AMWINS BROKERAGE

Broker Name
Broker Street Address
Broker City, State, Zip Code

LIFE SCIENCES LIABILITY APPLICATION

(To be attached to ACORD applications)

PLEASE ANSWER ALL QUESTIONS COMPLETELY. USE ADDITIONAL PAGES IF NECESSARY.

NOTICE: The insurance policy for which this application is made applies only to claims first made against the insured during the policy period or any applicable extended reporting period we provide. Defense costs will reduce the limit of insurance available, and will be first applied against the deductible.

ALL APPLICANTS MUST SUBMIT THE FOLLOWING INFORMATION IN ADDITION TO THE APPLICATION:

- ☐ Most recent audited financial statement
- ☐ Current and prior 4 years currently valued (within 60 days) loss history
- ☐ Sample informed consent form and protocol documents
- ☐ Sample service contract and indemnification agreement
- ☐ Sample contractual agreement with independent contractor physicians, hospitals and laboratories

Throughout this application, "you" refers to the applicant seeking coverage.

NAME OF APPLICANT:			Date:
Physical Address:	City:	State:	Zip Code:
Mailing Address:	City:	State:	Zip Code:

Company type: ☐ Individual ☐ Partnership ☐ Corporation ☐ Joint Venture ☐ Other Organization (describe) _____

General Information

1. Date established: _____
2. List any previous names under which you have operated:

_____

_____

3. Named Insureds (including Parent Company, if applicable):

_____

_____

4. Additional Insureds:

_____

_____

5. Acquired Companies Or Subsidiaries:

_____

_____

6. Description of operations:

7. Are you a member of any trade organization? ☐ Yes ☐ No

If yes, which ones:

Exposure Information

1. Provide the following information for the prior 3 years and projected current year:

	Annual Domestic Revenue	Annual Foreign Revenue	Total Annual Revenue	Annual Units Sold (Drugs/Devices)
Projected Current	$	$	$	
1 Year Prior	$	$	$	
2 Years Prior	$	$	$	
3 Years Prior	$	$	$	

2. Products/Services Profile

	Percentage	Description Of Product/Service	Complete Section
Pharmaceuticals (NDA)	%		
Generic pharmaceuticals (ANDA)	%		
Biopharmaceuticals (NDA)	%		
Biosimilars	%		
Medical devices	%		
Contract services	%		
Distribution	%		
Research	%		
Dietary supplements/nutritional	%		
Equipment rentals/leasing	%		
Repair/installation/service	%		
Other (describe)	%		

Coverage Requested

1. What coverages and limits are you seeking?

Coverage	Desired Limits Of Insurance	Desired Deductible	Retroactive Date
☐ Products And Services Liability (P&S):	$	$	
☐ Human Clinical Trials Liability (HCT):	$	$	
☐ Errors And Omissions Liability (E&O):	$	$	
☐ Healthcare Professional Services Liability (HPS):	$	$	

☐ General Liability (GL):	$	$

2. For each coverage you are seeking, provide details of coverage purchased in the past 5 years:

Policy Period	Carrier	Coverages	Limit	Deductible /SIR	Premium	Claims Made (CM) Retroactive Date/ Occurrence (OCC)
			$	$	$	☐ CM ☐ OCC
			$	$	$	☐ CM ☐ OCC
			$	$	$	☐ CM ☐ OCC
			$	$	$	☐ CM ☐ OCC
			$	$	$	☐ CM ☐ OCC
			$	$	$	☐ CM ☐ OCC
			$	$	$	☐ CM ☐ OCC
			$	$	$	☐ CM ☐ OCC
			$	$	$	☐ CM ☐ OCC
			$	$	$	☐ CM ☐ OCC

3. Have you had any insurance declined, cancelled or nonrenewed in the past 5 years? ☐ Yes ☐ No

If yes, explain:

Loss History

1. Is any person or organization proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in a product or general liability claim, such that would fall under the proposed insurance? ☐ Yes ☐ No

If yes, provide complete details:

2. Complete the following for all claims (regardless of fault and whether or not insured) and circumstance that may give rise to claims for the past 5 years:

☐ Check if none.

