

# Biomedical and life sciences combined

## 2018 Proposal form

### **Important notice:**

1. This is a proposal for a contract of insurance, in which 'proposer' or 'you/your' means the individual, company, partnership, trust, charity, establishment or association proposing for cover
2. This proposal must be completed in ink, signed and dated. All questions must be answered to enable a quotation to be given but completion does not bind you or Underwriters to enter into any contract of insurance. If space is insufficient to answer any question fully, please attach a signed continuation sheet. You should retain a copy of the completed proposal (and of any other supporting information) for future reference.
3. You are recommended to request a specimen copy of the proposed policy or certificate from your insurance broker and to consider carefully the terms, conditions, limitations and exclusions applicable to the cover. The proposed insurance covers only those losses which arise from certain events discovered or claims made against the Assured during the period of insurance, as specified in the policy or certificate.
4. Part A – General information is mandatory and must be completed by all proposers  
Part B – Property and business interruption is optional and should only be completed if cover is required  
Part C – Declarations is mandatory and must be completed by all proposers

## PART A – General information (mandatory)

### 1 General information

- (i) Name of Proposer
- (ii) Address
- (iii) Website address
- (iv) Year established


- (v) Employment Reference Number for each entity to be included in this agreement

Entity	ERN
a.	
b.	
c.	

### 2 Business description

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### 3 Income

- (i) Please provide a split in your projected annual revenue for the forthcoming period of insurance between the following geographical areas:

a. United Kingdom	£
b. United States of America	£
c. Elsewhere	£

- (ii) What percentage of your activities relate to the research and development of your own product \_\_\_\_\_ %

- (iii) To help us understand your business, please provide a further split in your projected annual revenue by type of activity and field of specialism.

	1) Own product manufacture &/or sale	2) Contract manufacture for third parties	3) Distribution or retail of third party branded product
a. Medicinal products	£	£	£
b. Medical devices	£	£	£
c. Laboratory equipment	£	£	£
d. Food supplement	£	£	£
e. Total diet replacement	£	£	£
f. Food for special medical purposes	£	£	£
g. Cosmetics	£	£	£
h. Cosmetic devices	£	£	£
i. Other	£	£	£
Total	£	£	£

- (iv) Do you provide professional services for a fee or where a fee would normally be charged

Yes  No

a. Please describe those services

b. What fee income do you derive from these services

£

- 4 Do you have any past, present or planned future products classified as or include any of the substances listed in appendix 1 Yes  No
- If Yes please indicate which are applicable on Appendix 1
- 5 Do you have any past, present or planned future products classified as or include any of the product categories listed in appendix 2 Yes  No
- If Yes please indicate which are applicable on Appendix 2
- 6 Are any of your past, present or planned future products classified as, or include;
- (i) an in vitro diagnostic listed under annex II of Directive 98/79/EC Yes  No
  - (ii) a class IIa or IIb invasive medical device for long term use (more than 30 days) Yes  No
  - (iii) class III medical device Yes  No
  - (iv) a custom made medical device Yes  No
  - (v) radioactive material Yes  No
  - (vi) an orthotic device with functional electric stimulation (FES) Yes  No
  - (vii) devices used for cleaning or disinfecting medical instruments or devices Yes  No
- 7 Are any of your past, present or planned future products classified as, or include;
- (i) a generic drug, biosimilar or advanced therapy medicinal product Yes  No
  - (ii) food supplements
    - a. that make claims of having properties of preventing or treating disease in human beings Yes  No
    - b. for animals Yes  No
    - c. specifically designed for children, pre natal or post natal care Yes  No
    - d. for sexual dysfunction Yes  No
  - (iii) a sports nutritional supplement Yes  No
  - (iv) cosmetics containing a classified Carcinogenic, Mutagenic or Reprotoxic (CMR) substance Yes  No
  - (v) hair dyes, skin lightening products, sunless tanning products, nail care products or chemical peels Yes  No
  - (vi) tattoo equipment and accessories / tattoo ink / black or natural henna (lawsone (2-hydroxy-1,4-naphthoquinone)) Yes  No
  - (vii) nanomaterial (1nm-100nm) Yes  No
  - (viii) sunscreen Yes  No
  - (ix) cosmetic skin rejuvenation devices Yes  No
  - (x) cosmetic laser systems, intense pulsed light (IPL) equipment or light emitting diode (LED) devices Yes  No

