Life Science Proposal Form

1. Applicant Details

Company Name (Include names of all subsidiaries or affiliated companies to be insured)

Name

ABN

Indicate company type

☐ Individual ☐ Corporation ☐ Joint Venture ☐ Partnership Other

2. Address of Firm

Address

Postcode

City

Date Established / /

Email

Website

3. Period of Insurance Required

Insurance required from / / expiring at 4pm on / /

4. Geographical Area in Which You Operate

Is Your Business represented outside Australia? ☐ Yes ☐ No

If 'yes' please give details

Does the Business provide any Products or Services in:

☐ Cuba ☐ Iran ☐ North Korea ☐ Syria ☐ Ukraine ☐ Russia ☐ Belarus

☐ any territory subject to any sanction, prohibition or restriction under United Nations resolutions or the trade or economic sanctions, laws or regulations of the European Union, the Commonwealth of Australia, United Kingdom or the United States of America?

If "Yes" to any of the above, We may require additional information to be provided to Us.

5. Financial Information

What is Your Annual Turnover broken down by Territory?

	Last Year	Current Year	Next Year
Australia and New Zealand	$	$	$
USA/Canada	$	$	$
Rest of the World	$	$	$
Total	$	$	$

Please provide a percentage breakdown of turnover by location

NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Overseas
%	%	%	%	%	%	%	%	%

No of employees

Full time	Part time

Please provide a description of your activities/operations

Limits of Insurance/Excess Requested

Section	Max Limit Available	Limit Requested	Excess Requested
Section 1 – Public Liability	AUD20,000,000	$	$
Section 2 – Products and Services Liability	AUD20,000,000	$	$
Section 3 – Human Clinical Trials Liability	AUD20,000,000	$	$
Section 4 – Professional Indemnity	AUD20,000,000	$	$
Section 5 – Medical Professional Liability	AUD5,000,000	$	$
Section 6 – First and Third Party Cyber	AUD250,000	$	$

Product/Service Profile

Source/Potential Source of Revenues	% of T/O	Product/Service Description
Blood/Plasma/Tissue Banks	%	
Manufacturing – Pharmaceuticals	%	
Manufacturing – Medical Devices	%	
Contract Manufacturing – Pharmaceuticals	%	
Contract Manufacturing – Medical Devices	%	
Clinical Research Organisation	%	
Distributor – Pharmaceuticals	%	
Distributor – Medical Devices	%	
Diagnostic Laboratories	%	
Equipment Rentals/Leasing	%	
Research	%	
Repair/Installation/Service	%	
Other (Please explain)	%	

Product/Service Types

Pharmaceuticals	% of T/O
Proprietary Pharmaceuticals	%
Diet Aids	%
Generic Pharmaceuticals	%
Vaccines	%
Clinical Research	%
Infusions	%
Imaging / Diagnostic Agents	%
Nutraceuticals	%
Other (Please explain)	%

Medical Devices	% of T/O
Cardiac Devices	%
Therapy/Rehabilitation	%
Anaesthesia/Respiratory	%
Dialysis Equipment	%
Implants (Active)	%
Drug Delivery Systems	%
Implants (Non-Active)	%
Non-Cardiac Catheters	%
Lasers	%
Analytical Instruments	%
Surgical Devices	%
Diagnostic Kits	%
Dental Instruments	%
Durable Medical Equipment	%
Monitoring Devices	%
Hospital Products/Supplies	%
Imaging Devices	%
Other (Please explain)	%

Are any products manufactured and/or sold under others' labels? ☐ Yes ☐ No

If 'yes', please explain

Are any products sold as components for other products? ☐ Yes ☐ No

If 'yes', please indicate the likely end product

Do You subcontract/utilize independent contractors for product development, manufacturing, sales, and/or distribution services? ☐ Yes ☐ No

If 'yes', please indicate activities contracted

Professional Services

Contracted Professional Services	% of T/O	Contracted Professional Services:	% of T/O
Preclinical Testing	%	Biostatistics	%
Pharmacodynamics	%	Submission of Regulatory Filings	%
Pharmacokinetics	%	Bioequivalency/Bioavailability Testing	%
Study Participant Selection or Monitoring	%	Quality Control Monitoring	%
Clinical Investigations (Please indicate phase.)	%	Manufacturing	%
Clinical Staff Recruitment	%	Repackaging/Assembly	%
Clinical Staff Training	%	Product/Equipment Sterilization	%
Case Report Form Design	%	Marketing	%
Data Entry/Database	%	Sales Management	%
Publications/Software Design	%	Distribution	%
Other (Please explain)	%		

Do any of Your employees provide direct patient care? ☐ Yes ☐ No

Do they carry their own individual medical professional liability coverage? ☐ Yes ☐ No

Do You operate an inpatient facility? ☐ Yes ☐ No

Do any of Your employees participate on an institutional review board/independent ethics board? ☐ Yes ☐ No

Do You or Your employees have a financial interest in the products of Your clients? ☐ Yes ☐ No

Products/Product Classes/Diseases

Do You have any products, services or studies involving any of the following (include past and future activities)?