Date Of Circumstance	Line Of Business	Description Of Circumstance Or Claim	Date Of Claim	Amount Paid	Amount Reserved
				$	$
				$	$
				$	$

				$	$

3. Provide the number and complete details of any customer complaints you have received concerning your products or services in the past 5 years:

4. Have you been in violation of any consumer product safety act or any other federal or local legislation? ☐ Yes ☐ No

If yes, provide complete details:

Products And Services Liability And/Or Human Clinical Trials Liability

1. Pharmaceuticals/Biopharmaceuticals (☐ Check if N/A)

a. Indicate the percentage of your pharmaceuticals/biopharmaceuticals that are:

Product	Percentage	Product	Percentage
Active pharmaceutical ingredients	%	Imaging/diagnostic agents	%
Injectables	%	Birth control	%
Oral	%	Hormones/steroids	%
Topical	%	Blood products	%
Over the counter	%	Vaccines	%
Drug delivery	%	Veterinary	%

b. Do you have any past, present, or planned products that do not have formal FDA approval for marketing (i.e. products subject to DESI, Prescription Drug Wrap-Up, or OTC drug review)? ☐ Yes ☐ No

If yes, explain:

2. Medical Devices (☐ Check if N/A)

a. FDA Registration Number (if applicable):

b. Indicate the annual sales and number of devices for each class:

Class	Projected Sales	Projected Units
FDA Class I	$	
FDA Class II	$	
FDA Class III	$	

c. Projected revenue by medical device type (indicate % of total medical device revenue):

Type	Percentage	Type	Percentage
Anesthesia	%	Monitoring devices	%
Cardiac	%	Imaging devices/instruments	%
Active implants	%	Therapy/rehab	%
Non-active implants	%	Dialysis	%
Lasers	%	Infusion	%
Surgical devices	%	Catheters	%
Dental instruments	%	Durable medical equipment	%
Diagnostic kits	%	Other (describe)	%

Pediatric	%	

3. Contract Services (☐ Check if N/A)

a. Specifically describe each of the following types of contract services and projected annual revenue of each:

Type Of Service	Description Of Services	Projected Annual Revenue
Pharmaceutical manufacturing for others		$
Biopharmaceutical manufacturing for others		$
Medical device manufacturing for others		$
R&D/lab instrument manufacturing		$
Repackaging/assembly		$
Repair/installation		$
Sterilization		$
Refurbishing		$
Clinical trials		$
Protocol design/development		$
Consulting		$
IRB		$
Laboratory		$
Pharmacovigilance/safety surveillance		$
Pre-clinical testing and development		$
Sales and marketing		$
Others (describe)		$

b. How many contracts are currently in force? _____

c. List your top clients (include contract size, length) and product/service provided:

d. Have you discontinued any services in the past 5 years? ☐ Yes ☐ No

If yes, explain:

e. What would be the largest financial and business impact on your customers from a failure of any of your products or services?

f. What is the projected total value of personal property of others at our facility? $

g. Do you purchase, sell or lease used equipment? ☐ Yes ☐ No

If yes, do you recondition or repair prior to resale? ☐ Yes ☐ No

h. Do you repair or install any products? ☐ Yes ☐ No

If yes:

(1) Are your employees factory trained? ☐ Yes ☐ No

(2) Is maintenance performed and documented according to manufacturer's guidelines? ☐ Yes ☐ No

i. Are there any healthcare services performed at your site? ☐ Yes ☐ No

If yes, explain:

4. Distribution (☐ Check if N/A)

a. Indicate the percentage of products distributed:

Product	Percentage	Product	Percentage
Pharmaceuticals	%	Active pharmaceutical ingredients	%
Biopharmaceuticals	%	Medical device components/software	%
Medical devices	%	Other (describe)	%
Dietary supplements/vitamins	%		

b. Do you distribute products under your name or label? ☐ Yes ☐ No

c. Do you repackage any of the products that are for distribution? ☐ Yes ☐ No

d. What type of business entities do you sell to? _____

e What types of entities do you source your product from? _____

f. Do you maintain the following records? (If yes, indicate the duration.)

