CHUBB®

Chubb Life Sciences Liability

Proposal Form

Completing the Proposal Form

- Please read the Important Information Section on page 19 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 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:				
6. Please provide a brief description of your operations below:				

7. Years in business:		
8. Do you have a parent company?		☐ Yes ☐ No
If YES to above, please provide details:		
9. Have you ever operated under another name?		☐ Yes ☐ No
If YES to above, please provide details:		
10. Any acquired subsidiaries in the last five (5) years?		☐ Yes ☐ No

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

Entity Name	Date Acquired (DD/MM/YY)

11. Any subsidiaries sold in the last five (5) years?	☐ Yes ☐ No

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

Entity Name	Date Sold (DD/MM/YY)

12. Who are your top three (3) competitors?

13. Have you filed for bankruptcy in the past seven (7) years?	☐ Yes ☐ No
14. Are any of your shareholders, directors, officers, partners or members thereof under investigation for any alleged criminal violations related to your business?	☐ Yes ☐ No
15. Are you in compliance with all applicable regulatory guidelines?	☐ Yes ☐ No

If NO to above, please provide details below:

16. In the past three (3) years, 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:

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

Additional insured	Explain relationship to your business

18. 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

Specific products			
☐ Botulinum toxin	☐ Bupropion	☐ Cisapride	☐ Clopidogrel
☐ Dexfenfluramine	☐ DEHP	☐ DES	☐ Dextropropoxyphene
☐ Fenfluramine	☐ 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	

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

22. 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		
Rest of Europe (all other European countries not listed above)		
Asia		
Latin America		
Middle East		
Africa		
Other (please specify):		

23. Are any products or product ingredients/components imported?	☐ Yes ☐ No

If YES to above, please provide details below:

Product, Component or Ingredient	Country Imported

24. 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):				

25. Annual payroll estimate:

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

26. Please select the level of cover for which you would like to receive a quotation. If you would like to change any of the limits please indicate desired limit in column labelled 'Custom'.

Coverage	Advantage	Essentials	Custom
Premises/Operations	$10,000,000	$10,000,000	
Products/Services and Human Clinical Trials	$10,000,000	$10,000,000	
Damage to Specific Property of Others (CCC)	$250,000	$100,000	
Crisis Response and Product Recall	$250,000	$100,000	
Advertising Injury and Personal Injury	$10,000,000	$10,000,000	
Errors or Omissions	$500,000	$250,000	
Technology Related Injury	$250,000	$100,000	

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.

Item 3 - Coverage History

Policy Period	Limit of Insurance	Insurer	Occurrence/ Claims Made	Retro Date

1. Has your insurance ever been cancelled or non-renewed by a previous insurer?	☐ Yes ☐ No
If YES to above, please provide details below:	
2. Are any of your products, clinical trials or services specifically excluded on your existing policy?	☐ Yes ☐ No
If YES to above, please provide details below:	
3. Have you had concurrent claims made insurance for the insurance you are requesting back to your stated requested retroactive date?	☐ Yes ☐ No
If YES to above, please provide details below:	

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...
All companies	10	• Five (5) years claims history • Most recent financial data (if private)
Drug or biologic products in trials	1 and 7	• Consent forms and protocols for actively sponsored trials
Drug or biologic products approved	1 and 8	
Medical device products in trials	2 and 7	• Consent forms and protocols for actively sponsored trials
Medical device products approved	2 and 8	
Complementary medicines/Dietary supplements/ Nutritional products	3	
Contract professional services	4 and 9	• Copies of largest standard contracts
Wholesale/Distribution of medical products	5, 8 and 9	• Copies of largest standard contracts
Not-for-profit/Independent research institution	6	

Item 1 - Drugs/Biologics

If you require insurance for your own drug or biologic products then complete this item, otherwise go to Item 2 - Medical Devices.

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 to above, please provide details below:	

C. Do you utilise nanotechnology in your product development, delivery or manufacturing?	☐ Yes ☐ No
If YES to above, please provide details below:	

D. Do you have any past, present, or planned products that do not have formal regulatory approval for marketing in the jurisdictions in which they are sold?	☐ Yes ☐ No
If YES to above, please provide details below:	

Item 3 - Complementary Medicines/Dietary Supplements/Nutritional Products

If you require insurance for your own complementary medicines, dietary supplements or nutritional products then complete this item, otherwise go to Item 4 - Contract Professional Services.

