Proposal

Advanced Medical Technology

This is a Proposal Form for a **CLAIMS MADE POLICY**. Should this application be accepted by the Company, coverage will apply to claims first made against the insured and reported to the company during the policy period. No coverage will apply for claims first made against the insured after the end of the policy period unless the extended reporting period applies. No coverage will apply for claims first made prior to the retroactive date shown in the declarations page of the policy.

The completion and submission of this Proposal Form to the Company does not constitute a binder of insurance.

All questions must be answered. If a question is not applicable, please answer "NA". If the answer to a question is none, state "None" or "0". If more space is required to answer a question completely, please provide a separate attachment and identify the question to which it responds.

Please check the appropriate block(s)

☐ Products Liability ☐ Public Liability ☐ Medical Professional Liability

☐ Professional Indemnity ☐ Clinical Trials Liability ☐ Employers Liability

Applicant Information

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

7. **If you have acquired any subsidiaries within the last five (5) years, identify:**

Entity	*Date Acquired*

8. **Named Insured is**

☐ Individual ☐ Partnership ☐ Corporation ☐ Joint Venture ☐ Other

If Other, describe

9. **How long has the Named Insured been in business?**

10. **Do you have a parent company?**

11. Have you operated under another name? *(Give full details)*

12. Projected revenues in the European Union and European Economic Area?

13. Projected US revenues?

14. Projected Rest of World Revenues?

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

(a) *(b)*

16. Product/Service Profile

Source/Potential Source of Revenues	*Percentage %*	*Product/Service Description*
a. Blood/Plasma/Tissue Banks		
b. Manufacturing-Pharmaceutical		
c. Manufacturing- Medical Devices		
d. Contract Manufacturing-Pharmaceutical		
e. Contract Manufacturing-Medical Devices		
f. Clinical Research Organisation		
g. Distributor -Pharmaceutical		
h. Distributor-Medical Devices		
i. Diagnostic Labs		
j. Equipment rentals/Leasing		
k. Research		
l. Repair/Installation/Service		
m. Other *(Please explain)*		

17. Product/Service Breakdown *(Indicate responses in percentages)*

Pharmaceutical

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

Medical Devices

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

Contracted Professional Services

a. Preclinical Testing		*e.* Biostatistics	
b. Pharmacodynamics		*f.* Submission of Regulatory Filings	
c. Pharmacokinetics		*g.* Bioequivalency/Bioavailability Testing	
d. Protocol Design		*h.* Quality Control	

i.	Study Selection or Monitoring		*p.*	Manufacturing	
j.	Clinical Investigations *(indicate phases)*		*q.*	Repackaging/Assembly	
k.	Clinical Staff Recruitment		*r.*	Product/Equipment Sterilization	
l.	Clinical Staff Training		*s.*	Marketing	
m.	Case Report Form Design		*t.*	Sales	
n.	Data Entry/Database Management		*u.*	Distribution	
o.	Publications/Software Design		*v.*	Other *(please explain)*	

18. Are any product manufactured sold under others' labels? yes ☐ no ☐

19. Are any products sold as components for Other products? yes ☐ no ☐
(Likely end product)

20. Do you contract out product development, manufacturing, sales, and/or distribution services? *(Please indicate activities contracted)* yes ☐ no ☐

21. Professional Services

a. Do any of your employees provide direct patient care? yes ☐ no ☐

b. Do they carry their own individual medical professional indemnity? yes ☐ no ☐

c. Do you operate an inpatient facility? yes ☐ no ☐

d. Do any of your employees participate on an Institutional Review Board/Independent Ethics Board? yes ☐ no ☐

e. Do you or any of your employees have a financial interest in the products of your clients? yes ☐ no ☐

f. List largest clients for current year:

22. Sponsored Clinical Trials

Product	*Number of New Subjects Over 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)