(Please note that some of these specific products may be excluded within the policy. These exclusions may be partially deleted subject to appropriate and satisfactory information.)

Products

- ☐ Acetaminophin
- ☐ Adalimumab
- ☐ Aprotinin
- ☐ Carbamazepine
- ☐ Cisapride
- ☐ Dasatinib
- ☐ Dexfenfluramine
- ☐ Diethylstilbestrol (DES)
- ☐ Divalproex Sodium
- ☐ Estrogen
- ☐ Fenfluramine
- ☐ Fentanyl
- ☐ Gadolinium-based Contrast Agents (GBCAs)
- ☐ Heparin
- ☐ Isotretinoin
- ☐ Norepinephrine
- ☐ Omalizumab
- ☐ Ondansetron
- ☐ Phentermine
- ☐ Phenyl proxyphene
- ☐ Phenytoin
- ☐ Protease Inhibitors
- ☐ Quetiapine
- ☐ Sibutramine
- ☐ Thimerosal
- ☐ Topiramate
- ☐ Varenicline
- ☐ Zolpidem

Product Class

- ☐ 5-Alpha Reductase Inhibitors
- ☐ Agonist/Antagonist [EPC]
- ☐ Alpha-Adrenergic Blocker [EPC]
- ☐ Angiotensin 2 Receptor Blocker [EPC]
- ☐ Angiotensin Converting-Enzyme (ACE) Inhibitors
- ☐ Anti-coagulant [EPC]
- ☐ Antidepressants
- ☐ Anti-epileptic Agent [EPC]
- ☐ Anti-fibrinolytic Agent [EPC]
- ☐ Anti-IgE [EPC]
- ☐ Atypical Antipsychotic [EPC]
- ☐ Beta2-Adrenergic Agonist [EPC]
- ☐ Bisphenol A (BPA)
- ☐ Bisphosphonates
- ☐ Botulinum Toxin Products
- ☐ COX-2 inhibitors
- ☐ Di-(2-ethylhexyl) Phthalate ("DEHP")
- ☐ Dipeptidyl Peptidase 4 (DPP-4) Inhibitors
- ☐ Efalizumab CD11a-directed Humanized IgG1 Antibody [EPC]
- ☐ Fertility goods or products
- ☐ Gamma-Aminobutyric Acid-ergic Agonist [EPC]
- ☐ Gene Therapy Products
- ☐ GI Prokinetic Agent
- ☐ Giltazones (TZDs)/ Thiazolinediones
- ☐ Glucagon-like Peptide-1 (GLP-1) Receptor Agonist [EPC]
- ☐ Gonadotropin Releasing Hormone Receptor Agonist [EPC]
- ☐ Gonadotropin-Releasing Hormone Agonists (GnRH-As)
- ☐ Hemotherapeutic Antibiotics/ Vaccines
- ☐ Hormone Replacement Products
- ☐ Human Immunoglobulin G [EPC]
- ☐ Incretin Mimetics
- ☐ Kinase Inhibitor [EPC]
- ☐ Long-acting Beta Agonists
- ☐ Metoclopramide Dopamine-2 Receptor Antagonist [EPC]
- ☐ Non-steroidal Anti-inflammatory drugs (NSAIDs)
- ☐ Opioid Agonist [EPC]
- ☐ Oral Sodium Phosphates
- ☐ Paramagnetic Contrast Agent [EPC]
- ☐ Partial Cholinergic Nicotinic Agonist [EPC]
- ☐ Peroxisome Proliferator Receptor alpha Agonist [EPC]
- ☐ Retinoid [EPC]
- ☐ Selective Serotonin Reuptake Inhibitors (SSRI)
- ☐ Serotonin and Dopamine Reuptake Inhibitor Anorectic [EPC]
- ☐ Serotonin-3 Receptor Antagonist [EPC]
- ☐ Standardized Chemical Allergen [EPC]
- ☐ Sympathomimetic Amine Anorectic [EPC]
- ☐ Thiazolidinedione [EPC]
- ☐ Tumor Necrosis Factor (TNF) Inhibitors
- ☐ Tumor Necrosis Factor Blocker [EPC]

Diseases

- ☐ Acquired Immune Deficiency Syndrome (AIDS)
- ☐ Transmissible Spongiform Encephalopathy (TSE)
- ☐ Transmissible Spongiform Encephalopathy (TSE)
- ☐ Coronavirus disease (COVID-19)

List any new products expected to be introduced in the next 12 months.

