

INSTRUCTIONS

For companies operating in the life sciences sector — medical devices, pharmaceuticals, biotechnology, nutraceuticals, skincare, MedTech, FemTech, telemedicine, wellness, and clinical research organisations. Complete all sections in full. Completion of this application does not bind coverage.

SECTION A — APPLICANT DETAILS

| | |
|---|---|
| LEGAL NAME OF APPLICANT <input style="width: 95%; height: 20px;" type="text"/> | WEBSITE <input style="width: 95%; height: 20px;" type="text"/> |
|---|---|

| | |
|--|--|
| BUSINESS ADDRESS <input style="width: 95%; height: 20px;" type="text"/> | PROVINCE / STATE <input style="width: 95%; height: 20px;" type="text"/> |
|--|--|

| | | |
|--|---|--|
| PRIMARY CONTACT NAME <input style="width: 95%; height: 20px;" type="text"/> | PHONE <input style="width: 95%; height: 20px;" type="text"/> | FINANCIAL YEAR END (MM/DD) <input style="width: 95%; height: 20px;" type="text"/> |
|--|---|--|

ENTITY TYPE (CHECK ONE)

- | | |
|---|---|
| <input type="checkbox"/> Private corporation | <input type="checkbox"/> Public company |
| <input type="checkbox"/> Partnership / LLP | <input type="checkbox"/> Non-profit / research organisation |
| <input type="checkbox"/> Start-up / pre-revenue | <input type="checkbox"/> Other |

LIFE SCIENCES SECTOR (CHECK ALL THAT APPLY)

- | | |
|--|---|
| <input type="checkbox"/> Medical devices | <input type="checkbox"/> Pharmaceuticals / drugs |
| <input type="checkbox"/> Biotechnology | <input type="checkbox"/> Nutraceuticals / supplements |
| <input type="checkbox"/> Skincare / cosmetics | <input type="checkbox"/> MedTech / digital health |
| <input type="checkbox"/> FemTech / FemHealth | <input type="checkbox"/> Telemedicine / telehealth |
| <input type="checkbox"/> Veterinary products | <input type="checkbox"/> Clinical research organisation (CRO) |
| <input type="checkbox"/> Medical cannabis | <input type="checkbox"/> Psilocybin / psychedelic R&D |
| <input type="checkbox"/> Active pharmaceutical ingredient (API) manufacturer | <input type="checkbox"/> Other (describe below) |

IF 'OTHER' — DESCRIBE ENTITY TYPE / SECTOR

KEY PERSONNEL

| NAME | TITLE / ROLE | QUALIFICATIONS / BACKGROUND | YEARS WITH COMPANY |
|--|--|--|--|
| <input style="width: 95%; height: 100%;" type="text"/> | <input style="width: 95%; height: 100%;" type="text"/> | <input style="width: 95%; height: 100%;" type="text"/> | <input style="width: 95%; height: 100%;" type="text"/> |
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SECTION B — PRODUCT & SERVICE DESCRIPTION

BUSINESS DESCRIPTION

Describe primary activities, products and services. Include scientific / medical purpose, intended end user, and stage of development.

PRODUCT / SERVICE LISTING

| PRODUCT / SERVICE NAME | TYPE / CATEGORY | MARKETS SOLD INTO | REVENUE (\$) — LAST FY |
|------------------------|-----------------|-------------------|------------------------|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Product characteristics — do any of the applicant's products or services:

- Include any software component, app, or algorithm (Software as a Medical Device — SaMD)? Yes No
- Collect, transmit, or process patient or user health data? Yes No
- Involve any implantable, surgically placed, or invasive device? Yes No
- Involve any injectable, infusible, or parenteral drug or biologic? Yes No
- Interact with or connect to other medical devices or hospital systems? Yes No
- Include any artificial intelligence or machine learning component? Yes No
- Have the potential to cause serious adverse events, injury, or death if they fail? Yes No

IF YES TO ANY — PROVIDE FULL DETAILS, SPECIFYING WHICH PRODUCT(S) AND ITEM(S) APPLY

SECTION B — REVENUE

| | LAST COMPLETE FY | CURRENT FY ESTIMATE | NEXT FY ESTIMATE |
|--------------------------------|------------------|---------------------|------------------|
| Canada / domestic revenue (\$) | | | |
| USA revenue (\$) | | | |
| Other territory revenue (\$) | | | |
| Total gross revenue (\$) | | | |
| Profit / (Loss) (\$) | | | |

