CHUBB®

Life Sciences Liability

Renewal Proposal Form

Completing The Proposal Form

- Please read the Important Information Section on page 10 before completing this Proposal Form.
- Please contact us if you would like a hard copy of the relevant insurance policy or a summary of cover provided by Chubb.
- Please read all the "Statutory Notices" before completing this Proposal Form.
- Please answer all questions in full leaving no blank spaces. If a question is not applicable, please answer NA. If the answer to a questions is None, please answer None or 0.
- If you have insufficient space to complete any of your answers, please attach a separate signed and dated sheet and identify the question number concerned.

Section I - General Information

Item 1 - Applicant Information

1. Name:				
2. Street address:				
	City:		Postcode:	
3. Mailing address (if different):				
	City:		Postcode:	
4. Website address:				
5. Type of organisation:	☐ Corporation ☐ Limited Liability Company ☐ Joint Venture ☐ Partnership ☐ Individual ☐ Other			
6. Please provide a brief description of any changes in the past twelve (12) months to your operations below:				

7. Any acquired subsidiaries in the past twelve (12) months?	☐ Yes ☐ No

If Yes to above, please provide entity name and date acquired below:

Entity Name	Date Acquired (DD/MM/YY)

8. Any subsidiaries sold in the past twelve (12) months?	☐ Yes ☐ No

If Yes to above, please provide entity name and date sold below:

Entity Name	Date Acquired (DD/MM/YY)

9. In the past twelve (12) months, have you been cited for any regulatory violations?	☐ Yes ☐ No
If Yes to above, has the applicable regulatory authority accepted your response(s) and closed the matter?	☐ Yes ☐ No

If No to above, please provide details below:

10. Please list any third parties you have agreed to name as an insured under your insurance Policy in the past twelve (12) months below:

Additional insured	Explain relationship to your business

11. Mark any items below where you have products, studies or services involving any of the following. Include past and future activities.

Diseases			
☐ Viral Hepatitis	☐ HIV	☐ TSE	
Classes of Products			
☐ Anticonvulsants	☐ Birth control or fertility	☐ Cox-2 inhibitor	☐ Diazepines, Oxazepines or Thiazepines
☐ Dopamine Agonists	☐ Fibrates	☐ Hormone Replacement	☐ HMG COA reductase inhibitors
☐ Impotence	☐ Infusion Pumps	☐ SSRIs or SNRIs	☐ Vaccines
☐ Hip replacement products	☐ Thiazolidinediodines	☐ Hydroxyquinoline derivatives	☐ Surgical Mesh

12. Mark any items below where you have products, studies or services involving any of the following. Include past and future activities.

Specific Products			
☐ Botulinum toxin	☐ Bupropion	☐ Cisapride	☐ Clopidogrel
☐ Dexfenfluramin	☐ DEHP	☐ DES	☐ Dextropropoxyphene
☐ Fenfluramin	☐ Ephedra or Ephedrine	☐ Hydroquinone	☐ Fentanyl
☐ Gadolinium	☐ Isotretinoin	☐ Latex Gloves	☐ Mercury
☐ Metaclopramide	☐ Orlistat	☐ Phentermine	☐ Propoxyphene
☐ PPA	☐ Remoxipride	☐ Risperidone	☐ Silicone (implanted)
☐ Thalidomide	☐ Thimerosal	☐ Troglitazone	☐ Varenclinine
☐ Piper Methysticum (Kava)	☐ L-Tryptophan (ingested)	☐ Opioids	

13. What are your projected annual prescriptions / units to be sold next year?	
14. What are your projected number of annual product users in the next year?	
15. Please indicate any trade association memberships:	

16. Please provide a break-up of your actual gross sales for the past twelve (12) months and your projected gross sales for the next twelve (12) months.

