Proposal Form

Specialty Liability

(Public and Products Liability, Professional Indemnity, Clinical Trials, Employers Liability)

Sections A (Page 2) and F (Page 22) should be completed by ALL proposers. Complete sections B to E as required:

Section B (Page 3)
– Public and Products Liability

Protects those who manufacture and/or distribute:

- Medical & Surgical Products
- Pharmaceuticals & Drugs
- Supplements & Cosmetics
- Scientific & Technical Equipment

Cover is also provided in respect of your general liabilities (for example, property owner's/ occupier's liability).

Section C (Page 12)
– Professional Indemnity

Insures the Professional Risks of

(i) Product Designers (including those who build 'prototypes'), and/or

(ii) Those who manage or report upon the outcome of clinical trials and investigations in respect of claims made against them for negligent acts, errors and omissions (but not in respect of claims by participants in clinical trials).

Section D (Page 18)
– Clinical Trials

Provides protection for those who conduct clinical trials and investigations in respect of claims made against them by the participants in the trials.

Section E (Page 21)
– Employers Liability

Insures the traditional employer risk but is only available if Public and Products Liability cover is taken.

N.B. THE EMPLOYERS LIABILITY SECTION IS NOT AVAILABLE IN ISOLATION

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. All facts material to the proposed insurance must be disclosed, fully and truthfully to the best of your knowledge and belief. Failure to do so may make the contract of insurance voidable or severely prejudice your rights in the event of a claim. A material fact is one likely to influence Underwriters' assessment or acceptance of the proposal; if you are uncertain what may be a material fact, you should consult your broker.

4. 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.

SECTION A - GENERAL SECTION (Mandatory)

1 Name of Proposer

Address of Registered or Principal Office

Post Code

Tel No.:

Fax No.:

E-mail address:

Web site address:

Registered Number (if applicable)

2 Date Business established

SECTION B - PUBLIC AND PRODUCTS LIABILITY (Optional)

This section provides protection in respect of claims made against you arising from your business activities (other than your professional services) and products which you have supplied etc.

Please attach any product literature, specimen brochures, conditions of sale, sales literature or technical information relating to your products.

3 Please state your turnover for each of your last three complete financial years and your estimated turnover for your current financial year:

Financial year 20___ to 20___	£
Financial year 20___ to 20___	£
Financial year 20___ to 20___	£
Financial year 20___ to 20___	£

4 For your current financial year please provide a breakdown of your estimated turnover by product and geographical area and indicate whether such turnover is derived from manufacture, wholesale/distribution, and/or as royalties:

(If insufficient space please continue on a separate sheet)

Product **(Provide brief description of the product, including how long you have been producing it and it's intended function)**	**Manufacture**	**Wholesale / Distribution**	**Royalties**	**UK/EU**	**USA**	**Canada**	**Elsewhere**
	(indicate ✔ as appropriate)						
Medical & Surgical Products							
1							
2							
3							
4							
5							
Pharmaceuticals & Drugs **(a) Ethical (prescribed)**							
1							
2							
3							
4							
5							
Pharmaceuticals & Drugs **(b) Non-ethical (over the counter)**							
1							
2							
3							
4							
5							

Product **(Provide brief description of the product, including how long you have been producing it and it's intended function)**	**Manufacture**	**Wholesale / Distribution**	**Royalties**	**UK/EU**	**USA**	**Canada**	**Elsewhere**
	(indicate ✔ as appropriate)						
Supplements & Cosmetics							
1							
2							
3							
4							
5							
Scientific & Technical Equipment							
1							
2							
3							
4							
5							
Other (please specify)							
1							
2							
3							
4							
5							
TOTAL							

5 Can you confirm that within the last five years there have been no major changes in the geographical distribution of your turnover?

YES ☐ NO ☐

If NO please provide full details

6 Can you confirm that your products do not include or involve the use of any drugs or ingredients specified in Addenda A (page 25) of this proposal form?

YES ☐ NO ☐

If NO please provide full details

(**N.B.** claims resulting from or relating to such drugs or ingredients are likely to be excluded from any cover agreed with underwriters)

7 Within the last five years has there been any fundamental change in either the products produced or your business activities (including any acquisition or disposal of operations or companies)?

