PROPOSAL FORM

Liberty Remedy for Life Sciences Insurance™

libertyinternational.com

Liberty®

Proposal form

Important Notice

The information requested and provided in this proposal will form the basis of any contract of insurance entered into. Please read the following notices carefully and ensure you (the Insured) answer all questions in full and read and sign the Declaration at the end.

Your Duty of Disclosure – Australia

Before you enter into a contract of general insurance with an insurer, you have a duty, under the Insurance Contracts Act 1984 (Cth), to disclose to the insurer every matter that you know, or could reasonably be expected to know, is relevant to the insurer's decision whether to accept the risk of the insurance and, if so, on what terms.

You have the same duty to disclose those matters to the insurer before you renew, extend, vary or reinstate a contract of general insurance.

Your duty however does not require disclosure of matter:

- that diminishes the risk to be undertaken by the insurer;
- that is of common knowledge;
- that your insurer knows or, in the ordinary course of its business, ought to know;
- as to which compliance with your duty is waived by the insurer.

Non Disclosure

If you fail to comply with your duty of disclosure, the insurer may be entitled to reduce their liability under the contract in respect of a claim or may cancel the contract. If your non-disclosure is fraudulent, the insurer may also have the option of avoiding the contract from its beginning.

Your Duty of Disclosure – Hong Kong

In completing this proposal form you are obliged to disclose material facts that you know, or could reasonably be expected to know, that are relevant to the insurer's assessment and acceptance of this proposal. If you are uncertain whether or not particular information is material, these facts should be disclosed.

Non Disclosure

Should you fail to comply with your disclosure obligations the insurer may void the policy.

Your Duty of Disclosure – Singapore

In accordance with section 23(5) of the Insurance Act 1966, as amended from time to time, you are to disclose in this proposal form, fully and faithfully, all the facts which you know or ought to know that are relevant to the policy.

Non Disclosure

If you do not fully and faithfully give the facts as you know them or ought to know them, the policy issued may be void and you may receive nothing under the policy.

Claims Made/Occurrence/Discovery-based Insurance

This is a proposal form for a policy which provides insurance:

- on an occurrence basis under Insuring Clause 1.1, Insuring Clause 1.2 and some extensions. This means that these parts of the policy will only cover you for injury and/or damage which first happens during the policy period;
- on a claims made and notified basis under Insuring Clause 1.3, Insuring Clause 1.4 and some extensions. This means that parts of the policy will only cover you in respect of claims which are first made against you and notified to the insurer during the policy period and any applicable reporting period; and
- on a discovery basis under Optional Extension 3.3. This means that Optional Extension 3.3 will only cover you for a product recall event first discovered and notified to the insurer during the policy period or any applicable reporting period.

Cover under the policy may be limited further by a retroactive date exclusion.

You should carefully read all of the policy, including all definitions and, in particular, the exclusions, to ascertain the precise scope of cover afforded by the policy. You are advised to consult your insurance agent or broker to ensure a clear understanding of your rights and obligations under the policy.

Inadequate space to answer

If there is inadequate space to answer any of the questions or make any comment or you need to disclose something to us because of your Duty of Disclosure, please include attachments to this proposal on your company letterhead, giving full details of additional information.

Instructions

Complete all Sections relevant to the named Insured's operations.

Save Print

Proposal form

1. THE INSURED'S DETAILS

All questions will be deemed to be answered in respect of all entities and persons to be insured under this policy. Any unanswered or illegible questions will delay our decision as to whether we can offer insurance cover.

a. Full name of proposed Insured

b. Trading name (if applicable)

c. ABN/ACN or equivalent identification number

d. Insured's address

e. Contact person

Name Phone

Email

f. Insured's years in business

g. Please provide a brief description of Insured's operations

h. List any third parties to be included as an Insured:

2. ORGANISATIONAL DETAILS

a. Name of parent company (if any)

b. Subsidiaries (if any), and any acquired/sold in the last five (5) years

c. Has there ever been any criminal investigations against any shareholder, director, officer, partner or member of the Insured, any subsidiaries or any other entities seeking insurance? Yes ☐ No ☐

d. Which countries does the Insured operate in? Please provide the percentages below:

