Proposal Form

Advanced Medical Technology

Proposer Details

Some of the coverages for which this Proposal form is being submitted are claims made. If there are questions concerning these coverages, please contact your insurance agent or broker.

Instructions

This Proposal form and all materials submitted shall be held in confidence.
All questions must be fully answered and all requested information and/or required attachments submitted to enable a quotation or indication to be given. However, the completion and submission of this form does not bind the applicant or underwriters to enter into any contract of insurance.

If a question does not apply, please write "N/A". If the answer is none, state "none" or "0". If more space is needed, please continue on a separate sheet of the applicant's letterhead and indicate the question number to which the information responds. This Proposal form and any separate continuation sheets must be completed, signed and dated by a principal of the business.

It is your duty to disclose to underwriters all facts material to the proposed insurance. Failure to do so could prejudice your rights to recover in the event of a claim or allow underwriters to void the policy. A material fact is one likely to influence the underwriters' assessment or acceptance of the Proposal.

Please check the appropriate block(s)

Product Liability	☐	Public Liability	☐	Medical Professional Liability	☐
Clinical Trials Liability	☐	Professional Liability	☐	Employers Liability	☐

A. Applicant Information

1.	**Name of Applicant**	
2.	**Corporate Address**	
	Postcode	
3.	**Mailing Address**	
	Postcode	
4.	**Locations** *(If other than above.)*	
5.	**All Named Insureds**	
6.	**Additional Insureds** *(Please explain relationship.)*	

7. If you have acquired any subsidiaries within the last five (5) years, please list below:

Entity	Date Acquired

8. Named Insured is a/an:

Individual ☐ Partnership ☐ Corporation ☐ Joint Venture ☐ Other ☐

If Other, describe:

9. How long has the applicant been in business?

10. Does the applicant have a parent company?
Yes ☐ No ☐

11. Has the applicant operated under another name? *(Please provide details.)*
Yes ☐ No ☐

12. Indicate projected revenues in the European Union (EU) and European Economic Area (EEA) and Switzerland.

13. Indicate projected United States (US) revenues.

14. Indicate projected Rest of World (ROW) revenues.

15. Indicate revenues from (a) previous year and (b) current year:
a. b.

16. Product/Service Profile

Source/Potential Source of Revenues	Percentage %	Product/Service Description
Blood/Plasma/Tissue Banks		
Manufacturing - Pharmaceuticals		
Manufacturing - Medical Devices		
Contract Manufacturing - Pharmaceuticals		
Contract Manufacturing - Medical Devices		
Clinical Research Organisation		
Distributor – Pharmaceuticals		
Distributor - Medical Devices		
Diagnostic Laboratories		
Equipment Rentals/Leasing		
Research		
Repair/Installation/Service		
Other (Please explain.)		

17. Product/Service Types *(Please indicate responses in percentages.)*

Pharmaceuticals

a. Proprietary Pharmaceuticals
b. Generic Pharmaceuticals
c. Clinical Research
d. Imaging/Diagnostic Agents
e. Nutraceuticals
f. Diet Aids
g. Vaccines
h. Infusions
i. Other *(Please explain.)*
j. Other (*Please explain.*)

Medical Devices

a. Cardiac Devices
b. Anaesthesia/Respiratory
c. Implants (*Active*)
d. Implants (*Non-Active*)
e. Lasers
f. Surgical Devices
g. Dental Instruments
h. Monitoring Devices
i. Imaging Devices
j. Therapy/Rehabilitation
k. Dialysis Equipment
l. Drug Delivery Systems
m. Non-Cardiac Catheters
n. Analytical Instruments
o. Diagnostic Kits
p. Durable Medical Equipment
q. Hospital Products/Supplies
r. Other (*Please explain.*)

Contracted Professional Services

a. Preclinical Testing
b. Pharmacodynamics
c. Pharmacokinetics
d. Protocol Design
e. Study Participant Selection or Monitoring
f. Clinical Investigations (*Please indicate phase.)*
g. Clinical Staff Recruitment
h. Clinical Staff Training
i. Case Report Form Design
j. Data Entry/Database
k. Publications/Software Design
l. Biostatistics
m. Submission of Regulatory Filings
n. Bioequivalency/Bioavailability Testing
o. Quality Control Monitoring
p. Manufacturing
q. Repackaging/Assembly
r. Product/Equipment Sterilization
s. Marketing
t. Sales Management
u. Distribution
v. Other (*Please explain.*)

18. Are any products manufactured and/or sold under others' labels?
Yes ☐ No ☐

19. Are any products sold as components for other products? *(Indicate the likely end product.)*
Yes ☐ No ☐

20. Do you subcontract/utilize independent contractors for product development, manufacturing, sales, and/or distribution services? *(Please indicate activities contracted.)*
Yes ☐ No ☐

21. Professional Services

a. Do any of the applicant's employees provide direct patient care? Yes ☐ No ☐

b. Do they carry their own individual medical professional liability coverage? Yes ☐ No ☐

c. Does the applicant operate an inpatient facility? Yes ☐ No ☐

d. Do any of applicant's employees participate on an institutional review board/independent ethics board? Yes ☐ No ☐

e. Does applicant or its employees have a financial interest in the products of the applicant's clients? Yes ☐ No ☐

f. List the applicant's largest clients for current year.

22. Sponsored Clinical Trials

Product	Number of New Subjects over the Next Policy Period	Indications	Country

(Please attach approved protocols and informed consent documents for active clinical trials.)

