Life Science Products and Medical Device & Laboratory Software

Insurance application form

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The purpose of this application form is for us to find out more about you. You must provide us with all information which may be material to the cover you wish to purchase and which may influence our decision whether to insure you, what cover we offer you or the premium we charge you.

How to complete this form

The individual who completes this application form should be a senior member of staff at the company and should ensure that they have checked with other senior managers and colleagues responsible for arranging the insurance that the questions are answered accurately and as completely as possible. Once completed, please return this form to your insurance broker.

Section 1: Company Details

1.1 Please state the name and address of the principal company for whom this insurance is required. Cover is also provided for the subsidiaries of the principal company, but only if you include the data from all of these subsidiaries in your answers to all of the questions in this form.

a) Company name:

b) Is the name of the company different to its trading name? ☐ Yes ☐ No

If "yes", please provide the trading name of the company:

Primary address (address, province, postal code, country):

Website:

1.2 Date the business was established (DD/MM/YYYY):

1.3 Number of employees:

1.4 Estimate for current financial year payroll: $

1.5 Please show the details of all partners/ directors:

Name	Years in position	Years experience	Qualifications

1.6 Please confirm if you are part of a corporate or other group structure where some parts of the group are not subject to this application for insurance: ☐ Yes ☐ No

If "yes", provide details:

1.7 Please state your gross revenue in respect of the following years:

	Last policy year	Current policy year	New policy year
Canada:	$	$	$
UK:	$	$	$
EUR:	$	$	$
USA:	$	$	$
Rest of World:	$	$	$

Section 2: General overview

2.1 Please indicate which statement(s) best describe your business activities by ticking all those that apply:

	Medical Devices, in vitro diagnostics and Medical Device Software	Pharmaceuticals	Life science research and medical laboratory equipment
Research and Development of your own product(s)	☐	☐	☐
Manufacturing of products under your label	☐	☐	☐
Contract manufacturing products or components under third party label	☐	☐	☐
Selling products under your label (manufactured by a third party)	☐	☐	☐
Distributor/wholesaler/retailer of products under third party label	☐	☐	☐
Development and sale of Tech products	☐	☐	☐

2.2 Please review all of the product categories listed below, and provide an approximate breakdown of how your revenue is generated.

Tangible Medical Devices, In Vitro Diagnostic and Medical Device Software	%
Pharmaceuticals	%
Life science research and medical labratory equipment	%
Other:	%

Note, once you finish completing Section 2:

Please complete Section 3 if you sell or supply Medical Devices.

Please complete Section 4 if you sell or supply pharmaceuticals.

Please complete Section 5 if you sell or supply laboratory equipment.

2.3 Please outline your top 5 selling products as a percentage of your revenue:

Product name	*Revenue Derived (%)*	*Unit cost*	*Date Product was first marketed*
		$	
		$	
		$	
		$	
		$	

2.4 Please confirm whether any of your products been discontinued for safety reasons? ☐ Yes ☐ No

If "yes", please provide all relevant details:

2.5 Please confirm whether any of your products have ever been recalled or whether you plan to recall a product, regardless of whether the recall itself was enforced or voluntary? ☐ Yes ☐ No

If "yes", please provide details of the product(s) including name, date of recall, number of affected batch(es), number of units recalled from affected batch(es), whether you have received any complaints or lawsuits:

2.6 Please confirm whether you plan to release any new products or software in the next 12 months? ☐ Yes ☐ No

If "yes", please provide details including the name and purpose of the product or software:

2.7 Please confirm whether any of your products or its parts are manufactured outside of Canada: ☐ Yes ☐ No

If "yes", please state what products and which territories:

2.8 Please confirm whether you repackage or relabel any products manufactured by others: ☐ Yes ☐ No

If "yes", please state what product(s):

2.9 Please confirm whether you rent or lease equipment to others? ☐ Yes ☐ No

If "yes", please provide details:

2.10 Please confirm whether you provide after sales care and repair services: ☐ Yes ☐ No

Section 3: Medical Devices, in vitro diagnostics and Medical Device Software

Please only complete this section if you sell or supply Medical Devices. If this subsection is not applicable to you please indicate here:

If "N/A", indicate here: ☐ N/A

3.1 Please provide a description of the medical device product(s) currently in R&D or within clinical trials:

3.2 Please provide us with a description of tangible products you currently sell:

3.3 Please confirm whether you are aware of product(s) sold off label? ☐ Yes ☐ No

a. If "yes", please confirm whether off-label product(s) are tracked? ☐ Yes ☐ No

b. Please confirm whether you have procedures in place for inhibiting employees from off label promotions? ☐ Yes ☐ No