Country		Country	
	%		%
	%		%
	%		%
	%		%
Total (must be equal to 100%)	0 %		

e. **Revenue details**

1. Revenue for last financial year $
2. Estimated revenue for current financial year $

Please provide details on the Insured's five (5) largest contracts, purchase orders or agreements:

Customer	Contract amount	Product/service	Duration
	$		
	$		
	$		
	$		
	$		

4. Does the Insured have any acquisition, tender offers, mergers or divestitures pending or under consideration? Yes ☐ No ☐

If yes, please provide details:

5. Has the Insured filed for bankruptcy over the last five (5) years? Yes ☐ No ☐

f. **Estimated payroll details including percentage split**

1. **Job description**	**Number of employees**	**Wages**	**% of workforce**
Clerical, sales and training/instruction		$	%
Management and administration		$	%
Manufacturing, installation, maintenance		$	%
Research and development		$	%
Other (please specify below)		$	%
		Total (must be equal to 100%)	0 %

Specify other here:

2. Has the Insured used the services of subcontractors, contractors and/or labour hire workers? Yes ☐ No ☐

If yes, provide details below:

Contractors/subcontractors How many? Estimated annual payments $

Describe the services provided:

Labour hire workers How many? Estimated annual payments $

Describe the activities performed:

3. PRODUCT AND SERVICE INFORMATION

a. Pharmaceuticals/biological medicines

1. **Does the Insured manufacture, distribute or import any of the following?**

Product/drug/class

Birth control or fertility products	☐	Infusion pumps	☐
Botulinum Toxin Type A or Type B	☐	Isotretinoin or Accutane	☐
Breast implants	☐	Metoclopramide	☐
Dexfenfluramine	☐	Opioid or opiate products	☐
Diazepines, Oxazepines or Thiazepines	☐	Phentermine	☐
Ephedrine or Ephedra	☐	Piper Methysticum or Kava Kava	☐
Fenfluramine	☐	Proton Pump Inhibitors	☐
Glucagon-like peptide-1 (GLP-1)	☐	Thiazolidinediones	☐
Hip and knee replacement products	☐	Synthetic or biologic mesh implants	☐
Hormone replacement products	☐		

For each of the options below, advise any veterinary and/or clinical trials use:

Diethylstilbestrol (DES)	☐	Veterinary (animal) use/and or in connection with clinical trials	☐
Phenylpropanolamine (PPA)	☐	Veterinary (animal) use/and or in connection with clinical trials	☐

2.

Medicine Categories	Manufactured ($)	Distributed ($)	Packed/ repacked ($)	Sold under others' label ($)	% turnover
Non-prescription medicines					
Non-prescription medicines (over the counter)					%
Listed medicines (lower risk medicines, assessed for quality and safety)					%
Prescription medicine					
Generic drugs					%
Proprietary drugs					%

3. **Product class**

Angiotensin II receptor blockers (ARBs)	☐	Fast-tracked new medicines	☐
Anticonvulsant products	☐	Gene therapies	☐
Antipsychotic drugs	☐	Medicinal cannabis	☐
Anti-obesity drugs	☐	Monoclonal antibodies	☐
Biologicals	☐	Unapproved therapeutic goods	☐
Biosimilars	☐	Vaccines (traditional types)	☐
Blood products	☐	Vaccines targeted at pandemic diseases	☐
Cell therapies	☐	Vaccines utilising mRNA or viral vector technologies	☐
Erectile dysfunction products	☐		

4. **Products**

Botox, Dysport or Xeomin	☐	Cisapride	☐	Risperidone	☐		
Nefazodone	☐	Thalidomide	☐	Thimerosal	☐		

5. Does the Insured export any pharmaceuticals/biological medicines? Yes ☐ No ☐

If yes, please provide details:

Country	Product details	Value
		$
		$
		$

b. Pharmaceutical components

1.