- (xi) muscle stimulation/toning devices Yes  No
- 8 Do any of your activities include
- (i) contract manufacturing of products where you deviate from specifications provided by your customer including but not limited to use of approved raw materials, ingredients, parts and methods. Yes  No
- (ii) the operation of an inpatient facility Yes  No
- (iii) testing for paternity, drug or substance abuse, HIV, TSE or Hep C, environmental, marine or agricultural pollution. Yes  No
- (iv) acting as a European Authorised Representative for a non-European manufacturer Yes  No
- (v) importing in to the territory a finished product from outside the European Economic Area Yes  No
- (vi) the distribution or retail of a third party branded product where you are NOT indemnified by the manufacturer for liability for damages arising from a defect in that product. Yes  No
- (vii) subcontracting the design, manufacture, assembly, packaging or installation of your product to a third party organisation Yes  No
- (viii) the personal fitting of orthopaedic devices Yes  No
- (ix) sterilisation, configuration, repair, adaptation, translation of, or writing of instructions or relabeling (other than delivery notes) of a third party product Yes  No
- (x) sponsoring clinical trials Yes  No
- (xi) selling products or services over the internet to territories outside the European Economic Area Yes  No
- (xii) laboratories NOT working to ISO15189 or compliant with EU 2004/9/EC and EU 2004/10/EC Yes  No
- (xiii) working with Group 3 or Group 4 biological agents Yes  No
- 9 Compliance
- (i) are you aware of any pervasive off label use, misuse or deviation from instructions for use of any of your products. Yes  No
- (ii) have any of your past or present products or services been provided by you without the required license or registration from the relevant regulatory body in the territory in which they are to be distributed e.g. marketing authorisation or CE mark. Yes  No
- (iii) are any of your products, subject to the European Black Triangle Scheme, a prohibited or restricted herbal ingredient, a Traditional Chinese Medicine or Herbal Medicine not granted a traditional herbal registration (THR) Yes  No
- (iv) are you aware of any circumstance where
- (a) your product or service is not lawfully allowed to be sold or performed in any of Your chosen markets Yes  No
- (b) there is any connection between you and/or your business, your product or service and a country or person subject to trade sanctions or embargoes asserted by the United Kingdom (UK), European Union (EU), United Nations (UN) or United States of America (USA) Yes  No

- (c) your back office systems have not prevented or will not prevent sales to these territories? Yes  No
- 10 Have you ever
- (i) been subject to an enforcement notice, warning letter or other punitive action by a relevant regulatory body Yes  No
- (ii) been subject to corrective or preventative action by a regulatory body in respect of good manufacturing practice (cGMP) Yes  No
- (iii) manufactured, sold or supplied any products subject to an unexpected or unintended serious side effect, adverse drug reaction, medical device adverse incident or serious undesirable effect Yes  No
- (iv) manufactured, sold or supplied any products withdrawn or discontinued due to a safety, efficacy or performance reason; initiated by you or a relevant regulatory body Yes  No
- 11 Do you always obtain qualified legal advice in all the countries to which You are selling or plan to sell your product or service to ensure compliance with all relevant legislation, regulation and local customs? Yes  No
- 12 Do you ever agree to
- (i) unilateral hold harmless agreements Yes  No
- (ii) waiver of any of your rights and remedies Yes  No
- (iii) any form of indemnification to anyone other than the parties to the contract Yes  No
- 13 Can you confirm you have a written contract with all your customers, vendors, partner companies and suppliers Yes  No
- 14 Where a written contract exists, can you confirm it includes
- (i) a force majeure clause Yes  No
- (ii) a consequential loss exclusion Yes  No
- (iii) a reasonable limitation of your liability Yes  No
- (iv) a detailed description of the obligations of each party Yes  No
- (v) a description of the standard of care that you will provide Yes  No
- (vi) a termination clause Yes  No
- (vii) dispute resolution / mediation procedure Yes  No
- (viii) a clause making the contract subject to the exclusive jurisdiction of English and Welsh or Scottish courts? Yes  No
- 15 Can you confirm
- (i) all changes to contracts are documented and signed off by all parties Yes  No
- (ii) the terms and conditions of your contract satisfy the "test of reasonableness" under the Unfair Contract Terms Act 1977 Yes  No