Country	Actual Gross Sales past twelve (12) months	Projected Gross Sales next twelve (12) months
New Zealand		
Australia		
United States of America		
Canada		
Belgium, France, Ireland		
Austria, Germany, Italy, Netherlands, Spain, Switzerland, U.K.		
Denmark, Norway, Sweden		

Country	Actual gross sales past twelve (12) months	Projected gross sales next twelve (12) months
Rest of Europe (all other European countries not listed above)		
Asia		
Latin America		
Middle East		
Africa		
Other (please specify):		

17. Projected percentage of sales by area:

Prescription medicines or biologics:		Patent Protected		Generic / Multi-Source
Over the counter medicines or biologics:		Patent Protected		Generic / Multi-Source
Medical Devices:				
Dietary supplements or nutritional products:				
Contract services:				
Distribution:				
Research:				
Other (please explain):				

18. Please provide percentage split of sales or clinical trial participants between each country or territory:

New Zealand	Australia	USA/UK	Overseas (please specify)

19. Annual Payroll Estimate:

Management, Administration:				
Manufacturing:				
Sales, Onsite Training or Instruction:				
Installation, Onsite Service:				
Research & Development:				
Other:				
Number of Employees:	Full Time:		Part Time:	

20. Host Employer Activities

i. Do you employ contractors?	☐ Yes ☐ No
If Yes to above, how many?	
Estimated annual payments?	
Activities performed:	
ii. Do you employ labour hire workers?	☐ Yes ☐ No
If Yes to above, how many?	
Estimated annual payments?	
Activities performed:	
iii. Do you require that all contractors and labour hire workers participate in training that instructs them on all applicable company policies and safety procedures?	

Item 2 - Loss History and Potential Loss

1. Any claims not yet reported to us or your previous insurer(s)?	☐ Yes ☐ No
If Yes to above, please provide details below:	

2. Please indicate any of your products or services, past or present, that have been involved with any certified, or attempted, representative action, class action or multi-district litigation below:

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 to above, please provide details below:	

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.

Section II - Products and Services (Including Human Clinical Trials)

If you are involved in this....	Then only complete these items...	And provide these additional documents as applicable...
Drug or biologic products in trials	1	• Consent forms and protocols for actively sponsored trials
Medical device products in trials	1	• Consent forms and protocols for actively sponsored trials
Drug or biologic products approved	2	
Medical device products approved	2	
Complementary medicines / Dietary supplements / Nutritional products	2	
Wholesale / Distribution of medical products	2, 4 and 5	• Copies of largest standard contracts
Contract professional services	3 and 5	• Copies of largest standard contracts
Not-for-profit / Independent research institution	6	

Item 1 - Human Clinical Trials

If you require insurance for Human Clinical Trials that you sponsor then complete this item, otherwise go to Item 2 - Regulatory.

A. Please List:
   i. Active Trials Currently Being Sponsored (including Phase 4); and
   ii. Sponsored trials (present and planned);
   for the next 12 month period.

Product Name and Protocol Number	No. of New Subjects to Enrolled Over Next Policy Period	Indication	Trial Phase	Country(ies)	Countries where local insurance is placed

Item 1 - Human Clinical Trials (Continued)

B. Number of expanded access / compassionate use subjects anticipated in the coming policy period?	
C. Total number of human subjects enrolled in the last three (3) years:	

D. Have there been any clinical trials during the past three (3) years involving your product which have been discontinued or suspended in whole, or in part, because of safety reasons?	☐ Yes ☐ No

If Yes to above, please provide details below:

E. Have any clinical investigators been cited during the past three (3) years for regulatory violations in connection with your trials?	☐ Yes ☐ No

If Yes to above, please provide details below:

F. Have you provided material or product for investigator-sponsored trials in the past twelve (12) months?	☐ Yes ☐ No
G. Have you provided material or product for another organisation's clinical study / trial the past twelve (12) months?	☐ Yes ☐ No
H. During the past twelve (12) months, have you agreed to use any new clinical trial compensation guidelines to compensate participants injured in your clinical trial(s)?	☐ Yes ☐ No

If Yes to above, please indicate which guidelines below:

☐ Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Trial	☐ The Association of the British Pharmaceutical Industry (ABPI) Clinical Trial Compensation Guidelines
☐ The Medical Technology Association of Australia (MTAA) Guidelines for Compensation for Injury Resulting from Participation in a Company Sponsored Clinical Investigation	☐ Other Compensation Guidelines not specified above (Please attach copy of such guidelines with this application)

☐ New Zealand Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting From Participation in an Industry-Sponsored Clinical Trial

Item 2 - Regulatory

If you market your own Medical Products or Wholesale / Distribute Medical Products of others then complete this item, otherwise go to Item 3 - Contract Professional Service.

