



## Life Sciences Products - Completed Operations Liability Insurance Application

### APPLICATION INSTRUCTIONS

**NOTICE: PORTIONS OF THE POLICY FOR WHICH THIS APPLICATION IS MADE MAY CONTAIN CLAIMS MADE COVERAGE WHICH APPLIES ONLY TO "CLAIMS" FIRST MADE AGAINST THE "INSURED" DURING THE "POLICY PERIOD" OR ANY APPLICABLE EXTENDED REPORTED PERIOD AND REPORTED TO THE UNDERWRITER DURING THE "POLICY PERIOD" OR DURING ANY APPLICABLE EXTENDED REPORTING PERIOD. PLEASE READ THE ENTIRE APPLICATION CAREFULLY BEFORE SIGNING.**

Prior to completing the attached application, please read and follow these instructions. Please verify that all required attachments are included so that we may process the Application promptly and efficiently.

- Please complete this form electronically or print responses legibly.
- Please sign and date the application where indicated.
- All information requested must be fully and accurately completed.
- If changes or corrections must be made to the completed application, strike out or line through the incorrect information, write in the modification, and initial and date the change.
- If a particular question does not apply, please write "N/A."
- If additional space is needed, please continue answers on a separate page and attach it to the Application.
- Claims information should be provided for a six-year experience period. This applies to open and closed claims and to any incidents reported to a previous carrier. It is important to provide complete and detailed claims information, including current carrier loss runs.

ACCOUNT INFORMATION	
1. Applicant Name Doing Business As Federal Employee ID# (FEIN) State of Domicile	
2. Mailing Address	Street:
	City: State: Zip:
	County: Website:
3. Risk Manager or Contact Person	Name/Title:
	Email Address:
	Telephone Number:
4. Applicant's Legal Structure	<input type="checkbox"/> Individual <input type="checkbox"/> Corporation <input type="checkbox"/> Partnership <input type="checkbox"/> Joint Venture <input type="checkbox"/> LLC
5. Tax Status	<input type="checkbox"/> For Profit – Private <input type="checkbox"/> For Profit – Publicly Traded <input type="checkbox"/> Not For Profit
6. Date Established	

7. Within the past 36 months or within the next 12 months, has the Applicant or does the Applicant expect to:
- a. Merge, acquire or consolidate with another entity?  Yes  No
  - b. Sell or divest another entity or facility?  Yes  No
  - c. Discontinue any operations or services?  Yes  No
  - d. Enter into any new business activities or services  
(Including new procedures or products being offered)?  Yes  No

If "Yes," describe the essential terms of such transaction.

8. List below all subsidiaries, description of operations, date acquired and ownership (ownership must be >50%).

Name & Address	Description of Operations	Relationship	Date Acquired	Ownership %	Retroactive Date

(Please note that coverage for these entities is not automatically included. The policy, if issued, will determine coverage.)

9. Does the Applicant own, operate or manage any business or facilities other than operations described in this Application?  Yes  No

If "Yes," please provide details, including name of entity and the Applicant's ownership interest/management role.

10. Is the Applicant owned or controlled by another entity?  Yes  No

If "Yes," please explain.

**FINANCIAL AND EXPOSURE DETAILS**

11. List amount of total revenue.	Year Ending	Domestic	Foreign
a. Upcoming Year			
b. Current Year			
c. Prior Year			
d. 2 Years Prior			
e. 3 Years Prior			

  

12. Clinical Trial Participants	Year Ending	Domestic	Foreign
a. Upcoming Year			
b. Current Year			
c. Prior Year			
d. 2 Years Prior			
e. 3 Years Prior			

13. Product or Service Revenue Profile (please provide percentages):

Source of Revenue	% of Revenue		Product or Service Description
	Domestic	Foreign	
Proprietary Pharmaceuticals/Biologics			
Biologics			
Generic Pharmaceuticals			
Over the Counter Medications			
Contract Manufacturing			
Contract Research Services			
Medical Devices			
Diagnostic Test Kits			
Durable Medical Equipment / Hospital Supplies			
Implants			
Instruments			
Lasers			
Monitors			
Dialysis			
Infusion			
Other (Describe):			

14. Please list the Applicant's top 5 products by revenue.

1.	4.
2.	5.
3.	