## **PART B – Property damage and business interruption (optional)**

- 16 Can you confirm that
- (i) the premises are in a good state of repair and the buildings do not have listed status and were built after 1800 Yes  No
- (ii) the buildings are constructed of brick, stone or other non-combustible materials and roofed with slates, tiles, metal, concrete, asphalt, asbestos or other non-combustible materials Yes  No
- (iii) the buildings are not fitted with composite insulated panels systems (internally or externally) Yes  No

- (iv) where the buildings have flat roof sections, the flat roof has been adequately maintained or is less than 10 years old. Yes  No
- (v) you have no property located in a basement Yes  No
- (vi) the buildings are securely locked and protected as per Appendix 3 Yes  No
- 17 Do your activities include
- (i) unattended heat processes or unattended overnight processes Yes  No
- (ii) the use of volatile chemicals/combustible materials not stored in accordance with The Dangerous Substances and Explosive Atmospheres Regulations (DSEAR) Yes  No
- (iii) work with combustible metals or filling of aerosols Yes  No
- (iv) storage of branded pharmaceuticals, computer hardware, electronic components, nonferrous metals, controlled drugs or radioactive materials Yes  No
- (v) work with property very sensitive to changes in its environment or contamination, including but not limited to temperature or humidity Yes  No
- (vi) use of clean rooms Yes  No
- (vii) the creation of physical property through research and development Yes  No
- 18 Can you confirm that
- (i) property stored on racking does not exceed 3 meters Yes  No  N/A
- (ii) attended processes using heat are covered by an appropriate automatic fire suppression system; or, the operator is provided with and trained to use suitable fire suppression apparatus for the process being undertaken Yes  No  N/A
- (iii) where rider operated lift trucks (e.g. fork lift truck) are in operation
- a. battery charging is undertaken in a dedicated and well-ventilated area, free of combustible materials. Yes  No  N/A
- b. vulnerable walls, supports and racking are protected from impact Yes  No  N/A
- (iv) extraction ducting of volatile or heat processes is compliant with EN1366-1,5,8 & 9 Yes  No  N/A
- 19 Can you confirm that
- (i) in the event of a loss suitable alternative premises and property (including stock, raw materials, research property, specialist tools/machinery and clean rooms) are available to you for the continuation of your business activities within 30 days. Yes  No
- (ii) you have no property that requires continuous power to prevent it being damaged Yes  No
- (iii) business critical information is backed up daily and removed from site at least once a week Yes  No

## **PART C – Declarations (mandatory)**

- 20 (i) Has any director, manager, partner or trustee of yours or any person insured or proposing for insurance
- a. been convicted, or charged but not yet tried, of any criminal offence other Yes  No

- than a motoring offence?
- b. been declared bankrupt, gone into insolvent liquidation or been the subject of receivership or an administration order? Yes  No
- (ii) Have you ever had an application for this type of insurance declined by an insurer, had a renewal of such insurance declined or had similar insurance cancelled or made subject to special conditions? Yes  No
- (iii) Within the last five years have you or any person insured or proposing for insurance to which this proposal relates
- a. had any claim, prosecution, proceedings or investigations made or instigated against them whether successful or otherwise? Yes  No
- b. suffered any loss or made any claim (whether insured or not) which would have fallen within the scope of the proposed insurance irrespective of whether or not such loss or claim relates to the property insured or proposed for insurance? Yes  No
- (iv) Are you or any person insured or proposing for insurance aware, AFTER ENQUIRY, of any CIRCUMSTANCE OR INCIDENT which they have reason to suppose might afford grounds for any future claim that would fall within the scope of the proposed insurance which has not already been advised to us? Yes  No

