



## I. GENERAL INFORMATION

ALL QUESTIONS IN THIS APPLICATION MUST BE ANSWERED TRUTHFULLY AND COMPLETELY FOR ALL PERSONS OR ORGANIZATIONS APPLYING FOR INSURANCE UNDER THIS APPLICATION. "YOU" OR "YOUR" REFER TO THE PERSON OR ORGANIZATIONS APPLYING FOR INSURANCE UNDER THIS APPLICATION. IF A QUESTION OR SECTION 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 ATTACHMENT AND IDENTIFY THE QUESTION TO WHICH IT RESPONDS.

### Applicant Information

Applicant Name: \_\_\_\_\_

Address: \_\_\_\_\_

Mailing Address (if different): \_\_\_\_\_

Website Address: \_\_\_\_\_

Type of organization: \_\_\_\_\_

1. Please provide a brief description of your operations:

2. Do you generate more than 50% of your sales from the following (either individually or in combination)? Yes      No
- active pharmaceutical ingredients (API) that are off patent
  - products approved under an ANDA
  - products with APIs that are off patent
  - drug delivery systems that incorporate APIs that are off patent

*IF YOU ANSWERED "YES", THEN DO NOT COMPLETE THIS APPLICATION. YOU MIGHT QUALIFY FOR AN EXCLUSIVE CHUBB PROGRAM THAT REQUIRES A SEPARATE APPLICATION BE COMPLETED.*

3. Years in business \_\_\_\_\_

4. Do you have a parent company? Yes      No  
 If Yes, provide name \_\_\_\_\_

5. Have you ever operated under another name? Yes      No  
 If Yes, provide details \_\_\_\_\_

6. Any acquired subsidiaries in the last 5 years? Yes      No  
 If Yes, please provide entity name and date acquired  
 Entity Name: \_\_\_\_\_  
 Date Acquired: \_\_\_\_\_

7. Who are your top 3 competitors?  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_



8. Have you filed for bankruptcy in the last 7 years? Yes No
9. Are any of your shareholders, directors, officers, partners, or members thereof under investigation for any alleged criminal violations related to your business? Yes No
10. Are you in compliance with all applicable regulatory guidelines? Yes No  
*(if no, provide details)*

11. In the last 3 years, have you been cited for any regulatory violations (such as those contained in a warning letter or 483)? Yes No  
 If yes, has the applicable regulatory authority accepted your response(s) and closed the matter? Yes No  
*(if no, provide details)*

12. Please list any third parties you have agreed to name as an insured under your insurance:

Additional Insureds	Explain Relationship To Your Business

13. Mark any items where you have products, studies, or services involving any of these. Include past and future activities.

**Diseases:**

Hepatitis      HIV      TSE

**Classes of Products:**

Birth control or fertility      Hormone replacement      SSRIs or SNRIs  
 Drug-eluting stents      Vaccines      Metal-on-metal hip implants

**Specific Products:**

Cisapride      Dexfenfluramine      DEHP      DES      Dextropropoxyphene  
 Ephedra or Ephedrine      Fenfluramine      Fentanyl      Gadolinium      Isotretinoin  
 Latex gloves      Mercury      Metoclopramide      Phentermine  
 Propoxyphene      PPA      Silicone (implanted)  
 Thalidomide      Thimerasol      Troglitazone

14. Total number of employees \_\_\_\_\_ and R&D Payroll \_\_\_\_\_
15. Do you have a direct sales force, a contracted sales force, or do you use a multi-level marketing system? Yes No



16. Indicate any industry trade association memberships

17. Total projected gross sales for the next year? \_\_\_\_\_  
*(Attach separate sheet, if necessary)*

- U.S. & Canada \_\_\_\_\_
- U.K. & Ireland \_\_\_\_\_
- Continental Europe \_\_\_\_\_
- Australia \_\_\_\_\_
- Asia \_\_\_\_\_
- Latin America \_\_\_\_\_
- Africa \_\_\_\_\_

18. Previous year gross sales (worldwide)? \_\_\_\_\_

19. Projected annual prescriptions/units to be sold in the next year? \_\_\_\_\_

20. Projected number of annual products users in the next year? \_\_\_\_\_

21. Any products or product ingredients/components imported? Yes No  
*(if yes, note ingredient/component and the country)*

22. Projected percentage of sales by area:

- Drugs/Biologics: \_\_\_\_\_ %
- Medical Devices: \_\_\_\_\_ %
- Dietary Supplements / Nutritional Products: \_\_\_\_\_ %
- Contract Services: \_\_\_\_\_ %
- Distribution: \_\_\_\_\_ %
- Research: \_\_\_\_\_ %
- Other (please explain): \_\_\_\_\_ % \_\_\_\_\_

COVERAGE	LIMIT OF LIABILITY REQUESTED
Products-Completed Operations (including Human Clinical Trials)	
Premises / Operations	
Errors & Omissions	



**LOSS HISTORY & POTENTIAL LOSS**

1. Any claims not yet reported?                      Yes          No  
 (if yes, provide details)
  
2. Indicate any product or service past or present that has been involved with any certified, or attempted, class action or multi-district litigation?
  
