Fiercely Committed.
Proudly Independent.

TEL 617 471 7171 / TF 800 972 5381
FAX 617 471 7180 / TF 888 628 1906
EMAIL info@xsbrokers.com

WEB xsbrokers.com

Life Sciences New Business Application

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 “NA”. 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 sheet and identify the question it responds to.

Name of Agent:

Please check the appropriate response:

[ ] **Products/Completed Operations Liability** or [ ] **Professional Liability**

1. Applicant:

2. Address:

3. Mailing address:

4. Other locations:

5. All Named Insureds:

6. Additional Insureds:
Explain relationship(s)

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

Entity	Date Acquired

8. Named Insured is a(n):

[ ] Individual
[ ] Partnership
[ ] Corporation
[ ] Joint venture
[ ] Other *(Describe):*

9. How long has the Named Insured been in business? [ ] Years [ ] Months

10. Do you have a parent company? [ ] Yes [ ] No

11. Have you operated under another name? [ ] Yes [ ] No

(If yes, please give details)

	This Year 20[ ]	Last Year 20[ ]
12. Annual U.S. gross revenue?		
13. Annual foreign gross revenue?		
14. Total gross revenue		

15. Product/Service Profile *(by percentage)*

Source of Revenue	%	Product or Service Description
Proprietary chemically synthesized pharmaceuticals		
Generic chemically synthesized pharmaceuticals		
Proprietary bio-pharmaceuticals		
Generic bio-pharmaceuticals		
Medical devices		
Diagnostics		
Contract research		
Contract manufacturing		
Distribution		
Equipment rentals/leasing		
Repair/installation/service		
Other *(please explain):*		

16. Product/Service Detail *(by percentage)*
Contracted Professional Services:

	%		%
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		Sterilization services	
Clinical staff training		Marketing	
Case report form design		Sales	
Data entry/database management		Distribution	
Publications/software design		Other *(please explain):*	

Medical Devices:

	%		%
Cardiac		Therapy/rehab	
Anesthesia/respiratory		Dialysis	
Implants - active		Infusion	
Implants - non-active		Non-cardiac catheters	
Lasers		Analytical instruments	
Surgical devices		Diagnostic kits	
Dental instruments		Durable medical equipment	
Monitoring		Hospital products/supplies	
Imaging devices		Other *(please explain):*	

Pharmaceuticals:

	%		%
Vaccines		Drug delivery	
Hormones & steroids		Imaging/diagnostic agents	
Birth Control of any kind		Nutraceuticals	
Injectable/oral prescription		Vitamins/food supplements	
Topical prescription		Diet aids	
		Other *(please explain)*	

17. Are any of your products undergoing clinical trials, or will be undergoing clinical trials during the current year? *If yes, please complete the attached clinical trials worksheet and attach the protocols and informed consent documents for each study to be covered.* [ ]Yes [ ]No

18. Will you be releasing any new products in the coming year? *If yes, on a separate sheet please list any new products, their indications and when they are expected to be introduced*. [ ]Yes [ ]No

19. Have you discontinued any products in the last 5 years? *If yes, on a separate sheet please list them, their indications and the reason why they were discontinued.* [ ]Yes [ ]No

20. Are any products you distribute manufactured outside of the U.S.? *If yes, on a separate sheet, please list all countries where your product is manufactured, whether the manufacturing facilities are certified by the FDA, and the date the facilities were last inspected by FDA?* [ ]Yes [ ]No

21. Are any of your products components/ingredients manufactured outside of the U.S.? *If yes, on a separate sheet, please list all countries where your components/compounds are manufactured, whether the manufacturing facilities are certified by the FDA, and the date the facilities were last inspected by FDA?* [ ]Yes [ ]No

22. Are any products you manufacture sold under others' labels? *If yes, on a separate sheet please list those products, and under whose label they are sold.* [ ]Yes [ ]No

23. Are any products sold as components or ingredients for other products? *If yes, on a separate sheet please list those components or ingredients and their likely end products.* [ ]Yes [ ]No

24. Do you require Certificates of Insurance from your suppliers? [ ]Yes [ ]No

25. Do you contract out product development, manufacturing, sales, or distribution services? *If yes, on a separate sheet, please indicate the activities you contract.* [ ]Yes [ ]No

26. Do any of your products training/certification programs require FDA approval? [ ]Yes [ ]No

27. Are your manufactured products UL listed and/or CSA certified? [ ]Yes [ ]No

28. Do you use a facility for reliability/design validation? [ ]Yes [ ]No

29. Professional Services:

Do any of your employees provide direct patient care? [ ]Yes [ ]No

Do they carry their own individual medical malpractice insurance? [ ]Yes [ ]No

Do you operate an in-patient facility? [ ]Yes [ ]No

Do any of your employees participate on an Institutional Review Board? [ ]Yes [ ]No

Do any of your employees participate on a Scientific Advisory Board? [ ]Yes [ ]No

Do you or your employees have a financial interest in your client's products? [ ]Yes [ ]No

On a separate sheet, please list your 5 largest clients for current year and the values of your contracts.

30. Regulatory:

To the best of your knowledge are you in compliance with FDA regulations or foreign agency equivalent? [ ]Yes [ ]No

Have you had any product recalls in the past year? *If yes, on a separate sheet, please list the product(s), the reason(s),and the date(s) of the recall(s)* [ ]Yes [ ]No

Within past 12 months, has there been any MDR's or AER's filed? *If yes, on a separate sheet, please indicate the number of and nature of each filing.* [ ]Yes [ ]No

What was the date and result of your most recent FDA inspection? *Please submit a copy of Form 483 and your documented response.*

Have any products or company practices been subject to an investigation by any government agency? *If yes, on a separate sheet, please explain.* [ ]Yes [ ]No

Have any of your clinical trials placed on a clinical hold? *If yes, on a separate sheet, please provide the details.* [ ]Yes [ ]No

Do you audit clinical investigators' performance? [ ]Yes [ ]No

Have any warning letters been issued against you in the last 3 years? *If yes, on a separate sheet, please provide the details.* [ ]Yes [ ]No

31. Risk Management

Do you have a documented loss prevention/loss control program? *If yes, on a separate sheet, please name person in charge of the program.* [ ]Yes [ ]No

Do you have a written quality control program? [ ]Yes [ ]No

Do you have a written product recall plan? [ ]Yes [ ]No

Do you have a written records retention program? [ ]Yes [ ]No

Are promotional materials, contracts, guarantees, and labeling jointly reviewed by each applicable discipline? [ ]Yes [ ]No

32. 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*

Describe all incurred losses of $10,000 or more:

Any known occurrence(s) not yet reported? *(If yes, please submit details)*

33. Coverage History

Policy Period	Primary & Excess Limits	Carriers	Retro Date

Has your insurance ever been canceled or non-renewed by a carrier? *If yes, on a separate sheet please explain.* [ ] Yes [ ] No

What limit of liability are you seeking?

What amount of Deductible or SIR are you prepared to carry? [ ] SIR or [ ] DED

****If requesting excess coverage, please provide the underlying premium and policy limits, terms & conditions.***

Please include the following with this application:

- Your most recent audited financial statement
- Clinical trials worksheet including the protocols and informed consent documents for each study requiring coverage
- Senior staff curriculum vitae
- Outline of your quality control program
- Advertisements, brochures, descriptive literature
- Sample service contracts and indemnification agreements

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.

Signature	**Title**
Print Name	**Date**