**OPERATIONS AND ADMINISTRATION**

**Products Sales**

15. Please list any:

- a. New products expected to be produced or introduced in the coming policy year:
  
- b. Discontinued products:
  
- c. Products or components imported from China:
  
- d. Products manufactured that are sold under another company's label:

16.	Are there any products or parts manufactured outside of the United States? If "Yes," is the facility FDA approved?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
17.	Are any products or components imported? If "Yes," is the facility FDA approved?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
18.	Do any of the Applicant's products include raw materials and/or components that contain or are composed of nanomaterials or involve nanomaterials or nanotechnology?	<input type="checkbox"/> Yes <input type="checkbox"/> No
19.	Is the Applicant aware of any off- label sales of its products? If "Yes," a. Does the Applicant track off-label sales? b. What percentage of the Applicant's total product sales comes from off-label sales? c. What are the Applicant's policies and procedures when learning of off-label sales?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No % _____
20.	Are any of the Applicant's products sold as components for other products? If "Yes," list component and end product:	<input type="checkbox"/> Yes <input type="checkbox"/> No
21.	Does the Applicant require certificates of insurance from its suppliers? If "Yes," what limits does the Applicant require?	<input type="checkbox"/> Yes <input type="checkbox"/> No
22.	Please list any activities the Applicant contracts out (e.g.: product development, manufacturing, sales, distribution services):	
23.	What percentage of sales representatives' compensation is commission?	% _____
24.	Does the Applicant use its own sales force? If "No," who does the Applicant use?	<input type="checkbox"/> Yes <input type="checkbox"/> No
25.	Does the Applicant train the sales force?	<input type="checkbox"/> Yes <input type="checkbox"/> No
26.	Do any of the Applicant's products training/certification programs require FDA approval?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Clinical Trial and Other Services</b>		
27.	Do any of the Applicant's employees:  a. Provide direct patient care? b. Participate on an Institutional Review Board? c. Have a financial interest in the products of the Applicant's clients? If "Yes," please explain:  d. Carry their own individual medical malpractice insurance?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
28.	Does the Applicant operate an inpatient facility?	<input type="checkbox"/> Yes <input type="checkbox"/> No

29. What financial or other incentives are provided to clinical investigators?  
 None  Money  Stock in company  
 Other (describe): \_\_\_\_\_  Position within company

30. Does the Applicant or any of the Applicant's employees ever act as both trial sponsor and clinical investigator?  Yes  No  
 If "Yes," please list trials on a separate attachment.

**Clinical Trials You Sponsor**  Not Applicable

31.	Product 1	Product 2	Product 3
Product			
Protocol Name & Number			
# of Test Subjects - Prior Year			
# of Test Subjects - Projected Next Year			
Indication or disease testing for			
City & County of Clinical Trials			
Ongoing or completed			

*Please attach FDA approved protocols & informed consent documents for active clinical trials, and draft protocols and informed consent documents for planned trials.*

**Regulatory**

32. Is the Applicant in compliance with the Food and Drug Administration (FDA) Regulations and to the extent applicable, the foreign agency equivalent?  Yes  No  
 List all of the FDA Centers the Applicant works with (e.g.: CDER, CBER, CDRH):

33. In the past 12 months, has the Applicant had any products recalled?  Yes  No  
 If "Yes," please provide details & recall status:

34. Within the past 12 months, have there been any MDRs or AERs filed?  Yes  No  
 If "Yes," indicate the number of filings and the nature of each such filing.

35. Please indicate the date and result of the most recent FDA Inspection: Date: \_\_\_\_\_  
 Please submit a copy of any Form 483 and your documented response. Result: \_\_\_\_\_

36. Have any of your products or company practices been subject to an investigation by any government agency?  Yes  No  
 If "Yes," explain:

37. Has the Applicant had any clinical trials placed on a clinical hold?  Yes  No

38. Does the Applicant audit clinical investigator performance?  Yes  No

39. Have any warning letters been issued against the Applicant or the Applicant's investigators in the last 3 years?  Yes  No  
 If "Yes," please explain and include copies of letters and responses.