3. Are you aware of any fact, circumstance, or situation which one might reasonably expect could give rise to a claim (or multiple claims) that would fall within the scope of the insurance being requested?                      Yes          No  
 (if yes, provide details)

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

**COVERAGE HISTORY**

Policy Period	Primary & Excess Limits	Carriers	Occurrence/Claims Made	Retro Date

1. Do you have any outstanding loss control recommendations with your current carrier?                      Yes          No  
 (if yes, provide details)
  
2. Has your insurance ever been canceled or non-renewed by a carrier?                      Yes          No  
 (if yes, provide details)
  
3. Are any of your products, clinical trials, or services specifically excluded on your existing policy?                      Yes          No  
 (if yes, provide details)
  
4. Have you had concurrent claims made insurance for the insurance you are requesting back to your stated requested retroactive date?                      Yes          No



## II. PRODUCTS-COMPLETED OPERATIONS (including Human Clinical Trials)

NOTICE: This is an application for a policy that may include a claims made trigger (and for certain accounts, claims made and reported) and that the limit of liability under any policy to be issued in response hereto may include both the indemnity payments for claims and payment of claim and defense expenses, as defined in the policy.

If the limit of liability is reduced by payment of claim and defense expenses, please note that the defense cost provision of this policy stipulates that the limits of liability may be completely exhausted by the cost of legal defense. Any deductible or retention shall apply to investigation expense and defense costs as well as indemnity.

<i>If you are involved in this...</i>	<i>Then complete these sections...</i>	<i>And provide this additional information...</i>
All companies	10	Five years of loss information Most recent financial data (if private)
Drug/Biologic products in trials	1, 7	Consent forms & protocols for actively sponsored trials
Drug/Biologic products approved	1, 8	
Medical device products in trials	2, 7	Consent forms & protocols for actively sponsored trials
Medical device products approved	2, 8	
Dietary supplements / nutritional products	3	
Contract services	4, 9	Copies of largest & standard contracts
Distribution	5, 8, 9	Copies of largest & standard contracts
Non-profit/independent research	6	

### 1. DRUGS / BIOLOGICS

A. Mark any items where you have past, present, or planned association with these products:

Known Teratogen	Known Carcinogen
Known Mutagen	Weight loss products
Addictive substances	Highly potent cytotoxin

B. Do you manufacture any active pharmaceutical ingredients? Yes    No  
*(If yes, provide details)*

C. Do you utilize nanotechnology in your product development, delivery, or manufacturing? Yes    No  
*(If yes, provide details)*

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



2. MEDICAL DEVICES

A. Mark any items where you have past, present, or planned association with products or substances in these areas:

- |                            |   |
|----------------------------|---|
| Cold therapy               | Implantable products                                |
| IUD devices                | Orthopedic pain management device (e.g. pain pumps) |
| Radiation-emitting devices |   |

B. Do you utilize nanotechnology in your product development, delivery, or manufacturing? Yes      No  
*(If yes, provide details)*

3. DIETARY SUPPLEMENTS / NUTRITIONAL PRODUCTS

A. Do any of your products make either health or structure/function claims? Yes      No  
*If yes, what are the claims and how are they substantiated?*

B. Have any of your products ever fit the definition of a new dietary ingredient? Yes      No  
 If so, have pre-market safety reviews been conducted per regulations? Yes      No

C. 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, what are they?*

D. Do you sell any weight loss, muscle-building or sexual enhancement products? Yes      No

E. Are you compliant with the most current regulatory requirements related to manufacturing and adverse event reporting? Yes      No

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

4. CONTRACT PROFESSIONAL SERVICE

Describe the products or services you provide:

Types of Products	Description of Products	Projected Annual Revenue
Pharmaceutical manufacturing for others		
Medical device manufacturing for others		
R&D / Lab instrument manufacturing		
Software development		