### **Important information concerning your personal information**

*Please carefully read the following before you sign and date the declaration.*

Your insurance cover includes cover for individuals who are either insureds or beneficiaries under the policy (individual insureds). We collect and use relevant information about individual insureds to provide you with your insurance cover and to meet our legal obligations.

This information includes individual insureds' details such as their name and address [and may include more sensitive details such as information about their health and criminal convictions].

We will process individual insureds' details, as well as any other personal information you provide to us in respect of your insurance cover, in accordance with our full Markel privacy notice, a copy of which is available online at <http://www.markelinternational.com/foot/privacy-policy/> or on request.

#### Information notices

To enable us to use individual insureds' details in accordance with current data protection laws, we need you to provide those individuals with certain information about how we will use their details in connection with your insurance cover.

You agree to provide to each individual insured this short form information notice on or before the date that the individual becomes an individual insured under your insurance cover or, if earlier, the date that you first provide information about the individual to us.

#### Minimisation and notification

We are committed to using only the personal information we need to provide you with your insurance cover. To help us achieve this, you should only provide to us information about individual insureds that we ask for from time to time.

You must promptly notify us if an individual insured contacts you about how we use their personal details in relation to your insurance cover so that we can deal with their queries.

### **Important information concerning your duty to make a fair presentation of risk**

*Please carefully read the following before you sign and date the declaration.*

Before the insurance policy takes effect you have a duty to make a fair presentation of the risks to be insured.

A *fair presentation of the risk* is one

- which discloses to us every material circumstance which you know of or ought to know of, or

- gives us sufficient information to put us on notice that we will need to make further enquiries for the purpose of revealing those material circumstances, and
- which makes that disclosure in a manner which is reasonably clear and accessible to us, and
- in which every material representation as to a matter of fact is substantially correct and every material representation as to a matter of expectation or belief is made in good faith.

A *material circumstance* is one that would influence our decision as to whether or not to agree to insure you and, if so, the terms of that insurance. If you are in any doubt as to whether a circumstance is material you should disclose it to us.

Failure to make a fair presentation of risk could prejudice, reduce or modify your rights under the policy.

21. I declare that

- I am authorised to complete this proposal on behalf of the Proposer
- every statement and particular within this proposal form
  - which is a statement of fact, is substantially correct, and
  - which is a matter of expectation or belief, is made in good faith

If any such facts, expectations and/or beliefs materially change before the insurance policy takes effect I will undertake to provide details of all such changes to you in order to comply with my obligation to provide a fair presentation of the risk to be insured under the insurance policy.

Signed :

Name:

Capacity:

Date:

## Appendix 1

As per Part A – General information; Question 4. Please indicate which categories or ingredients are applicable; including any derivative, extract, adulterated botanical or botanical derivative or that contains or has the same or similar chemical formula, structure of function of the following substances