A. Do any of your products make either health or structure/function claims?	☐ Yes ☐ No
If YES to above, what are those claims and how are they substantiated?	

B. Do your labels include all required statements per New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) or equivalent ?	☐ Yes ☐ No
C. Do any of your products contain active ingredients which are not included on the MEDSAFE or equivalent 'Substances that may be used in 'Listed' medicines in New Zealand'?	☐ Yes ☐ No
If YES to the above, have pre-market safety reviews been conducted by the Complementary Medicine Evaluation Committee per regulations?	☐ Yes ☐ No
D. Do any of your products carry indications or claims which require them to be registered with MEDSAFE or equivalent?	☐ Yes ☐ No
If YES to the above, what are those products and has the evidence you hold to support such claims been published in peer review publications?	

E. Do you sell any weight loss, muscle-building or sexual enhancement products?	☐ Yes ☐ No
F. Are you in compliance with the most current regulatory requirements related to manufacturing and adverse event reporting?	☐ Yes ☐ No
G. Do you sell any of your products through a multi-level marketing system?	☐ Yes ☐ No

Item 4 - Contract Professional Service

If you provide contract professional services then complete this item, otherwise go to Item 5 - Distribution on page 8.

A. Please 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/Laboratory instrument manufacturing		
Software development		

Types of Services	Description of Services	Projected Annual Revenue
Clinical trials		
Consulting		
IRB/HREC		
Laboratory		
Pharmacovigilance/Safety surveillance		
Pre-Clinical		
Sales and marketing		

B. Do you currently purchase specific professional liability insurance?	☐Yes ☐No
If YES to above, please complete the following:	
i. What is the limit of insurance for your professional liability insurance?	
ii. Who is your current professional liability insurer?	
C. How many of your customers each represent more than 10% of your total revenue?	

Please provide more detailed information about these customers:

Customer	Revenue	Product or Service

D. How many distinct products or services do you offer?	
E. Do your customised customer management procedures include the following?	
i. Written proposal or request for information in order to determine customer performance expectations?	☐N/A ☐Yes ☐No
ii. Written contract of specifications or services you will provide, signed by the customer?	☐N/A ☐Yes ☐No
iii. Contract/statement of work which outlines responsibilities of all parties?	☐N/A ☐Yes ☐No
iv. Written agreement outlining the scope of the project or services?	☐N/A ☐Yes ☐No
v. Interim changes documented with customer sign-off?	☐N/A ☐Yes ☐No
vi. Performance milestones acknowledged and accepted with customer sign-off when achieved	☐N/A ☐Yes ☐No
F. What would be the largest financial and business impact on your customers from a failure of any of your products or services?	

G. Have you discontinued any products or services in the past three (3) years?	☐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 (MM/YY)	Still Service/Maintain?
		☐Yes ☐No
		☐Yes ☐No
		☐Yes ☐No
		☐Yes ☐No

H.	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 below:

I.	Do you have formalised client complaint resolution policies and procedures?	☐ Yes ☐ No
J.	Do you store or hold customer's property at your facilities?	☐ Yes ☐ No

If YES to above, please describe type of property and maximum value of such property at any one of your locations:

Description of customer's property	Maximum value at any one location

K.	Are any healthcare services performed on your site?	☐ Yes ☐ No

If YES, please describe the services below:

Item 5 - Distribution

If you wholesale/distribute medical products then complete this item, otherwise go to Item 6 - Research Institutions.

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 or equivalent:

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.	What type of business entities do you sell to?	
C.	Do you utilise a computerised system that manages customers 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 below:

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

F. What is your customer return policy? If you accept returned product, what do you do with the 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 licence holder's product liability policy?	☐ Yes ☐ No
H. Do you require indemnification for damages, including defence costs?	☐ Yes ☐ No
I. 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 6 - Research Institutions

If you are a medical research institution then complete this item, otherwise go to Item 7 - Human Clinical Trials.

A. Projected percentage by institution's total activities by area:			☐ Yes ☐ No
Basic research		Pre-clinical testing	
Clinical testing		Product commercialisation	
HREC/IRB services		Product licensing	
Medical product research		Other (please describe:)	
B. Do you perform any service for third parties?			☐ Yes ☐ No
If YES to above, please explain the services rendered below. If NO, skip to question D.			