A. Have any of your products discontinued for safety reasons during the past twelve (12) months?	☐ Yes ☐ No

If Yes to above, please provide details below:

B. How many product recalls have you had in the past twelve (12) months?	

Please describe any Class 1 recalls below:

C. Identify any product requiring the addition of a black box or other significant safety warning to existing labelling or instructions in the past twelve (12) months:

D. Identify any product requiring a Risk Evaluation & Mitigation Strategy (REMS), or relevant regulatory equivalent in the past twelve (12) months:

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

i. "Healthcare Professional" Letter	☐ Yes ☐ No
ii. Additional studies	☐ Yes ☐ No
iii. Expanded product monitoring	☐ Yes ☐ No

Item 3 - Contract Professional Service

If you provide Contract Professional Services then complete this item, otherwise go to Item 4 - Distribution.

A. How many of your customers each represent more than 10% of your total revenue?	☐0 ☐1 ☐2 ☐3 ☐4+

Please provide more detailed information about these customers:

Customer	Revenue	Product or Service

B. How many distinct products or services do you offer?	☐1-3 ☐4-6 ☐7+
C. Have you modified your customised customer management procedures in the past twelve (12) months?	☐Yes ☐No
If Yes to above, please explain changes:	
D. Have you discontinued any products or services in the past twelve (12) months?	☐Yes ☐No
If Yes to above, do you continue to provide service or maintenance?	☐Yes ☐No

If Yes to above, please provide more detailed information about these discontinued products or services:

Product / Service	Date Discontinued (DD/MM/YY)	Still Service / Maintain?
		☐Yes ☐No
		☐Yes ☐No
		☐Yes ☐No

E. 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
If Yes to above, please provide details below:	

Item 4 - Distribution

If you Wholesale/Distribute Medical Products then complete this item, otherwise go to Item 5 - Contracts.

A. Projected percentage of your total revenue by area for products that you purchase from New Zealand suppliers, import from foreign suppliers and/or for which you are the sponsor with MEDSAFE:

Product Category	Purchased From New Zealand Supplier	Imported or Sponsored By You
APIs		
Dietary Supplements		
Drug/Biologics		
Drug/Biologic/Dietary Supplementary Ingredients		
Equipment		
Medical devices		
Medical device components/software		
Other (please describe):		

B. Do you sell any medical implants?	☐ Yes ☐ No

If Yes to above, please indicate revenues that they represent for the following categories:

Implant Category	Actual Revenue Past 12 months	Estimated Revenue Next 12 months
Orthopaedic - Hip or Knee		
Cardiovascular, Obstetrics & Gynaecology, Orthopaedic - Spine		
Dental, Ear/Nose/Throat (ENT), Gastrointestinal (GI) / Urological, Neurological, Opthalmic		
Orthopaedic - Other than Hip, Knee or Spine		
Other (please describe):		

Item 5 - Contracts

If you provide Contract Professional Services or Wholesale / Distribute Medical Products of others then complete this item, otherwise go to Item 6 - Research Institutions.

A. What is the value of your average performance-based contract, purchase order or agreement?

☐ <$50K ☐ <$100K ☐ <$250K ☐ <$1M ☐ $1M+

B. What is the duration of your average performance-based contract, purchase order or agreement?

☐ 1-3 Months ☐ 4-6 Months ☐ 6-12 Months ☐ 12 Months +

C. Does the value of any performance-based contract, purchase order or agreement exceed $2.5M?	☐ Yes ☐ No
D. In the past three (3) years, have you been involved in any contract disputes or have any contracts past due acceptance?	☐ Yes ☐ No

If Yes to the above, please provide details below:

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

Customer	Contract Amount	Product or Service	Duration

Item 6 - Research Institutions

If you are a Medical Research Institution then complete this item, otherwise go to Section III - Errors or Ommissions Liability

A. Projected percentage of total activities by area:

	Basic Research		Pre-clinical testing
	Clinical testing		Product commercialisation
	HREC / IRB Services		Product licensing
	Medical product research		Other (please describe):

B. Do you have any unpaid volunteers or students working in your organisation?	☐ Yes ☐ No

If Yes to above, how many?

C. What are your top two sources of funding?

Section III- Errors or Ommissions Liability

If you do not wish to apply for errors or omissions liability, or only require the errors or omissions cover automatically included in our 'Advantage' and 'Essentials' product options, then skip this item and go to Section IV Signature / Certification.

Item 1 - Types Of Products & Services, Industries Served, Revenue.

If you have completed Item 3 - Contract Professional Service of Section II Products and Services (including Human Clinical Trials), then skip this item and go to Item 2 - Contracts.

