surgical Mesh	
IVC Filters	
Breast Implants	
Orthopaedic Implantables	
None	

b. Does applicant have any past, present or planned association with any of the following:

Nutraceuticals					
	Yes	No		Yes	No
1,3 Dimethylamylamine (DMAA)			Jin Bu Huan		
1,3-dimethylbutylamine, AMP Citrate (DMBA)			Kava/kava-kava		
Aconite			Lobelia		
Androsteredione			Over-The-Counter drugs (OTC)		
Aristolochic acid			Pennyroyal Oil		
Bitter orange/ Synephrine			Prescription drugs		
Chaparral			R-Beta-Methylphenylethylamine/ N-Methyl-Beta-Methylphenylethylamine (PEA)		
Colloidal silver			Stephania		
Comfrey			Tiratricol		
Dendrobium			Yohimbe		
Ephedra/ephedrine			None		
Germander					

Pharmaceuticals/vaccines/biologics/medical devices

16. Products/Services (CMO, Distributors, others) Supplementary Questions.

Nutraceuticals:

a. Do any of the applicant's products contain an active ingredient that would be defined as a drug b the FDA/MHRA? Yes ☐ No ☐

b. Does applicant promote any products to cause weight gain, weight loss, muscle enhancement, sports nutrition or sexual enhancement? Yes ☐ No ☐

If 'Yes', please provide percentage turnover: ____ %

c. Does applicant import any ingredients or products? Yes ☐ No ☐

If 'Yes', please include country of origin and percentage of material:

Ingredient/Product	Country of Origin	Percentage of Material

d. Does applicant test raw materials for product integrity, purity and quality? Yes ☐ No ☐

If 'Yes', In-house ☐ Contract Out ☐

e. Does applicant manufacture or package products under its own name or label? Yes ☐ No ☐

f. Does applicant manufacture or package products for others under its name or label? Yes ☐ No ☐

If 'Yes', please list 5 largest clients, products and sales:

Client	Product Name	Annual Sales

g. Is applicant responsible for formulating any products? Yes ☐ No ☐

If 'Yes', what percentage? ____ %

h. Are applicant's formulas reviewed, tested and verified by independent third parties? Yes ☐ No ☐

i. Are applicant's finished products tested? Yes ☐ No ☐

i. Does applicant distribute any products under its own label or brand? Yes ☐ No ☐

j. Do others manufacture or package products for applicant under applicant's own name or label? Yes ☐ No ☐

If 'Yes', please list 5 largest contract manufacturers, products and sales:

Contract Manufacturer	Product Name	Annual Sales

k. Are Products or Parts manufactured in other countries? Yes ☐ No ☐ N/A ☐

l. Do you manufacture, package and/or sterilise products for others under their name or label? Yes ☐ No ☐ N/A ☐

m. Do Products/Components contain or are they composed of nano-material? Yes ☐ No ☐ N/A ☐

n. Are you aware of Products sold off-label? If so, are off-label products tracked? Yes ☐ No ☐ N/A ☐

o. Are any products repackaged or relabelled? Yes ☐ No ☐ N/A ☐

p. Do Products have a Black Box Warning or other significant safety warning label(s)? Yes ☐ No ☐ N/A ☐

q. Are Products sold as components of other products? Yes ☐ No ☐ N/A ☐

If answered 'Yes', to any questions 16k.–16q. please explain below:

17. Has any product ever been associated with death/permanent injury or hospitalisation? Yes ☐ No ☐ N/A ☐

18. Has any product been recalled in the past 5 years, and/or are you considering recalling, any known or suspected defective products from the market? Yes ☐ No ☐ N/A ☐

19. Are any products specifically approved for, and used by: minors, pregnant women, and/or prisoners? Yes ☐ No ☐ N/A ☐

20. Do any products contains cannabis/cannabidiol? Yes ☐ No ☐ N/A ☐

21. Have you discontinued or are you considering discontinuing any product or service? Yes ☐ No ☐ N/A ☐

22. Is applicant considering introducing any new products or services? Yes ☐ No ☐ N/A ☐

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

24. 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

If answered 'Yes', to any questions 17 - 24, please explain below:

Section 3 – Contractual Agreements

25. a. Do you have formal written contracts/agreements in place with all clients/customers? Yes No

b. Do you ever assume liability of others in your contract? Yes No

c. Do the contracts include the following provisions:

i. All duties and responsibilities of each party Yes No

ii. Arbitration Clause Yes No

iii. Choice of Law or Jurisdiction Yes No

iv. Force Majeure Yes No

v. Guarantees/Warranty Disclaimers Yes No

vi. Hold Harmless Agreements/Indemnification Yes No

vii. Limitation Of Consequential Damages Yes No

viii. Limitation Of Liabilities/Capping of Limits Yes No

d. Does a lawyer review all contracts or agreements including changes prior to use? Yes No

e. Do you contract out product development, manufacturing, packaging, sales, distribution, sterilisation and/or validation? Yes No

f. Do you receive a hold harmless agreement from each contractor? Yes No

g. Do you obtain Certificate of Insurance from all manufacturers/suppliers evidencing Product Liability insurance? Yes No

If so, what are the minimum limits required? £

What is the largest contract by revenue: £

Section 4 – Clinical Trials

Check here if coverage is not applicable ☐

26. a. Human Clinical Trials # of Test Subjects Enrolled:

Protocol Number	Product Name	Trial Phase	Country	Number of Subjects	Any subjects enrolled under the age of 18?

b. 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

Section 5 – Clinical trial/ services (CRO/SMO, others) – Supplementary questions.

(If answered 'Yes', please explain below)

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

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

If so, how many beds?

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

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

e. Has any of your trials been suspended/place on hold? Yes ☐ No ☐

f. Are any of the following incentives provided to the Clinical Investigator: Money, Stock, Position, Other Yes ☐ No ☐

g. In the past 12 months have there been any AER's or SAER's field? Yes ☐ No ☐

h. Have any warning letters been issued against you or your Investigators? Yes ☐ No ☐

i. Do any Clinical Trial trials involve minors (under the age of 18)? Yes ☐ No ☐

j. Are any contracts past due, customers stopped payments or requested refunds? Yes ☐ No ☐

k. Are any subjects approved for expanded access/compassionate use? Yes ☐ No ☐

If so, how many

a. Do you ever provide material or product for investigator sponsored trials? Yes ☐ No ☐

b. Do you publish all clinical trial results? Yes ☐ No ☐

c. Are any of the clinical trials listed above testing products that are 'First in Man'? Yes ☐ No ☐

If 'Yes', please provide details below:

d. Are any of the clinical trials listed involve studies being performed on pregnant women, woman who are lactating or breast feeding? If 'Yes', please provide details below: Yes ☐ No ☐

e. Are all clinical trials conducted in accordance with all relevant local laws and regulations? Yes ☐ No ☐

If 'Yes', please provide details below:

f. Have you stopped or suspended any clinical trials for safety reasons? Yes ☐ No ☐

If 'Yes', please provide details below:

g. Have any research subjects suffered death, injury, disease or illness (physical or mental) as a result of participation in a clinical trial sponsored by you in the past 5 years? Yes ☐ No ☐

If 'Yes', please provide more details below:

h. In respect of all completed and ongoing trials have you:

Made all necessary filings? Yes ☐ No ☐

Received all required authorisations? Yes ☐ No ☐

Had the protocol approved by an independent Ethics Committees? Yes ☐ No ☐

If 'No', please explain why:

Section 6 – Medical Malpractice

a. Please complete the following table using Full Time Equivalents (FTEs) for all Healthcare Professionals at your facility (excluding Doctors and Surgeons)

Healthcare Professionals	Employed		Non-Employed		Healthcare Professionals	Employed		Non-Employed	
Cover required?	**Yes**	**No**	**Yes**	**No**		**Yes**	**No**	**Yes**	**No**
Acupuncturists					Link Nurses				
Advanced Nurse Practitioners					Minor Conditions Nurses				
Allied Healthcare Professionals					Nurses (Other)				
Audit Nurses					Nurse Advisors				
Call Handlers					Nurse Midwives				
Clinical Shift Managers					Nurse practitioners				
Clinical Trainees					Paramedics				
Complementary Medicine Doctor					Pharmacists				
Dental Nurses					Physician Assistants				
District nurses					Physiotherapists				
Emergency Clinical Physicians					Prison Nurses				
Health Care Assistants					Registered Nurses				
Lab Technicians					Students				
Other (please specify)									

b. Please complete the following table using Full Time Equivalents (FTEs) for all Medical Practitioners at your facility