List any discontinued products. (Please indicate reason(s)).

Contract Management

Details of Your three (3) largest contracts (only applicable for contacts over $250k).

Name of customer	Value of contract	Description	Duration
	$		Months
	$		Months
	$		Months

Contract Terms

1. What is the value of Your largest contract? $
2. What is the maximum contract length?
3. Do You always have a written contract in place with Your customers? ☐ Yes ☐ No
4. How often do You use Your own standards terms and conditions of trade %?
5. Do the standard customer contract terms and conditions:
   - a) Exclude Consequential / indirect losses? ☐ Yes ☐ No
   - b) Limit the Insureds liability to the contract value? ☐ Yes ☐ No
   - c) Limit the Insureds liability to a fixed amount? ☐ Yes ☐ No
6. What % of all customer contracts include a limitation of liability? %
7. Who approves any deviation from Your standard terms and conditions of trade with Your customers?

8. Are You able to confirm that:

a)	Contracts are always drafted by legal professionals or vetted by legal advisors?	☐ Yes ☐ No
b)	Written procedures or checklists are used for the professional services provided?	☐ Yes ☐ No
c)	Contracts or terms of acceptance are evidenced in writing, specify the work to be undertaken and the extent of the insureds responsibility?	☐ Yes ☐ No
d)	Records are kept of all contracts, letters of engagement, client meetings and telephone calls?	☐ Yes ☐ No
e)	All variations from the initial scope of works are documented in writing, with client acceptance?	☐ Yes ☐ No
f)	Diary systems or other procedures are in operation to ensure that deadlines are met?	☐ Yes ☐ No
g)	Working papers are retained for at least 3 years?	☐ Yes ☐ No

Clinical Trials

Sponsored Clinical Trials (Please attach approved protocols and informed consent documents for active clinical trials).

Product	Phase	No. of new subjects over next policy period	Indications	Country/State

No. of expanded access/compassionate use subjects anticipated in the coming policy period?

Total number of human subjects enrolled in the last three (3) years?

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

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

Have You provided material or product for investigator-sponsored trials in the past twelve (12) months? ☐ Yes ☐ No

Have You provided material or product for another organisation's clinical study / trial the past twelve (12) months? ☐ Yes ☐ No

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 provide details below

Regulatory

Have You provided material or product for another organisation's clinical study/trial the past twelve (12) months? ☐ Yes ☐ No ☐ N/A

Do You have operations in/exports to the United States? ☐ Yes ☐ No

If 'yes', are such products approved by the U.S. Food and Drug Administration (FDA)? ☐ Yes ☐ No

Supply the dates of the most recent TGA or similar authority inspection:

Have any products or company practices been subject to an investigation by any government agency? ☐ Yes ☐ No

If 'yes', please explain

Are any product components imported? ☐ Yes ☐ No

If yes, are they TGA approved? ☐ Yes ☐ No

Do any of Your products training/certification programs require the approval of the TGA or any other similar national organisation? ☐ Yes ☐ No

Are manufactured products UL listed and/or CSA certified? ☐ Yes ☐ No

Are the manufactured products listed or certified by any national organisation? ☐ Yes ☐ No

Do You use another organisation for reliability/design validation? ☐ Yes ☐ No

Do You require certificates of insurance from suppliers? ☐ Yes ☐ No

If yes, indicate limits required:

Have You had any product recalls in the past year? ☐ Yes ☐ No

If 'yes', please provide details and current recall status

Within the past twelve months, have You filed any medical device reports? ☐ Yes ☐ No

If 'yes', indicate the number of filings and the nature of each filing

Have any clinical trials been placed on hold? ☐ Yes ☐ No

If 'yes', provide details

Do You audit clinical investigator performance? ☐ Yes ☐ No

Have You received any warning letters during the last three (3) years? ☐ Yes ☐ No

If 'yes', please explain

Is there a written and implemented loss prevention/control programme? ☐ Yes ☐ No

If 'yes', please note the name and title of the individual responsible for the programme

Is there a written and implemented quality control programme? ☐ Yes ☐ No

Is there a written and implemented product recall plan? ☐ Yes ☐ No

Are promotional materials, contracts, guarantees, and labelling reviewed by risk management and legal counsel? ☐ Yes ☐ No