Types of Services	Description of Services	Projected Annual Revenue
Clinical trials		
Consulting		
IRB		
Laboratory		
Pharmacovigilance / Safety Surveillance		
Pre-clinical		
Sales & marketing		

- A. Do you currently purchase specific professional liability insurance? Yes    No  
*(If yes, indicate type of insurance, limit, and insurer)*  
 Type of insurance \_\_\_\_\_  
 Limit \_\_\_\_\_  
 Insurer \_\_\_\_\_
- B. How many of your customers represent >10% of your sales? \_\_\_\_\_
- C. Do your customized customer management procedures include the following?
- |  |     |    |     |
|--|-----|----|-----|
| 1. Written proposal or request for information in order to determine customer performance expectations | Yes | No | N/A |
| 2. Written contract of specifications of services you will provide, signed by the customer             | Yes | No | N/A |
| 3. Contract/statement of work which outlines responsibilities of all parties                           | Yes | No | N/A |
| 4. Written agreement outlining the scope of the project or services                                    | Yes | No | N/A |
| 5. Interim changes documented with customer sign-off; or <span style="float: right;">Yes</span>        |     | No | N/A |
| 6. Performance milestones acknowledged and accepted with customer sign-off when achieved               | Yes | No | N/A |
- D. What would be the largest financial and business impact on your customers from a failure of any of your products or services? \_\_\_\_\_
- E. Have you discontinued any services in the past 3 years? Yes    No  
*(If yes, please explain)*
- F. Do you have any services you will be offering to the market within the next year that are substantially different in scope or end-use than your current services? Yes    No
- G. Do you have formalized client complaint resolution policies and procedures? Yes    No
- H. Describe the type and value of the personal property of others at your facilities?



I. Are any healthcare services performed on your site?                      Yes      No  
*(If yes, please describe)*

**5. DISTRIBUTION**

A. Projected percentage of revenue by area:

_____ % APIs	_____ % Equipment
_____ % Dietary Supplements	_____ % Medical devices
_____ % Drugs/Biologics	_____ % Medical device components/software
_____ % Drug/Biologic/Dietary Supp. Ingredients	_____ % OTHER (describe): _____

B. What types of business entities do you sell to?

C. Do you utilize a computerized system that manages customer orders including validation, expiration date, flagging abnormal requests and verifying customer contract/order?                      Yes      No

D. Describe your inventory management system in terms of track and trace systems. Highlight the distribution chain from suppliers through final customer distribution.

E. What type of entities do you source your product from? If your primary product source is another wholesaler, please describe the product validation process you employ.

F. What is your customer return policy? If you accept returned product, what do you do with returned items?

G. If you are a supplier of components or ingredients, or a distributor of products of others, do you require additional insured status on the product license holder's products liability policy?                      Yes      No  
 Do you require indemnification for damages, including defense costs?                      Yes      No





H. Do you sell any medical implants? Yes      No  
*(If yes, describe the products and approximate percentage of your revenues that they represent)*

I. Do you sell any OTC products? Yes      No  
*(If yes, describe the products and approximate percentage of your revenues that they represent)*

**6. RESEARCH INSTITUTIONS**

A. Projected percentage of revenue by area:

_____ % Basic research	_____ % Pre-clinical testing
_____ % Clinical testing	_____ % Product commercialization
_____ % IRB services	_____ % Product licensing
_____ % Medical product research	_____ % OTHER (describe): _____

B. Do you perform any service for third parties? Yes      No  
*(If yes, please explain the services rendered. If no, skip to question 4.)*

C. Do you provide the service as part of an open-ended contract? Yes      No

D. Do you have any unpaid volunteers or students working in your organizations? Yes      No  
 If yes, how many? \_\_\_\_\_

E. Are any healthcare services performed on your site? Yes      No  
*(If yes, please describe)*

F. What are your top two funding sources?



**7. HUMAN CLINICAL TRIALS**

<i>Active Trials Currently Being Sponsored. (include phase 4)Sponsored trials (present and planned) for the next year</i>					
Product Name & Protocol Number	# of New Subjects to be Enrolled Over Next Policy Period	Indication	Trial Phase	Country(ies)	Countries where local insurance is placed

- A. Number of expanded access/compassionate use subjects anticipated in the coming policy term? \_\_\_\_\_
- B. Total number of human subjects enrolled in the last 3 years: \_\_\_\_\_
- C. Any clinical trials past, present, or planned involving minors? Yes    No  
*(If yes, provide details)*
  
