



# CHUBB INSURANCE COMPANY OF EUROPE SE

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## Life Sciences New Business Application

**NOTICE: This is an application for a claims made and reported policy and 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.**

**Please note that the defense cost provision of the 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.**

**ALL QUESTIONS IN THIS APPLICATION MUST BE ANSWERED TRUTHFULLY AND COMPLETELY FOR ALL PERSONS 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 IT RESPONDS TO.**

*This application is a word document that allows applicant to enter information in the empty sections. Any alteration of this application (other than sections reserved for answers) is expressly prohibited. 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.*

### **BEFORE CONTINUING, PLEASE ATTACH COPIES OF THE FOLLOWING WITH THIS APPLICATION:**

1. Detailed loss information for the last 5 years
  2. Copies of standard and 3 largest sales, service & license contracts or agreements
  3. If private, most recent financial statement
  4. Protocols and Informed Consent documents for active sponsored clinical trials
- Other materials as applicable

### **GENERAL INFORMATION**

1. Applicant:	
2. Please provide brief description of your operations:	
3. Address:	
4. Mailing Address: <i>(if different)</i>	
5. Web Site Address:	
6. Locations: <i>(if other than above)</i>	
7. All Named Insureds:	
8. Additional Insureds: <i>(explain relationship)</i>	
9. Any acquired subsidiaries in the last 5 years? <i>(if yes, please provide entity name and date acquired)</i>	
10. Applicant is:	Individual <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation <input type="checkbox"/> Joint Venture <input type="checkbox"/> LLC <input type="checkbox"/> Other <input type="checkbox"/> (describe)
11. Years in business?	
12. Does applicant have a parent company? <i>(if yes, provide name)</i>	
13. Has applicant operated under another name? <i>(if yes, provide full details)</i>	
14. Who are applicant's top 3 competitors?	

15. Is the applicant or any shareholders, directors, officers, partners, or members thereof under any investigation for alleged criminal violations relating to your business?	
16. Is applicant in compliance with all applicable regulatory guidelines? <i>(if no, provide details)</i>	
17. Has applicant been cited for any regulatory violations in the last 3 years? <i>(if yes, provide details)</i>	
18. Total projected gross sales (USA/Canada and rest of world)?	
19. Previous year gross sales (USA/Canada and rest of world)?	

**DRUGS/BIOLOGICS R&D OR PRODUCT REVENUE PERCENTAGES.** *If N/A indicate here:*

Single Source Prescription		Single Source Over the Counter	
Multi-Source/Generic Prescription		Multi-Source/Generic Over the Counter	

**SPECIALTY BREAKDOWN**

Cardiology/Vascular Diseases		Oncology	
Dental/Maxillofacial Surgery		Ophthalmology	
Dermatology/Plastic Surgery		Otolaryngology	
Endocrinology		Pediatrics/Neonatology	
Gastroenterology		Pharmacology/Toxicology	
Hematology		Psychiatry/Psychology	
Immunology/Infectious Diseases		Pulmonary/Respiratory Diseases	
Musculoskeletal		Rheumatology	
Nephrology/Urology		Trauma/Emergency Medicine	
Neurology		Other	
Obstetrics/Gynecology			

1. Does applicant have any past, present or planned association with substances in any of the following categories: *(if yes, provide details)*

Known Teratogen		Vaccines		Plant Derived		Anti-Depressant	
Known Mutagen		Animal Derived		Birth Control		Hormone	
Known Carcinogen		Human Derived		Weight Reduction		Addictive Substances	

Details:

**MEDICAL DEVICES R&D OR PRODUCT REVENUE PERCENTAGES.** *If N/A indicate here:*

Anesthesiology		Hematology and Pathology	
Cardiovascular		Immunology and Microbiology	
Clinical Chemistry and Clinical Toxicology		Neurology	

Dental		Obstetrical and Gynecological	
Ear, Nose, and Throat		Ophthalmic	
Gastroenterology and Urology		Orthopedic	
General and Plastic Surgery		Physical Medicine	
General Hospital and Personal Use		Radiology	
		Other	

1. Does applicant have any past, present, or planned association with any of the following products: *(if yes, provide details)*

Breast Implants		Spinal Devices		Latex Gloves		
IUD Devices		Animal Derived		DEHP		
Pedicle Screws		Human Derived				

Details:

**DIETARY SUPPLEMENT PRODUCT REVENUE PERCENTAGES.** *If N/A indicate here:*

Vitamin		Concentrate, metabolite, constituent or extract	
Mineral		Enzymes	
Herb or other botanical		Medical foods (prescription required)	
Amino acid		Other	

1. Please identify any of your product categories currently listed on the FDA's Dietary Supplement Warnings and Safety Information Site ( <a href="http://www.cfsan.fda.gov/~dms/ds-warn.html">http://www.cfsan.fda.gov/~dms/ds-warn.html</a> ) or similar regulatory database.	
2. Do any of your products contain any animal derived substances?	
3. Do any of your products make health claims? If yes, which ones and have they been published in peer review publications?	
4. Have any of your products ever fit the definition of a new dietary ingredient? If so, have pre-market safety reviews been conducted per regulations?	
5. Have any of your products ever had an active ingredient that would be defined as a drug by a regulatory agency? If so, what are they?	