Cyber

Do You have controls in place ensuring timely removal of system access when an employee leaves the organisation, or when access is no longer required for business purposes?	Yes	No
Do You perform backups of data, applications and system configurations at least weekly?	Yes	No
If the backups are physically stored off-site, are they are encrypted?	Yes	No
Do You know what sensitive or private information is in Your custody, where it is stored and how to contact individuals in the event of a breach?	Yes	No
Do You have and follow a data retention and destruction policy?	Yes	No
Do You have the following security standards in place:		
• regularly updated firewalls and anti-virus systems?	Yes	No
• security patches for Your system are implemented as soon as practical?	Yes	No
If remote access is allowed to Your corporate network, do You limit to 2FA (e.g. some combination of VPN or Access Token, and password/account login) only?	Yes	No
Do You encrypt sensitive data that is physically removed from Your premises by mobile device (e.g. laptop/USB/ mobile phones)?	Yes	No
Are You aware of a matter that is reasonably likely to give rise to any loss or claim, or have You suffered any loss or has any claim being made against You in the last 5 years?	Yes	No
Have You been subject to any government action, investigation or subpoena regarding any alleged violation of any privacy/data security law or regulation?	Yes	No

Insurance and Loss History

Loss History

(Provide total aggregate losses from ground up, including related claim defence expenses, for the last five (5) years and attach previous insurer loss history.)

Policy Period	Insurer	No. of Claims	Total Incurred

Have any known occurrence(s) not yet been reported? ☐ Yes ☐ No

If 'yes', please submit details

Coverage History

Policy Period	Primary and Excess Limits	Insurer(s)	Retroactive Date

Has any insurer ever cancelled or non-renewed any of Your insurance coverages? ☐ Yes ☐ No

If 'yes', please explain

Important Information

General Advice Warning

Any advice about this insurance that We or SURA give You is of a general nature. We do not consider Your individual objectives, financial situation or needs. It is up to You to choose the cover You need, and You should carefully read this document and any other documents that form part of the Policy before deciding whether this insurance is right for Your individual objectives, financial situation and/or needs.

Duty of Disclosure

Before the contracting insured enters into an insurance contract (referred to as "You" and "Your" in this notice), You have a duty to tell Us of anything that You know, or could reasonably be expected to know, that may affect Our decision to insure You and on what terms. You have this duty until We agree to insure You.

You have the same duty before You renew, extend, vary, or reinstate an insurance contract.

You do not need to tell Us anything that:

– reduces the risk We insure You for;
– is of common knowledge;
– 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 fail to comply with Your Duty of Disclosure, and We would not have entered into the contract, for the same premium and on the same terms and conditions, had the failure not occurred, We may, subject to applicable law:

- be entitled to cancel Your contract or reduce the amount We will pay You if You make a claim, or both; or
- If Your failure to tell Us is fraudulent, We may refuse to pay a claim and treat the contract as if it never existed.

Subject to applicable law or unless We state otherwise, a breach of the duty by one Insured affects all insureds in these ways.

Claims Made and Notified

Section 5 – Medical Professional Liability and Section 6(2) – Third Party Cyber Liability are issued on a claims made and notified basis. This means that the Policy covers "Claims" that are first made against You by another person (as defined) during the Period of Insurance and notified to Us also during that Period of Insurance, after any retroactive date on the Policy. The Policy doesn't cover facts or circumstances which You first became aware of prior to the Period of Insurance, and which You knew or ought reasonably to have known had the potential to give rise to a claim against You.

Not a Renewable Contract

The Life Science Policy is not a renewable contract so the Policy will terminate on the expiry date indicated. If You therefore require a subsequent Policy, You will need to complete and submit a new proposal form for assessment prior to the termination of the current Policy.

Privacy

Your personal information will be collected and handled in accordance with our Privacy Policy. A copy of Our Privacy Policy is located on Our website at www.sura.com.au.

SURA TECHNOLOGY RISKS

Level 14 / 141 Walker St
North Sydney NSW 2060
PO Box 1813
North Sydney NSW 2059

Life Science Proposal Form

Telephone: 02 9030 9500
Web: www.sura.com.au

Declaration

By signing this document You represent that You are authorised to sign on behalf of all persons/entities identified as the intending inured(s). A misstatement or misrepresentation by one applicant of any material facts relevant to the Insurer's decision whether to accept or reject this risk is treated as a misstatement or misrepresentation by all applicants.

I/we have read and understood the information herein, including the Important Information and the SURA Privacy Policy.

I/we agree that this Proposal Form together with any other information supplied by me/us shall form the basis of any Contract of Insurance effected.

I/we declare that the statements and particulars contained in this Proposal Form are true, correct, and complete and that I/we have not omitted, misstated or suppressed any material facts.

I/we undertake to inform the Insurer of any material alteration to this information occurring before the proposed insurance commences.

Name of firm

Signature

(This Proposal is to be signed by a Principal, Partner or Director of the Proposed Insured)

Title of signatory

Full name

Date

/ /