Non-prescription medicines	Manufactured ($)	Distributed ($)	Packed/ repacked ($)	Sold under others' label ($)	% turnover
Active pharmaceutical ingredient (API)					%
Excipients (all types)					%
Packaging					%
Proprietary drugs					%

2. Does the Insured export any pharmaceuticals/biological medicines? Yes ☐ No ☐

If yes, please provide details:

Country	Component details	Value
		$
		$
		$
		$
		$

c. Medical devices

1.

Device type	Manufactured ($)	Distributed ($)	Packed/ repacked ($)	Sold under others' label ($)	% turnover
Active implantable devices					%
Surgical/urogynecological/transvaginal mesh products					%
Orthopaedic – completed kits for knee, hip or other joints					%
Orthopaedic – Other than hip and knee					%
In vitro diagnostic medical devices					%
Contraceptive intrauterine devices (IUDs) and surgically implanted contraceptive devices					%
Infusion pumps					%
Radiation emitting devices					%
Software as Medical Device (SaMD)					%
Other (please provide details):					%

2. Does the Insured export any medical devices? Yes ☐ No ☐

If yes, please provide details:

Country	Type of medical device	Value
		$
		$
		$
		$
		$
		$
		$
		$
		$
		$
		$

d. Complementary medicines/dietary supplements/nutritional products

1.

Product type	Manufactured ($)	Distributed ($)	Packed/ repacked ($)	Sold under others' label ($)	% turnover
Vitamins					%
Nutritional supplements					%
Herbal medicines					%
Homoeopathic products					%
Diet/fat burning pills/supplements					%
Virility/sexual performance boosters					%
Products are imported directly from the internet					%
TCM ingredients and products					%
Other (please provide details):					%

2. Are any of the Insured's ingredients/products derived from, or use parts of endangered species? Yes ☐ No ☐

3. Does the Insured utilise multi-level marketing for any product sales? Yes ☐ No ☐

e. Additional product-related questions

1. Have any of the products referred to in the previous tables:
   - i. have any black box or significant warning labels? Yes ☐ No ☐
   - ii. ever been associated with death/permanent injury or hospitalisation? Yes ☐ No ☐
   - iii. been specifically approved for, and used by: minors, pregnant women, the cognitively impaired and/or prisoners? Yes ☐ No ☐
   - iv. been discontinued? Yes ☐ No ☐

   If yes, please provide details below:

2. Are any of the products referred to in the Section 3(a), (b), (c) and (d) tables new products/ services for either the Insured's or associated supply chains? Yes ☐ No ☐

   If yes, please provide details below:

3. Does the Insured source products from:

   Original equipment manufacturer ☐ Contractors/manufacturers ☐ Wholesalers ☐ Other ☐

4. In respect of potential nitrosamine contamination:

   i. have nitrosamine risk assessments been completed for every product and site? Yes ☐ No ☐

   ii. is there an enterprise-wide nitrosamine control strategy in place? Yes ☐ No ☐

   iii. has the Insured adopted incoming testing for all high-nitrite excipients? Yes ☐ No ☐

   If no, please provide details below:

f. Contract professional services

1. **Contract manufacturers**

   List the types of products and projected annual revenue

Product type	Projected annual revenue
	$
	$
	$
	$
	$
	$

2. **List of customers**

Name	Contract value	Contract duration	Service/s provided
	$		
	$		
	$		
	$		
	$		
	$		

3. Has the Insured manufactured products that are used as components for other companies products? Yes ☐ No ☐

4. Has the Insured manufactured products sold under other companies' labels? Yes ☐ No ☐

5. Is the Insured involved in any design work? Yes ☐ No ☐

   If yes, please provide details:

6. **Contract research organisations and site management organisations**

i. does the Insured operate an in-patient facility? Yes ☐ No ☐

ii. do any of the Insured's employees participate on a human research ethics committee (HREC), or equivalent? Yes ☐ No ☐

iii. does the Insured ever act as the clinical trial sponsor? Yes ☐ No ☐

iv. does the Insured ever serve as the legal representative for a clinical trial? Yes ☐ No ☐

v. does the Insured provide global services for multinational Phase III drug trials? Yes ☐ No ☐

