CHUBB®

Life Sciences Liability

Proposal Form

Completing The Proposal Form

- 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:		State:		Postcode:	
3. Mailing address (if different):		City:		State:		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 sold 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 (such as those contained in a FDA form 483 or warning letter)?	☐ 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

18. 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
☐ 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
Australia		
New Zealand		
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. Please provide percentage split of sales or clinical trial participants between each state, territory and overseas:

NSW	VIC	QLD	SA	WA	ACT	NT	TAS	O/S

26. Annual payroll estimate:

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

27. 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 (e.g. products subject to FDA's DESI, Prescription Drug Wrap-Up or OTC drug review)?	☐ Yes ☐ No
If Yes to above, please provide details below:	

Item 2 - Medical Devices

If you require insurance for your own Medical Device products then complete this item, otherwise go to Item 3 - Dietary Supplements / Nutritional Products.

A. Mark any items where you have past, present, or planned association with these products:

☐ Cold Therapy Products	☐ Implantable Products	☐ IUD Devices
☐ Orthopaedic pain management device (e.g. pain pumps)	☐ Radiation-emitting devices	

B. Do you utilise nanotechnology in your product development, delivery or manufacturing?	☐ 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 TGA 'Required Advisory Statements for Medicine Labels'?	☐ Yes ☐ No
C. Do any of your products contain active ingredients which are not included on the TGA 'Substances that may be used in 'Listed' medicines in Australia'?	☐ 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 on the Australian Register of Therapeutic Goods (ARTG)?	☐ 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.

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

Item 4 - Contract Professional Service (continued)

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:	☐ Yes ☐ No

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 Australian suppliers, import from foreign suppliers and / or for which you are the registered sponsor with TGA:

Product Category	Purchased From Australian 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:

☐ 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:
Active trials currently being sponsored (including Phase 4); and
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

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:	
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

Item 7 - Human Clinical Trials (continued)

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 'Medicines Australia Form of Indemnity for Clinical Trials' for any agreements entered into with hospitals/ institutions or HRECs?	☐ 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:

☐ 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 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.

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:

Item 8 - Regulatory (continued)

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?	☐ Yes ☐ No

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 PC / 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)

Section III. Premises / Operations (continued)

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 Section 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?	

Item 1 - Types Of Products & Services, Industries Served, Revenue (continued)

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

Item 2 - Contracts (continued)

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:

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:	

IV. SIGNATURE / CERTIFICATION

Notice to Applicant - Please Read Carefully
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. Completion of this application does not bind insurance. Applicant's acceptance of the company's quotation is required prior to binding insurance and policy issuance.

Certification
For the purposes of this application, the undersigned declares and acknowledges by clicking where indicated below that, 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.

Chubb is authorised to make 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 that 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 insurance, the applicant must notify Chubb, and Chubb may modify or withdraw any quotation.

You understand the limit of liability under any policy issued based on this New Business Proposal Form shall include both indemnity payments for claims and payment of claim and defence expenses, as defined in the policy.

Name:		Date:	
Title:		Authorised Signature of Applicant:	

Statutory Notice

For the purposes of this statutory notice, Chubb Insurance Australia Limited ABN 23 001 642 020 AFSL 239687 means "we", "us" and "our".

Duty of Disclosure

Your Duty of Disclosure
Before You enter into this contract of insurance, You have a duty of disclosure under the Insurance Contracts Act 1984.

The duty applies until We first agree to insure You, and where relevant, until We agree to any subsequent variation, extension, reinstatement or renewal (as applicable).

Answering our questions
In all cases, if We ask You questions that are relevant to Our decision to insure You and on what terms, You must tell Us anything that You know and that a reasonable person in the circumstances would include in answering the questions.

It is important that You understand You are answering Our questions in this way for Yourself and anyone else that You want to be covered by the contract.

Variations, extensions and reinstatements
For variations, extensions and reinstatements, You have a broader duty to tell Us anything that You know, or could reasonably be expected to know, may affect Our decision to insure You and on what terms.

Renewal
Where We offer renewal, We may, in addition to or instead of asking specific questions, give You a copy of anything You have previously told Us and ask You to tell Us if it has changed. If We do this, You must tell Us about any change or tell Us that there is no change.

If You do not tell Us about a change to something You have previously told Us, You will be taken to have told Us that there is no change.

What You do not need to tell Us
You do not need to tell Us anything that:

- reduces the risk We insure You for; or
- is common knowledge; or
- We know or should know as an insurer; or
- We waive Your duty to tell Us about.