A. How many of your customers each represent more than 10% of your total revenue?	☐0 ☐1 ☐2 ☐3 ☐4+

Please provide the following details for these customers:

Customer	Revenue	Product or Service

B. How many distinct products or services do you offer?	☐1-3 ☐4-6 ☐7+
C. Have you discontinued any products or services in the past twelve (12) months?	☐Yes ☐No
If Yes to above, do you continue to provide service or maintenance?	☐Yes ☐No

If Yes to above, please provide more detailed information about these discontinued products or services:

Product / Service	Date Discontinued (DD/MM/YY)	Still Service/Maintain?
		☐Yes ☐No
		☐Yes ☐No
		☐Yes ☐No
		☐Yes ☐No

D. Will you be offering any services to the market within the next year that are substantially different in scope or end-use than your current services?	☐Yes ☐No
If Yes to above, please provide details:	
E. Have you modified your customised customer management procedures in the past twelve (12) months?	☐Yes ☐No
If Yes to above, please provide details:	

Item 2 - Contracts

If you have completed Item 5 - Contracts Of Section II - Products and Services (including Human Clinical Trials), then skip this item and go to Item 3 - Historical Information Below.

A. What is the value of your average performance-based contract, purchase order or agreement?

☐<$50K ☐<$100K ☐<$250K ☐<$1M ☐$1M+

B. What is the duration of your average performance-based contract, purchase order or agreement?

☐1-3 Months ☐4-6 Months ☐6-12 Months ☐12 Months +

C. Does the value of any performance-based contract, purchase order or agreement exceed $2.5M?	☐Yes ☐No
D. In the past five (5) years, have you been involved in any contract disputes or have any contracts past due acceptance?	☐Yes ☐No
If Yes to above, provide details below:	

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

Customer	Contract Amount	Product or Service	Duration

Item 3 - Historical Information	
A. In the past twelve (12) months, have you been sued or threatened with suit for any act, error or omission relating to your products or services?	☐ Yes ☐ No
B. In the past twelve (12) months, have any of your products or services been recalled from use?	☐ Yes ☐ No
C. In the past twelve (12) months, has there been any current or past administrative, civil or criminal investigation or litigation by any governmental or regulatory authority?	☐ Yes ☐ No
D. 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
If Yes to above, please provide details below:	

Declaration

On behalf of the applicant, I/we declare that:

a) I/we have read and understood Chubb's Financial Strength Rating, Duty of Disclosure and Privacy Statement in this form;
b) all information provided (and where applicable, previously provided) is true and correct and I/we have made a fair presentation of the risk, by disclosing all material matters which I/we know or ought to know or, failing that, by giving the insurer sufficient information to put a prudent insurer on notice that it needs to make further enquiries in order to reveal material circumstances;
c) I/we undertake to inform the insurer promptly in writing of any material alteration to the facts declared that occurs prior to completion of the contract of insurance;
d) I/we have obtained, and will obtain in the future, the consent to the disclosure and use of personal information from those persons whose personal information is supplied in relation to this form for the purposes of (i) underwriting the risks and (ii) administering and performing any resulting insurance contract.

This form must be signed by the applicant's Chairman of the Board, Managing Director, Chief Executive Officer or Chief Financial Officer.

Signed			
Name		Date	
Position			

Important Information

In this section "We", "Our" and "Us" means Chubb Insurance New Zealand Limited (Chubb). "You" and "Your" refers to Our customers and prospective customers as well as those who use Our website.

Duty of Disclosure

Your Duty of Disclosure
Before entering into a contract of insurance with Chubb, each prospective insured has a duty to disclose to Chubb information that is material to Chubb's decision whether to accept the insurance and, if so, on what terms. This includes material information about the insured, any other people and all property and risks insured under the policy. Information may be material whether or not a specific question is asked.

There is the same duty to disclose material information to Chubb before renewal, extension, variation or reinstatement of a contract of insurance with Chubb. You should also provide all material information when You make a claim or if circumstances change during the term of the contract of insurance.

It is important that each prospective insured understands all information provided in support of the application for insurance and that it is correct, as each prospective insured will be bound by the answers and by the information they have provided.

The duty of disclosure continues after the application for insurance has been completed up until the time the contract of insurance is entered into.

Consequences of Non-Disclosure
If an insured fails to comply with their duty of disclosure, Chubb may be entitled, without prejudice to its other rights, to reduce its liability under the contract in respect of a claim or refuse to pay the entire claim. Chubb may also have the right to avoid the contract from its beginning. This means the contract will be treated as if it never existed and no claims will be payable.