Details:

**PROFESSIONAL SERVICE REVENUE PERCENTAGES.** *If N/A indicate here:*

CLIA Certified Lab Services (indicate type of lab services)		Product Recall/Withdrawal	
Phase 1 Site Services		Clinical Site Management	
Clinical Trials Packaging		Equipment Installation/Maintenance/Sterilization	
Clinical Site Selection, Training, Monitoring		Quality Systems & Regulatory Compliance	

Communications & Publications		Sales & Marketing	
Health Management, Economic, & Policy Research		Software Development or Product Design	
Information Services/Databases		Manuf/Distribution/Packaging/Mixing/Labeling	
Institutional Review Board		Pharmacovigilance/Safety Surveillance	
Pre-clinical Services		Warehouse storage	
Financial Services (please describe)		Other (please explain)	

1. Does applicant have formalized project-planning policies and procedures?	
2. Does applicant have formalized client complaint resolution policies and procedures?	
3. Are any contracts past due or has a client stopped paying or asked for a refund or credit in the last 3 years? (if yes, provide details)	
4. Total # of current contracts?	
5. Any discontinued services within the last 10 years? (if yes, provide details)	
6. Average dollar value of applicant's contracts? Average duration of applicant's contracts?	
7. Indicate largest client for upcoming policy year, and include contract amount/volume and duration:	
8. What is the total value of the personal property of others at applicant's facilities?	

Details:

**DRUG DISCOVERY TECHNOLOGY R&D OR PRODUCT REVENUE PERCENTAGES.** If N/A indicate here:

Bioinformatics		Proteomic		Genomics	
• Software:		• Software:		• Software:	
• Hardware:		• Hardware:		• Hardware:	
• Data:		• Data:		• Data:	

Other:

Details:

**RESEARCH INSTITUTIONS REVENUES/FUNDING.** If N/A indicate here:

Product Licensing		Product Commercialization	
Basic Research		Medical Product Research	
Pre-clinical Testing		Non Medical Product Research	
Clinical Testing		Other	

Details:

**SUPPLIER AND/OR WHOLESALE DISTRIBUTOR REVENUE PERCENTAGES.** *If N/A indicate here:*

Drugs/Biologics		Medical Device Component Parts/Software	
Medical Devices		Drugs/Biologic Ingredients	
Dietary Supplements		Medical Products Manufacturing Equipment	
Active Ingredients		Medical Products R&D Equipment	
Other			

<p>1. If a supplier of components or ingredients, or a distributor for the products of others, do require additional insured status on the product license holder's products liability policy? Do you require indemnification for damages including defense cost?</p>	
<p>Details:</p>	

**HUMAN CLINICAL TRIALS.** *If N/A indicate here:*

Active Trials Currently Being Sponsored. (include phase 4)					
Product Name & Protocol Number	# of New Enrollees Over Next Policy Period	Indication	Trial Phase	Country(ies)	Number of sites
1. Number of expanded access/compassionate use participants anticipated in the coming policy term?					
2. Total number of completed human clinical trials applicant sponsored in last 3 years:					
3. Total number of human participants enrolled in the last 3 years:					
4. Any clinical trials past, present, or planned involving minors?					
5. Any clinical trials discontinued or suspended due to safety reasons? <i>(if yes, provide details)</i>					
6. What are the minimum standards for Clinical Investigator selection requirements?					
7. Have any Clinical Investigators been cited for regulatory violations in connection with your trials? <i>(if yes, provide details)</i>					
8. Has applicant had any evidence of serious regulatory non-compliance or fraud by Clinical Investigators in connection with your trials in the past 5 years? <i>(if yes, provide details)</i>					
9. Number of clinical trial "For Cause Audits" conducted by applicant or regulatory agency in the last 5 years?					
10. Do you provide Clinical Investigators with compensation other than charges for specific services rendered, such as enrollment bonuses, equity interest, etc.?					
11. What is the targeted reading grade level for your informed consent documents?					
12. Does applicant require Clinical Investigators to test participants on their understanding of the informed consent document?					
13. Does applicant incorporate financial disclosures in the informed consent documents or process?					

14. What has been the maximum compensation applicant has offered trial participants?	
15. Who monitors compliance with the individual state and country clinical trial regulations?	
16. Does applicant have formalized Clinical Trial Suspension SOP's in place?	
17. 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?	
18. Does applicant ever act as both trial sponsor and clinical investigator?	
19. Does applicant provide material/product, or both, for clinical trials for trials you do not sponsor?	
20. Does applicant operate an in-patient facility? If so, does applicant have an accredited emergency care facility?	
21. 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)	
22. Does the applicant publish all clinical trial results?	
23. Is applicant in compliance with all applicable regulatory guidelines? (if no, provide details)	
24. Has applicant been cited for any regulatory violations in the last 3 years? (if yes, provide details)	
Details:	

**MEDICAL STAFF PROFILE.** If N/A indicate here:

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

**LEGAL**

1. Does applicant have any contracts that: (if so, please explain)	
a. Assume the tort liability of another party	
b. Does not limit damages to direct damages only	
c. Does not extend Force Majeure to any and all events outside applicant's control	
d. Does not indicate a mutual hold harmless agreement	
2. Does applicant use a written contract or agreement with all clients, including changes?	
3. Does applicant's attorney review all contracts or agreements including changes prior to use?	