If yes, please provide details:

vi. Please select the scope of services the Insured provides:

a. clinical development strategy and program planning (e.g. IND strategy) ☐
b. clinical trial planning ☐
c. clinical trial investigator and site selection and diligence ☐
d. clinical trial and protocol design (primary and second endpoints, parameters, metrics) ☐
e. clinical trial protocol drafting ☐
f. regulatory affairs (e.g. strategy, interaction with the agency, preparations and filings, responses) ☐
g. site training and investigator meeting organisation ☐
h. study start-up services (e.g. contracts, budgets, insurance) ☐
i. site and patient engagement services ☐
j. clinical trial monitoring and surveillance ☐
k. clinical trial data management and biostatistics ☐
l. laboratory and bioanalysis services ☐
m. clinical trial supply chain management ☐
n. quality assurance and compliance ☐
o. technology and eClinical solutions ☐
p. staffing services ☐

Please provide specific details for each of the services the Insured provides/offers:

7. Does the Insured currently purchase professional liability insurance? Yes ☐ No ☐

If yes, please complete the following questions:

i. what is the limit of insurance for the Insured's professional liability insurance?

ii. who is the Insured's current professional liability insurer?

8. How many of the Insured's customers each represent more than 10% of revenue?

   Please provide more detailed information about these customers:

Name	Revenue	Service
	$	
	$	
	$	
	$	

9. Does the Insured's customised customer management procedures include the following?

   i. written proposal or request for information in order to determine customer performance expectations? Yes ☐ No ☐

   ii. written contract of specifications or services the Insured will provide, signed by the customer? Yes ☐ No ☐

   iii. contract/statement of work which outlines responsibilities of all parties? Yes ☐ No ☐

   iv. written agreement outlining the scope of the project or services? Yes ☐ No ☐

   v. interim changes documented with customer sign-off? Yes ☐ No ☐

   vi. performance milestones acknowledged and accepted with customer sign-off when achieved? Yes ☐ No ☐

10. What would be the largest financial and business impact on Insured's customers from a failure of any of the Insured's products or services?

11. Has the Insured discontinued any products or services in the past three (3) years? Yes ☐ No ☐

    If yes to above, is service or maintenance still provided?

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

Product or service	Date discontinued	Still service/ maintain
		Yes ☐ No ☐
		Yes ☐ No ☐
		Yes ☐ No ☐
		Yes ☐ No ☐

12. Will the Insured be offering any services to the market within the next year that are substantially different in scope or end-use than current services? Yes ☐ No ☐

    If yes to above, please provide details below:

13. Does the Insured have a formalised client complaint resolution policies and procedures? Yes ☐ No ☐
14. Is customers' property held or stored at the Insured's facilities? Yes ☐ No ☐

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

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

15. Are any healthcare services performed on the Insured's site? Yes ☐ No ☐

    If yes to above, please provide details below:

4. DISTRIBUTION

a. For any of the products referred to in Section 3 – Product and Service Information as being distributed, please provide the following information:

1. What type of business entities does the Insured sell to?

2. Is a computerised system in place that manages customers orders including validation, expiration date, flagging abnormal requests and verifying customer contract/order? Yes ☐ No ☐
3. Describe the inventory management system in terms of track and trace systems. Highlight the distribution chain from suppliers through final customer distribution below:

4. What type of entities does the Insured source product from? If the primary product source is another wholesaler please describe the product validation process employed below:

5. What is the Insured's customer return policy? If returned products are accepted, what is done with the returned items?