(1) When and where the product was manufactured: ☐ Yes Duration ☐ No

(2) Who manufactured the product: ☐ Yes Duration ☐ No

(3) To whom the product was sold and the date of sale: ☐ Yes Duration ☐ No

(4) Changes in the product's formula: ☐ Yes Duration ☐ No

(5) Changes in the product's advertising material: ☐ Yes Duration ☐ No

g. Describe in detail your customer return policy:

_____

h. Do you obtain certificates of product liability insurance from:

(1) Manufacturers/suppliers? ☐ Yes ☐ No

(2) Customers? ☐ Yes ☐ No

i. Are you listed as an additional insured under the product liability insurance for:

(1) Manufacturers/suppliers? ☐ Yes ☐ No

(2) Customers? ☐ Yes ☐ No

5. Dietary Supplements (☐ Check if N/A) ☐ Yes ☐ No

a. Provide the name and description of each product sold that is not a dietary supplement as defined under the Dietary Supplement Health and Education Act of 1994 (and amendments thereto) or by the FDA:

Name	Description

b. Provide the percentage of the total estimated gross receipts to be generated from the following products:

Product	Percentage
Weight loss:	%
Body building/sports nutrition:	%
Sexual enhancement/erectile dysfunction:	%

c. Provide details on the products for which you are seeking coverage that contain the following ingredients:

Ingredient	Product Containing Ingredient	Ingredient Dosage	Estimated Sales
Creatinine			$
Kava			$
Magnolia			$
Yohimbe			$

d. Are you compliant with the most current regulatory requirements (FDA and FTC) related to manufacturing, labelling, advertising and adverse event reporting? ☐ Yes ☐ No

e. Have any of your products ever fit the definition of a new dietary ingredient? ☐ Yes ☐ No

If yes, have pre-marketed safety reviews been conducted according to regulations? ☐ Yes ☐ No

f. Have any of your products ever had an active ingredient that would be defined as a drug by a regulatory agency? ☐ Yes ☐ No

If yes, which product and ingredient? _____

g. Do you sell any of your products through a multi-level marketing system? ☐ Yes ☐ No

h. Do any of your products make health or structure/function assertions? ☐ Yes ☐ No

If yes, describe and explain how such assertions are substantiated:

_____

6. Human Clinical Trials (☐ Check if N/A)

a. Complete the following information and provide all trial documents applicable to each trial:

Trial Product	Protocol Number	Trial Phase	County	Number Of Subject Enrolled		Status (Planned, Ongoing Or Completed)
				Last Policy Period	Upcoming Policy Period	

b. Has any human clinical trial been excluded, uninsured or self-insured from any previous coverage? ☐ Yes ☐ No

If yes, explain: _____

c. Are you currently in compliance with all applicable regulatory guidelines regarding clinical trials? ☐ Yes ☐ No

d. How many subjects have you enrolled in clinical trials in the past 3 years? _____

e. Do any clinical trials involve:

(1) Persons under 18 years of age? ☐ Yes ☐ No

(2) Pregnant women? ☐ Yes ☐ No

f. Do you anticipate any expanded access/compassionate use subjects during the policy period? ☐ Yes ☐ No

g. Have there been any Side Adverse Events Reported (SAER) in connection with your trials? ☐ Yes ☐ No