YES ☐ NO ☐

If YES please provide full details

8 Within the last five years have any products been

(a) withdrawn or recalled (whether voluntary or not)?

(b) discontinued because of incidences of injury or damage or where potential hazards have been identified?

YES ☐ NO ☐

If YES please provide full details

9 Do all goods or products sold, supplied etc **and** all imported materials, components etc comply with both

(a) UK and EU regulatory requirements and standards **and**

(b) the government (whether federal, state, or local) and/or regulatory requirements of the countries outside of the European Community to which the goods or products are exported?

YES ☐ NO ☐

If NO please provide full details

10 Do others produce products (including assembly, packaging or installation) under your name or label?

YES ☐ NO ☐

If YES please provide full details including details of how you maintain your rights and remedies against such persons (a copy of your standard contract terms and conditions should be provided)

11 Do you sell, supply, process, install, service, repair, alter, treat or renovate goods or products on behalf of others?

YES ☐ NO ☐

If YES please provide full details

12 Can you confirm that

(a) you have a quality control and testing procedure in place (including in respect of imported materials and components)?

(b) you can identify your product from those of your competitors?

(c) your records show to whom and when each product was sold or supplied?

(d) you ensure that your suppliers have adequate Products Liability insurance in force which provides an indemnity to you?

YES ☐ NO ☐

If NO please provide full details

13 Please provide details of any industry standards to which you conform

14 How long are quality control and testing records kept?

15 Who designs your products?

16 Can you confirm that

(a) designs of products are reviewed, tested and verified by others?

(b) you maintain a version control procedure which records all changes in design, advertisements, sales brochures, instructions, operating manuals etc?

(c) all instructions, operating manuals, advertisements warranties and all other documentation produced by you or on your behalf (and intended for distribution to others) are periodically reviewed by suitably experienced legal advisors to avoid misunderstandings relative to product safety or intended use?

(d) you have specific procedures in place for recalling goods and products should the need arise (e.g. in respect of suspected defects etc)?

(e) you are not considering discontinuing or recalling any product to be covered by this insurance?

(f) all your products are designed, tested, labelled and manufactured to meet or exceed all applicable government and industry standards?

YES ☐ NO ☐

If NO please provide full details

SECTION C - PROFESSIONAL INDEMNITY (Optional)

This section provides protection in respect of claims made against you arising from your professional services (professional negligence) as

(i) a Product Designer, and/or

(ii) a Manager, Sponsor, Investigator etc. of clinical trials (but not in respect of claims made against you by participants)

Please attach a copy of your standard contract Terms and Conditions, together with any brochures, literature or technical information relating to your professional services.

17 Please state your gross income/fees for your last three complete financial years and your estimated gross income/fees for your current financial year

Financial year 20___ to 20___	£
Financial year 20___ to 20___	£
Financial year 20___ to 20___	£
Financial year 20___ to 20___	£

(i) Product Designers

18 Do you design products for others?

YES ☐ NO ☐

If YES please answer the following questions:
If NO, please go to question 19

(a) For your current financial year please provide a breakdown of your estimated gross income/fees by product type (provide brief detail) and geographical area

Product Design Categories	UK/EU	USA	Canada	Elsewhere
Medical & Surgical Products				
1				
2				
3				
4				
5				
Pharmaceuticals & Drugs **(a) Ethical (prescribed)**				
1				
2				
3				
4				
5				

Product Design Categories	UK/EU	USA	Canada	Elsewhere
Pharmaceuticals & Drugs **(b) Non-ethical ('over the counter')**				
1				
2				
3				
4				
5				
Supplements & Cosmetics				
1				
2				
3				
4				
5				
Scientific & Technical Equipment				
1				
2				
3				
4				
5				
Other (please specify)				
1				
2				
3				
4				
5				
TOTAL				

(b) Please provide brief details of the qualification and experience of all directors, partners, principals and consultants involved in product design

(c) Please provide details of products designed by you in the past

(d) Please provide details of any Standards for which your facilities are accredited and/or to which you operate

(e) Please provide details of any industry standards to which your products are designed

(f) Do you build prototypes for any of the products you design?

