



## *Chubb Group of Insurance Companies*

### **Life Science New Business Application**

This application is a word document that allows applicant to enter information in the empty sections. This document is configured so that each data entry section will expand to accommodate the information. A box for detailed commentary has been provided below each major section of the application. **If a question or section is not applicable, please answer "NA".**

This is an application for a **CLAIMS MADE POLICY**. Should this application be accepted by the Company, the policy will apply to claims first made against the insured during the policy period. This policy will not apply to claims first made against the insured after the end of the policy period (unless the extended reporting period applies) or claims first made prior to the retroactive date shown in the declarations page. **The completion and submission of this application to the Company does not constitute a binder of insurance under any circumstances. All questions must be answered. 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 it responds to.



A. General Information	
1. Applicant:	
2. Address:	
3. Mailing Address: <i>(if different)</i>	
4. Web Site Address:	
5. Locations: <i>(if other than above)</i>	
6. All Named Insureds:	
7. Additional Insureds: <i>(explain relationship)</i>	

8. If applicant has acquired any subsidiaries within the last 5 years, identify:

Entity	Date Acquired

9. Applicant is:  Individual  Partnership  Corporation  Joint Venture  LLC  Other *(describe)*

10. Years in business?							
11. Does applicant have a parent company? <i>(if yes, provide name)</i>							
12. Has applicant operated under another name? <i>(if yes, provide full details)</i>							
13. Projected gross USA sales?							
14. Projected gross non-USA sales?							
15. Projected R&D expenditures for human clinical trials?							
16. Average annual expenditures for medical treatments for side effects sustained by clinical trial participants over the last 3 years?							
17. Projected annual prescriptions / units to be sold?							
18. Projected Number of annual products users?							
19. Who are applicant's top 3 competitors?							
20. Any product components/ingredients imported? <i>(if yes, provide details)</i>							
21. Any products manufactured sold under others' labels? <i>(if yes, provide details)</i>							
22. Any products sold as components/ingredients for other products? <i>(if yes, provide details)</i>							
23. Any products manufactured outside the U.S. <i>(if yes, provide details)</i>							
24. Indicate revenue percentages per operational activities:	<table border="1"> <thead> <tr> <th>Manufacturing</th> <th>Distribution</th> <th>Services</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Manufacturing	Distribution	Services			
Manufacturing	Distribution	Services					
Details:							

**B. Product/Service Profile (percentages)**

Potential Source of Revenues	%	Potential Source of Revenues	%
Medical Devices		Contract Research, Manufacturing, Sales, etc.)	
Diagnostics		Equipment Rentals/Leasing	
Drugs/Biologics/Dietary Supplements		Repair/Installation/Service	
Information Services/Databases/Software		Other <i>(please explain)</i>	
Details:			

**C. Drugs/Biologics/Dietary Supplements Product Breakdown (percentages). If N/A Indicate Here:**

Animal		Gene Therapy/Transfer		Vaccines	
Birth Control/Fertility		Genetic Testing		Vitamins/Dietary Supplements	
Blood/Plasma		Hormones & Steroids		Other Therapeutics	



Diagnostic		Topical		Other (please explain)	
<b>Indicate product percentages:</b>	Brand Name Prescription	Generic Prescription	OTC	Pediatric	

Does applicant have any past, present or planned association with any of the following: animal derived products, oral contraceptives, vaccines, weight reduction products, psychotropic products, products that are known teratogens, products that are known mutagens, Ephedrine, Phenylalanine, Androstenedione, Estazolam, Phenylpropanolamine (PPA), Aristolochic Acid, St. John's Wort, Phentermine, Butanediol, Gamma Butyrolactone, Stephania or Magnolia, Chaparral, Gamma Hydroxybutyric Acid, Chomper, Germander, Thimerosal, Comfrey, Germanium, Tiractricol, Creatine, Indinavire, Trix Metabolic Accelerator, Dehydroepiandrosterone, Jin Bu Huan, Willow Bark, Yohimbe, Dieter's Tea, L-tryptophan, Diethylstilbestrol, and Melatonin. (if yes, please explain).