If yes, explain: _____

h. Have there been any trials involving your product which has been discontinued or placed on hold for safety reasons? ☐ Yes ☐ No

i. Have any trials resulted in death? ☐ Yes ☐ No

If yes, explain: _____

j. Do you or any of your employees act as both trial sponsor and clinical investigator? ☐ Yes ☐ No

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

l. Do any of your employees provide direct patient care? ☐ Yes ☐ No

If yes, do you require them to carry their own individual medical malpractice insurance? ☐ Yes ☐ No

m. What is the targeted reading grade level for your informed consent documents? _____

n. Is the IRB accredited by the Association for the Accreditation of Human Research Protection Programs? ☐ Yes ☐ No

o. Do you incorporate financial disclosures in the informed consent documents or process? ☐ Yes ☐ No

p. Do you have a formalized Clinical Trial Suspension SOPs in place? ☐ Yes ☐ No

q. Do you audit your clinical investigators to ensure procedures are followed? ☐ Yes ☐ No

r. Have you or any clinical investigators been cited for regulatory violations in connection with your trials? ☐ Yes ☐ No

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

Contracts

1. Do you require written contracts with all of your customers? ☐ Yes ☐ No

2. Does an attorney review all contracts or agreements including changes prior to use? ☐ Yes ☐ No

3. Do your standard contracts contain the following provisions:

a. Duties and responsibility of each party? ☐ Yes ☐ No

b. Arbitration clause? ☐ Yes ☐ No

c. Choice of law or jurisdiction? ☐ Yes ☐ No

d. Force majeure (extends to any and all events outside applicants control)? ☐ Yes ☐ No

e. Guarantees? ☐ Yes ☐ No

f. Disclaimer of warranties? ☐ Yes ☐ No

g. Term and termination? ☐ Yes ☐ No

h. Limitations of liability ☐ Yes ☐ No

i. Limitation of consequential damages? ☐ Yes ☐ No

j. Hold harmless /mutual indemnification language? ☐ Yes ☐ No

k. Changes in writing signed by both parties? ☐ Yes ☐ No

4. Do your global contracts or agreements comply with stated minimum standards? ☐ Yes ☐ No

5. What is the average projected value of your contracts? _____

6. What is the average length of your contract? _____

7. Have you been involved in any contract disputes or have any contracts past due acceptance? ☐ Yes ☐ No

If yes, explain: _____

8. How do you track and manage customer complaints? _____

Regulatory

1. To the best of your knowledge, are you in compliance with FDA regulations or foreign agency equivalent? ☐ Yes ☐ No
2. Are any products manufactured or sold under other's labels? ☐ Yes ☐ No
3. Are any products sold as ingredients/components of other's products? ☐ Yes ☐ No
4. Do any of your products require a black box warning? ☐ Yes ☐ No
5. Are you involved in the sale of any controlled substances as defined by the Controlled Substances Act, or any other products requiring the DEA registration? ☐ Yes ☐ No
6. Do you promote or are you aware of off-label production? ☐ Yes ☐ No

   If yes, explain: _____
7. Are any products approved for persons under the age of 18? ☐ Yes ☐ No
8. Have any products been discontinued for safety reasons? ☐ Yes ☐ No
9. Do you have any association with banned products? ☐ Yes ☐ No
10. When was your last FDA inspection? _____
11. Where you issued an FDA 483 form? ☐ Yes ☐ No
12. Have you received any warning letters from the FDA? ☐ Yes ☐ No

    If yes, please provide a copy and your response.
13. How many product recalls have you had in the past 3 years? _____

    Indicate the type of recall and provide details on Class I:

14. Complete the following information and provide a copy of the most recently completed safety report associated with each of the top three products in terms of adverse event reports:

Product	Associated With:	Number Of Adverse Event Reports
	☐ Death ☐ Permanent Injury ☐ Hospitalization	
	☐ Death ☐ Permanent Injury ☐ Hospitalization	
	☐ Death ☐ Permanent Injury ☐ Hospitalization	