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 organisation?	☐ Yes ☐ No
If YES to above, how many?	
E. Are any healthcare services performed at your site?	☐ Yes ☐ No
If YES to above, please describe below:	

F. What are your top two sources of funding?

Item 7 - Human Clinical Trials

If you require insurance for human clinical trials that you sponsor then complete this item, otherwise go to Item 8 - 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 & Protocol Number	No. of New Subjects to Enrolled Over Next Policy Period	Indication	Trial Phase	Country(ies)	Countries where local insurance is placed

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. Any clinical trials, past or present, involving minors?	☐ Yes ☐ No
If YES to above, please provide details below:	
E. 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:	
F. 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:	
G. Number of clinical trial "For Cause Audits" conducted by you or any regulatory agency in the last five (5) years:	☐ Yes ☐ No
H. Do your provide Clinical Investigators, CROs or Sites with compensation other than charges for specific services rendered (e.g. enrolment bonuses, equity interest)?	☐ Yes ☐ No
I. What is the targeted reading grade level for your informed consent documents?	
J. Do you require Clinical Investigators to test participants on their understanding of the informed consent document?	☐ Yes ☐ No
K. Do you incorporate financial disclosures in the informed consent documents or process?	☐ Yes ☐ No
L. What has been the maximum compensation you have offered to trial participants for completing some or all of your trials?	
M. Do you have formalised Clinical Trial Suspension SOPs in place?	☐ Yes ☐ No
N. Do you ever act as both trial sponsor and clinical investigator?	☐ Yes ☐ No

O. Do you ever provide material or product for investigator-sponsored trials?	☐ Yes ☐ No
P. Do you operate an in-patient facility?	☐ Yes ☐ No
If YES to the above, do you have an accredited emergency care facility?	☐ Yes ☐ No
Q. Do you ever provide material or product for another organisation's clinical study/trial?	☐ Yes ☐ No
R. Do you publish all clinical trial results?	☐ Yes ☐ No
S. Do you use the Human Research Ethics Committees (HREC) for any agreements entered into with hospitals/institutions?	☐ Yes ☐ No
T. Have you agreed to use any clinical trial compensation guidelines to compensate participants injured in your clinical trial(s)?	☐ Yes ☐ No

If YES to above, please indicate which guidelines below:

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

☐ Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Trial

Item 8 - Regulatory

If you market your own medical products or wholesale/distribute medical products of others then complete this item, otherwise go to Item 9 - Contracts on page 13.

A. Are any of your products manufactured or sold under others' labels?	☐ Yes ☐ No

If YES to above, please provide details below:

B. Are any of your products sold as ingredients/components for other products?	☐ Yes ☐ No

If YES to above, please provide details below:

C. Are any of your products approved for use by minors?	☐ Yes ☐ No

If YES to above, please provide details below:

D. Have any of your products discontinued for safety reasons?	☐ Yes ☐ No

If YES to above, please provide details below:

E. Do you have any past or current association with banned products?	☐ Yes ☐ No

If YES to above, please provide details below:

F. How many product recalls have you had in the past three (3) years?	

Please describe any Class 1 recalls below:

G. Indicate the top three (3) products in terms of number of Adverse Event Reports where the product was associated with death, permanent injury or hospitalisation 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 labelling or instructions in the past three (3) years.

I. Identify any product requiring a Risk Evaluation & Mitigation Strategy (REMS), or relevant regulatory equivalent in the past three (3) years.

J. 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

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 off-label information dissemination?	☐ Yes ☐ No
If YES to above, under what conditions?	

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 past three (3) years?	☐ Yes ☐ No
If YES to above, please provide details below:	

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

T. How do you track and trace your product?

Item 9 - Contracts

If you provide contract professional services or wholesale/distribute medical products of others then complete this item, otherwise go to Item 10 - Healthcare Professional Staff.

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 to above, please provide details below:	

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

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

H. Does the value of any performance-based contract, purchase order or agreement exceed $2.5M?	☐ Yes ☐ No
I. Do you accept customised contracts, purchase orders or agreements?	☐ Yes ☐ No
If YES to above, does legal counsel or senior management review all such documents prior to mutual assent?	☐ Yes ☐ No
J. 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:	

K. Do you have a formal, written records retention policy?	☐ Yes ☐ No
L. i. How often do you agree to name third parties as additional insureds under your policy?	
ii. Under what circumstances do you agree to do this?	