Details:

**D. Medical Devices Product Breakdown (percentages). If N/A Indicate Here:**

Analytical Instruments		Drug Delivery		Lasers Systems	
Anesthesia/respiratory		Durable Medical Equipment		Monitoring Equipment	
Cardiovascular		Hospital Products/Supplies		Surgical Devices	
Dental Instruments		Imaging Devices		Therapy/rehab	
Diagnostic Kits		Implants – Active		Other (please explain)	
Dialysis		Implants – Non-Active			
<b>Targeted application percentages:</b>	Clinical	Ambulatory	Home	Pediatrics	Other

Does applicant have any past, present, or planned association with any of the following: breast implants, IUD devices, pedicle screws, spinal devices, or latex gloves.

Details:

**E. Professional Service Breakdown (percentages). If N/A Indicate Here:**

Clinical Trials Management		Product Recall/Withdrawal	
Site Phase 1 Services		Equipment Maintenance/Sterilization	
Clinical Trials Packaging		Quality Systems & Regulatory Compliance	
CLIA Certified Lab Services		Sales & Marketing	
Communications & Publications		Software Development or Product Design	
Health Management, Economic, & Policy Research		Manuf/Distribution/Packaging/Mixing/Labeling	
Information Services/Databases		Pharmacovigilance/Safety Surveillance	
Institutional Review Board		Other (please explain)	
Pre-clinical Development			

Details:

**F. Clinical Trials - Active Trials Currently Being Sponsored. If N/A Indicate Here:**

Product Name & Protocol Number	Number of New Enrollees Over Next Policy Period	Indication	Trial Phase	Country(ies)	Expanded Access Participants	Devices SR/NSR

**Complete the following questions if applicant has been or is involved with clinical trials. If N/A Indicate Here:**

1. Total number of completed human clinical trials applicant sponsored in last 3 years:	
2. Total number of human test subjects enrolled in the last 3 years:	
3. Any clinical trials discontinued or suspended due to safety reasons? (if yes, provide details)	



4. Which of the following are not required in meeting the applicant's IRB acceptability standards: accreditation, registration with the OHRP/HHS, confirmation of formal training, workload demand assessments, and specialty and patient group expertise?	
5. Which of the following are not required of the applicant's CRA's (Clinical Research Associate): certification, professional designation, and formal training?	
6. What percentages of applicant's CRA's have less than 5 years experience?	
7. What percentages of applicant's clinical sites are academic versus non-academic?	
8. Which of the following are not required in meeting the applicant's CI (Clinical Investigator) acceptability standards: formal training, accreditation, certifications, workload demand assessments, specialty & patient group expertise?	
9. Please indicate which of the following are allowed by the applicant: CI's enrolling their own patients, enrollment bonuses, contacting patients directly via patient databases, or patient referral fees?	
10. Has any of applicant's CI's been cited for regulatory violations? <i>(if yes, provide details)</i>	
11. Has applicant had any evidence of serious regulatory non-compliance or fraud by applicant's CI's and their staff in the past 5 years? <i>(if yes, provide details)</i>	
12. Number of clinical trial "For Cause Audits" conducted by applicant, FDA, or OHRP in the last 3 years?	
13. Does applicant put all informed consent documents through well-established readability testing, for example, the Flesch-Kincaid Grade level Scoring?	
14. Does applicant use information videos as part of the informed consent process?	
15. Does applicant perform a final approval of IRB approved informed consent documents?	
16. Does applicant require CI's to test participants on their understanding of the informed consent document?	
17. Is applicant in compliance with the FDA requirements concerning financial disclosures?	
18. Does applicant incorporate financial disclosures in the informed consent documents or process?	
19. Does applicant ever use Data Safety Monitoring Boards?	
20. What has been the maximum compensation applicant have offered trial participants?	
21. Does applicant have formalized policies for expanded access/compassionate use?	
22. Is applicant in compliance with applicable state regulations regarding human clinical trials?	
23. Do any of applicant's employees or sub-contractors provide direct patient care on applicant's behalf? Do they carry their own medical malpractice insurance?	
24. Does applicant ever act as both trial sponsor and clinical investigator?	
25. Does applicant operate an in-patient facility? If so, does applicant have an accredited emergency care facility?	
Details:	

**G. Medical Staff Profile. If N/A Indicate Here:**

Health professionals	Specialty	Estimated hours of direct patient interactions annually	# Applicant Employees	# Independent Contractors
Physicians				
RN's				
LPN's				
Pharmacist				
Medical Technician				
EMT's				
Others <i>(please describe)</i>				
Details:				

**H. Professional Services. If N/A Indicate Here:**

1. Any GLP, GCP, GMP, or QS Regulatory violations in last 3 years? <i>(if yes, provide details)</i>	
2. Does applicant have formalized project-planning policies and procedures?	
3. Does applicant have formalized client complaint resolution policies and procedures?	