- |   |                          |   |                          |
|---|--------------------------|---|--------------------------|
| • 1,4 butanediol (BD)   | <input type="checkbox"/> | • kava-kava (piper methysticum)   |                          |
| • 1,3-dimethylbutylamine, (1,3 DMBA) AMP citrate (4-amino -2-methylpentane citrate) | <input type="checkbox"/> | • larrea tridentata (chaparral)   | <input type="checkbox"/> |
| • alosetron   | <input type="checkbox"/> | • lobelia   | <input type="checkbox"/> |
| • anabolic steroids (natural or synthetic)  | <input type="checkbox"/> | • l-tryptophan (only when used for or as part of a physically ingestible product) | <input type="checkbox"/> |
| • aprotinin   | <input type="checkbox"/> | • magnolia  | <input type="checkbox"/> |
| • aristolochic acids  | <input type="checkbox"/> | • meprobamate   | <input type="checkbox"/> |
| • bismacine   | <input type="checkbox"/> | • methyl methacrylate (MMA)   | <input type="checkbox"/> |
| • botulinium toxin  | <input type="checkbox"/> | • methylphenidate   | <input type="checkbox"/> |
| • cannabidiol (CBD)   | <input type="checkbox"/> | • metoclopramide  | <input type="checkbox"/> |
| • cisapride   | <input type="checkbox"/> | • mibefradil  | <input type="checkbox"/> |
| • clopidogrel   | <input type="checkbox"/> | • mitragyna speciosa (kratom)   | <input type="checkbox"/> |
| • cox-2-inhibitor products  | <input type="checkbox"/> | • olmesartan  | <input type="checkbox"/> |
| • dabigatran  | <input type="checkbox"/> | • orlistat  | <input type="checkbox"/> |
| • dextropropoxyphene and/or propoxyphene  | <input type="checkbox"/> | • phentermine   | <input type="checkbox"/> |
| • diethylstilbestrol (DES) or stilbestrol   | <input type="checkbox"/> | • phenylpropanolamine   | <input type="checkbox"/> |
| • dimethylamylamine (DMAA)  | <input type="checkbox"/> | • p-Phenylenediamine (PPD)  | <input type="checkbox"/> |
| • ephedra or ephedrine or ephedrine derivatives                                     | <input type="checkbox"/> | • primodos  | <input type="checkbox"/> |
| • fenfluramine or dexfenfluramine   | <input type="checkbox"/> | • pyrrolizidine alkaloids (comfrey)   | <input type="checkbox"/> |
| • finasteride   | <input type="checkbox"/> | • stephania tetrandra   | <input type="checkbox"/> |
| • flupirtine  | <input type="checkbox"/> | • tetrazepam  | <input type="checkbox"/> |
| • gamma buyrolactone (GBL)  | <input type="checkbox"/> | • thalidomide   | <input type="checkbox"/> |
| • gamma hydroxy butyrate (GHB)  | <input type="checkbox"/> | • thiazolidindiones   | <input type="checkbox"/> |
| • germander   | <input type="checkbox"/> | • thimerosal  | <input type="checkbox"/> |
| • germanium   | <input type="checkbox"/> | • triclosan (where sold in the United States of America)                          | <input type="checkbox"/> |
| • glyburide   | <input type="checkbox"/> | • Triphenyl Phosphate (TPP/TPHP)  | <input type="checkbox"/> |
| • hydroquinone  | <input type="checkbox"/> | • trovafloxacin   | <input type="checkbox"/> |
| • isotretinoin  | <input type="checkbox"/> | • varenicline   | <input type="checkbox"/> |
| • jin bu huan   | <input type="checkbox"/> | • yohimbe   | <input type="checkbox"/> |

## Appendix 2

As per Part A – General information; Question 5. Please indicate which product categories are applicable;