YES ☐ NO ☐

If YES please provide details

(g) Please provide a brief description of the products that you design, how long you have been designing them and their intended function

(h) Can you confirm that you do not design products containing or involving the drugs or ingredients specified in Addenda A (page 25) of this proposal form?

YES ☐ NO ☐

If NO please provide details

(**N.B.** claims resulting from or relating to such drugs or ingredients are likely to be excluded from any cover agreed with underwriters)

(ii) Clinical Trial Managers/Sponsors/Investigators etc.

19 Do you manage or are you involved in clinical trials/investigations?

YES ☐ NO ☐

If YES please answer the following questions:
If NO please go to question 21, 23 or 24 (as appropriate)

Please note if you require cover against claims brought against you by those participating in clinical trials you should complete Section D of this proposal form. This section specifically excludes such claims, but does provide cover in respect of your professional duties to third parties such as those for whom you are conducting the trial.

(a) For your current financial year please provide a breakdown of your estimated gross income/fees from each of the three geographical areas

	UK	EU	Elsewhere
Estimated gross income/fees	£	£	£

If income/fees are obtained from outside of the UK/EU please provide details

(b) Are you involved in any trials or investigations involving drugs or ingredients specified in Addenda A (page 25) of this proposal form?

YES ☐ NO ☐

If YES please provide details

(**N.B.** claims resulting from or relating to such drugs or ingredients are likely to be excluded from any cover agreed with underwriters)

(c) Please provide a brief description of the trials you are involved in and your role and responsibilities in those trials (e.g. details of whether or not you act as 'sponsor' within the meaning of the Medicines for Human Uses (Clinical Trials) Regulations), details of your clients and full details of the professional service(s) you provide (e.g. involvement with Protocols, Ethics Committees, Criteria Setting, Consent Forms, Information Sheets, Applications, etc)

20 Can you confirm that

(a) there have not been any fundamental changes in your activities over the last five years and you do not anticipate any major changes in the forthcoming twelve months?

(b) you do not anticipate any major changes in the proportion of total income emanating from the three geographical areas?

(c) no contract or client represents more than 50% of your work in any of your last three financial years or your current financial year?

(d) whilst you may operate anywhere in the world, all work undertaken by you is subject to the jurisdiction of a court of law within the European Union?

YES ☐ NO ☐

If NO please provide full details

PART D – CLINICAL TRIALS (Optional)

This provides protection in respect of claims made against you by those participating in clinical trials conducted by you.

N.B. Cover will only be provided for the trials specified

21 Please provide the following details for each trial for which cover is required *(If insufficient space please continue on a separate sheet)*

Please attach a copy of the following in respect of each trial

- **The Protocol**
- **Ethics Committee opinion**
- **Criteria for research subject selection**
- **Consent Forms**
- **Information Sheets**
- **Clinical Investigation Application Forms PCA 1 and PCA 2 (if applicable)**

	Trial 1	**Trial 2**
(a) Name of trial		
(b) Commencement date of trial		
(c) Planned end date of trial		
(d) Description of trial		
(e) What are your responsibilities in the trial and in what capacity do you act? (e.g. do you act as Sponsor within the meaning of the Regulations?)		
(f) Has funding been obtained for the trial?	YES ☐ NO ☐	YES ☐ NO ☐
If YES please provide full details		
(g) Is this a clinical trial to which the Medicines for Human Use (Clinical Trials) Regulations apply?	YES ☐ NO ☐	YES ☐ NO ☐
If YES please advise whether a Phase I, II, III, or IV trial.		
(h) Is this a clinical investigation to which the Medical Devices Regulations apply?	YES ☐ NO ☐	YES ☐ NO ☐
(i) Does the trial involve or relate to any herbal and/or homoeopathic medicines?	YES ☐ NO ☐	YES ☐ NO ☐
Please advise the number of research subjects involved in or being recruited for, the trial in the following categories		
minors (i.e. under 16)		
incapable adults		
capable adults		