3.4 Please state whether your product(s) contain:

☐ Hardware ☐ Software ☐ Firmware

3.5 In the event of a cyber event, please state whether your product(s):

a. impact the functionality, continuity of clinical operations, and/or patient safety: ☐ Yes ☐ No

b. have multi-patient repercussions: ☐ Yes ☐ No

c. would be safe for use in a reduced capacity: ☐ Yes ☐ No

3.6 Are any medical devices/legacy devices that cannot be easily secured, put on their own dedicated and protected network segment, separate from general IT asset? ☐ Yes ☐ No

3.7 Please state whether the applicant has a medical device cybersecurity response plan, including:

a. spare/extra device/loaner devices available for customers? ☐ Yes ☐ No

b. open cybersecurity advisories and alerts if devices are found to be vulnerable or compromised? ☐ Yes ☐ No

c. conducting/participating in clinical simulations? ☐ Yes ☐ No

d. tracking incidents? ☐ Yes ☐ No

3.8 Following a cyber event, does the applicant provide support/fulfil service level agreements? ☐ Yes ☐ No

3.9 Please state whether the applicant participates in the healthcare delivery organisations' cybersecurity exercise? ☐ Yes ☐ No

3.10 Please state how often users are trained on the device and the potential for cybersecurity incidents?

3.11 Please state whether the product has a Software Bill of Materials (SBoM), which identifies and addresses vulnerable device components? ☐ Yes ☐ No

If "yes", please provide a copy.

3.12 Please state how often the applicant conducts a Hazard Vulnerability Analysis (HVA)?

3.13 Please state whether the applicant employs any of the following:

a. Information Security Officer (ISO) ☐ Yes ☐ No

b. Medical Device Cybersecurity Liaison ☐ Yes ☐ No

3.14 Please state whether the applicant has an intrusion detection and/or security information and event management resource/capability? ☐ Yes ☐ No

If "yes", please provide an explanation

3.15 Please state whether the applicant hires skilled cybersecurity incident responders or allocates resources to the training of designated staff: ☐ Yes ☐ No

If "yes", please provide an explanation

Section 4: Pharmaceuticals

Please only complete this section if you sell or supply pharmaceuticals.

If "N/A", indicate here: ☐ N/A

4.1 Please provide a description of the pharmaceutical product(s) currently in R&D or within clinical trials:

4.2 Please describe the products you currently sell or supply:

If you have an inventory list, please attach this to this application:

Section 5: Laboratory equipment

You should not complete this section if your products are classified as either a Medical Devices or an in vitro diagnostic product. If your products are classified as either a Medical Devices or in vitro diagnostic product please complete Section 3.
If this subsection is not applicable to you please indicate here:

If "N/A", indicate here: ☐ N/A

5.1 Please describe the nature of the products you either manufacture or distribute:

5.2 Please confirm whether your products are designed to further biotechnology and pharmaceutical research and development: ☐ Yes ☐ No

If "yes", please confirm what stage of research your customers are likely to use your product (for example, discovery, pre-clinical, clinical or other):

5.3 Please state which statement(s) are true:

a. our products are only used for life science research purposes: ☐ Yes ☐ No

b. our products are used in a medical testing laboratory: ☐ Yes ☐ No

c. our products are used for purposes other than life science research or used within a medical testing laboratory: ☐ Yes ☐ No

If your products are used for purposes other than life science research or used within a medical testing laboratory, please list the product and its intended use:

Section 6: Risk Management

6.1 Please confirm whether you always secure certificates of product liability insurance from your manufacturers and suppliers? ☐ Yes ☐ No

If "yes", please confirm the minimum limit of products liability you request they maintain:

If "no", please provide the company name and the country of origin for the suppliers you do not require evidence of product liability insurance:

6.2 Please confirm whether you are added as an additional insured to your manufacturers or suppliers product liability insurance policies:
☐ Yes ☐ No

6.3 Please confirm the following in regards to regulatory compliance:

a) when your last external regulatory audit was conducted:

b) who you were audited by:

c) whether you received any recommendations or requirements: ☐ Yes ☐ No

If you answered "yes" to c) above, please provide a copy of the audit report, your responses and whether any items remain outstanding.

6.4 Please confirm whether you have a written quality control program: ☐ Yes ☐ No

If "yes", please provide the most recent revision date?

If "no", please confirm when one will be implemented?

6.5 Please confirm whether you have a written product recall plan in place? ☐ Yes ☐ No

If "yes", please provide the most recent revision date?

If "no", please confirm when one will be implemented?

6.6 Please confirm whether you maintain a written record of incidents and/or complaints relating to your products? ☐ Yes ☐ No

If "yes", please:

a) state who is responsible for maintaining these records:

b) confirm that a complaints investigation and closure process is in place: ☐ Yes ☐ No

If "no", please state why no records are maintained?

