



Medical Device & Pharmaceutical Recall

PROPOSAL FORM

libertyspecialtymarketsap.com



Liberty
Specialty Markets

Important Notice

The clauses herein are made pursuant to laws applicable in Hong Kong and Malaysia and pursuant to the Insurance Act 1966 of Singapore.

Before you enter into a contract of general insurance with an insurer, you have a duty 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.

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 attach a separate piece of paper to this questionnaire giving full details of additional information.

1. THE APPLICANT

a) Name of applicant to be insured under this policy

b) Nature of business

c) No. of years in business

d) Address of insured

Street

Suburb

State

Postcode

e) List all subsidiary companies to be included under this policy

f) Applicant's website

2. PARENT COMPANY

a) Parent company of applicant

b) Address of parent company

3. FINANCIALS

a) Actual total turnover for the last 12 months USD

b) Estimated turnover for the next 12 months USD

c) Actual gross earnings for the last 12 months USD

4. SCOPE OF OPERATION

a) Is the applicant the

1. Sponsor/importer

Yes

No

2. Manufacturer

Yes

No

5. PRODUCT CLASSIFICATION

a) Product information (attach additional pages as needed)

Product(s)	% of total sales	Commercial or consumer end user
	%	
	%	
	%	
	%	
	%	

b) What class do the applicant's products fall under, as categorised by the FDA or equivalent?

Class							
% of turnover	%	%	%	%	%	%	%
Others (please specify)							

c) Are all products approved by the FDA or equivalent?

Yes No

Others (please specify)

d) Are any applicant's products implantable medical devices?

Yes No

e) What percentage (%) of products are sold as components

%

f) Do products work with rechargeable battery?

Yes No

g) Does the applicant contract manufacture, bottle or pack for any third parties?

Yes No

If yes, what is the % and work?

h) **Geographical distribution:**

Region	Product(s)	Turnover USD
North America, Europe, ANZ, Japan		\$
Asia excluding Japan		\$
Other (please specify)		\$

i) **Top three (3) products (by turnover):**

	Product 1	Product 2	Product 3
Product name			
Annual turnover (USD)	\$	\$	\$
Top customer			
Failure rate (%)	%	%	%
Manufacturing cost per unit	\$	\$	\$
Batch size (number of units)			
Batch size (USD)	\$	\$	\$

j) Does the applicant import any goods?

Yes No

If yes, please provide details

Country	Goods/use of goods	Value USD
		\$
		\$
		\$
		\$

k) What percentage of your products are manufactured by outside contractors?

%

l) Product by plant – daily output in USD

Total number of plants/facilities

If three or more plants, please attach a schedule with the following information:

Plant	Max daily output per plant in USD	Max daily output any one product line in USD
	\$	\$
	\$	\$
	\$	\$

m) Has the applicant agreed to indemnify or hold harmless any suppliers of goods or services (e.g. supplier of raw materials/contract packers) or other parties? Yes No

n) Do products require external power source to operate? Yes No

o) Do products require installation or assembly after delivery? Yes No

p) Do you have a written, in-force quality assurance plan? Yes No

q) Do all products meet registration standards? If yes, please list out all the certification: Yes No

r) Do all of the products which are the subject of this proposal form, conform in all respects with requirements of law or regulation, including applicable industry guidelines? Yes No

s) Is there a quality control department? Yes No

t) Are suppliers standards monitored? Yes No

u) Do you require your suppliers to abide by specified standards? Yes No

v) What steps are taken to assess the quality standards adhered to by your suppliers? (Application, references, health inspection reports, etc)

w) Does the applicant conduct site visits/audits to major/critical suppliers? Yes No

x) Are all finished goods/components manufactured under GMP licensed conditions? Yes No

y) How do you collect and monitor customer complaints?

6. AUDITS

a) Are quality assurance audits performed internally? Yes No

b) How often are these audits performed?

c) Are quality assurance audits performed by an independent third party? Yes No

d) How often are these audits performed?

Please attach a copy of the most recent audit performed by an independent third party.

e) Has the FDA or equivalent audited the applicant's facilities?

Yes No

f) When was the date of this last audit?

g) Was any major or critical non-conformity raised during this audit?

Yes No

Please attach a copy of the most recent audit performed by an independent third party.

h) Do all manufacturing premises hold a valid GMP certificate?

Yes No

i) Is the quality management system certified under ISO 13485 or any other relevant standard?

Yes No

7. RECALL PREPAREDNESS

a) Does the applicant have an in-force recall plan?

Yes No

If yes, please describe and attach a copy:

b) Are mock recalls conducted?

Yes No

If yes, what was the date of the of last mock recall:

c) Does the applicant have an in-force crisis management plan?

Yes No

If yes, please describe and attach a copy:

d) Estimate the cost to recall your leading brand

8. PRODUCT TESTING

a) Is product testing utilised?

Yes No

If yes, at what point in the manufacturing process is testing performed?

In line End product Raw materials Other

b) Do you have an in-house testing laboratory?

Yes No

c) Do you retain an outside testing laboratory?

Yes No

d) Are labels routinely inspected for accuracy and content?

Yes No

e) Who reviews labels?

Technical Legal Other

f) How often are labels reviewed?

