QBE Insurance

Life Sciences application

New business & renewal | claims-made coverage

Important claims-made notice and instructions

This is an application for a claims-made policy. Should this application be accepted by the company, coverage will apply to claims first made against the insured during the policy period. No coverage will apply for claims first made after the end of the policy period unless an 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 application to the company does not constitute a binder of insurance.

All questions must be answered. If not applicable, answer "N/A." If none, state "none" or "0." Attach additional pages as needed and reference the applicable section.

If this is a QBE renewal, please proceed directly to section 18

Section 1 – Applicant/insured information

Applicant name (legal name)		DBA(s) (if any)	
Entity type (corporation/ LLC/partnership/other)		Year established	
Corporate address		Mailing address	
Website			

Part of a larger corporate group? If 'Yes', describe to below. Yes ◯ No ◯

Other named insured(s): provide names (other than the first named insured) and descriptions of operations for all legal entities intended for coverage.

Entity name	Description of operations	% owned	Date acquired	Retroactive date

Section 2 — Description of operations

Describe operations (products/services, lifecycle stage, customers/end users, countries of operation):

Do any employees or contractors provide direct patient care or professional medical services? Yes ◯ No ◯

If 'Yes', briefly describe.

Primary business type:

◯ Pharma/biologic ◯ Medical device ◯ Diagnostics/IVD/LDT ◯ CRO/SMO ◯ CDMO/CMO ◯ Lab/testing

◯ Distribution/3PL ◯ Nutraceuticals ◯ Other:

Section 3 — Revenue (domestic vs. foreign)

Domestic = U.S./Canada | Foreign = rest of world

Period	Domestic (U.S./Canada) $	Foreign (rest of world) $	Total $
Prior fiscal year			
Projected next 12 months			

Section 4 — Insurance history and loss experience

Attach valued five-year loss runs if available:

Coverage	Carrier	Policy period	Limits	Retention (deductible)	Retro date

Any known losses/claims/circumstances? Yes ◯ No ◯

If 'Yes', describe/attach.

Any mass tort/class action/MDL involvement? Yes ◯ No ◯

If 'Yes', explain/attach.

Section 5 — Coverage requested

Requested coverages (check all that apply):

- ☐ Products/completed operations (claims-made)
- ☐ Clinical trials
- ☐ Contracted professional/E&O (claims-made)
- ☐ Healthcare Professional Liability (HPL - claims-made; only with products or E&O)
- ☐ General Liability — premises/operations
- ☐ Hired and Non-Owned Auto (HNOA)

Coverage	Limit	Aggregate	Retention	Retro date

Section 6 — Products/services profile (all applicants)

Products and services	Applicant acts as a(n)					No. of years	% of gross receipts	Products and goods sold to:						
	M	W	R	I	MR			M	W	R	I	MR	C	O
	☐	☐	☐	☐	☐			☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐			☐	☐	☐	☐	☐	☐	☐
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	☐	☐	☐	☐	☐			☐	☐	☐	☐	☐	☐	☐

M: Manufacturer W: Wholesaler R: Retailer I: Importer MR: Manufacturer's rep C: Consumer direct O: Other (describe)

List manufacturer(s)/supplier(s):

Section 7 — Pharmaceuticals (if applicable)

Revenue breakdown (% of total revenue):

Description	%	Description	%
Vaccines		Imaging/diagnostic agents	
Hormones & steroids		Nutri Pharmaceuticals	
Injectable/oral prescription		Vitamins/food supplements	
Topical prescription		Diet aids	
Drug delivery		Other (explain)	

Section 8 — Medical devices (if applicable)

Revenue breakdown (% of total revenue):

Description	%	Description	%
Cardiac		Anesthesia/respiratory	
Therapy/rehab		Dialysis	
Implants – active		Implants - non-active	
Infusion		Catheters	
Lasers		Analytical instruments	
Surgical devices		Diagnostic kits	
Dental instruments		Durable medical equipment	
Monitoring		Hospital products/supplies	
Imaging devices		Other (explain)	

Section 9 — Clinical trials (if applicable)

Attach protocols and informed consent forms for active/sponsored trials.

Trial sponsor? Yes ◯ No ◯

Foreign trials? If 'Yes', list countries below: Yes ◯ No ◯

Any clinical holds/suspensions/SAEs? If 'Yes', explain: Yes ◯ No ◯

Are all your clinical trials approved and subject to oversight by an institutional review board? If 'No', explain: Yes ◯ No ◯

Do you operate an in-patient facility? Yes ◯ No ◯

If 'Yes', how many beds?

Do you or your employees ever act as both the trial sponsor and clinical investigator? If 'Yes', explain: Yes ◯ No ◯

Are any subjects approved for expanded access/compassionate use? Yes ◯ No ◯

If 'Yes', how many?

Protocol/study name & number	Product	Phase of trial	Indication/disease tested	Countries	Ongoing/completed

Clinical trial participants (US	Clinical trial participants outside of the U.S	Number of minor participants

Section 10 — Nutraceuticals/dietary supplements (if applicable)

Ingredient disclosure: check if ingredient applies and provide % sales last 12 months and estimated % within the next 12 months.