**Risk Management**

40. Does the Applicant have:
- a. A loss prevention / control program?  Yes  No  
 If "Yes," please provide the name and title of the person responsible: \_\_\_\_\_
  - b. A quality control program?  Yes  No
  - c. A product recall plan?  Yes  No
  - d. A records retention program?  Yes  No
  - e. Promotional materials, contracts, guarantees & labeling jointly reviewed by each applicable discipline?  Yes  No

41. Please describe any other risk management processes, procedures or techniques:

**Contractual Agreements**

42. Does the Applicant have any contractual agreements with independent contractors who provide services at its facility where additional insured coverage is required to be provided to the contractor?  Yes  No  
 If "Yes," please describe the services:
43. Are all contracts reviewed by legal counsel prior to execution?  Yes  No
44. Does the Applicant indemnify (hold harmless) any other party for liability?  Yes  No  
*If yes, submit a copy of the agreement with this application.*
45. Does the Applicant provide services to others on a contractual agreement?  Yes  No  
 If "Yes," please describe the services and provide a copy of the contract.

**CURRENT AND REQUESTED COVERAGE**

46. Requested Effective Date of Coverage:

47. Coverage Requested

Coverage	Limit / Aggregate	Deductible	Retro Date (N/A if Occurrence)
Products Completed			
Operations Liability			
Excess Limits			

48. Provide the following information for Products Completed Operations Liability Insurance for the current and previous policy years.

Policy Period	Carrier	Limits	Ded/SIR	Retro (if CM)	Premium

49. MISSOURI RESIDENTS – DO NOT ANSWER: Has any insurer cancelled or declined to renew Professional or General Liability insurance for the Applicant?  Yes  No

If "Yes," please provide details:

## CLAIMS HISTORY

50. During the past five (5) years, has any claim that may fall within the scope of the proposed insurance been made against the Applicant or against any entity or individual proposed for coverage under this insurance? Yes No

If "Yes," please provide dates of loss, claimant name, all defense and indemnity payments, all defense and indemnity reserves (if claims are open), and claim status (open/closed):

**NOTE:** WITHOUT PREJUDICE TO ANY OTHER RIGHTS OR REMEDIES OF THE UNDERWRITER, IT IS AGREED THAT ANY CLAIM REQUIRED TO BE DISCLOSED IN RESPONSE TO QUESTION 50 IS EXCLUDED FROM THE PROPOSED INSURANCE.

51. Is the Applicant or any entity or individual proposed for coverage under this insurance aware of any fact, circumstance, situation, transaction, event, act, error or omission which they have reason to believe may or could reasonably be foreseen to give rise to a claim that may fall within the scope of the proposed insurance? Yes No

If "Yes," please provide details:

**NOTE:** WITHOUT PREJUDICE TO ANY OTHER RIGHTS OR REMEDIES OF THE UNDERWRITER, IT IS AGREED THAT ANY CLAIM ARISING FROM ANY FACT, CIRCUMSTANCE, SITUATION, TRANSACTION, EVENT, ACT, ERROR OR OMISSION REQUIRED TO BE DISCLOSED IN RESPONSE TO QUESTION 51 IS EXCLUDED FROM THE PROPOSED INSURANCE.

## FRAUD WARNINGS

Any person who knowingly and with intent to defraud any insurance company or another person, files an application for insurance containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto, may be guilty of committing a fraudulent insurance act, which is a crime and subjects the person to criminal and civil penalties.

**ALABAMA AND MARYLAND APPLICANTS:** Any person who knowingly or willfully presents a false or fraudulent claim for payment of a loss or benefit or who 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.

**ARKANSAS, MINNESOTA AND OHIO APPLICANTS:** Any person who, with intent to defraud or knowing that he/she is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud, which is a crime.

**COLORADO APPLICANTS:** 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 policy holder or claimant for the purpose of defrauding or attempting to defraud the policy holder 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.

**DISTRICT OF COLUMBIA APPLICANTS: WARNING:** It is a crime to provide false or misleading information to any insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, any insurer may deny insurance benefits, if false information materially related to a claim was provided by the applicant.

**FLORIDA APPLICANTS:** 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.

**KENTUCKY APPLICANTS:** Any person who knowingly and with intent to defraud an insurance company or other person files an application for insurance containing any false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime.