- D. Have there been any clinical trials involving your product which have been discontinued or suspended in whole, or in part, because of safety reasons? Yes    No  
*(if yes, provide details)*
  
- E. Have any clinical investigators been cited for regulatory violations in connection with your trials (e.g., serious regulatory non-compliance, fraud)? Yes    No  
*(If yes, please provide details)*
  
- F. Number of clinical trial "For Cause Audits" conducted by you or regulatory agency in the last 5 years? \_\_\_\_\_  
*(Please provide details)*



- |    |   |     |    |
|----|---|-----|----|
| G. | Do you provide Clinical Investigators, CROs or Sites with compensation other than charges for specific services rendered (e.g., enrollment bonuses, equity interest)? | Yes | No |
| H. | What is the targeted reading grade level for your informed consent documents? _____   |     |    |
| I. | Do you require Clinical Investigators to test participants on their understanding of the informed consent document?   | Yes | No |
| J. | Do you incorporate financial disclosures in the informed consent documents or process?  | Yes | No |
| K. | What has been the maximum compensation you have offered trial participants? _____   |     |    |
| L. | Do you have formalized Clinical Trial Suspension SOPs in place?   | Yes | No |
| M. | Do you ever act as both trial sponsor and clinical investigator?  | Yes | No |
| N. | Do you ever provide material or product for investigator-sponsored trials?  | Yes | No |
| O. | Do you operate an in-patient facility? <span style="margin-left: 100px;">Yes</span>   |     | No |
|    | If so, do you have an accredited emergency care facility?   | Yes | No |
| P. | Do you ever provide material or product for another organization's clinical study/trial?  | Yes | No |
| Q. | Do you publish all clinical trial results? <span style="margin-left: 100px;">Yes</span>   |     | No |

**8. REGULATORY**

- |    |   |     |    |
|----|---|-----|----|
| A. | Any products manufactured or sold under others' labels?<br><i>(if yes, provide details)</i>         | Yes | No |
| B. | Any products sold as ingredients/components for other products?<br><i>(if yes, provide details)</i> | Yes | No |
| C. | Any products approved for use by minors?<br><i>(if yes, provide details)</i>                        | Yes | No |
| D. | Any products discontinued for safety reasons?<br><i>(if yes, provide details)</i>                   | Yes | No |
| E. | Any association with banned products?<br><i>(if yes, provide details)</i>                           | Yes | No |



F. How many product recalls have you had in the past 3 years? \_\_\_\_\_  
 Describe in detail any Class 1 recalls.

G. Indicate the top 3 products in terms of number of Adverse Event Reports where the product was associated with a death, permanent injury, or hospitalization outcome? Please provide copy of most recently completed Safety Report associated with these products.

H. Identify any product requiring the addition of a black box or other significant safety warning to existing labeling or instruction manuals in the last 3 years.

I. Identify any product requiring a Risk Evaluation & Mitigation Strategy (REMS).

J. Are there any safety surveillance team recommendations involving any of the following forms of remedial actions, which have yet to be implemented or completed?

"Healthcare Professional" letter;	Yes	No
additional studies; or	Yes	No
expanded product monitoring	Yes	No

K. What, if any, steps would be taken if you became aware of a pervasive off-label use of your products?

L. Do you allow any off-label information dissemination? If yes, under what conditions?	Yes	No
--	-----	----

M. Do compliance audits include follow-up discussions with physicians?	Yes	No
--	-----	----

N. Do you do any direct-to-consumer ("DTC") advertising?	Yes	No
--	-----	----

O. Is there a required waiting period after product launch before DTC is conducted?	Yes	No
---	-----	----

P. Do you have a written policy prohibiting physician incentives?	Yes	No
---	-----	----



Q. Have there been any incidents of non-compliance regarding regulations concerning sales and marketing practices by either internal or external product sales personnel? Yes No

R. Do you have a formal policy specifically prohibiting physical patient contact by internal and external product sales personnel? Yes No  
 Have there been any incidents of non-compliance in the last 3 years? Yes No  
*(If yes, please describe)*

S. How often is formal and documented compliance training required of your internal and external sales force?

T. How do you track and trace your product?

9. CONTRACTS

A. Do you use a written contract or agreement with all clients, subcontractors, and suppliers? Yes No

B. Do you have stated minimum contract standards pertaining to your products or your services? Yes No

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

D. Do all of your contracts include a mutual hold harmless clause? Yes No

E. Do you ever assume the tort liability of another party? Yes No  
*(If yes, please explain)*

F. What is the value of your average performance-based contract, P.O. or agreement? \_\_\_\_\_

G. What is the duration of your average performance-based contract, P.O. or agreement? \_\_\_\_\_

H. Do you accept customized contracts, P.O.s or agreements? Yes No  
 If yes, does legal counsel or senior management review all such documents prior to mutual assent? Yes No