23. List new products expected to be introduced.

24. List any discontinued products.
(Please indicate reason(s).)

25. Are the applicant's facilities approved by the European Medicines Agency (EMEA) or any other regulatory agency?
Yes ☐ No ☐

a. Does applicant have operations in/receipts to the United States?
Yes ☐ No ☐

b. If yes, are they approved by the U.S. Food and Drug Administration (FDA)?
Yes ☐ No ☐

26. **Supply the dates of the most recent FDA or EMEA inspection**

27. **Have any products or company practices been subject to an investigation by any government agency?** *(If yes, please explain.)*
Yes ☐ No ☐

28. **Are any product components imported?** *(If yes, are they FDA or EMEA approved?)*
Yes ☐ No ☐

29. **Do any of applicant's products training/certification programs require the approval of the FDA, EMEA, or any other similar national organisation?**
Yes ☐ No ☐

30. **Are manufactured products UL listed and/or CSA certified?**
Yes ☐ No ☐

31. **Are the manufactured products listed or certified by any national organisation?**
Yes ☐ No ☐

32. **Does the applicant use another organisation for reliability/design validation?**
Yes ☐ No ☐

33. **Does the applicant require certificates of insurance from suppliers?** *(If yes, indicate limits required.)*
Yes ☐ No ☐

34. **Has the applicant had any product recalls in the past year?** *(If yes, please submit details and current recall status.)*
Yes ☐ No ☐

35. **Within the past twelve months, has the applicant filed any medical device reports or adverse drug reaction reports?** *(If yes, indicate the number of filings and the nature of each filing.)*
Yes ☐ No ☐

36. **Have any clinical trials been placed on hold?** *(If yes, provide details.)*
Yes ☐ No ☐

37. **Does the applicant audit clinical investigator performance?**
Yes ☐ No ☐

38. **Has the applicant received any warning letters during the last three (3) years?** *(If yes, please explain.)*
Yes ☐ No ☐

39. **Is there a written and implemented loss prevention/control programme?** *(If yes, please note the name and title of the individual responsible for the programme.)*
Yes ☐ No ☐

40. Is there a written and implemented quality control programme?
Yes ☐ No ☐

41. Is there a written and implemented product recall plan?
Yes ☐ No ☐

42. Is there a written and implemented records retention programme?
Yes ☐ No ☐

43. Are promotional materials, contracts, guarantees, and labelling reviewed by risk management and legal counsel?
Yes ☐ No ☐

44. Loss History *(Provide total aggregate losses from ground up, including related claim defence expenses, for the last five (5) years and attach previous carrier loss runs.)*

Policy Period	Insurer	Number of Claims	Total Incurred

45. Have any known occurrence(s) not yet been reported? *(If yes, please submit details.)*
Yes ☐ No ☐

46. Coverage History

Policy Period	Primary and Excess Limits	Carriers	Retroactive Date

a. Has any carrier ever cancelled or non-renewed any of the applicant's insurance coverages? *(If yes, please explain.)*
Yes ☐ No ☐

b. What limits of liability are being requested by the applicant?

c. What deductible or self-insured retention amount is the applicant prepared to assume? *(Please indicate risk retention type and amount to be retained.)*

47. a.) If the applicant requires Employers Liability Cover then please state the Employer Reference No. (ERN):

b.) Do you have any subsidiaries in the UK? *(If 'yes', please add the additional information required at the back of this proposal form on page 9)*
Yes ☐ No ☐

c.) Please provide the estimated annual wageroll details split into the following sections:

Nature of Work	**Estimated Wageroll (£)**
Clerical / Managerial staff not involved in manual work	
Sales and Marketing	
Laboratory Workers	
Manual Workers	
Other (*please describe*.)	
Total Estimated Wageroll	

Please enclose any documents, lists or explanations, as required, in response to various questions throughout the body of this insurance Proposal. In addition, please provide copies of the following:

- Marketing or advertising brochures or descriptive materials provided to clients
- Senior staff members' curriculum vitae
- Latest annual report/audited financial statement
- Clinical trial protocols and informed consent documents
- Claim loss runs for the past five (5) or more years for all coverages for which you are applying, in Excel format, if available
- Professional qualifications (i.e. resume or curriculum vitae) of each owner, partner, officer and key employee, if the applicant is new business
- Most recent survey reports, licensure reports and accreditation/regulatory agency survey reports
- Quality improvement, risk management, and patient safety plans/programmes
- Policy and procedures for reporting patient accidents, incidents, or severe and unexpected patient outcomes
- Policy and procedure for annual evaluation of doctors' competence
- Sample contract reflecting requirements for indemnification and liability insurance coverages from other parties

B. Authorisation

Declaration
I/we declare that, after full enquiry, the contents of this proposal are true and that I/we have not misstated, omitted or suppressed any material fact or information. I/we agree that this proposal together with any other information supplied by me/us shall form the basis of any contract of insurance which may be effected. If there is any material alteration to the facts and information which I/we have provided or any new material matter arises before the completion of the contract of Insurance, I/we undertake to inform Underwriters.

Signature in Full

Name *(Please print.)*

Date

This Proposal Form and all materials submitted with it will be held in confidence. For further information about CNA's policies and practices with regard to the privacy and confidentiality of information provided by you to us, please see our Privacy Statement at www.cnaeurope.com or contact our Company Secretary at the address listed below.

ALL QUESTIONS MUST BE ANSWERED AND THE APPLICATION MUST BE SIGNED AND DATED.

Agency Name and Address	Person Submitting Application	Telephone Number	E-mail

Completing and signing this Proposal form does not bind coverage.
Coverage will not be bound, nor will a policy be issued until the applicant signifies acceptance of the Company's premium quotation

This product will be underwritten in one of the CNA property/casualty companies.
CNA is a registered service mark and trade name of CNA Financial Corporation.

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SUPPLEMENTARY INFORMATION IN RELATION TO QUESTION 4.b.

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:

Please use this page to expand on any details where you ran out of space in any box.
Please insert the question number to which your additional information applies.