6. If the Insured is a supplier of components or ingredients, or a distributor of products of others, is additional insured status on the product licence holder's product liability policy required? Yes ☐ No ☐

7. Does the Insured require indemnification for damages, including defence costs? Yes ☐ No ☐
8. Does the Insured have indemnification agreements with all manufacturers distributed to? Yes ☐ No ☐
9. Does the Insured obtain annual Certificates of Insurance from suppliers? Yes ☐ No ☐
10. Does the Insured provide any installation, repair, refurbishing, or maintenance services? Yes ☐ No ☐

    If yes, please provide details:

5. REGULATORY AND QUALITY CONTROL

a. Do all products comply with applicable jurisdictional regulations and standards? Yes ☐ No ☐

   If no, please provide details below:

b. In the past three (3) years, has the Insured been cited for any regulatory violations (such as those contained in TGA Close Out Records, post inspection letters, FDA Form 483, EUDRA Statements of non-disclosure or warning letters)? Yes ☐ No ☐

   If yes, has the Insured's response been accepted by the appropriate regulatory authority and the matter concluded? Yes ☐ No ☐

   If no, please provide the details below:

c. Provide details of regulatory audits for the last three (3) years, including any regulatory violations:

Date	Regulatory body	Result of audit

d. List the top three (3) products with the most adverse event reports resulting in death, permanent injury or hospitalisation.

   Please provide the latest safety report for each.

   1.

   2.

   3.

e. Please identify any product or service requiring a Risk Management Plan (RMP), or relevant regulatory equivalent in the past three (3) years:

f. Are there any safety surveillance team or member recommendations requiring remedial actions that have yet to be implemented? Yes ☐ No ☐

If yes, provide details below (such as additional studies, black box warning label /updates, direct healthcare professional communication, expanded product monitoring and product recall/withdrawal/s, field safety corrective actions etc.)

g. Who has the authority to approve a label change, or withdraw a product from the marketplace?

h. Does the Insured have written procedures to address and communicate these actions? Yes ☐ No ☐

i. Is the dissemination of "off-label" information permitted? Yes ☐ No ☐

If yes, please describe the circumstances and controls in place:

j. What steps are taken if pervasive "off-label" use was discovered on any products?

k. Does the Insured comply with relevant codes of conduct? Yes ☐ No ☐

l. Have any internal or external sales staff breached regulations governing sales and marketing practices? Yes ☐ No ☐

m. Is there a written policy in place that prohibits sales staff (internal or external) from making physical contact with patients? Yes ☐ No ☐

n. Have there been any instances of non-compliance during the past three (3) years? Yes ☐ No ☐

If yes, please provide details below:

o. How regularly is formal, documented compliance training required for internal and external sales staff?

p. Does the Insured's labels comply with all regulatory requirements, for example the TGA's 'Required Advisory Statements for Medicine Labels? Yes ☐ No ☐

q. Does the Insured's quality control procedures, including those for any external party certifications, encompass the following:

1. A documented and structured quality-control program — Yes ☐ No ☐
2. Initial phase testing (Alpha) — Yes ☐ No ☐
3. Secondary phase testing (Beta) — Yes ☐ No ☐
4. Established client sign-off procedures — Yes ☐ No ☐
5. Documented systems development framework — Yes ☐ No ☐
6. Established product-recall procedure — Yes ☐ No ☐
7. Established framework for recording and addressing client complaints or modification and rectification requests — Yes ☐ No ☐

r. Does the Insured's quality control procedures include: cGMP ☐ GLP ☐ GCP ☐ Other ☐

6. PRODUCT RECALL

a. Use the table below to provide the Insured's five (5) year product recall history, if any.

Recall event #	Date of recall	Recall class	Provide comments if Class I, or if unclassified and expected to be classified as Class I
1			
2			
3			
4			

7. CLINICAL TRIALS

a. This section is intended only for Insureds who will sponsor any clinical trial(s).
Please complete the table on page 21 with all active or planned clinical trials for the policy period and attach a copy of the Insured's clinical trial protocol(s) and respective master informed consent document.

b. Has each trial received all necessary approvals from the relevant national health regulatory authority in the country where it is being conducted? Yes ☐ No ☐

c. For each trial, is the legal sponsor a registered entity in the country where the trial is being conducted? Yes ☐ No ☐
If no, please explain sponsor arrangements:

d. Are there formal processes in place for selecting and evaluating principal investigators, clinical investigators, and clinical trial sites? Yes ☐ No ☐
Please attach a copy of the Insured's standard operating procedure.