I. In the last three years, have you been involved in any contract disputes or have any contracts past due acceptance? Yes No  
*(Please explain)*

J. Do you have a formal, written records retention policy? Yes No



K. How often do you agree to name third parties as additional insureds under your policy? \_\_\_\_\_  
 Under what circumstances, do you agree to this?

L. Provide the following information for your five largest contracts, purchase orders or agreements:

Customer	Contract Amount	Product or Service	Duration

**10. HEALTHCARE PROFESSIONAL STAFF**

Health professionals	Specialty	# Applicant Employees	# Independent Contractors	Est. # hours of direct patient care annually	Est. % of time providing direct patient care annually
Physicians					
RN's Nurse					
LPN's Phlebotomist					
Pharmacist					
Medical/Lab Technician					
EMT/Paramedic's					
Others (please describe)					
Details:					

A. Does your organization carry medical malpractice insurance for claims arising out of the acts of your employees?      Yes      No  
 If so, who is the carrier and what is the limit of insurance provided?  
 Carrier: \_\_\_\_\_  
 Limit of Insurance: \_\_\_\_\_

B. Do you require that all employees and independent contractors who have direct patient interaction carry medical malpractice insurance?      Yes      No  
 If so, what are the limits of insurance required? \_\_\_\_\_  
 Do you obtain evidence of coverage on an annual basis?      Yes      No  
 Details:



### III. PREMISES / OPERATIONS

1. Indicate which of the following applies to your premises:

a. access is not allowed without card and/or authorized employee	Yes	No		
b. front desk registration only	Yes		No	
c. no restricted access.	Yes	s	No	
  
2. Indicate how many gallons of hazardous substances are kept on site? \_\_\_\_\_
  
3. Which of the following apply to the storage of hazardous substances on site?

a. outdoor storage	Yes	No	NA		
b. indoor cut-off area in approved containers	Yes	No	NA		
c. indoor cut-off area in unapproved containers just-in-time supply levels			Yes	No	NA
d. just-in-time supply	Yes	No	NA		
  
4. Are you in compliance with Hazardous Materials Regulations? Yes No NA
  
5. Highest Biohazard Lab rating? \_\_\_\_\_
  
6. Do you have an animal facility or house animals? Yes No
  
7. What are the main focal areas of your Enterprise Risk/Safety Program?  
*(Areas might include Regulatory Compliance, Company practices that foster "Best in Class" product, worker and facility risk mitigation efforts (e.g., Code of Conduct), Privacy, Biohazard Management, Disaster Recovery Program)*
  
  
  
  
  
  
  
  
  
  
8. Do you require that all new employees participate in training that instructs them on all applicable company policies and procedures? Yes No
  
9. Do you require Certificates of Insurance from all of your suppliers and sub-contractors? Yes No  
What limits and terms do you require?
  
  
  
  
  
  
  
  
  
  
10. How often are the risk management programs and SOP's audited annually? \_\_\_\_\_
  
  
  
  
  
  
  
  
  
  
11. Please indicate any risk management programs and SOPs that are audited by independent non-governmental organizations/individuals?
  
  
  
  
  
  
  
  
  
  
12. Do you have a formalized information security policy that dictates the protocols that control access to or use of all critical data, processes or information systems for all authorized users, including business partners and third parties? Yes No



- |  |     |    |
|--|-----|----|
| 13. Do you have an information security officer?   | Yes | No |
| 14. Do you have a formalized Privacy Policy in place?<br>If yes, when was it last updated and audited? _____ | Yes | No |
| 15. Do you have a crisis management team in place?   | Yes | No |





## IV. ERRORS & OMISSIONS LIABILITY

NOTICE: This is an application for a policy that may include a claims made trigger (and for certain accounts, claims made and reported) and that the limit of liability under any policy to be issued in response hereto may include both the indemnity payments for claims and payment of claim and defense expenses, as defined in the policy.

If the limit of liability is reduced by payment of claim and defense expenses, please note that the defense cost provision of this policy stipulates that the limits of liability may be completely exhausted by the cost of legal defense. Any deductible or retention shall apply to investigation expense and defense costs as well as indemnity.