25. Are facilities approved by the European Medicines Agency or another regulatory agency? yes ☐ no ☐

Do you have facilities in the United States? yes ☐ no ☐

If so, are they approved by the Food and Drug Administration? yes ☐ no ☐

26. Supply the date of the most recent FDA or EMEA inspection? yes ☐ no ☐

Have any products or company practices been subject to an investigation by any government agency? (If yes, please explain) yes ☐ no ☐

27.	**Are any product components imported?**	yes	☐	no	☐
	If yes, are they FDA or EMEA approved?	yes	☐	no	☐
28.	**Do any of your products training/certification programs require the approval of the FDA, EMEA, or any other similar national organisation?**	yes	☐	no	☐
29.	**Are manufactured products UL listed and/or CSA certified? Are the manufactured products listed or certified by any national organisation?**	yes	☐	no	☐
30.	**Do you use a facility for reliability/design validation?**	yes	☐	no	☐
31.	**Do you require Certificates of Insurance from your suppliers?**	yes	☐	no	☐
	What limits do you require?				
32.	**Have there been any product recalls in the past year?** ***(If yes, please submit details and recall status)***	yes	☐	no	☐
33.	**Within the past twelve months, have there been any medical device reports or adverse drug reactions filed?** ***(if yes, indicate the number of filings and the nature of each)***	yes	☐	no	☐
34.	**Have any clinical trials been placed on a clinical hold?** ***(if yes, provide details)***	yes	☐	no	☐
35.	**Do you audit Clinical Investigator performance?**	yes	☐	no	☐
36.	**Have any warning letters been issued against you in the last three (3) years?** ***(if yes, please explain)***	yes	☐	no	☐
37.	**Loss Prevention/Control Programme?** ***(if yes, please note the name and title of the individual responsible for the programme***	yes	☐	no	☐
38.	**Written Quality Control Programme?**	yes	☐	no	☐
39	**Written Product Recall Plan?**	yes	☐	no	☐
40.	**Written Records Retention Programme?**	yes	☐	no	☐
41.	**Promotional materials, contracts, guarantees, and labelling jointly reviewed by risk management and legal counsel?**	yes	☐	no	☐
42.	**Other** ***(please explain)***	yes	☐	no	☐

43. Loss History

**Total aggregate cost (losses from ground up, including related defence expenses) for the last five (5) years*

Policy Period	*Insurer*	*Number of Claims*	*Total Incurred*

**Attach previous carrier loss runs*

Describe all incurred losses of $25,000 or more:
Have any known occurrence(s) not yet been reported? yes ☐ no ☐
(If yes, please submit details)

Have any known occurrence(s) not yet been reported? yes ☐ no ☐
(If yes, please submit details)

44. Coverage History

Policy Period	*Primary and Excess Limits*	*Carriers*	*Retroactive Date*

Has your insurance ever been cancelled or non-renewed by a carrier? yes ☐ no ☐
(if yes, please explain)

What limits of liability are you seeking?

What deductible or SIR are you prepared to assume?
(Please indicate which type)

** When requesting excess coverage, please provide underlying premium figures and policy terms and conditions*

Please enclose the following with this Proposal form

- Most recent Annual Report/Audited Financial Statement ☐
- Clinical trial protocols and informed consent documents ☐
- Senior staff members curriculum vitae ☐
- Outline of Quality Control Programme ☐
- Advertisements, brochures, descriptive literature ☐
- Sample service contracts and indemnification agreements ☐

Declaration

I declare that to the best of my knowledge the statements set forth herein are true and correct and that reasonable efforts have been made to obtain sufficient information from all of the proposed insureds to facilitate the proper and accurate completion of the proposal form for the proposed Policy

I agree that this Proposal Form, together with any other information supplied shall form the basis of the contract should a Policy be issued. I undertake to inform the Insurer of any material alteration to the statements set forth herein which occurs prior to the effective date of any Policy.

Signed	
	To be signed by the Chairman of the Board of Chief Executive
Title	
Company	
Date	