e. Does the Insured classify product and trial-level risks and implement a risk-based monitoring plan accordingly? Yes ☐ No ☐

f. Please describe the Insured's risk assessment approach:

g. Who is responsible for the Insured's formal clinical trial suspension standard operator procedures (SOP), should an emerging issue arise?

h. Do the suspension procedures cover sponsor, investigator and site actions and communications to the relevant ethics/advisory committees and regulatory agency, and include immediate hazard management and CAPA? Yes ☐ No ☐

i. Do any of the Insured's employees sit on Ethics/Advisory Committees (HRECs/BACs/HKCRECs etc.), or equivalent, reviewing the Insured's trials? Yes ☐ No ☐

If yes, how are conflicts of interest identified and managed to ensure independence of ethical review?

j. Who oversees the Insured's clinical trial program from a planning, management, monitoring, and regulatory perspective?

k. **Internal and/or external resource(s)**

1. Does the Insured utilise a third-party contract research organisation (CRO) to assist in clinical trials? Yes ☐ No ☐

   If yes, please identify:

2. Who reviews the Insured's contracts and indemnification agreements with any CRO's, clinical trial sites, or clinical trial investigators?

   Please identify internal and external resource(s).

3. Do any of the clinical investigators involved in any of the Insured's clinical trials have a financial interest in the Insured's business or the outcome of the study (e.g. equity interest)? Yes ☐ No ☐

   If yes, please provide details:

4. Are enrolment bonuses or incentives paid to any party involved in the Insured's clinical trials (CRO's, clinical investigators, or sites)? Yes ☐ No ☐

5. Does the Insured have a formal expanded access/compassionate use program? Yes ☐ No ☐

   If yes, please provide details:

6. What is the maximum amount of monetary compensation offered to an enrolled clinical trial participant, from inception through completion of the trial? $

7. Do any clinical trials involve minors (under the age of 18)? Yes ☐ No ☐

   If yes, please provide details:

8. Does the Insured provide any product(s), good(s), or material(s) for any clinical trials for which they are not the sponsor (e.g. collaboration partner or research partner)? Yes ☐ No ☐

   If yes, please provide details:

l. **Ethics and Consent**

1. In the Insured's informed consent content development, is there a process for final review to ensures readability, inclusion of reasonably foreseeable risks from preclinical data, and all required elements per applicable regulatory guidelines? Yes ☐ No ☐
2. Does the Insured's consent processes include any consent when new information arises, processes for remote/electronic consent, assent for minors, and tailored approaches for special populations (emergency, cognitive impairment, dependent relationships and pregnant women)? Yes ☐ No ☐

m. **Quality Management and Monitoring**

1. Does the Insured have a documented quality management system for trials (risk identification, evaluation,control, communication, review and reporting) per ICH E6(R3)? Please attach the Insured's monitoring plan, including use of central/remote/on-site monitoring and criteria for targeted visits. Yes ☐ No ☐
2. Does the Insured's establish a Data Safety Monitoring Board (DSMB) or other independent committee for appropriate trials? Yes ☐ No ☐

   If yes, please identify:

3. How are important protocol deviations and non-compliance, including root cause analysis and corrective/preventive actions identified, classified and managed?

n. **Regulatory**

1. Within the past five (5) years, have any clinical trials sponsored by the Insured been subject to a clinical hold, suspension, stoppage, or similar restriction by a regulatory authority, HREC/Institutional Review Board (IRB)/ Research Ethics Committee (REC), Data Safety Monitoring Board (DSMB), or other oversight body? Yes ☐ No ☐

   If yes, please provide details:

2. Within the last five (5) years, have any for-cause audits, warning letters, cited for violations in connection with the Insured's clinical trials been conducted by any applicable governmental or regulatory authority or other oversight body? Yes ☐ No ☐

   If yes, please provide details:

3. Within the last five (5) years, have any clinical investigators been cited for any regulatory violation(s)or fraud in connection with the Insured's clinical trials? Yes ☐ No ☐