### 1. TYPES OF PRODUCTS & SERVICES, INDUSTRIES SERVED, REVENUE

*IF YOU HAVE COMPLETED THE CONTRACT SERVICES SECTION OF THE PRODUCTS-COMPLETED OPERATIONS APPLICATION, THEN SKIP THIS SECTION AND GO TO SECTION 2 "CONTRACTS" BELOW.*

Types of Products	Description of Products	Projected Annual Revenue
Pharmaceutical manufacturing for others		
Medical device manufacturing for others		
R&D / Lab instrument manufacturing		
Software development		

Types of Services	Description of Services	Projected Annual Revenue
Clinical trials		
IRB		
Laboratory		
Pre-clinical		
Sales & marketing		
Pharmacovigilance / Safety Surveillance		
Consulting		

A. Do you currently purchase any healthcare professional liability or other professional liability insurance? Yes No

If Yes, provide the following:

Type of Insurance Purchased \_\_\_\_\_

Limits of Insurance \_\_\_\_\_

Effective Date \_\_\_\_\_

Carrier \_\_\_\_\_

B. How many distinct products or services do you offer? 1-3 4-6 More than 6

C. How many of your customers represent 10 percent or more of your total revenue? 0 1 2 3

D. Please provide more detailed information about these customers:

Customer	Revenue	Product or Service



- E. What would be the largest financial and business impact on your customers from a failure of any of your products or services? \_\_\_\_\_
- F. Have you discontinued any products or services in the past three years? Yes No  
 If yes, do you continue to provide service or maintenance? Yes No
- G. Do you have any products or services entering the market within the next year that are substantially different in scope or end use than your current products or services? Yes No
- H. Do you have a process to evaluate the financial conditions of your customers and suppliers? Yes No

**2. CONTRACTS**

*IF YOU HAVE COMPLETED THE CONTRACTS SECTION OF THE PRODUCTS-COMPLETED OPERATIONS APPLICATION, THEN SKIP THIS SECTION AND GO TO SECTION 3 "QUALITY CONTROL" BELOW.*

- A. Do you have stated minimum contract standards pertaining to your products or your services? Yes No
- B. Do your global contracts or agreements comply with stated minimum standards? Yes No
- C. Do you accept customized contracts, purchase orders or agreements? Yes No  
 If Yes, does legal counsel or senior management review all such contracts, purchase orders or agreements prior to mutual assent? Yes No
- D. What is the average value of your average performance-based contract, purchase order or agreement? \_\_\_\_\_
- E. Does the value of any performance-based contract, purchase order or agreement exceed \$2.5M? Yes No
- F. What is the duration of your average performance-based contract, purchase order or agreement? \_\_\_\_\_
- G. Provide the following information for your five largest contracts, purchase orders or agreements:

Customer	Contract Amount	Product or Service	Duration

**3. QUALITY CONTROL**

- A. Do your quality-control procedures include the following?
- |  |     |    |     |
|--|-----|----|-----|
| • Written and formalized quality-control program   | Yes | No | N/A |
| • Alpha testing <span style="float: right;">Yes</span>   |     | No | N/A |
| • Beta testing <span style="float: right;">Yes</span>  |     | No | N/A |
| • Formal customer-acceptance procedure <span style="float: right;">Yes</span>                          |     | No | N/A |
| • Systems-development methodology in writing   | Yes | No | N/A |
| • Formal product-recall plan <span style="float: right;">Yes</span>                                    |     | No | N/A |
| • Formal policy for documenting and responding to customer complaints or requests for changes or fixes | Yes | No | N/A |
- B. Do your products/services comply with any accepted industry standards? \_\_\_\_\_



C. Do your customized customer-management procedures include the following?

- |   |     |    |     |
|---|-----|----|-----|
| 1. A written proposal or request for information in order to determine customer performance expectations  | Yes | No | N/A |
| 2. A written contract of specifications of products and services you will provide, signed by the customer | Yes | No | N/A |
| 3. Contract/statement of work which outlines responsibilities of all parties                              | Yes | No | N/A |
| 4. A written agreement outlining the scope of the project or services                                     | Yes | No | N/A |
| 5. Interim changes documented with customer sign-off  | Yes | No | N/A |
| 6. Performance milestones acknowledged and accepted with customer sign-off when achieved                  | Yes | No | N/A |

D. Does your information-security officer or development QC manager have responsibility for ensuring that all products are continually evaluated throughout their life cycle for known security vulnerabilities?      Yes      No      N/A