Doctors and Surgeons / specialty	Employed		Non-Employed		Doctors and Surgeons / specialty	Employed		Non-Employed	
Cover required?	**Yes**	**No**	**Yes**	**No**		**Yes**	**No**	**Yes**	**No**
Abdominal					Nephrology				
Anaesthesiology					Neurology				
Bariatric					Nuclear Medicine				
Cardiac					Obstetrics				
Colon and Rectal					Occupational Medicine				
Colonoscopy					Oncology				
Cosmetic Surgery					Ophthalmology				
Cytopathology					Optometrists				
Dentistry					Oral / Maxillofacial				
Dermatology					Orthopaedic				
Diabetes					Otology				
Endocrinology					Otorhinolaryngology				
Family Physicians (private)					Paediatric				
Gastroenterology					Pathology				
General Practice					Perinatology				
Geriatrics					Pharmacology				
Gynaecology					Plastic Surgery				
Haematology					Podiatrist				
Hand					Psychiatry				
Head and Neck					Psychology				
Infectious Disease					Radiology				
Intensive Care Medicine					Sports Medicine				
Intensivist/Urgent Care/A&E					Thoracic Surgery				
Laryngology					Transplant				
Legal and Forensic Experts					Traumatic Surgery				
Lymphangiography					Urology				
Neonatology					Vascular Surgery				

Other (please specify)

c. Do any of the above Doctors and/or Surgeons have direct patient care responsibility at the applicant's facilities? (if 'Yes', please provide further details on the supplementary pages provided) Yes ☐ No ☐

d. Please indicate the minimum professional liability insurance limits and deductibles required for Healthcare Professionals and Medical Practitioners

Healthcare Professionals		Medical Practitioners	
Each and every claim	£	Each and every claim	£
In the annual aggregate	£	In the annual aggregate	£

e. Is evidence of cover required? Yes ☐ No ☐

f. Has any Healthcare Professional or Medical Practitioner ever been reported to the General Medical Council? Yes ☐ No ☐

(if 'Yes', please provide further details on the supplementary pages provided).

Medical Malpractice – Supplementary Questions:

a. 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 state? Yes ☐ No ☐

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

c. Do any of the physicians have direct patient care responsibilities? Yes ☐ No ☐

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

i. Education background/training? Yes ☐ No ☐

ii. Employment references with at least two previous employers? Yes ☐ No ☐

iii. Are full criminal background checks performed for all employees/ contractors? Yes ☐ No ☐

iv. Driving record? Yes ☐ No ☐

v. Drug Test? Yes ☐ No ☐

vi. Are references checked? Yes ☐ No ☐

vii. Are written job descriptions created for all staff members? Yes ☐ No ☐

viii. Does the applicant verify any pending licence suspensions, revocations or pending disciplinary actions by another facility? Yes ☐ No ☐

ix. Does the applicant utilise Criminal Records Bureau checks and for what length of time is this information retained? Yes ☐ No ☐

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

Section 7 – Regulatory/risk management

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

a. To the best of your knowledge, are you in compliance with the FDA, MHRA regulations or the foreign agency equivalent? Yes ☐ No ☐

b. Do you have a formal Quality Control program? Yes ☐ No ☐

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

d. Do you have a formal written Product Recall plan? Yes ☐ No ☐

e. Do you have a Records Retention Plan? Yes ☐ No ☐

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 ☐

g. Do you have any products that do not have a formal FDA approval for marketing? Yes ☐ No ☐

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

Were you issued a 483? Yes ☐ No ☐

Section 8 – Loss details

Please provide details of applicant's total aggregate losses, from the 1st pound, 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 ☐

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

c. Has any claim for professional indemnity or malpractice ever been made against applicant or any employees/staff working on its behalf? Yes ☐ No ☐

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

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

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

Any other information

Please add any additional information below:

Declaration

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

Prior to the commencement of the contract of insurance, you must make a fair presentation of the risk to be insured under this Policy in accordance with the terms of the Insurance Act 2015.

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).

In accordance with the Insurance Act 2015, I/we declare that I/we have made a fair presentation of the risk. If you are unsure of your duty of fair presentation, please ask your broker for further information.

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

Signature:

Print name:

Position held (Owner, partner, authorised officer):

Title:

Date: / /

ALL QUESTIONS MUST BE ANSWERED AND THE APPLICATION MUST BE SIGNED AND DATED

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

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