PH

INSURANCE FOR PHARMACEUTICAL COMPANIES

BioSurance™ PH Application Form

This is an application for a liability package policy aimed at the Pharmaceutical sector. As well as products liability, the policy includes pollution and general liability. Limits are available up to £15,000,000. Simply complete the form and return it to your insurance broker.

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INSURANCE FOR PHARMACEUTICAL COMPANIES

APPLICATION FORM

INTRODUCTION

The purpose of this application form is for us to find out who you are and to obtain information relevant to the cover provided by the BioSurance™ PH policy. Completion of this application form does not oblige either party to enter into a contract of insurance.

Insurance is a contract of utmost good faith. This means that the information you provide in this application form must be complete, accurate and not misleading. It also means that you must tell us about all facts and matters which may be relevant to our consideration of your application for insurance. Any failure by you in this regard may entitle us to treat this insurance as if it never existed. If a contract of insurance is agreed between you and us this application form will form the basis of the contract.

Important: Insuring Clauses 3 and 7 provide cover on a claims made and reported basis. Under these Insuring Clauses a claim must be first made against the Insured and notified to us during the period of the policy to be covered. These Insuring Clauses do not cover any claim arising out of any actual or alleged bodily injury or damage occurring before the retroactive date.

HOW TO COMPLETE THIS FORM

Whoever fills out the form must be a senior executive officer of the applicant company and should make all the necessary enquiries of their fellow directors, officers and employees to enable all the questions to be answered.

If you require any extra space to complete the answers to questions contained within this application form please continue your response in the Additional Information section at the back of the form. Once you have completed the form please return it directly to your insurance broker.

SECTION 1: COMPANY DETAILS

1.1 Please provide the following details:

Full name(s) of all companies to be included:

Address:

Postcode:

Company registration number: Country of incorporation:

Year of establishment: Website:

1.2 a) Please state your Employer Reference No. (ERN):

b) Do you have any subsidiaries in the UK? ☐ Yes ☐ No

If 'yes', please complete the Supplementary Information section at the back of this application form.

1.3 Please provide details of your total product sales:

	Last year	Current year	Next year
Total product sales:			

Currency: ☐

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1.4 Please complete the table below with your estimated product sales for the next year:

Product	Ethical on patent		Ethical generic		Over the counter on patent		Over the counter generic	
Licence holder/designer	USA		USA		USA		USA	
	Eur/Can		Eur/Can		Eur/Can		Eur/Can	
	Row		Row		Row		Row	
Own design/ & manufacture	USA		USA		USA		USA	
	Eur/Can		Eur/Can		Eur/Can		Eur/Can	
	Row		Row		Row		Row	
Contract manufacture for others	USA		USA		USA		USA	
	Eur/Can		Eur/Can		Eur/Can		Eur/Can	
	Row		Row		Row		Row	
Final formulator/mixer	USA		USA		USA		USA	
	Eur/Can		Eur/Can		Eur/Can		Eur/Can	
	Row		Row		Row		Row	
Wholesaler/distributor	USA		USA		USA		USA	
	Eur/Can		Eur/Can		Eur/Can		Eur/Can	
	Row		Row		Row		Row	
Importer	USA		USA		USA		USA	
	Eur/Can		Eur/Can		Eur/Can		Eur/Can	
	Row		Row		Row		Row	
Retailer	USA		USA		USA		USA	
	Eur/Can		Eur/Can		Eur/Can		Eur/Can	
	Row		Row		Row		Row	
Other – please describe	USA		USA		USA		USA	
	Eur/Can		Eur/Can		Eur/Can		Eur/Can	
	Row		Row		Row		Row	

1.5 Please provide details of your top 5 products by sales:

Usage	Product	Sales

1.6 Please provide details of any products that fall into these categories:

Usage	Product	Sales
Blood products:		
Weight management / anti-obesity:		
Diabetes:		
Vaccines:		

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1.7 *Please note that the standard CFC policy wording excludes liability arising from or caused by the production, sale, design or provision of the following products:*
If you would like any of these products considered for coverage, please tick 'Y' next to the product and complete the box at the bottom of the page.