6.7 Please confirm whether your company follows regulatory guidelines in respect of:

a) Good Manufacturing Practice (GMP) if you are a manufacturer of products; or ☐ Yes ☐ No

b) Good Distribution Practice (GDP) if you are a distributor of products ☐ Yes ☐ No

6.8 Please confirm whether you are ISO registered?

6.9 Please state whether your company consults with legal counsel for issues concerning the following:

Contractual Liability	☐ Yes	☐ No	☐ N/A
Product Labeling	☐ Yes	☐ No	☐ N/A
Package Inserts	☐ Yes	☐ No	☐ N/A
Product Guarantees	☐ Yes	☐ No	☐ N/A
Promotional Materials	☐ Yes	☐ No	☐ N/A
Instruction Manuals	☐ Yes	☐ No	☐ N/A

6.10 When offering technology services, please state whether you always carry out work under a written contract signed by every client. ☐ Yes ☐ No

If "yes", please describe:

a) how, if at all, you limit your liability for consequential loss or financial damages under a written contract

b) your legal review process, if any, before entering into new contracts or agreements

Section 7: Cyber Security Risk Management

7.1 *Please describe the type, nature and volume of the data stored on, accessed or processed through your network, including a rough estimate of the total volume of unique individuals you hold data on:*

7.2 Please describe your data back-up policy in detail, including the frequency of back-ups, the technology used, the types of back-ups, the storage method used (online or offline), how often you text the back-ups and how you protect your back-ups:

7.3 a) Please confirm whether multi-factor authentication (MFA) is always enabled for remote access to your network (including any remote desktop protocol (RDP) connections) and on all email accounts: ☐ Yes ☐ No

b) If "no", please explain in what circumstances MFA is not used and why:

7.4 Please confirm the number of records attributed to residents in California:

7.5 Please confirm full details on this data, including the type and nature:

7.6 Please describe your approach towards protecting sensitive and confidential information (e.g. access controls, encryption, network segmentation etc.):

7.7 Please describe your data purging and retention policy:

7.8 Please tick all the boxes below that relate to any cyber incident that you have experienced in the last three years (there is no need to highlight events that were successfully blocked by security measures):

☐ Cyber Crime ☐ Cyber Extortion ☐ Data Loss ☐ Denial of Service Attack

☐ Malware Infection ☐ Privacy Breach ☐ Ransomeware

☐ Other (please specify):

If you ticked any of the boxes above, did the incident(s) have a direct financial impact upon your business of more than $10,000? ☐ Yes ☐ No

If "yes", please provide more information below, including details of the finacial impact and measures taken to prevent the incident from occuring again:

Section 8: Hired/ not owned automobiles (HNOA)

Please only complete this section if you use automobiles, not owned by the business, for business use. If this subsection is not applicable to you please indicate here:

If "N/A", please indicate here: ☐ N/A

8.1 For what purpose are you seeking HNOA coverage?

8.2 What is your total employee account?

8.3 How many people drive for or on behalf of your company?

8.4 Please confirm the approximate numbers of business miles driven per year?

8.5 How frequently are HNOA vehicles used as part of your business operations?

8.6 Please state whether driver motor vehicle records are checked prior to hire? ☐ Yes ☐ No

8.7 Please state what limits of insurance do the owners of the vehicles maintain?

Section 9: Claims Experience

9.1 Please state whether you are aware of any incident:

a) which may result in a claim under any of the insurance for which you are applying to purchase in this application form: ☐ Yes ☐ No

b) which resulted in legal action being made against any of the companies to be insured within the last 5 years: ☐ Yes ☐ No

If you have answered "yes" to a) or b) above then please describe the incident, including the monetary amount of the potential claim or the monetary amount of any claim paid or reserved for payment by you or by an insurer. Please include all relevant dates, including a description of the status of any current claim which has been made but has not been settled or otherwise resolved.

Section 10: Insurance Requirements

10.1 *Please provide details of your current Errors & Omissions, Cyber and General Liability insurance or the cover you require if this is the first time you are applying for this type of insurance:*

	Effective Date (MM/YY)	Limit	Deductible
Errors & Omissions			
Cyber			
General Liability			

Additional Information

Please use this space below to provide us with any other relevant information:

Important Notice

By signing this form you agree that the information provided is both accurate and complete and that you have made all reasonable attempts to ensure this is the case by asking the appropriate people within your business. CFC Underwriting will use this information solely for the purposes of providing insurance services and may share your data with third parties in order to do this. We may also use anonymised elements of your data for the analysis of industry trends and to provide benchmarking data. For full details on our privacy policy please visit **https://www.cfc.com**

Contact name: Position:

Signature: Date (DD/MM/YYYY):