4. Are there formal incidents and claims escalation procedures in place?	
5. Are there formal procedures in place regarding litigation document control?	
6. Is there formal training on internal and external communication policies and procedures?	
Details:	

**PRODUCT SALES & MARKETING.** *If N/A indicate here:*

1. Projected annual prescriptions/units to be sold?	
2. Projected # of annual products users?	
3. Any product ingredients/components imported? <i>(if yes, provide details)</i>	
4. Any products manufactured sold under others' labels? <i>(if yes, provide details)</i>	
5. Any products sold as ingredients/components for other products? <i>(if yes, provide details)</i>	
6. Any products manufactured outside the domestic country? <i>(if yes, provide details)</i>	
7. Any products approved for use by minors?	
8. Any products discontinued for safety reasons? <i>(if yes, provide details)</i>	
9. Any association with banned products? <i>(if yes, provide details)</i>	
10. How many product recalls has applicant had in the past 3 years? Describe in detail any Class 1 recalls?	
11. 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.	
12. 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?	
13. 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, "Healthcare Professional" letter, additional studies, or expanded product monitoring.	
14. What steps if any would the company take if applicant became aware of a pervasive off-label use of applicant's products?	
15. Please indicate known revenues from off-label use of your products.	
16. Does the company allow any off-label information dissemination?	
17. Have there been any incidents of non-compliance regarding regulations concerning sales and marketing practices by either internal or external product sales personnel?	
18. How often are compliance audits performed on your internal and external sales staff?	
19. Do compliance audits include follow-up discussions with physicians?	
20. What % of the company's advertising budget is allocated to Direct to Consumer advertising?	
21. Is there a required waiting period after product launch before DTC is conducted?	

22. What are the top 3 most expensive perks applicant provide to physicians?	
23. Does applicant have formal policy specifically prohibiting physical patient contact by internal and external product sales personnel? Have there been any incidents of non-compliance in the last 3 years?	
24. How often is formal and documented compliance training required of your internal and external sales force?	

**OPERATIONS RISK MANAGEMENT & LOSS CONTROL**

1. Does applicant have a formalized Enterprise Risk/Safety Program? <i>(if yes please provide name of person in charge of program)</i>	
2. What are the main focal areas of your Enterprise Risk/Safety Program? <i>(Areas might include Code of Conduct, Privacy, Biohazards, Disaster Recovery, etc.)</i>	
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 of applicants' suppliers and sub-contractors? What limits and terms does applicant require?	
5. Are all risk management programs and SOP's audited annually?	
6. Please indicate any risk management programs and SOP's that are audited by independent non-governmental organizations/individuals?	
7. Indicate Industry Trade Associations Memberships.	
8. Does applicant have a crisis management team in place?	
9. Does applicant have a full time risk manager on staff?	
Details:	

**PREMISES/OPERATIONS.** *If N/A indicate here:*

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. Do you have an animal facility or house animals?	
6. If applicable is the applicant in compliance with Hazardous Materials Regulations?	
7. Has applicant ever hired key employees from direct competitors?	
8. Does applicant ever do direct product comparisons against competitor products?	
9. Does applicant have any competitors making similar products?	
10. Does applicant have a formalized Privacy Policy in place? When was it last updated and audited?	

Details:

**LOSS HISTORY & POTENTIAL LOSS**

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

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

\*Attach previous carrier loss runs

1. Describe all incurred losses of \$10,000 or more:	
2. Any claims not yet reported? <i>(if yes, provide details)</i>	
3. Indicate any product or service past or present that has been involved with any certified, or attempted, class action or multi-district litigation?	
4. Is the Applicant aware of any fact, circumstance, or situation which one might reasonably expect could give rise to a claim that would fall within the scope of the insurance being requested? <i>(if yes, provide details)</i>	

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. Does applicant have any outstanding risk engineering 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>	
3. Any of your products, clinical trials, or services specifically excluded on your existing policy? <i>(if yes, provide details)</i>	
4. Have you had concurrent claims made insurance for the insurance you are requesting back to your stated retro date?	

Details:

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.

For the purposes of this application, the above-signed officer of all person(s) and organization(s) proposed for this insurance declares and acknowledges by executing this application that, no alterations were made to this application (other than sections reserved for answers), 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 for all persons or organizations applying for insurance under this application. 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.

Authorized Signature of Applicant (Position in Company)	Date
Address (No., Street, City, State)	