SECTION C — REGULATORY STATUS & APPROVALS

CANADIAN REGULATORY STATUS

PRIMARY REGULATORY PATHWAY

Health Canada — Medical Device Licence Health Canada — Drug ID Number (DIN) Natural Health Product

LICENCE / DIN / NHP NUMBER(S)

LICENCE ISSUE DATE

INTERNATIONAL REGULATORY STATUS

FDA cleared / approved CE marked (Europe) TGA approved (Australia) Other intl approval Not approved

OTHER INTERNATIONAL APPROVALS — DESCRIBE COUNTRY AND APPROVAL TYPE

SECTION C — REGULATORY (continued)

Regulatory history — has the applicant or any product:

- Ever had a licence, approval, or registration refused, suspended, revoked, or subject to conditions? Yes No
- Ever been subject to a Health Canada, FDA, or other regulatory authority inspection or audit? Yes No
- Ever received a warning letter, compliance order, or notice of violation from any regulatory authority? Yes No
- Ever initiated or been subject to a product recall, field safety corrective action, or market withdrawal? Yes No
- Ever filed a mandatory incident report / medical device report (MDR) with any regulatory authority? Yes No

IF YES TO ANY — PROVIDE FULL DETAILS INCLUDING DATES, AUTHORITY, AND OUTCOME

SECTION D — MANUFACTURING & QUALITY MANAGEMENT

HOW ARE PRODUCTS MANUFACTURED?

- In-house / own facility Contract manufacturer (CMC) Both in-house and contract N/A — service only

PRIMARY MANUFACTURING LOCATION(S) — CITY / COUNTRY

Quality management systems — does the applicant hold or operate under:

- ISO 13485 certification (Medical Devices Quality Management System)? Yes No
- Good Manufacturing Practice (GMP) certification or compliance? Yes No
- Good Clinical Practice (GCP) compliance for any clinical activities? Yes No
- Good Laboratory Practice (GLP) compliance for any laboratory activities? Yes No
- A written quality management system (QMS) appropriate to the product type? Yes No

FOR EACH HELD — PROVIDE CERTIFYING BODY AND EXPIRY / LAST AUDIT DATE

SECTION D — MANUFACTURING (continued)

- Supply chain, manufacturing & quality risk — does the applicant:
- Source any critical components or materials from a single supplier? Yes No
 - Use any contract manufacturers outside of Canada or the USA? Yes No
 - Perform incoming inspection or testing on all critical components or raw materials? Yes No
 - Maintain a product traceability / lot tracking system? Yes No
 - Have a documented supplier qualification and audit programme? Yes No
 - Hold full rights of recourse in written agreements with all manufacturers, CMOs, licence owners, and subcontractors prior to product launch or policy inception? Yes No
 - Conduct batch testing on all products prior to release for sale? Yes No
 - Where products are relabelled, or training/advice/advertising is provided, confirm this is conducted strictly in accordance with the original manufacturer's specifications? Yes No
 - Maintain records sufficient to identify the source of all raw materials, component parts, and design inputs used in each product or batch? Yes No
 - Have the ability to trace any individual product or batch to the ultimate end customer or user to facilitate a targeted recall? Yes No
 - Have a formal, documented emergency product recall procedure in place? Yes No

IF YES TO SINGLE-SOURCE SUPPLIER OR OFFSHORE MANUFACTURING — DESCRIBE RISK MANAGEMENT IN PLACE

SECTION E — DISTRIBUTION & SALES

DISTRIBUTION CHANNELS (CHECK ALL THAT APPLY)

- | | |
|--|---|
| <input type="checkbox"/> Direct to hospitals / healthcare facilities | <input type="checkbox"/> Direct to physicians / clinics |
| <input type="checkbox"/> Direct to consumers (DTC) | <input type="checkbox"/> Wholesale / distributors |
| <input type="checkbox"/> Retail pharmacy / health stores | <input type="checkbox"/> Online / e-commerce |
| <input type="checkbox"/> Subscription / SaaS model | <input type="checkbox"/> Other (describe below) |

| | | |
|--|---|--|
| # OF ACTIVE DISTRIBUTORS / CHANNEL PARTNERS | LARGEST SINGLE DISTRIBUTOR AS % OF REVENUE | # OF COUNTRIES PRODUCTS ARE SOLD INTO |
| <input style="width: 100%;" type="text"/> | <input style="width: 100%;" type="text"/> | <input style="width: 100%;" type="text"/> |