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

Customer	Contract Amount	Product or Sevice	Duration

Item 10 - Healthcare Professional Staff

All applicants must complete this item.

Health Professionals	Specialty	No. Applicant Employees	No. Independent Contractors	Estimated No. hours of direct patient care annually	Estimated percentage of time providing direct patient care annually
Physicians					
RN's Nurse					
LPN's Phlebotomist					
Pharmacist					
Medical/Lab Technician					
EMT/Paramedics					
Others (please describe:)					

A. Does your organisation carry medical malpractice insurance for claims arising out of the acts of your employee?	☐Yes ☐No
If YES to above, who is the Insurer?	
What was the limit of insurance provided?	
B. Do you require that all employees and independent contractors who have direct patient interaction carry medical malpractice insurance?	☐Yes ☐No
If YES to above, what is the limit of insurance provided?	
Do you obtain evidence of coverage on an annual basis?	☐Yes ☐No
Details:	

Section III - Premises/Operations

A. Which of the following applies to your premises:	
B. How many litres of hazardous substances are kept at your premises?	
C. Please indicate which of the following apply to the storage of hazardous substances at your premises:	
i. Outdoor storage	☐N/A ☐Yes ☐No
ii. Indoor cut-off area in approved containers	☐N/A ☐Yes ☐No
iii. Indoor cut-off area in unapproved containers just-in-time supply levels	☐N/A ☐Yes ☐No
iv. Just-in-time supply	☐N/A ☐Yes ☐No
D. Are you in compliance with Hazardous Materials Regulations?	☐Yes ☐No
E. What is your highest Physical Containment/Biohazard Lab rating?	
F. Do you have an animal facility or house animals?	☐Yes ☐No
G. 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 (OH&S, Code of Conduct), Biohazard Management, Disaster Recovery Program)	
H. Do you require that all new employees participate in training that instructs them on all applicable company policies and procedures?	☐Yes ☐No

I. Do you require Certificates Of Insurance from your suppliers or sub-contractors?	☐ Yes ☐ No
If YES to above, what limits of insurance and terms to do you require?	

Do you have a diary system to ensure fresh certificates are obtained each year?	☐ Yes ☐ No
J. 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?	☐ Yes ☐ No
K. How often are your risk management programs and SOPs audited each calendar year?	
L. Please indicate any risk management programs and SOPs that are audited by independent non-government organisations/individuals:	

M. Do you have a formalised information security policy that dictates the protocols that control access to or use of all critical data, processes or information systems for all authorised users, including business partners and third parties?	☐ Yes ☐ No
N. Do you have an information security officer?	☐ Yes ☐ No
O. Do you have a formalised Privacy Policy in place?	☐ Yes ☐ No
If YES to above, when was it last updated and audited?	
P. Do you have a crisis management team in place?	☐ Yes ☐ No

Section IV - 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 V. Signature/Certification.

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

If you have completed Item 4 - Contract Professional Service of Section II Products and Services (including Human Clinical Trials), then skip this item and go to Item 2 - Contracts.

Type of Products	Description of Products	Projected Annual Revenue
Pharmaceutical R&D or manufacturing for self		
Pharmaceutical manufacturing for others		
Medical Device R&D or manufacturing for self		
Medical Device R&D or manufacturing for others		
R&D/Laboratory instrument manufacturing		
Software development		

Type of Services	Description of Services	Projected Annual Revenue
Clinical trials		
Consulting		
IRB/HREC		
Laboratory		
Pharmacovigilance/Safety surveillance		
Pre-Clinical		
Sales and marketing		

A. Do you currently hold specific professional liability insurance?	☐Yes ☐No
If YES to the above, what is the limit of insurance for your professional liability?	
Who is your current professional liability insurer?	
B. How many of your customers each represent more than 10% of your total revenue?	

Please provide the following details for these customers:

Customer	Revenue	Product or Service

C. How many distinct products or services do you offer?	
D. What would be the largest financial and business impact on your customers from a failure of any of your services?	