If You do not tell Us something
If You do not tell Us anything You are required to tell Us, We may cancel Your contract or reduce the amount We will pay You if You make a claim, or both.

If Your failure to tell Us is fraudulent, We may refuse to pay a claim and treat the contract as if it never existed.

Privacy Statement

Chubb Insurance Australia Limited (Chubb) is committed to protecting your privacy. This document provides you with an overview of how we handle your personal information. Our Privacy Policy can be accessed on our website at www.chubb.com/au.

Personal Information Handling Practices
Collection, Use and Disclosure
We collect your personal information (which may include sensitive information) when you are applying for, changing or renewing an insurance policy with us or when we are processing a claim in order to help us properly administrate your insurance proposal, policy or claim.

Personal information may be obtained by us directly from you or via a third party such as your insurance intermediary or employer (e.g. in the case of a group insurance policy).

When information is provided to us via a third party we use that information on the basis that you have consented or would reasonably expect us to collect your personal information in this way and we take reasonable steps to ensure that you have been made aware of how we handle your personal information.

The primary purpose for our collection and use of your personal information is to enable us to provide insurance services to you. Sometimes, we may use your personal information for our marketing campaigns, in relation to new products, services or information that may be of interest to you.

We may disclose the information we collect to third parties, including service providers engaged by us to carry out certain business activities on our behalf (such as assessors and call centres in Australia). In some circumstances, in order to provide our services to you, we may need to transfer personal information to other entities within the Chubb Group of companies (such as the regional head offices of Chubb located in Singapore, UK or USA), or third parties with whom we or those other Chubb Group entities have sub-contracted to provide a specific service for us, which may be located outside of Australia (such as in the Philippines or USA). Please note that no personal information is disclosed by us to any overseas entity for marketing purposes.

In all instances where personal information may be disclosed overseas, in addition to any local data privacy laws, we have measures in place to ensure that those parties hold and use that information in accordance with the consent you have provided and in accordance with our obligations to you under the Privacy Act 1988 (Cth).

Your Choices
In dealing with us, you agree to us using and disclosing your personal information as set out in this statement and our Privacy Policy. This consent remains valid unless you alter or revoke it by giving written notice to our Privacy Officer. However, should you choose to withdraw your consent it is important for you to understand that this may mean we may not be able to provide you or your organisation with insurance or to respond to any claim.

How to Contact Us
If you would like a copy of your personal information, or to correct or update it, please contact our customer relations team on 1800 815 675 or email CustomerService.AUNZ@chubb.com.

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 the Privacy Officer, Chubb Insurance Australia Limited, GPO Box 4907, Sydney NSW 2001, Tel: +61 2 9335 3200 or email Privacy.AU@chubb.com.

If your policy, or a part of your package policy, provides cover on a claims made or claims made and notified basis, the following two sections will apply, but not otherwise.

Claims-Made and Claims-Made and Notified Coverages
These coverages apply only to claims that are either first made against you during the period of insurance or both first made against you and notified to us in writing before the expiration of the period of the insurance cover provided by the Policy. If your Policy does not have a continuity of cover provision or provide retrospective cover then your Policy may not provide insurance cover in relation to events that occurred before the contract was entered into.

Notification of Facts that might give rise to a claim
Section 40(3) of the ICA only applies to the claims-made and the claims-made and notified coverages available under the Policy.

Pursuant to Section 40(3) of the ICA, and only pursuant to that section, if you give notice in writing to us of facts that might give rise to a claim against you as soon as reasonably practicable after you become aware of such facts but before the insurance cover provided by the Policy expires, then we are not relieved of liability under the Policy in respect of the claim, when made, by reason only that it was made after the expiration of the period of the insurance cover provided by the Policy.

About Chubb in Australia

Chubb is the world's largest publicly traded property and casualty insurance company. With operations in 54 countries, Chubb provides commercial and personal 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 and other locations, and employs approximately 31,000 people worldwide.

Chubb, via acquisitions by its predecessor companies, has been present in Australia for over 50 years. Its operation in Australia (Chubb Insurance Australia Limited) provides specialised and customised coverages, including Marine, Property, Liability, Energy, Professional Indemnity, Directors & Officers, Financial Lines, Utilities, as well as Accident & Health insurance, to a broad client base. Chubb is a major insurer of many of the country's largest companies. With five branches and over 500 staff in Australia, it has a wealth of local expertise backed by its global reach and breadth of resources.

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

Contact Us

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