15. Identify any product requiring a Risk Evaluation & Mitigation Strategy:

16. Are there any safety surveillance team recommendations involving any of the following forms of remedial actions, which have yet to be implemented or completed?
    - **a.** Healthcare professional letter? ☐ Yes ☐ No
    - **b.** Additional studies? ☐ Yes ☐ No
    - **c.** Expanded product monitoring or testing? ☐ Yes ☐ No
    - **d.** Product recall or withdrawal? ☐ Yes ☐ No
17. Have there been any incidents of non-compliance with company SOPs or Regulatory requirements, regarding sales and marketing? ☐ Yes ☐ No
18. Are any of your employees/contractors present during patient procedures, surgeries or examinations? ☐ Yes ☐ No

    If yes, provide details: _____

19. In the past 5 years, have you been cited for non-compliance with any GCP, GLP, GMP, QS or advertising or promotion guidelines? ☐ Yes ☐ No

20. Were there any FTC violations in the past policy term? ☐ Yes ☐ No

Quality Control

1. Do you have a risk manager on site? ☐ Yes ☐ No

2. Do you have a formal written quality control program? ☐ Yes ☐ No

3. Do you have a formal product recall plan? ☐ Yes ☐ No

If yes, provide a copy.

4. Do you have a written records retention program? ☐ Yes ☐ No

5. Are your Standard Operating Procedures (SOPs) in writing? ☐ Yes ☐ No

a. How often are these audited? _____

b. Who conducts the audits? _____

c. Who receives the audit report? _____

6. How do you ensure the contract procedures are being followed?

_____

7. Provide details of how you control your materials to assure product purity and safety:

_____

8. What type of auditing is implemented?

_____

Healthcare Professional Services Liability (Complete this section only if HPS coverage is desired). ☐ **N/A**

1. Indicate the number of each position staffed by you:

Position	# Full Time	# Part Time	# Contracted	Position	# Full Time	# Part Time	# Contracted
MD/Physicians:				Therapists:			
Nurses:				Pathologists:			
Pharmacists:				Medical/Lab Technicians:			
Phlebotomists:				Other (describe):			

2. Are you seeking coverage for any of the medical professionals staffed by you? ☐ Yes ☐ No

3. Do any of your employees provide direct patient care? ☐ Yes ☐ No

If yes, do you require them to carry their own individual medical malpractice insurance? ☐ Yes ☐ No

4. Identify each procedure performed prior to hiring new staff (check all that apply):

☐ Criminal background check
☐ Drug and alcohol screening
☐ Reference check
☐ Other (describe): _____
☐ Professional malpractice litigation (prior and pending)
☐ Sexual offenders registration
☐ Verification of professional licensing

5. Do you keep all information on file and verify its completion prior to employment commencement? ☐ Yes ☐ No

6. List all associations your staff is currently a member of:

_____

Premises/Operations (Complete this section only if GL coverage is desired). ☐ **N/A**

1. Indicate which applies to your premises:

☐ Access not allowed without card or accompanied by an authorized employee

☐ Front desk registration only

☐ No restricted access

2. Do you keep hazardous substances on site? ☐ Yes ☐ No

If yes:

a. How many gallons are kept on site? _____

b. Which of the following apply with respect to hazardous substances kept on site?

☐ Outdoor storage ☐ Indoor cut-off area in approved containers

☐ Just in time supply ☐ Indoor cut-off areas in unapproved containers just in time levels

c. Are you in compliance with hazardous substance regulations? ☐ Yes ☐ No

3. Highest biohazard lab rating? _____

4. Do you have an animal facility or house animals ☐ Yes ☐ No

5. What are the main focal areas of your enterprise risk/safety program?

_____

6. Do you require that all new employees participate in training that instructs them on all applicable company policies and procedures? ☐ Yes ☐ No