- |   |                          |  |                          |
|---|--------------------------|--|--------------------------|
| • anticonvulsants   | <input type="checkbox"/> | • hydroxyquinoline derivative products   | <input type="checkbox"/> |
| • antidepressants   | <input type="checkbox"/> | • impotence; medicinal products for  |                          |
| • antiepileptics  | <input type="checkbox"/> | treatment of   | <input type="checkbox"/> |
| • antiperspirants containing aluminium                                      | <input type="checkbox"/> | • incretin mimetics  | <input type="checkbox"/> |
| • attention deficit hyperactivity disorder (adhd) drugs                     | <input type="checkbox"/> | • infusion systems and pumps   | <input type="checkbox"/> |
| • atypical antipsychotics   | <input type="checkbox"/> | • metal-on-metal implants  | <input type="checkbox"/> |
| • birth control or fertility products (other than male and female condoms)  | <input type="checkbox"/> | • opiates/opioids  | <input type="checkbox"/> |
| • bisphosphonates   | <input type="checkbox"/> | • pregnant women; medicinal products specifically designed for                                   | <input type="checkbox"/> |
| • blood products / products derived from human blood                        | <input type="checkbox"/> | • prohibited or restricted herbal ingredient (as defined by MHRA or local equivalent)            | <input type="checkbox"/> |
| • di-(2-ethylhexyl)phthalate (DEHP)   | <input type="checkbox"/> | • retinoids  | <input type="checkbox"/> |
| • diazepines oxazepines or thiazepines                                      | <input type="checkbox"/> | • silicone gel or liquid silicone when used as part of an implantable medical device             | <input type="checkbox"/> |
| • dopamine agonists   | <input type="checkbox"/> | • supplements used in body building or sport other than Sports Nutrition                         | <input type="checkbox"/> |
| • gadolinium-containing contrast agents                                     | <input type="checkbox"/> | • surgical mesh used in urogynecology  | <input type="checkbox"/> |
| • gliptins  | <input type="checkbox"/> | • Traditional Chinese Medicine or herbal medicines not granted a traditional herbal registration | <input type="checkbox"/> |
| • hmg coa reductase inhibitor products (statins)                            | <input type="checkbox"/> | • vaccines (prophylactic)  | <input type="checkbox"/> |
| • hormone pregnancy tests (HPT)   | <input type="checkbox"/> | • weight management; medicinal products specifically designed for                                | <input type="checkbox"/> |
| • hormone replacement products / hormone replacement therapy products (HRT) | <input type="checkbox"/> |  |                          |
| • hydroxyethyl starch (HES) solutions for infusion                          | <input type="checkbox"/> |  |                          |

## Appendix 3

### SECURELY LOCKED AND PROTECTED SHALL MEAN

- (a) automatic intruder detection systems are operational throughout unoccupied areas of your premises and out of business hours, which
  - (1) Were installed by a NSI Gold certified installer
  - (2) incorporate both perimeter and infrared detection, and
  - (3) are connected to an automatic intruder alarm, and
  - (4) features confirmed technology, and
  - (5) signals to a manned central station via a dual path communication system
- (b) level 1 police response is in force at all premises
- (c) all external doors (and any internal doors leading to any part of the Buildings not in your sole occupation) are secured with either
  - (1) if an aluminium door: a cylinder mortice deadlock, or
  - (2) if an armoured plate door: the door manufacturer's locks as supplied, or
  - (3) if a UPVC door: a multi-point locking system incorporating a minimum of 3 deadbolts
  - (4) if any other type of single leaf door
    - (i) where the door thickness is at least 4.5 cm: a five lever mortice deadlock to at least British Standard 3621 together with a 17.5 cm boxed steel striking plate
    - (ii) where the door is less than 4.5 cm thick: a deadlocking rim latch keyed into the deadlock position or a mortice deadlock and two key operated security bolts engaging with the door frame and with internal operation only
  - (5) if double leaf doors:
    - (i) the standing leaf is secured with internal surface mounted key operated security bolts or concealed flush bolts sited top and bottom engaging with the door frame and the floor, and
    - (ii) the final closing leaf is secured with either a lock fitted as above dependent on door type or both leaves fitted with a coach-bolted locking bar secured with a close shackle padlock (or, if the locking bar is sited internally, either a close or open shackle padlock) having at least five levers
  - (6) if a designated fire door: either
    - (i) a panic bar locking system incorporating bolts which engage both the head and sill of the door frame, or
    - (ii) a mortice lock having specific application for emergency exit doors and which is operated from the inside by means of a conventional handle and/or thumb turn mechanism
- (d) all external ground floor windows, accessible windows and/or skylights, originally designed to open are secured with either
  - (1) key operated window locks, or
  - (2) adequately secured metal bars or grilles, external or internal metal shutters or internal collapsible metal security grill, or
  - (3) screwed shut.