TOTTEN GROUP
INSURANCE

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PHARMACEUTICAL CONTAMINATION INSURANCE APPLICATION

Underwriters will rely upon each and every response given in this Proposal Form and any Supplementary Proposal Form in deciding whether or not to insure this risk and if so at what premium, terms and conditions. Underwriters regard every response to be material to their decisions. Failing to answer or answering any question below incorrectly could invalidate any policy of insurance written by Underwriters for this risk.

We have a professional duty of confidentiality and are committed to holding personal information in strict confidence. The information provided to us will only be disclosed where required by law to do so or required to do so in conducting negotiations with third parties, such as insurance companies, on your behalf.

We will further safeguard the security of such information in a manner appropriate to sensitivity of that information.

1. Name of Company _____
   (and all subsidiaries) _____
2. Mailing Address _____
   _____ Website _____
3. Main Contact Name _____ Main Contact phone _____
4. Describe business of Applicant and any subsidiaries _____
   _____
5. Product category ☐ Over the counter drugs ☐ Generic Drugs ☐ Drugs under patent
6. Products to be insured under this coverage

Product	% of Total Sales	Target Market	% Share of Market

7. Please indicate estimated annual sales _____ Total number of plants/facilities _____
8. Please provide the following

Sales by country	20____	20____	20____
United Kingdom			
European Union			
USA/Canada			
Rest of World			

9. Is any sales are registered in the European Community and Rest of World, please indicate in which states
   European Union _____
   _____
   _____
   _____
   Rest of World _____
   _____
   _____

10. List company's products sold as part of or under another company's label or brand name _____

What percentage of your products are an ingredient/raw material of other products? _____ %

11. Please indicate any new products that have commenced production or have entered the public stream of commerce within the last 12 months _____

12. What percentage of your products is manufactured by an outside vendor? _____ %

13. Has the applicant agreed to indemnify, hold harmless or contractually restrict in any way, liability in respect of suppliers of products, goods or services (eg suppliers of raw materials or packaging, or contract packers)? ☐ Yes ☐ No

If yes, please provide details _____

14. Total number of company employees _____

List below any strikes, riots, work stoppages and/or plant closings in the last three (3) years _____

15. Has the company ever been a direct target of political, racial, environmental, or other extremist or special interest groups? ☐ Yes ☐ No

If yes, please provide details _____

Does the company use or pay for animal testing of products? ☐ Yes ☐ No

If yes, please provide details _____

Does the company import/export with volatile countries or undertake other activities which might make it a target of extremist or special interest groups? ☐ Yes ☐ No

If yes, please provide details _____

16. Please provide the following information for the top 3 selling products

	Product 1	Product 2	Product 3
Product Name			
Product Type			
Is it a finished product			
How long have you been manufacturing the product? (for generics only)			
Shelf Life (weeks, months or years)			
Packaging Type (please specify)			
Annual Turnover (£/$)			
Daily Production (£/$)			
Daily Production (Units)			
Plant Locations where product is produced			
Number of Production Lines at each location			
Country(ies) where sold			
Largest Batch Size by Value (£/$)			

QUALITY AND SAFETY

17. Do you have a documented and active Quality and Safety Program? **(please attach copy)** ☐ Yes ☐ No

18. Does the program incorporate and comply with FDA Current Good Manufacturing Practice Regulations (cGMPs) and incorporate Quality Risk Management, such as FDA Guidance: Guidance for Industry, Q9 Quality Risk Assessment) for all products? ☐ Yes ☐ No

Date cGMPs last reviewed and updated _____

Does the plan incorporate a Quality Risk Management Process? ☐ Yes ☐ No

When was the date of the last Good Manufacturing Practices (cGMPs) audit? _____

(Please attach copy of the most recent audit report)

Which allergens are used? _____

_____

_____

Is there an Allergen Management Program in place to prevent cross contamination? _____

_____

_____

19. Is there a Quality and Safety Department? ☐ Yes ☐ No

Who is responsible for overseeing and implementing cGMPs? _____

_____

Is this person dedicated full time to such work? ☐ Yes ☐ No

If "no", please indicate other responsibilities held by this person _____

_____

_____

20. In respect of the manufacture and distribution of pharmaceutical products, are you audited to confirm compliance with the regulatory requirements of:

☐ MHRA ☐ FDA ☐ EMEA ☐ Other

How often are audits performed? _____

Are audits performed at all your sites? ☐ Yes ☐ No

Give details of any major recommendations made that have not been implemented _____

_____

_____

21. Do you require your suppliers to abide by quality and safety standards that include cGMPs and Quality Risk Management? ☐ Yes ☐ No