DRUG GROUPINGS

Y	N	
		Antipsychotics
		Contraceptives including birth control pills
		Cox - 2 inhibitors
		Dioxins
		Fertility drugs and products specifically designed and marketed for use during and in connection with pregnancy.
		Fibrates
		Erectile dysfunction drugs
		Hormone replacement therapies (HRT)
		Monoclonal antibodies
		Selective serotonin reuptake inhibitors
		Serotonin neorepinephrine reuptake inhibitors
		Statins
		Skin whitening or lightening agents

INDIVIDUAL DRUGS

Y	N	
		Alosetron hydrochloride
		Aprotinin (bovine pancreatic trypsin inhibitor)
		Canthaxanthin
		Cisapride
		Dabigatran
		Danthron
		Debendox
		Dicyclomine (when given to children under 4 years of age)
		Diethylstilbestrol (DES)
		Doxazosin
		Ephedrine (but the exclusion shall not apply to over the counter cough and/or cold medication)
		Fenfluramine (individually or in combination with phentermine)
		Germanium
		Leflunomide
		Metoclomapride
		Methylphenidate
		Nefazodone
		Pioglitazone
		Phenylpropanolamine (PPA)
		Primodos/ amenorone forte
		Tacrolimus
		Thalidomide
		Thimerosal and/or thiomersal
		Thiazolidinediones
		Tretininoin/isotretinoin (retinoic acid or its salts)
		Vigabatrin

If you have ticked "Y", to any of the above, please explain in the box below.

Product	Sales to	Sourced from	Sales

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1.8 If you export products to the USA please provide a full description of all products exported:

Usage	Product	Year first exported	Sales

1.9 Do you have assets in the USA? ☐ Yes ☐ No

1.10 Do the USA importers of your product have Products Liability Insurance which covers your products exported? ☐ Yes ☐ No

If you have ticked "Yes" to questions 1.8 or 1.9, please provide details:

1.11 If you import products or raw materials please state from where and percentage of total sales:

Country	% of total sales
	%
	%
	%
	%

SECTION 2: RISK MANAGEMENT

2.1 Do you sample and keep records of incoming products or raw materials and outgoing products? ☐ Yes ☐ No

2.2 Is there an emergency product recall process in place? ☐ Yes ☐ No

2.3 Are all products licenced in accordance with legislation or regulations relating to licencing of medicines, drugs, cosmetics, dietary or medical devices in the country in which the product is sold? ☐ Yes ☐ No

2.4 Are all products approved for marketing by the applicable regulatory body in the country in which the product is sold where prior approval is required by legislation or regulations? ☐ Yes ☐ No

2.5 Are all products labelled and supplied with clear instructions in the language of the country to which they are supplied? ☐ Yes ☐ No

2.6 Are product hazard warnings clearly shown on product packaging and instructions? ☐ Yes ☐ No

2.7 Are adequate records in place to identify the source of design and supply of products or raw materials supplied to you? ☐ Yes ☐ No

2.8 Are rights of subrogation maintained against all suppliers? ☐ Yes ☐ No

2.9 Has any insurer has ever declined to insure, declined to renew or terminated a policy of insurance of yours? ☐ Yes ☐ No

If you have ticked "No" to any of the above, please explain in the box below:

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SECTION 3: CLAIMS EXPERIENCE

3.1 In the last ten years have any of your products:

Been withdrawn or recalled from the market? ☐ Yes ☐ No Been discontinued for safety reasons? ☐ Yes ☐ No

Been subject of an FDA Black Box Warning? ☐ Yes ☐ No

If you have ticked "Yes" to any of the above, please give full details in the box below:

Date	Details

3.2 Have any claims or incidents occurred during the last five years resulting, or alleged to have resulted in death, injury or disease to third parties or damage to their property? ☐ Yes ☐ No

OR

Are you aware of any circumstances which may give rise to such a claim? ☐ Yes ☐ No

If you have ticked "Yes" to any of the above, please give full details in the box below:

Date	Details	Paid	Reserved

SECTION 4: COMMERCIAL PROPERTY & BUSINESS INTERRUPTION INSURANCE

Only complete section if you require this cover.

