Chubb European Group SE

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Chubb.com

New Business Application

Life Sciences

Please fill in this form as completely and clearly as possible.

Please include the following with this application: Tick the relevant box(es).

☐ Brochures, description of main product(s) or service(s)

☐ Instruction For Use (IFU's);

☐ Certificates, a.o. CE, ISO & FDA;

☐ If applicable, please include a copy of the ISO 13485 audit report

☐ General contract, including terms & conditions

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. **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 broker / intermediary

Name:

Relationship number:

Contact person:

Phone:

E-mail:

General information applicant

Name:

Website:

Date of incorporation:

Address:

Postal code and city:

Locations (if other than above):

Additional insureds

Company name including legal entity, place and country, other than listed under 'general information applicant':

If applicant has acquired any subsidiaries within the last 5 years, please identify:
Company name and legal entity, place and country, other than registered under general information applicant':

Applicant is a: ☐ Partnership ☐ Private company ☐ LLC ☐ Other

1. Years in business:

2. Number of employees:

3. Does applicant have a parent company? (if yes, provide name)

4. Has applicant operated under another name? (if yes, provide full details)

5. Projected gross sales (excluding USA and Canada)?

6. Projected gross sales USA and Canada?

7. Projected R&D expenditures for human clinical trials?

8. Average annual expenditures for medical treatments for side effects sustained by clinical trial participants over the last 3 years?

9. Projected annual prescriptions / units to be sold?

10. Projected number of annual product users?

11. Who are applicant's top 3 competitors?

1.
2.
3.

12. Any product components/ingredients imported? (if yes, please provide details)

13. Any products manufactured sold under others' labels? (if yes, please provide details)

14. Any products sold as components/ingredients for other products? (if yes, please provide details)

15. Any products manufactured outside the E.U.? (if yes, please provide details)

16. Indicate revenue percentages per operational activities

Manufacturing: %

Distribution: %

Services: %

Details:

B. Product/service profile (percentages)

Potential Source of Revenues	%	Potential Source of Revenues	%
Medical devices		Contract Research Organisation and/or Contract Manufacturing Organisation	
Diagnostics		Equipment rentals / leasing	
Drugs / biologics / dietary supplements		Repair / installation / service	
Information services / databases / software		Other (please explain)	

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)	

Indicate product percentages:

Brand name prescription		%	OTC		%
Generic prescription		%	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, Androsteredione, 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		Anaesthesia / respiratory	
Lasers systems		Monitoring equipment	
Durable medical equipment		Hospital products/supplies	
Cardiovascular		Dental instruments	
Surgical devices		Therapy / rehab	
Imaging Devices		Implants – Active	
Diagnostic kits		Dialysis	
Implants – Non-Active		Other (please explain)	
Drug Delivery			

Targeted application percentages:

Clinical:		%	Ambulatory:		%	Home:	%
Paediatrics:		%	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 Services - Product 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		Manufacturing / distribution / packaging / mixing / labelling	
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 enrolees over next policy period	Indication	Trial phase	Country / countries	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 required of the applicant's CRA's (Clinical Research Associate): certification, professional designation, and formal training?
5. What percentages of applicant's CRA's have less than 5 years' experience?
6. What percentages of applicant's clinical sites are academic versus non-academic?
7. Which of the following are required in meeting the applicant's CI (Clinical Investigator) acceptability standards: formal training, accreditation, certifications, workload demand assessments, specialty & patient group expertise?
8. Please indicate which of the following are allowed by the applicant: CI's enrolling their own patients, enrolment bonuses, contacting patients directly via patient databases, or patient referral fees?
9. Has any of applicant's CI's been cited for regulatory violations? (if yes, provide details)
10. 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? (if yes, provide details)
11. **USA**: Number of clinical trial "For Cause Audits" conducted by applicant, FDA, or OHRP in the last 3 years?
12. Does applicant put all informed consent documents through well-established readability testing (for example, the Flesch-Kincaid Grade level Scoring)? (if yes, provide details)
13. Does applicant use information videos as part of the informed consent process?
14. Does applicant perform a final approval of IRB approved informed consent documents?
15. Does applicant require CI's to test participants on their understanding of the informed consent document?
16. **USA**: Is applicant in compliance with the FDA requirements concerning financial disclosures?
17. Does applicant incorporate financial disclosures in the informed consent documents or process?
18. Does applicant use Data Safety Monitoring Boards?

19. What has been the maximum compensation applicant have offered trial participants?

20. Does applicant have formalized policies for expanded access/compassionate use?

21. Is applicant in compliance with applicable state regulations regarding human clinical trials?

22. 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?