E. Have you discontinued any products or services in the past three (3) years?	☐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

F. 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:	

G. Do your customised customer management procedures include the following?	
i. Written proposal or request for information in order to determine customer performance expectations	☐N/A ☐Yes ☐No
ii. Written contract of specifications or services you will provide, signed by the customer	☐N/A ☐Yes ☐No
iii. Contract/statement of work which outlines responsibilities of all parties	☐N/A ☐Yes ☐No
iv. Written agreement outlining scope of the project or services	☐N/A ☐Yes ☐No
v. Interim changes documented with customer sign-off	☐N/A ☐Yes ☐No
vi. Performance milestones acknowledged and accepted with customer sign-off when achieved	☐N/A ☐Yes ☐No

Item 2 - Contracts

If you have completed Item 9 - Contracts of Section II - Products and Services (including Human Clinical Trials), then skip this Item and go to Item 3 - Quality Control.

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 to above, please provide details below:	

F. What is the value of your average performance-based contract, purchase order or agreement?	
G. What is the duration of your average performance-based contract, purchase order or agreement?	
H. Does the value of any performance-based contract, purchase order or agreement exceed $2.5M?	☐ Yes ☐ No
I. Do you accept customised contracts, purchase orders or agreements?	☐ Yes ☐ No
If YES to above, does legal counsel or senior management review all such documents prior to mutual assent?	☐ Yes ☐ No
J. 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:	

K. Do you have a formal, written records retention policy?	☐ Yes ☐ No
L. How often do you agree to name third parties as additional insureds under your policy?	
Under what circumstances do you agree to do this?	

M. Provide the following information for your five largest contracts, purchase orders or agreements:	☐ Yes ☐ No

Customer	Contract Amount	Product or Service	Duration

Item 3 - Quality Control

A. Do your quality-control procedures include the following?

i. Written and formalised quality-control program	☐ N/A ☐ Yes ☐ No
ii. Alpha testing	☐ N/A ☐ Yes ☐ No
iii. Beta testing	☐ N/A ☐ Yes ☐ No
iv. Formal customer-acceptance procedure	☐ N/A ☐ Yes ☐ No
v. Systems development methodology in writing	☐ N/A ☐ Yes ☐ No
vi. Formal product-recall plan	☐ N/A ☐ Yes ☐ No
vii. Formal policy for documenting and responding to customer complaints or requests for changes or fixes	☐ N/A ☐ Yes ☐ No

B. Do your quality-control procedures include the following?

☐ GCP	☐ cGMP	☐ CLIA	☐ Other

Item 4 - Customer Support

A. Do you have at least two (2) forms of customer or product support?	☐N/A ☐Yes ☐No
B. Do your quality-control procedures include the following?	
i. Is there customer support 24 hours a day?	☐Yes ☐No
ii. Do you maintain written logs for customer complaints of problems or downtime?	☐Yes ☐No
iii. How long are such logs retained? (number of whole or partial months)?	☐Yes ☐No
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 below:	

Item 5 - Historical Information

A. 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
B. In the past five (5) years, have any of your products or services been recalled from use?	☐Yes ☐No
C. 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
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 insurance company. With operations in 54 countries and territories, Chubb provides corporate and commercial property and casualty insurance, personal accident and supplemental health insurance, reinsurance and life insurance to a diverse group of clients. As an underwriting company, we assess, assume and manage risk with insight and discipline. We service and pay our claims fairly and promptly. The company is also defined by its extensive product and service offerings, broad distribution capabilities, exceptional financial strength and local operations globally. Parent company Chubb Limited is listed on the New York Stock Exchange (NYSE: CB) and is a component of the S&P 500 index. Chubb maintains executive offices in Zurich, New York, London, Paris and other locations, and employs approximately 33,000 people worldwide.

Chubb's operation in New Zealand (Chubb Insurance New Zealand Limited) offers corporate and commercial property & casualty, group personal accident and corporate travel insurance products. Chubb in NZ also serves individuals with a substantial home and contents portfolio to protect, and individuals purchasing travel and personal accident insurance. It leverages global expertise and local acumen to tailor solutions to mitigate risks for clients ranging from large multinational companies to local corporates and SMEs, with all product offerings transacted through brokers.

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

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Financial Services Provider No. 35924

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