4.1 Please state the address of the premises to be insured (if different from the address given earlier):

PREMISES 1

Address:

Postcode:

PREMISES 2

Address:

Postcode:

Please continue on a separate sheet if more than 2 premises are to be insured.

4.2 Please detail below any other party (such as a bank or building society) whose financial interest in the premises should be noted on the policy:

Name of party:

Interest of party:

Address:

Postcode:

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4.3 Please provide details of the premises of your supply chain partners that carry out significant work on your behalf, including those where you require cover for damage to your property and those where you have a significant reliance on them for your business activities:

SUPPLY CHAIN PARTNER 1

Address:

Postcode:

Details of usage:

SUPPLY CHAIN PARTNER 2

Address:

Postcode:

Details of usage:

Please continue on a separate sheet if more than two premises are to be insured.

4.4 Are all of the premises:

a) Constructed with external walls of brick, stone or concrete and roofed with slate, tiles, concrete, metal, asbestos or any other non-combustible material? ☐ Yes ☐ No

b) Free from cracks or other signs of damage that may be due to subsidence, landslip or heave and have not previously suffered damage by any of these causes? ☐ Yes ☐ No

c) In an area free from flooding and not near the vicinity of any rivers, streams or tidal waters? ☐ Yes ☐ No

d) In a good state of repair and occupied solely as offices? ☐ Yes ☐ No

e) Self contained with a lockable entrance door? ☐ Yes ☐ No

f) Protected by an intruder alarm that is subject to an annual maintenance contract? ☐ Yes ☐ No

NOTE: We may refuse to pay a claim if all of the devices for the security of your premises (including locks and the intruder alarm) are not put into full and effective operation whenever the premises are closed for business or left unattended.

g) Heated by a conventional electric, gas, oil or solid fuel heating system? ☐ Yes ☐ No

h) Fitted with electrical installations which are inspected at least every 5 years by a qualified electrician and any defect remedied? ☐ Yes ☐ No

i) Lifts, boilers, steam and pressure vessels inspected and approved to comply with all of the statutory requirements? ☐ Yes ☐ No

j) Fitted with sprinklers, either fully or partially? ☐ Yes ☐ No

NOTE: Assuming you have answered 'yes' to questions h) and i) above, it is important to keep records of all relevant inspections as we may ask for evidence of these before paying a claim.

If you have answered 'no' to any of the above questions then please give further details:

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4.5 If any of the premises listed in 4.1 and 4.3 contain composite or sandwich panels, please provide details:

Address	Are panels exterior or interior?	Type of panel (Make, model, core material)	Are products LPS1181: 2003 or FMRC4880 (1994) approved?

4.6 Please provide details of your contingency plans to continue your business activities, if damage at the premises listed in 2.2 means your supply chain partners are unable to fulfil contractual commitments:

Supplier name	Nature of reliance	Contingency plans

4.7 Is your stock sensitive to changes in environmental conditions? ☐ Yes ☐ No

If 'yes', please answer the following:

a) What proportion of stock is temperature sensitive? %

b) Is all stock stored in fridges / freezers which are less than 3 years old, or subject to maintenance agreements? ☐ Yes ☐ No

c) Is all electrical equipment and switch gear protected by anti-power surge devices? ☐ Yes ☐ No

d) Are all fridges / freezers connected to automatic self starting power generators? ☐ Yes ☐ No