If no, what steps are taken? _____

_____

_____

What steps are taken to assess the quality and safety standards adhered to by your suppliers? (e.g., supplier audits, application, questionnaire, references, health inspection reports, etc.) _____

_____

_____

Who (what position(s)) decides whether a supplier is approved? _____

Do you have a formal supplier qualification process? ☐ Yes ☐ No

22. Relating to your Product Testing (please select the applicable boxes)

Product Test Type	Raw Materials	In-Line	End of Line
Microbiological			
X-Ray			
Metal Detectors			
Physical			
Chemical			

23. Do you have an in-house testing laboratory? ☐ Yes ☐ No

If yes, what types of tests are conducted by the in-house laboratory? _____

_____

If no, do you retain an outside testing laboratory? ☐ Yes ☐ No

If yes, Name of laboratory _____

Location of laboratory _____

Is it open 24 hours? ☐ Yes ☐ No

Are they accredited to ISO EN 17025 ☐ Yes ☐ No

Is there a hold period before shipping? ☐ Yes ☐ No

Is there a "positive release" procedure? ☐ Yes ☐ No

Is there an incoming quarantine process? ☐ Yes ☐ No

Are certificates of product conformance or certificates of analysis (COAs) from the suppliers received? ☐ Yes ☐ No

24. Are all your product labels inspected? ☐ Yes ☐ No

If yes, when and by whom? _____

_____

25. Do you collect and monitor customer complaints ☐ Yes ☐ No

If yes, how? ☐ Internet Site ☐ Free phone number ☐ Electronic (i.e. database) ☐ Other _____

RECALL PREPAREDNESS

26. Is there a written and active recall plan? ☐ Yes ☐ No

Is there a formal recall team in place? ☐ Yes ☐ No

Has the recall plan been tested within the past 12 months? ☐ Yes ☐ No

Have all members of the recall team been trained within the past 12 months? ☐ Yes ☐ No

Please provide a copy of the recall plan

27. Is there a written and active MPT/defense plan? ☐ Yes ☐ No

Is there a formal MPT/defense team in place? ☐ Yes ☐ No

Have all members of the MPT/defense team been formally trained within the past 12 months? ☐ Yes ☐ No

Please provide a copy of the plan

28. Have the company's products or any of its premises ever been the subject of comment or complaint by any governmental agency or department? ☐ Yes ☐ No

If yes, Which agency or department? _____

Date and nature of comment or complaint _____

_____

Outcome of such comment or complaint _____

_____

Date resolved _____

29. Claims history of the company

Products recalled due to an accidental contamination and/or malicious tampering in the last ten (10) years

Division and product _____

Reason for recall _____

Date of recall _____

Recall method utilized _____

Cost of recall _____

Were any contracts lost/discontinued as a result? (continue on separate sheet if necessary) ☐ Yes ☐ No

30. Does the company know of any actual, threatened or suspected product tampering involving any of the company's products during the last twelve (12) months? ☐ Yes ☐ No

If yes, please give details _____

_____

_____

31. Does the company, its directors and officers, or any other person known to the Insured have knowledge or information regarding any specific fact which may reasonably give rise to a claim under the proposed policy? ☐ Yes ☐ No

Limits of Liability Requested

Accidental Contamination _____ Malicious Tampering _____

Self-Insurance Retention Requested

Accidental Contamination _____ Malicious Tampering _____

Please enclose with this proposal form

☐ Recall Plan ☐ Crisis Management Plan ☐ cGMP Audit Report ☐ MPT/Defense Plan ☐ Quality and Safety Program Policy

Duty of Disclosure

It is your responsibility to disclose all material information that is known to you (or which ought to be known to you in the ordinary course of your business) and which might influence an insurer's judgment in determining whether or not to accept your risk. If you are in any doubt as to whether any information is material, you should disclose it. Failure to disclose all material information may entitle insurers to avoid the contract of insurance thereby enabling them not to pay any outstanding claims and to require repayment of all claims previously paid.

Declaration

I/We declare that to the best of my/our knowledge and belief the answers given are true and complete in every respect and all material particulars which may affect the assessment of the risk have been disclosed. Furthermore, I/We undertake to inform you if there is any material change to the information already provided whether before or after a contract of insurance is finalised.

I/We understand that the signing of this Application Form does not bind me to a contract of insurance, but agree that should a contract of insurance be concluded, this Application Form will be deemed incorporated into such contract of insurance.

_____ _____

Applicant Signature Date

_____ _____

Printed Name Position in Organization

Note: In respect of European Union domiciled Insured's you and we are free to choose the law applicable to this contract, unless specifically agreed to the contrary, this insurance shall be subject to English Law and the policy and wording will be in English.

_____

Complete Name and Address of Insurance Brokerage

Broker Email Address: _____