E. Do you have a document-retention policy?      Yes      No      N/A

**4. CUSTOMER SUPPORT**

A. Do you have at least two forms of customer or product support?      Yes      No      N/A

B. Describe your customer training and support:

Is there customer support 24 hours a day?      Yes      No

Do you maintain written logs for customer complaints of problems or downtime?      Yes      No

How long are they retained? (number of whole or partial months) \_\_\_\_\_

C. Do you inform customers of problems you discover?      Yes      No

D. Describe your escalation procedure for customer or product-support complaints or issues that are not easily resolved:

**5. HISTORICAL INFORMATION**

In the past five (5) years, have you been sued or threatened with suit for any act, error or omission relating to your products or services?      Yes      No

In the past five (5) years, have any of your products or services been recalled from use?      Yes      No

In the past five (5) years, has there been any current or past administrative, civil or criminal investigation or litigation by any governmental or regulatory authority?      Yes      No

Are you aware of any act, error or omission, unresolved contract dispute, or any other circumstance that may reasonably be expected to result in a claim or suit to which this insurance applies?      Yes      No



## V. WORKERS' COMPENSATION

Answers to these industry-specific questions are requested as a supplement to standard industry (e.g. Acord) Workers' Compensation application.

1. How many of your employees currently (or will, in the next year) work with compounds known to be teratogens, mutagens, or carcinogens? \_\_\_\_\_
  
2. How many of your employees currently (or will, in the next year) work with nano-materials (including, but not limited to, carbon nanotubes, buckyballs, fullerenes, nano-scale gold, nano-scale silver, nano-scale oxides, nano-scale liposomes)? \_\_\_\_\_
  
3. How many of your employees currently (or will, in the next year) work with materials or equipment emitting ionizing radiation? \_\_\_\_\_
  
4. Do you have any employees who currently (or will, in the next year) work with blood, body fluids, or tissue samples that are known to contain human pathogens or animal pathogens known to infect humans?                      Yes              No  
 If Yes, go to 5. If No, go to 6.
  
5. Fill in the number of your employees who currently (or will, in the next year) work with materials requiring specific biohazard safety controls.  
 BSL 1 \_\_\_\_\_  
 BSL 2 \_\_\_\_\_  
 BSL 3 \_\_\_\_\_  
 BSL 4 \_\_\_\_\_
  
6. Do you have any contracts with U.S. government agencies where Defense Base Act coverage is required?                      Yes              No



## VI. SIGNATURE / CERTIFICATION

**NOTICE TO APPLICANT - PLEASE READ CAREFULLY.**

INFORMATION OR DATA CONTAINED IN OR SUBMITTED IN CONNECTION WITH THIS APPLICATION (OR OTHERWISE TO ANY OF THE MEMBER INSURERS OF CHUBB GROUP OF INSURANCE COMPANIES ("CHUBB") IN CONNECTION WITH THE UNDERWRITING PROCESS) DOES NOT CONSTITUTE NOTICE OF AN OCCURRENCE, WRONGFUL ACT, CLAIM, SUIT OR OTHER CIRCUMSTANCE AND DOES NOT SATISFY ANY OF THE REPORTING NOTIFICATION OR OTHER PROVISIONS OF ANY POLICY. ALL SUCH NOTICES MUST BE GIVEN SEPARATELY IN ACCORDANCE WITH THE APPLICABLE POLICY CONDITIONS.

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.

COMPLETION OF THIS APPLICATION DOES NOT BIND INSURANCE. APPLICANT'S ACCEPTANCE OF THE COMPANY'S QUOTATION IS REQUIRED PRIOR TO BINDING INSURANCE AND POLICY ISSUANCE.

**CERTIFICATION**

For the purposes of this application, the undersigned declares and acknowledges by clicking where indicated below that, he/she has reviewed this application and the statements contained therein with his/her Chief Executive Officer, Chief Financial Officer, Chief Operating Officer or their equivalents, and that to the best of their knowledge and belief, after reasonable inquiry, the statements in this application, and in any attachments, are true and complete.

Chubb is authorized to make any inquiry in connection with this application. Signing this application shall not constitute a binder or obligate Chubb to complete this insurance, but it is agreed this application shall be the basis upon which a policy may be issued.

If the statements in this application or in any attachment change materially before the effective date of any proposed policy, the applicant must notify Chubb, and Chubb may modify or withdraw any quotation.

You understand that the limit of liability under any policy to be issued in response hereto shall include both indemnity payments for claims and payment of claim and defense expenses, as defined in the policy.