If 'yes', how many hours back up is provided? Hours

e) Do you have an alarm system that activates if the temperature falls outside the prescribed range? ☐ Yes ☐ No

f) Is the alarm system monitored by a third party central station? ☐ Yes ☐ No

g) Is stock duplicated in more than one freezer on the same site? ☐ Yes ☐ No

h) Is stock duplicated in more than one freezer at different sites? ☐ Yes ☐ No

i) Do you have a formal Business Continuity Plan for a power outage or failure in storage arrangements? ☐ Yes ☐ No

j) Are specialist couriers used if stock is moved? ☐ Yes ☐ No

4.8 a) Is cover for stock in transit required? ☐ Yes ☐ No

If 'yes', please state the stock consignement values:

	Annual value	Maximum value of one consignment
Domestic:		
Outside (domestic) country, but within the continent:		
Elsewhere in the world:		

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b) Will you transport stock to areas where the government currently advises against travel? ☐ Yes ☐ No
If 'yes', please provide details:

4.9 Please detail the amounts to be insured below for each premises:

NOTE: The amounts insured you state below should be the full rebuilding or replacement cost in each of the categories. If you understate these amounts you will be under-insuring and we may not pay the full amount of your claim. It is therefore essential that these amounts are as close to the true values of the insured items as possible.

ITEM	AMOUNT INSURED PREMISES 1	AMOUNT INSURED PREMISES 2
Main building:		
Landlord's fixtures & fittings and tenant improvements:		
Personal computers, printers and ancillary computer equipment at your premises:		
All other contents at your premises:		
Portable computers and associated equipment at home / away from your premises:		
All other contents at home / away from your premises:		

4.10 Please state, in respect of portable computers and associated equipment at home / away from your premises, the maximum value of any one item (not the total value of all items):

4.11 Please detail the amounts to be insured below for Business Interruption cover. Note that the maximum indemnity period available is 12 months. You should bear in mind how long it will take you to re-commence trading at another premises when stating the amount insured and indemnity period.

We provide our Business Interruption cover on a 'Flexible First Loss' basis – please specify a total amount insured for Business Interruption cover. This amount applies regardless of whether your business interruption loss is loss of income, extra expense, loss of research and development expenditure, project delay costs or accounts receivable. This often enables a smaller total amount insured to be specified and therefore often results in a cheaper premium.

ITEM	AMOUNT INSURED	INDEMNITY PERIOD
Business Interruption cover (Flexible First Loss):		

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SECTION 5: INSURANCE HISTORY

5.1 Please provide details of your current insurance:

Type	Expiry Date	Retroactive Date	Insurer
Property & Business Interruption:	DD / MM / YY	N/A	
Employers' & Public Liability:	DD / MM / YY	N/A	
Products Liability:	DD / MM / YY	DD / MM / YY	
Clinical Trials:	DD / MM / YY	DD / MM / YY	

5.2 Has any insurer ever declined to insure, declined to renew or terminated a policy of insurance of yours? ☐ Yes ☐ No

If you have ticked "Yes", please give full details in the box below:

SECTION 6: DECLARATION

I declare that AFTER ENQUIRY the information provided in this application form is true and complete and that I have not mis-stated or suppressed any material fact.

- I agree that this application form, together with any other material information supplied by me, shall form the basis this contract of insurance.
- I undertake to inform underwriters of any material alteration to these facts occurring before the inception of the Policy.

Signed ______________________ Full Name ______________________

Position held ______________________ Date DD / MM / YY

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ADDITIONAL INFORMATION:

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SUPPLEMENTARY INFORMATION

SUBSIDIARY 1

Company name: ERN:

Address:

Postcode:

SUBSIDIARY 2

Company name: ERN:

Address:

Postcode:

SUBSIDIARY 3

Company name: ERN:

Address:

Postcode:

SUBSIDIARY 4

Company name: ERN:

Address:

Postcode:

If you have more than 4 subsidiaries please continue your response in the Additional Information section.

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