23. Does applicant ever act as both trial sponsor and clinical investigator?

24. 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	Number of applicant employees	Number of independent contractors
Physicians				
Nurses				
Doctors				
Other medical staff (please describe)				

Details:

H. Professional services

☐ If N/A indicate here

1. Any GLP[1], GCP[2], GMP[3], or QS[4] Regulatory violations in last 3 years? (if yes, provide details):

1 GLP = Good Laboratory Practice, 2 GCP = Good Clinical Practice (related to clinical trials), 3 GMP = Good Manufacturing Practice, 4 QS = Quality System

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, please 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

Do all contracts from Applicant contain the following provisions that benefit applicant? (if not, 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. Does applicant use a written contract or agreement with all clients, including changes?

10. 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. **USA**: Has any company product submitted to a FDA Advisory Committee in the last 3 years received less than a 2/3rd 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 cited for any GLP, GCP, GMP, QS, or Advertising & Promotion violations in the last 3 years? (if yes, provide details)
12. **USA**: 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. Have there been any ACM (NL), FTC (USA) or similar authority violations in the last 3 years? (if so, provide details)
14. What percentage of the regulatory staff has less than 5 years of experience?
15. Does applicant have formalized information privacy policies and procedures that are in compliance with applicable local, state, and federal regulations?

Details:

K. Sales and marketing

☐ If N/A indicate here

1. Does the company allow any off-label information dissemination?
2. **USA**: 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 of experience?
4. What percentage 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, has the 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?

L. Risk management & loss control

☐ If N/A indicate here

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 to participate in a 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[6] 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?

6 Standard Operating Procedure

Details:

M. 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. If applicable, what is the biohazard lab rating?
5. **USA**: 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:

N. Loss history

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

Policy period	Insurer	Number of claims	Total amount	Description of loss(es)

*Please attach previous carrier loss runs

O. 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? (if yes, provide details)
2. Has applicant's insurance ever been cancelled or non-renewed by a carrier? (if yes, provide details)

Details:

P. Liability coverage request

Coverage	Limits requested
Liability insurance including Product Liability and Employers' Liability	
Pure Financial Loss	
Recall	
Other	

Details:

Q. Final questions

1. Are there any contracts involving (delivery) issues? (if yes, please provide details)
2. Any known incidents or circumstances that might reasonably be expected to give rise to a claim? (If yes, provide details)
3. Indicate any product or service past or present that has been involved with class action or multi-district litigation (if yes, provide details)

4. Are there other facts or circumstances that may be relevant for Chubb's risk assessment? (if yes, please provide details)

The undersigned authorized officer of the applicant knows of no other relevant facts which might affect the Company's judgment when considering this application and represents that the statements herein are true, accurate, and complete. The undersigned understands and agrees that the company is relying on such statements in determining whether or not to accept this application and provide insurance.

Please note that contrary to the provisions of article 7: 928 BW et seq. Chubb is released from any obligation to pay out if it appears that the policyholder provided incorrect or incomplete information when applying for the insurance and Chubb would not have taken out the insurance (under the same conditions) if Chubb had known the correct facts.

Authorized signature of applicant:	Place & Date:
Name:	Title:
Company name:	Insurance agency / broker:

N.B. Filling in and signing this application form does not bind the applicant to enter into an agreement, nor does receipt of the completed and signed application form bind Chubb European Group SE to do so. However, if all this results in the conclusion of an insurance agreement, the applicant agrees that the insurance will be based on the information stated in this application form, which forms the basis of that agreement and is considered to be an integral part of the policy.

This document respects the WCAG guidelines however the complexity of the form might make the reading order difficult.
If you need assistance please contact ecommunications@chubb.com.

Chubb. Insured.℠

Chubb European Group SE, with registration number 450 327 374 RCS Nanterre, is an undertaking governed by the provisions of the French insurance code. Registered offices: La Tour Carpe Diem, 31 Place des Corolles, Esplanade Nord, 92400 Courbevoie, France. Chubb European Group SE has fully paid share capital of €896,176,662 and falls under the conduct of the 'Autorité de controle prudentiel et de résolution' (ACPR), 4 Place de Budapest, CS 92459, 75436 PARIS CEDEX 09.

Chubb European Group SE, Netherlands Branch, Marten Meesweg 8-10, 3068 AV Rotterdam, is registered at the Dutch chamber of commerce under number 24353249. In the Netherlands, it falls under the conduct of business rules of the Authority Financial Markets (AFM).