4. Are any contracts past due or has a client stopped paying or asked for a refund in the last 3 years? (if yes, provide details)	
5. Total number of current contracts?	
6. Any discontinued services? (if yes, provide details)	
7. Average dollar value of applicant's contracts? Average length of applicant's contracts?	
8. Indicate largest client for upcoming policy year, and include contract size and length:	
9. What is the total value of the personal property of others at applicant's facilities?	
Details:	

**I. Contracts**

**Does applicant have any contracts that do not contain the following provisions that inure to applicant's benefit? (if so, please explain)**

1. All duties and responsibilities of each party	
2. Arbitration Clause	
3. Choice of Law or Jurisdiction	
4. Force Majeure (extends to any and all events outside applicant's control)	
5. Guarantees	
6. Hold Harmless Agreements/Indemnification	
7. Limitation Of Consequential Damages	
8. Limitation Of Liabilities	
9. Warranty Disclaimers	
10. Does applicant use a written contract or agreement with all clients, including changes?	
11. Does an attorney review all contracts or agreements including changes prior to use?	
Details:	

**J. Safety Surveillance & Regulatory**

1. How many product recalls has applicant had in the past 3 years? Describe in detail any Class 1 recalls?	
2. Indicate the top 3 products in terms of number of Adverse Event Reports where the product was associated with a death or permanent injury outcome? Please provide copy of most recently completed Quarterly Periodic Safety Report (or Annual Report if applicable) associated with these products.	
3. Identify any product requiring the addition of a black box warning to existing labeling in the last 3 years?	
4. What is the make-up of applicant's safety surveillance team and whom do they report to?	
5. Identify any safety surveillance team recommendations involving any of the following forms of remedial actions that have yet to be implemented or completed: product recall/withdrawal, black box warning label, "Dear Healthcare Professional" letter, additional studies, or expanded product monitoring.	
6. Indicate all standard sources of product Adverse Event monitoring used by applicant.	
7. What steps if any would the company take if applicant became aware of a pervasive off-label use of applicant's products?	
8. Has any company product submitted to a FDA Advisory Committee in the last 3 years received less than a 2/3 <sup>rd</sup> majority committee approval vote? (if yes provide details)	
9. Any product discontinued for safety reasons? (if yes, provide details)	
10. Is applicant in compliance with all applicable GLP, GCP, GMP, and QS Guidelines?	
11. Has applicant been [redacted] for any GLP, GCP, GMP, QS, or Advertising & Promotion violations in the last 3 years? (if yes, provide details)	
12. How many untitled letters did the company receive from the FDA in the last 3 years that ultimately ended up as a warning letter?	
13. Has there been any FTC violations in the last 3 years? (if yes, provide details)	
14. What percentage of the regulatory staff has less than 5 years experience?	



15. Does applicant have formalized information privacy policies and procedures that are in compliance with applicable local, state, and federal regulations?	
Details:	

<b>K. Sales &amp; Marketing. If N/A Indicate Here:</b>	
1. Does the company allow any off-label information dissemination?	
2. Is applicant in compliance with Title 21 CFR PART 99--Dissemination Of Information On Unapproved/New Uses For Marketed Drugs, Biologics, And Devices?	
3. What percentage of the sales & marketing staff has less than 5 years experience?	
4. What % of the company's advertising budget is allocated to Direct to Consumer advertising?	
5. What are the top 3 most expensive perks applicant provide to physicians?	
6. In the last 3 years have applicant published any study results without including other studies that were conducted by applicant that did not support the same findings? (if yes, provide details)	
7. Does applicant have formal policy specifically prohibiting direct patient contact by product sales personnel? Have there been any incidents of non-compliance in the last 3 years?	