7. Do you require certificates of insurance from all of your suppliers and sub-contractors? ☐ Yes ☐ No

If yes, what limits and terms do you require? _____

8. How often are the risk management programs and SOPs audited? _____

9. Identify any risk management program or SOP that is audited by independent non-governmental organizations/individuals:

_____

10. Do you have a formalized information security policy that dictates the protocols that control access to use all critical data, process or information systems for all authorized users, including business partners and third parties? ☐ Yes ☐ No

11. Do you have an information security officer? ☐ Yes ☐ No

12. Do you have a formalized privacy policy in place? ☐ Yes ☐ No

13. Do you have a crisis management team in place? ☐ Yes ☐ No

Fair Credit Report Act Notice

Personal information about you, including information from a credit or other investigative report, may be collected from persons other than you in connection with this application for insurance and subsequent amendments and renewals. Such information as well as other personal and privileged information collected by us or our agents may in certain circumstances be disclosed to third parties without your authorization. Credit scoring information may be used to help determine either your eligibility for insurance or the premium you will be charged. We may use a third party in connection with the development of your score. You have the right to review your personal information in our files and can request correction of any inaccuracies. A more detailed description of your rights and our practices regarding such information is available upon request. Contact your agent or broker for instructions on how to submit a request to us.

Applicable in Alabama, Arkansas, District of Columbia, Louisiana, Maryland, New Mexico, Rhode Island and West Virginia

Any person who knowingly (or willfully)* presents a false or fraudulent claim for payment of a loss or benefit or knowingly (or willfully)* presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison. *Applies in Maryland only.

Applicable in Colorado

It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete, or misleading facts or information to a policyholder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

Applicable in Florida and Oklahoma

Any person who knowingly and with intent to injure, defraud, or deceive any insurer files a statement of claim or an application containing any false, incomplete, or misleading information is guilty of a felony (of the third degree)*. *Applies in Florida only.

Applicable in Kansas

Any person who, knowingly and with intent to defraud, presents, causes to be presented or prepares with knowledge or belief that it will be presented to or by an insurer, purported insurer, broker or any agent thereof, any written, electronic, electronic impulse, facsimile, magnetic, oral, or telephonic communication or statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance which such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act.

Applicable in Kentucky, New York, Ohio and Pennsylvania

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 (not to exceed five thousand dollars and the stated value of the claim for each such violation)*. *Applies in New York only.

Applicable in Maine, Tennessee, Virginia and Washington

It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties (may)* include imprisonment, fines and denial of insurance benefits. *Applies in Maine only.

Applicable in New Jersey

Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

Applicable in Oregon

Any person who knowingly and with intent to defraud or solicit another to defraud the insurer by submitting an application containing a false statement as to any material fact may be violating state law.

Applicable in Puerto Rico

Any person who knowingly and with the intention of defrauding presents false information in an insurance application, or presents, helps, or causes the presentation of a fraudulent claim for the payment of a loss or any other benefit, or presents more than one claim for the same damage or loss, shall incur a felony and, upon conviction, shall be sanctioned for each violation by a fine of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), or a fixed term of imprisonment for three (3) years, or both penalties. Should aggravating circumstances [be] present, the penalty thus established may be increased to a maximum of five (5) years, if extenuating circumstances are present, it may be reduced to a minimum of two (2) years.

Applicable in all other states

Any person who knowingly and with intent to defraud any Insurance Company or another 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 the person to criminal and civil penalties.

Representation Statement

The undersigned authorized officer of the applicant declares that the statements set forth herein are true to the best of his or her knowledge. The undersigned authorized officer agrees that if the information supplied on the application changes between the date of the application and the effective date of the insurance, he/she (undersigned) will immediately notify the insurer of such changes, and the insurer may withdraw or modify any outstanding quotations and/or authorization or agreement to bind the insurance. Signing of this application does not bind the applicant to the insurer to complete the insurance.

Name of applicant	Title
Signature of applicant	Date

(Florida only) Agent license number: _____