Distribution & liability — does the applicant:

- | | |
|--|--|
| Use written distribution or reseller agreements with all channel partners? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Include indemnification provisions in distributor agreements in favour of the applicant? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Require distributors to carry their own products liability insurance? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Provide labelling, instructions for use (IFU), and warnings in the language of the country of sale? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Have a post-market surveillance or complaint handling process for adverse events? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Sell any products under a private label or white-label arrangement for third parties? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Have all advertising materials, sales brochures, app store listings, and operating manuals reviewed by legal and/or regulatory affairs prior to publication? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Ensure all product claims, indications for use, and promotional statements are consistent with the applicable regulatory approval or clearance? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Have a documented process for reviewing and approving digital content, social media, and influencer marketing prior to publication? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

IF NO TO ANY PROTECTIVE PROVISION — DESCRIBE ARRANGEMENTS IN PLACE

Does the applicant sell, distribute, or have plans to sell any products into the United States? Yes No

IF YES — DESCRIBE PRODUCTS, REGULATORY STATUS, AND % OF REVENUE FROM USA SALES

SECTION E(ii) — IMPORTS & SOURCING

Does the applicant import any finished products, raw materials, active ingredients, or component parts from outside Canada? Yes No

IF YES — COMPLETE THE TABLE BELOW

| COUNTRY OF ORIGIN | MATERIAL / PRODUCT IMPORTED | % OF TOTAL INPUT COST / REVENUE |
|-------------------|-----------------------------|---------------------------------|
| | | |
| | | |
| | | |
| | | |
| | | |

Imports risk — does the applicant:

Perform quality testing or inspection on all imported goods upon receipt? Yes No

Hold written supplier agreements with all international suppliers? Yes No

Have a documented process for qualifying and auditing international suppliers? Yes No

Source any critical ingredient or component from a single international supplier? Yes No

IF YES TO SINGLE-SOURCE INTERNATIONAL SUPPLIER — DESCRIBE RISK MITIGATION IN PLACE

SECTION F — CLINICAL TRIALS & RESEARCH

Does the applicant conduct, sponsor, or participate in any clinical trials? Yes No

| TRIAL NAME / PRODUCT | PHASE | CONDITION / INDICATION | # SITES | # PARTICIPANTS | JURISDICTION(S) | STATUS |
|----------------------|-------|------------------------|---------|----------------|-----------------|--------|
| | | | | | | |
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SECTION F — CLINICAL TRIALS (continued)

Clinical trials risk management — does the applicant:

- Have all trials approved by an independent ethics committee or IRB? Yes No
- Have informed consent processes in place for all trial participants? Yes No
- Carry clinical trials liability insurance or no-fault compensation cover? Yes No
- Have a Data Safety Monitoring Board (DSMB) or independent safety review? Yes No
- Have written agreements in place with all trial sites and investigators? Yes No

IF NO TO ANY — DESCRIBE ARRANGEMENTS OR EXPLAIN WHY NOT APPLICABLE

- Has any clinical trial sponsored or conducted by the applicant ever been suspended, terminated early, or placed on clinical hold by a regulatory authority? Yes No

IF YES — PROVIDE FULL DETAILS

SECTION G — INTELLECTUAL PROPERTY

IP portfolio — does the applicant:

- Hold any patents (granted or pending) in Canada, USA, or internationally? Yes No
- Hold any trade secrets, proprietary formulations, or confidential know-how central to the business? Yes No
- License any IP from third parties for use in its products or services? Yes No
- License any of its own IP to third parties? Yes No
- Use any open-source software components in its products or software? Yes No

IF YES TO PATENTS — PROVIDE JURISDICTION, STATUS, AND BRIEF DESCRIPTION OF WHAT IS PROTECTED

IP risk history — has the applicant:

- Ever sent or received a cease and desist letter relating to intellectual property? Yes No
- Ever been subject to a patent infringement claim or opposition? Yes No
- Ever had a patent application rejected, challenged, or invalidated? Yes No
- Ever had any trade secret misappropriation claim made against or by it? Yes No

IF YES TO ANY — PROVIDE FULL DETAILS INCLUDING DATES, PARTIES, AND OUTCOME

SECTION H — PRIOR INSURANCE & CLAIMS HISTORY

No prior products / professional liability insurance Currently insured — see details below

| POLICY YEAR | COVERAGE TYPE | INSURER | LIMIT (\$) | RETENTION (\$) | PREMIUM (\$) | RETRO DATE |
|-------------|---------------|---------|------------|----------------|--------------|------------|
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Has any insurer ever:

- Declined to offer or renew coverage? Yes No
- Cancelled a policy mid-term? Yes No
- Imposed special conditions, endorsements, or exclusions outside of standard terms? Yes No
- Required a premium loading above standard rates? Yes No

IF YES TO ANY — PROVIDE FULL DETAILS INCLUDING INSURER NAME, DATE, REASON GIVEN, AND OUTCOME

Have there been any gaps in insurance coverage in the last 10 years? Yes No

IF YES — PROVIDE DATES OF GAP AND REASON

Has any coverage ever been declined, cancelled, or non-renewed? Yes No

SECTION H — CLAIMS HISTORY (continued)

Claims history — has the applicant, or any past or present director, officer, or employee:

- Ever had a products liability claim made against them in connection with a product defect or failure? Yes No
- Ever had a professional indemnity or malpractice claim made against them? Yes No
- Ever had a claim arising from an adverse event, patient injury, or clinical trial incident? Yes No
- Ever been subject to regulatory action, investigation, or enforcement relating to any product? Yes No
- Ever initiated or been subject to a product recall or field safety corrective action? Yes No
- Ever had an IP infringement claim or cease and desist demand made against them? Yes No
- Ever experienced a cyber incident, data breach, or ransomware attack? Yes No

| DATE | NATURE OF CLAIM / INCIDENT | PRODUCT INVOLVED | AMOUNT CLAIMED (\$) | STATUS | AMOUNT PAID (\$) |
|------|----------------------------|------------------|---------------------|--------|------------------|
| | | | | | |
| | | | | | |
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Is the applicant currently aware of any of the following:

- Any product defect, failure, or adverse event that has not yet resulted in a formal claim? Yes No
- Any threatened or pending regulatory action, recall, or corrective action? Yes No
- Any circumstances that might reasonably give rise to a claim under this policy? Yes No

IF YES TO ANY — PROVIDE FULL DETAILS

SECTION I — COVERAGE REQUESTED

COVERAGE REQUIRED (CHECK ALL THAT APPLY)

- | | |
|--|--|
| <input type="checkbox"/> Products liability <input type="checkbox"/> Medical malpractice <input type="checkbox"/> Cyber & privacy liability <input type="checkbox"/> Public liability | <input type="checkbox"/> Professional indemnity <input type="checkbox"/> Clinical trials liability <input type="checkbox"/> Intellectual property <input type="checkbox"/> Product recall costs |
|--|--|

LIMIT OF LIABILITY REQUESTED (EACH CLAIM / AGGREGATE)

- \$1,000,000
 \$2,000,000
 \$5,000,000
 \$10,000,000
 \$25,000,000
 Other (specify)

IF 'OTHER' LIMIT — SPECIFY

RETROACTIVE / PRIOR ACTS DATE

Note: Section J High Hazard Product & Activity Checklist follows — complete on the attached schedule if any high-hazard items apply.

SECTION K — DECLARATION**IMPORTANT NOTICE**

The undersigned declares that the statements and information contained in this application, and any supplementary materials submitted in connection with it, are true, accurate, and complete in all material respects. The applicant understands and agrees that this application shall form the basis of and be incorporated into any policy issued. The applicant acknowledges that the insurer will rely upon the representations made herein when underwriting and issuing coverage. Any material misrepresentation, misstatement, or failure to disclose relevant information may render the policy void from inception or result in the denial of coverage, subject to applicable law.

FULL NAME (PRINT)

TITLE / POSITION

DATE (MM / DD / YYYY)

SIGNATURE OF AUTHORIZED REPRESENTATIVE