	Trial 3	Trial 4
(a) Name of trial		
(b) Commencement date of trial		
(c) Planned end date of trial		
(d) Description of trial		
(e) What are your responsibilities in the trial and in what capacity do you act? (E.g. do you act as Sponsor within the meaning of the Regulations?)		
(f) Has funding been obtained for the trial?	YES ☐ NO ☐	YES ☐ NO ☐
If YES please provide full details		
(g) Is this a clinical trial to which the Medicines for Human Use (Clinical Trials) Regulations apply?	YES ☐ NO ☐	YES ☐ NO ☐
If YES please advise whether a Phase I, II, III, or IV trial.		
(h) Is this a clinical investigation to which the Medical Devices Regulations apply?	YES ☐ NO ☐	YES ☐ NO ☐
(i) Does the trial involve or relate to any herbal and/or homoeopathic medicines?	YES ☐ NO ☐	YES ☐ NO ☐
Please advise the number of research subjects involved in or being recruited for, the trial in the following categories		
minors (i.e. under 16)		
incapable adults		
capable adults		

22 Can you confirm that in respect of each trial listed under question 21

(a) approval for the trial has been provided by the United Kingdom regulatory and licensing authorities?

(b) the trial is conducted exclusively within the United Kingdom and is subject only to, and fully complies with, the statutory requirements, guidelines and approval requirements of the United Kingdom regulatory and licensing authorities?

(c) you have not sought any amendments to the Protocol or made any amendments to your submissions to the United Kingdom regulatory and licensing authorities?

(d) you have not experienced any serious adverse events in respect of the trial (irrespective of whether or not such events were reported to the United Kingdom regulatory and licensing authorities)?

(e) if applicable, you have retained all rights of recourse against the trial Sponsors and/or product manufacturers?

(f) the trial does not involve the use of any of the drugs or ingredients specified in Addenda A (page 25) of this proposal form?

(g) the trial does not involve

(i) the assisting with or altering the process of conception?

(ii) investigating or participating in methods of contraception?

(iii) genetic engineering other than a Clinical Trial in which the purpose is treating or diagnosing disease?

(iv) any drug, product or other subject of the Clinical Trial that has been designed and/or manufactured by you?

(v) the use of research subjects who are:

1. your Employees?

2. pregnant?

3. under the age of five years?

YES ☐ NO ☐

If NO please provide full details

SECTION E - EMPLOYERS LIABILITY (Optional – not available in isolation)

This provides protection in respect of claims made against you by your employees.

23 Please provide a breakdown of all wages/salaries paid during your last complete financial year

Clerical	£
Laboratory Technicians	£
Other	£

Please provide details of role(s) if 'Other'

SECTION F - GENERAL SECTION (Mandatory)

24 Please state whether the following classes of insurance have been carried during the past three years, together with appropriate detail

(a) Public and Products Liability

YES ☐ NO ☐

If YES please provide details of Insurer, Period, Indemnity Limit and Retroactive Date of Your current policy

(b) Professional Indemnity

YES ☐ NO ☐

If YES please provide details of Insurer, Period, Indemnity Limit and Retroactive Date of your current policy

(c) Clinical Trials

YES ☐ NO ☐

If YES please provide details of Insurer, Period, Indemnity Limit and Retroactive Date of your current policy and confirm whether or not the trials being proposed for were included within the cover

(d) Employers Liability

YES ☐ NO ☐

If YES please provide details of Insurer and Period

25 Can you confirm that

(a) no person proposing for insurance has been convicted, or charged but not yet tried, of any criminal offence other than a motoring offence?

(b) the Proposer has never had an application for this type of insurance declined by an insurer, had a renewal of such insurance declined, nor had similar insurance cancelled or made subject to special conditions?

(c) no claims, prosecutions, proceedings or investigations (successful or otherwise) have been made or instigated against the Proposer and/or any person proposing for insurance to which the proposal relates?

(d) no person proposing for insurance is aware, AFTER ENQUIRY, of any circumstance or incident which they have reason to suppose might afford grounds for any future claim such as would fall within the scope of the proposed insurance?