**LOUISIANA, NEW MEXICO, RHODE ISLAND APPLICANTS AND WEST VIRGINIA APPLICANTS:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to civil fines and criminal penalties.

**MAINE, TENNESSEE, VIRGINIA AND WASHINGTON APPLICANTS:** 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 or a denial of insurance benefits.

**MISSOURI APPLICANTS:** Any person commits a "fraudulent insurance act" if such person knowingly 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 oral or written statement including computer generated documents as part of, or in support of, an application for the issuance of, or the rating of, an insurance policy for commercial or personal 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 if such person conceals, for the purpose of misleading another, information concerning any fact material thereto.

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

**OKLAHOMA APPLICANTS: WARNING:** Any person who knowingly and with intent to injure, defraud or deceive any insurer, makes any claim for the proceeds of an insurance policy containing any false, incomplete or misleading information is guilty of a felony.

**OREGON AND TEXAS APPLICANTS:** Any person who makes an intentional misstatement that is material to the risk may be found guilty of insurance fraud by a court of law.

**PENNSYLVANIA APPLICANTS:** 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.

**PUERTO RICO APPLICANTS:** Any person who knowingly and with the intent to defraud, presents false information in an insurance request form, or who presents, helps or has presented a fraudulent claim for the payment of a loss or other benefit, or presents more than one claim for the same damage or loss, will incur a felony, and upon conviction will be penalized for each violation with a fine of no less than five thousand dollars (\$5,000) no more than ten thousand dollars (\$10,000); or imprisonment for a fixed term of three (3) years, or both penalties. If aggravated circumstances prevail, the fixed established imprisonment may be increased to a maximum of five (5) years; if attenuating circumstances prevail, it may be reduced to a minimum of two (2) years.



**SIGNATURE AND AUTHORIZATION**

The undersigned, as authorized agent of all individuals and entities proposed for this insurance, declares that, to the best of his/her knowledge and belief, after reasonable inquiry, the statements in this Application and any attachments or information submitted with this Application (together referred to as the "Application") are true and complete. For Florida accounts, the preceding sentence is replaced with the following: The undersigned, as authorized agent of all individuals and entities proposed for this insurance, represents that, to the best of his/her knowledge and belief, after reasonable inquiry, the statements in this Application and any attachments or information submitted with this Application (together referred to as the "Application") are true and complete. The information in this Application is material to the risk accepted by us. If a policy is issued it will be in reliance upon the Application, and the Application will be the basis of the contract.

We will maintain the information contained in and submitted with this Application on file and along with the Application will be considered physically attached to, part of, and incorporated into the policy, if issued. For North Carolina, Utah and Wisconsin accounts, this Application and the materials submitted with it shall become part of the policy, if issued, if attached to the policy at issuance.

We are authorized to make any inquiry in connection with this Application. Our acceptance of this Application or the making of any subsequent inquiry does not bind you or us to complete the insurance or issue a policy.

The information provided in this Application is for underwriting purposes only and does not constitute notice to us under any policy of a Claim or potential Claim.

If the information in this Application materially changes prior to the effective date of the policy, you must notify us immediately and we may modify or withdraw any quotation or agreement to bind insurance.

**NOTICE TO NEW YORK APPLICANTS:** 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 shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each such violation.

Applicant Name			
By (Authorized Signature)			
Name/Title			
Date			

**NOTE: THIS APPLICATION MUST BE SIGNED BY A PARTNER, PRINCIPAL, DIRECTOR OR OFFICER OF THE APPLICANT ACTING AS THE AUTHORIZED AGENT OF ALL INDIVIDUALS AND ENTITIES PROPOSED FOR THIS INSURANCE.**

Produced By (Insurance Agent)			
Insurance Agency			
Insurance Agency Taxpayer ID			
Agent License No. or Surplus Lines No.			
Address	Street:		
	City:	State:	Zip:
Email Address			

Submitted By (Insurance Agency)			
Insurance Agency Taxpayer ID			
Agent License No. or Surplus Lines No.			
Address	Street:		
	City:	State:	Zip:

**NOTE: FOR NEW HAMPSHIRE APPLICANTS, PRODUCER'S NAME AND SIGNATURE ARE REQUIRED.**