The undersigned persons understand and further agree that the completion and signing of this APPLICATION neither binds Chubb to sell nor the Applicant to purchase the insurance.

**PLEASE NOTE: ONLY DULY APPOINTED AGENTS OF CHUBB AND LICENSED BROKERS ARE AUTHORIZED TO SOLICIT APPLICATIONS FOR INSURANCE. AGENTS AND BROKERS ARE NOT AUTHORIZED TO BIND INSURANCE. NO INSURANCE SHALL BE PROVIDED UNLESS CHUBB ACCEPTS THE APPLICATION AND BINDS THE INSURANCE.**

By signing below, applicant hereby certifies that the statements made and the information and data supplied herewith are true, accurate and complete.

<u>Authorized Signature of Applicant</u>		<u>Date</u>	
<u>Print Name</u>		<u>Title</u>	
Applicant		Authorized Agent <i>(Please Print Name)</i>	
Authorized Agent <i>(Signature)</i>		Title	Date
Submitted By <i>(Insurance Agent)</i>		Insurance Agency	
Agent License No. <i>(For non-admitted placements a copy of valid surplus lines license will be required)</i>			
Address <i>(No., Street, City, State, and ZIP Code)</i>			



**NOTICE TO APPLICANT - PLEASE READ CAREFULLY.**

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. APPLICABLE IN:

**ARKANSAS**

ANY PERSON WHO KNOWINGLY PRESENTS 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 FINES AND CONFINEMENT IN PRISON.

**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.

**DISTRICT OF COLUMBIA**

WARNING: IT IS A CRIME TO PROVIDE FALSE OR MISLEADING INFORMATION TO AN INSURER FOR THE PURPOSE OF DEFRAUDING THE INSURER OR ANY OTHER PERSON. PENALTIES INCLUDE IMPRISONMENT AND/OR FINES. IN ADDITION, AN INSURER MAY DENY INSURANCE BENEFITS IF FALSE INFORMATION MATERIALLY RELATED TO A CLAIM WAS PROVIDED BY THE APPLICANT.

**FLORIDA**

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**

ANY PERSON WHO KNOWINGLY AND WITH INTENT TO DEFRAUD ANY INSURANCE COMPANY OR OTHER PERSON FILES AN APPLICATION FOR INSURANCE 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.

**LOUISIANA**

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 FINES AND CONFINEMENT IN PRISON.

**MAINE**

IT IS A CRIME TO KNOWINGLY PROVIDE FALSE, INCOMPLETE OR MISLEADING INFORMATION TO INSURANCE COMPANY FOR THE PURPOSE OF DEFRAUDING THE COMPANY. PENALTIES MAY INCLUDE IMPRISONMENT, FINES OR A DENIAL OF INSURANCE BENEFITS.

**MARYLAND**

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.

**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.

**NEW MEXICO**

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.

**NEW YORK**

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.

**OHIO**

ANY PERSON WHO, WITH THE INTENT TO DEFRAUD OR KNOWING THAT HE 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.

**OKLAHOMA**

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**

ANY PERSON, WHO KNOWINGLY AND WITH INTENT TO DEFRAUD ANY INSURANCE COMPANY OR OTHER PERSON, FILES AN APPLICATION FOR INSURANCE CONTAINING ANY FALSE INFORMATION, OR CONCEALS FOR THE PURPOSE OF MISLEADING INFORMATION CONCERNING ANY MATERIAL FACT THERETO, MAY BE GUILTY OF AN INSURANCE FRAUD.



Chubb Group of Insurance Companies  
15 Mountain View Rd.  
Warren, NJ 07059

## APPLICATION FOR LIFE SCIENCES POLICY

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### 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.

### TENNESSEE, VIRGINIA AND WASHINGTON

IT IS A CRIME TO KNOWINGLY PROVIDE FALSE, INCOMPLETE OR MISLEADING INFORMATION TO INSURANCE COMPANY FOR THE PURPOSE OF DEFRAUDING THE COMPANY. PENALTIES INCLUDE IMPRISONMENT, FINES AND DENIAL OF INSURANCE BENEFITS.

### RHODE ISLAND AND WEST VIRGINIA

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 FINES AND CONFINEMENT IN PRISON.

This is an application for a policy that may be issued in a state that requires us to advise you that if available, the following condition is added to your policy: All references in the policy to "spouse" include a party to a civil union or domestic partnership recognized under the applicable law of the jurisdiction having authority.

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