YES ☐ NO ☐

If NO please provide full details

26 What indemnity limits are required?

Public and Products Liability	£
Professional Indemnity	£
Clinical Trials	£

DECLARATION

I hereby declare that I am authorised to complete this proposal on behalf of the Proposer and that, to the best of my knowledge and belief, the statements and particulars in this proposal are true and complete and no material facts have been mis-stated or suppressed.

I undertake to inform Underwriters of any material alteration or addition to these statements or particulars which occurs before any contract of insurance based on this proposal is effected and acknowledge that this proposal (together with any other information supplied to Underwriters) shall be the basis of such contract.

*Signed: Name:

*Capacity: Date:

*the signatory should be a director or senior officer of, or partner in, the Proposer.

N.B. Please remember to submit copies of the relevant additional information requested in respect of:-

- Public and Products Liability (Section B)
- Professional Indemnity (Products Designers and Clinical Trial Managers/Sponsors/Investigators) (Section C)
- Clinical Trials (Section D)

ADDENDUM A – Specified Products (Drugs, Herbs/Ingredients, Cosmetic Components & General)

The following Products (or any derivative or any that contains or has the same or a similar chemical formula, structure or function to any of the product specified below) would generally be **excluded** by endorsement in respect of Products Liability and Professional Indemnity cover.

If the following are being used in or are the subject of any clinical trial being proposed for insurance you should provide full details to underwriters under question 3 and/or 15(c) as appropriate

1,4 Butanediol (BD)

Alosetron,

Amenorone Forte,

Aristolochia,

Aristolochia fangchi,

Aristolochia spp.,

Aristolochic acids,

Asarum spp.,

Ava,

Ava pepper,

Awa,

Benoxaprofen,

Bragantia spp.,

Bromfenac Sodium,

Bromocriptine,

Bupropion,

Canthaxanthin,

Cervastatin,

Cisapride,

Clindamycin,

Cox-2 Inhibitors,

Danthron,

Debendox,

Deflenfluramine or Dexfen,

Dicyclomine,

Diethylstilbestrol (DES),

Ephedra,

Ephedra Alkaloid,

Ephedra E equisetina,

Ephedra sinica,

Ephedrine,

Ethylenediaminetetraacetic Acid (EDTA),

Fang Chi,

Fang ji,

Fenfluramine,

Gamma Butyrate (GBL),

Gamma Hydroxy Butrate (GHB),

Germander,

Germanium,

Glyburide,

Guang fang ji,

Halogenated 8,

Hydrochloride,

Hydroquinone,

Intoxicating pepper,

Isotretinoin (Accutane),

Itraconazole,

Jin Bu Haun,

Kan-Mokutsu,

Kava,

Kava kava,

Kava kava pepper,

Kava root,

Kawa,

Kawa kawa,

Kew,

Latex (including Latex Examination Gloves),

Lead,

Ligiang Xiao Ke Ling (Liqiang thirst Quenching Efficacious),

Liqiang 4,

Lobelia,

Lotronex,

L-tryptophan,

Lymeix,

Magnolia,

Ma huang,

Mercury,

Methylphenidate,

Metronidazole,

Mibefradil,

Mokotsu,

Mu Tong,

Nefazodone,

Paxil,

Pertussis Vaccine,

Phentermine,

Phenylpropanolamine,

Piper Methysticum,

Piper Methysticum Forst. F.,

Piper Methysticum G. Forst,

PPA,

Primodos,

Propulsid,

Pseudoephedrine,

Rapacuronium Bromide,

Rauschpfeffer,

Rosiglitazone,

Rotasheild Vaccine,

Sakau,

Selective Serotonin Reuptake Inhibitors (SSRI's),

Sibutramine,

Silicone,

Sinomenium spp.,

Stephania,

Stephania spp,

Thalidomide,

Thimerosal,

Tobacco,

Tonga,

Tretinoin (Retinioc Acid),

Troglitazone,

Trovafloxacin,

Tryptophan,

Unla beled glyburude,

Wurzelstock,

Yangona,

Yohimbe Aristolochia spp.

ADDITIONAL INFORMATION

Please make reference to applicable question