- | | | |
|--|-----|----|
| g) Is a batch coding system utilised?
Details of coding (e.g. by date, shift line, operator): | Yes | No |
| h) Can all products be tracked so that the source and destination of individual batches can be identified?
If no, please provide details: | Yes | No |

9. WORKPLACE

- | | | |
|---|-----|----|
| a) Has the applicant had strikes/riots/work stoppages/plant closings in the past three (3) years?
If yes, please describe: | Yes | No |
| b) Has the applicant been the subject of or been threatened with a wrongful termination legal action?
If yes, please describe below or attach details: | Yes | No |

10. HISTORY

- | | | |
|--|-----|----|
| a) Have any products or any of applicant's premises been the subject of comment or complaint by any government agency or department in the past five (5) years? | Yes | No |
| b) Have any products been recalled due to actual, threatened or suspected malicious alteration in the past five (5) years? | Yes | No |
| c) Have any products been recalled in the past five (5) years? | Yes | No |
| d) Has the applicant had any product liability claims in the past five (5) years?
If yes, please describe below or attach details: | Yes | No |
| e) Does the applicant, its directors, officers or any other person to the knowledge of the applicant have knowledge of or information about any fact or circumstance which may reasonably give rise to a claim under the proposed policy?
If yes, please provide details: | Yes | No |

- f) Has any insurer:
- | | | |
|---|-----|----|
| 1. declined to insure the applicant in respect of any coverage(s) proposed for in this application? | Yes | No |
| 2. cancelled or refused to renew the applicant's insurance? | Yes | No |
| 3. imposed special terms to insure the applicant? | Yes | No |
- If yes to any of the above, please provide details including name of insurer:

- g) The answers you have provided to the above questions usually provide sufficient information for a proper consideration of your application, however, if there are any matters which are material to the risk to which this application relates, you must disclose those fact to us in the space provided below:

11. DECLARATION

(To be signed by a Partner, Principal or Director.)

I, the undersigned understand, declare and acknowledge that:

- I am to disclose in this form, fully and faithfully, all the facts that I know or ought to know, otherwise the Policy may not respond to any claim;
- I am, after enquiry, authorised by all person(s) or entities seeking insurance, to make this proposal;
- After enquiry, all information supplied in this proposal and any supporting documents attached to this proposal or supplied separately, is true and correct and that until a Contract of Insurance is entered into, I am obliged to inform Liberty Specialty Markets of any changes to any information supplied or of any new information that is relevant;
- Liberty Specialty Markets relies on the accuracy of the information and documentation supplied proposing for this insurance;
- If a Contract is entered into, all information and documentation supplied in proposing for this insurance shall be incorporated into and form part of such Contract of Insurance;
- I have read the Important Notices including the Privacy Notice which form part of this proposal;
- No insurance is in force until a Contract of Insurance is entered into, which is upon the Proposers acceptance of an offer by Liberty Specialty Markets, if any.

Signature

Date

Name (please print)

Title

Privacy Notice

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Liberty's contact information relevant to your location is set out below.

Hong Kong

Liberty Hong Kong's contact details are:

Address: Suites 2401-4 24/F, 1111 King's Road Tai Koo Shing, Hong Kong
Phone: +852 3655 2600

Liberty is bound by the Personal Data (Privacy) Ordinance (Cap. 486) and its associated Data Protection Principles when it collects and handles your personal data.

Singapore

Liberty Singapore's contact details are:

Address: One Raffles Quay, #40-01 North Tower, Singapore 048583
Phone: +65 6622 9160

Liberty is bound by the Personal Data Protection Act 2012 when it collects and handles your personal data.

Malaysia

Liberty Labuan's contact details are:

Address: 9-7, Wisma UOA Damansara II, No. 6, Jalan Changkat Semantan, Damansara Heights 50490 Kuala Lumpur, Malaysia
Phone: +60 3 2082 4000

Liberty is bound by the Personal Data Protection Act 2010 and its associated Personal Data Protection Principles when it collects and handles your personal data.

Liberty Specialty Markets (**Liberty**) ialah nama dagangan Liberty Specialty Markets Hong Kong Limited (UBI 66395065) (**Liberty Hong Kong**) dan Liberty Specialty Markets Singapore Pte Limited (UEN 201538069C) (**Liberty Singapore**) dengan cawangan di Labuan (No. Syarikat LF12903) (**Liberty Malaysia**). Liberty ialah ahli Liberty Mutual Group yang berpangkalan di Amerika Syarikat.

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Maklumat hubungan Liberty yang berkaitan dengan lokasi anda dinyatakan di bawah.

Hong Kong

Butiran hubungan Liberty Hong Kong adalah seperti berikut:

Alamat: Suites 2401-4 24/F, 1111 King's Road Tai Koo Shing, Hong Kong
Telefon: +852 3655 2600

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Alamat: One Raffles Quay, #40-01 North Tower, Singapore 048583
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Malaysia

Butiran hubungan Liberty Labuan adalah seperti berikut:

Alamat: 9-7, Wisma UOA Damansara II, No. 6, Jalan Changkat Semantan, Damansara Heights 50490 Kuala Lumpur, Malaysia
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