<b>L. Risk Management &amp; Loss Control</b>	
1. Does applicant have a formal safety program (which includes biohazard & disaster recovery)? (if yes please provide name of person in charge of program)	
2. Does applicant have formalized Intellectual Property policies and procedures?	
3. Does applicant require all new employees participate in training program that instructs them on all applicable company policies and procedures?	
4. Does applicant require Certificates of Insurance from all applicants' suppliers and sub-contractors? What limits and terms does applicant require?	
5. Does applicant have formalized product anti-counterfeiting measures?	
6. Are all risk management programs and SOP's audited at least annually?	
7. Does applicant's marketing/sales, safety surveillance, product development, and regulatory teams receive regular training in product liability concepts and regulatory requirements?	
8. Indicate Industry Trade Associations Memberships.	
9. Does applicant have a crisis management team in place?	
10. Does applicant have a full time risk manager on staff?	
Details:	

<b>M. Premises/Operations</b>	
1. Indicate which of the following applies to applicant's premises: access is not allowed without card and/or authorized employee, front desk registration only, or no restricted access.	
2. Indicate which of the following applies: hazardous substances are kept outdoors or in a cut-off within approved containers, just in time supply levels, cut-off area with unapproved containers.	
3. Indicate how many gallons of hazardous substances are kept on site?	
4. Biohazard Lab Rating if applicable?	
5. If applicable is the applicant in compliance with 49 CFR 172.702PART 172--Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, And Training Requirements?	
6. Has applicant ever hired key employees from direct competitors?	
7. Does applicant ever do direct product comparisons against competitor products?	
8. Does applicant have any competitors making similar products?	
Details:	

<b>N. Property</b>	
1. Is temperature sensitive property stored on site (i.e. reagents, cell cultures, etc.) If no, proceed to question number 5	
2. Is the temperature sensitive property monitored by a central station temperature alarm?	



3. Does applicant have automatic, self-starting back-up power units with a minimum 6-hour fuel supply to provide continuous power to all temperature sensitive areas?	
4. What is the estimated value of temperature sensitive property, and roughly how much would it cost to re-create such property?	
5. Does applicant have an animal lab on site? If no, proceed to question number 8	
6. Is the animal facility physically separated from other parts of the building?	
7. Does the animal facility have it's own HVAC system?	
8. Is applicant scheduled to receive any grants, endowments or milestone payments in the upcoming year, which are contingent upon performance of your R&D operations? If so, please describe source and amounts.	
9. Does applicant produce or utilize radioisotopes in applicant's manufacturing process? If so, is applicant in compliance with the relevant government regulations with respect to their use?	
10. Are applicant's products exposed to radioisotopes at other facilities (i.e. off-site sterilization)? If so, does applicant obtain certificates of insurance from those third party firms evidencing liability coverage and naming applicant as additional insured with respect to such work?	
11. Does applicants fire detection and protection systems comply with NFPA Standards?	
12. What is the total value of the personal property of others at applicant's facilities?	
13. Does applicant ship any temperature sensitive property, narcotics or live animals?	
Details:	

**O. Loss History**

*\*Total aggregate cost (losses from ground up including defense, deductibles, and SIR's) for last five years*

Policy Period	Insurer	# of Claims	Total Incurred	Total Paid	Loss Ratio

*\*Attach previous carrier loss runs*

1. Describe all incurred losses of \$10,000 or more:	
2. Any known incidents or circumstances that might reasonably be expected to give rise to a claim? <i>(If yes, provide details)</i>	
3. Any claims not yet reported? <i>(If yes, provide details)</i>	
4. Indicate any product or service past or present that has been involved with class action or multi-district litigation?	
Details:	

**P. Coverage History**

Policy Period	Primary & Excess Limits	Carriers	Occurrence/Claims Made	Retro Date
1. Does applicant have any outstanding loss control recommendations with applicant's current carrier? <i>(if yes, provide details)</i>				
2. Has applicant's insurance ever been canceled or non-renewed by a carrier? <i>(if yes, provide details)</i>				
Details:				

**Q. Liability Coverage Request**

Coverage	Limits Requested	Deductible/SIR Requested
Premises & Operations Liability		
Products & Completed Operations Liability		



<b>Professional Liability</b>		
<b>Errors &amp; Omissions Liability</b>		
<b>Other</b>		
<i>Details:</i>		

*\*When requesting excess coverage please provide underlying premium figures and policy terms & conditions.*

**PLEASE INCLUDE THE FOLLOWING WITH THIS APPLICATION:**

- Previous carrier loss runs for last 5 years
- If private, most recent financial statement.
- Protocols or Investigator Brochures & Master Informed Consent documents for active sponsored clinical trials.
- Safety Surveillance & Clinical Trial Monitoring SOPs

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

"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."

<b>Authorised Signature of Applicant</b>	<b>Date</b>
<b>Print Name</b>	<b>Title</b>

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