   If yes, please provide details:

o. **Data governance and privacy**

1. Does the Insured's handling of personal information comply with applicable data privacy laws and guidance including any medical council and clinical trials guidance? Yes ☐ No ☐

p. **Single trial information**

1. Countries where clinical trial will take place:

2. Expected trial start date — Expected trial completion date (last patient, last control)
3. Name of product being tested
4. ANZCTR number (if applicable) — EudraCT number (if applicable)
5. Clinical trials government identifier (if applicable)
6. Total number of research subjects to be enrolled — Placebol/control
7. Estimated research subject split by country (if applicable)

   Country

   Subjects

   If additional space is required to list all countries for covered trial, please provide a separate document.

8. PREMISES AND OPERATIONS

a. Please provide details on the Insured's premises and operations:

Premises **Operations**

b. Please provide information on hazardous materials (if applicable):

Tick if yes	Storage type	Hazardous substance	Volume (litres)
☐	Outdoor storage		
☐	Indoor cut-off area in approved containers		
☐	Indoor cut-off area in unapproved containers		
☐	Just-in-time supply		

c. Are there any below ground storage tanks? Yes ☐ No ☐

If yes, please provide details:

Contents	Year installed	Construction	Monitoring

d. Please provide details of any environmental management procedures:

e. Does the Insured operate an animal facility or keep animals on site? Yes ☐ No ☐

f. How often are the Insured's risk management programs and SOPs audited each calendar year?

g. Please identify any SOPs that are audited by independent, non-government organisations or individuals:

9. CYBER SECURITY

a. Does the Insured have an established cyber security strategy in place that extends beyond data protection Yes ☐ No ☐

b. How does the Insured ensure that cyber security risk management is integrated in the company's overall risk management practices?

c. What is the Insured's approach towards external and internal penetration tests and vulnerability assessments?

d. How are critical vulnerabilities remedied once identified? What changes are now being implemented as a result of a recent breach (if applicable)?

Please attach a copy of the Insured's cyber incident response plan (executive summary would suffice), or equivalent for our review.

10. CLAIMS HISTORY

Please note: It is critical that you make appropriate enquires of all persons and entities intending to be insured under this insurance before answering Questions 10.a -10.c

a. Has any application for Life Sciences insurance made by yourself, principals or partners ever been declined, or coverage cancelled or non-renewed? Yes ☐ No ☐

If yes, please provide details:

b. Has any claim, suit, or demand for money or services ever been made against the Insured, the Insured's subsidiaries, or principals? Yes ☐ No ☐

If yes, please provide details:

c. Is the Insured including any of its directors or employees aware of any facts which might give rise to a claim under a Life Sciences Insurance Policy against any of them? (If more than one, please provide details via attachment). Yes ☐ No ☐

If yes, please provide details including but not limited to the allegations of the act, error or omission by the Insured:

PROPOSAL FORM

7. CLINICAL TRIALS

Active and planned clinical trials

Protocol ID/ Study Title	Product	Date		Trial Phase	Countries/ Sites	Recruited subjects	Estimated subjects	Active placebo ratio
		Start	End					

Return to page 15

11. DECLARATION

I, the undersigned, declare and acknowledge:

- that I am, after enquiry, authorised by all person(s) or entities seeking insurance, to make this proposal;
- that after enquiry, all information supplied in this proposal and any supporting documents attached to this proposal or supplied separately, is true and correct and I have not withheld any material information from this proposal;
- that this proposal and any accompanying documents shall form or partly form the basis of the contract proposed.
- that until a Contract of Insurance is entered into, I am obliged to inform Liberty of any changes to any information supplied or of any new information that is relevant;
- that I understand Liberty relies on the accuracy of the information and documentation supplied proposing for this insurance;
- that I have read and understood the Important Notices which form part of this proposal;
- that I understand that no insurance is in force until a Contract of Insurance is entered into, which is upon the Proposer's acceptance of an offer by Liberty, if any.

To be signed by the partner, director or authorised representative of the Insured.

Please indicate your authority as a signatory: Partner ☐ Director ☐ Authorised Agent ☐

Signature Date

Name (please print)

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