Financial Strength Rating

At the time of print, Chubb has an "AA-" insurer financial strength rating given by S&P Global Ratings. The rating scale is:

The rating scale is:			
AAA Extremely Strong	BBB Good	CCC Very Weak	SD or D Selective default or default
AA Very Strong	BB Marginal	CC Extremely Weak	R Regulatory Action
A Strong	B Weak		NR Not Rated

The rating from 'AA' to 'CCC' may be modified by the addition of a plus (+) or minus (-) sign to show relative standings within the major rating categories. A full description of the rating scale is available on the S&P Global Ratings website.

Our rating is reviewed annually and may change from time to time, so please refer to Our website for Our latest financial strength rating.

Fair Insurance Code

We are a member of the Insurance Council of New Zealand (**ICNZ**) and a signatory to ICNZ's Fair Insurance Code (**the Code**). The Code and information about the Code is available at www.icnz.org.nz and on request.

Privacy Statement

This statement is a summary of Our privacy policy and provides an overview of how We collect, disclose and handle Your personal information. Our privacy policy may change from time to time and where this occurs, the updated privacy policy will be posted on Our website.

Chubb is committed to protecting Your privacy. Chubb collects, uses and retains Your personal information in accordance with the requirements of New Zealand's Privacy Act, as amended or replaced from time to time.

Personal Information Handling Practices
When do We collect Your personal information?
Chubb collects Your personal information (which may include health information) from You when You interact with Us, including when You are applying for, changing or renewing an insurance policy with Us or when We are processing a claim, complaint or dispute. Chubb may also (and You authorise Chubb to) collect Your personal information from other parties such as brokers or service providers, as detailed in Our privacy policy.

Purpose of Collection
We collect and hold the information to offer products and services to You, including to assess applications for insurance, to provide and administer insurance products and services, and to handle any claim, complaint or dispute that may be made under a policy.

If You do not provide Us with this information, We may not be able to provide You or Your organisation with insurance or to respond to any claim, complaint or dispute, or offer other products and services to You or Your organisation.

Sometimes, We may also use Your personal information for Our marketing campaigns and research, to improve Our services or in relation to new products, services or information that may be of interest to You.

Recipients of the Information and Disclosure
We may disclose the information We collect to third parties, including:

- contractors and contracted service providers engaged by Us to deliver Our services or carry out certain business activities on Our behalf (such as actuaries, loss adjusters, claims investigators, claims handlers, professional advisers including lawyers, doctors and other medical service providers, credit reference bureaus and call centres);
- intermediaries and service providers engaged by You (such as current or previous brokers, travel agencies and airlines);
- other companies in the Chubb group;
- the policyholder (where the insured person is not the policyholder);
- insurance and reinsurance intermediaries, other insurers, Our reinsurers, marketing agencies; and
- government agencies or organisations (where We are required to by law or otherwise).

These third parties may be located outside New Zealand. In such circumstances We also take steps to ensure Your personal information remains adequately protected.

From time to time, We may use Your personal information to send You offers or information regarding Our products that may be of interest to You. If You do not wish to receive such information, please contact Our Privacy Officer using the contact details provided below.

Rights of Access to, and Correction of, Information
If You would like to access a copy of Your personal information, or to correct or update Your personal information, want to withdraw Your consent to receiving offers of products or services from Us or persons We have an association with, please contact the Privacy Officer by posting correspondence to Chubb Insurance New Zealand Limited, PO Box 734, Auckland; telephoning: +64 (9) 3771459; or emailing Privacy.NZ@chubb.com.

How to Make a Complaint
If You have a complaint or would like more information about how We manage Your Personal Information, please review Our Privacy Policy for more details, or contact Our Privacy Officer at the details above.

You also have a right to address Your complaint directly to the Privacy Commissioner by telephoning 0800 803 909, emailing enquiries@privacy.org.nz or using the online form available on the Privacy Commissioner's website at www.privacy.org.nz.

About Chubb in New Zealand

Chubb is the world's largest publicly traded property and casualty insurer. Chubb's operation in New Zealand (Chubb Insurance New Zealand Limited) offers corporate Property & Casualty, Group Personal Accident and corporate Travel Insurance products through brokers.

More information can be found at www.chubb.com/nz.

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Company No. 104656
Financial Services Provider No. 35924

Chubb. Insured.℠