	Ingredient	% sales (last 12 months)	% sales (next 12 months)
☐	Androstenedione		
☐	Aristolochia		
☐	Cannabis (CBD}		
☐	Cascara sagrada		
☐	Colloidal silver		
☐	DHEA		
☐	Gamma-Hydroxybutyrate (GHB)		
☐	Germanium		
☐	Hydroquinone		
☐	Kava		
☐	Lobelia		
☐	Pennyroyal oil		
☐	Skullcap		
☐	Steroids		
☐	Willow bark		
☐	Yellow oleander		

	Ingredient	% sales (last 12 months)	% sales (next 12 months)
☐	Animal derived products		
☐	Bitter orange/synephrine		
☐	Cannabis (THC)		
☐	Chaparral		
☐	Comfrey		
☐	Ephedra		
☐	Germander		
☐	Hormone replacement therapy		
☐	Jin Bu Huan		
☐	Kratom		
☐	Magnolia		
☐	Sildenafil/tadalafil/vardenafil		
☐	Stephania		
☐	Synephrine		
☐	Yohimbe		

Other ingredient(s) (describe):

1. Are any of the above-listed products marketed for children or for use in pre-natal or post-natal care? If 'Yes', identify such products:

2. Percentage of total estimated gross sales to be generated from the following products:

Weight loss % Body building & sports nutrition % Sexual enhancement and erectile dysfunction %

Section 11 — Cosmetics/topical products (if applicable)

UV protective products (sunscreen/sunblock)? Yes ◯ No ◯

If 'Yes', describe benzene screening protocols:

Do any products contain formaldehyde? Yes ◯ No ◯

Do any products contain stones/metals/minerals/talc? Yes ◯ No ◯

If 'Yes', describe lead/asbestos screening protocols:

Do any products intentionally cause peeling/sloughing? Yes ◯ No ◯

If 'Yes', identify agent(s):

Section 12 — Contracted professional/E&O (and HPL if applicable)

Describe professional services performed (and countries where services are provided):

Section 13 — Contract analysis (attach contract template as applicable)

Confirm the applicant's service agreements contain the following provisions.

Provision	Yes	No	If 'No', explain:
Attorney review of contracts/changes prior to use	◯	◯	
Duties/responsibilities defined	◯	◯	
Arbitration clause	◯	◯	
Choice of law/jurisdiction	◯	◯	
Force majeure	◯	◯	
Guarantees addressed	◯	◯	
Hold harmless/indemnification	◯	◯	
Limitation of consequential damages	◯	◯	
Limitation of liability	◯	◯	
Warranty disclaimers	◯	◯	
Written contract with all clients	◯	◯	

How often are contracts reviewed?	
Who manages the contracts?	

Provide the following information for your five largest contracts, purchase orders or agreements:

Customer	Contract amount	Product or service	Duration

Section 14 — Regulatory

1. Have there been any product recalls during the current policy period? Yes ◯ No ◯

   If 'Yes', provide details including product name, number of units produced, number of units retrieved, number of units outstanding, FDA/other regulatory body recall classification, and status of recall.

Products	Units affected	Units retrieved	Location	Recall classification	Status

2. When was your last FDA inspection?

3. Have you received any FDA Form 483 observations or warning letters during the current policy period? Yes ◯ No ◯

If 'Yes', please attach copies of:

- Observation letter(s), response letter(s), and close out confirmation (if issued).

Brief description (optional):

Section 15 — Quality control

1. How do you ensure that contract procedures (including third party agreements) are being followed?

◯ Internal audits
◯ SOP driven controls
◯ Management review
◯ Third party oversight
◯ Other (describe):

2. Describe how materials, components, or ingredients are controlled to assure product purity and safety:

◯ Supplier qualification
◯ Incoming material inspection
◯ Batch testing
◯ Environmental monitoring
◯ Deviation/CAPA process
◯ Other (describe):

3. What type of auditing is implemented? (check all that apply)

☐ Internal quality audits
☐ Supplier audits
☐ Contract manufacturer audits
☐ Regulatory inspections
☐ Independent third party audits

Audit frequency: ◯ Ongoing ◯ Supplier audits ◯ Bi-annual ◯ Ad hoc/event driven

4. List any additional risk management/quality control systems in place:

Section 16 — General Liability, premises/operations (if requested) claims-made or occurrence basis

Describe premises-based operations and public-facing exposures:

- [ ] Locations open to the public?
- [ ] Does the applicant sponsor any recreational activities, sporting or special events or training?
- [ ] Alcohol served or sold?
- [ ] Property leased to others?
- [ ] Are secure medication storage facilities provided for controlled substances and narcotics?
- [ ] Does the applicant have a written emergency evacuation plan?
- [ ] Do the premises have emergency back-up systems for the loss of essential utilities?
- [ ] Type of security provided for the protection of the applicant's clients/residents?

◯ Guards ◯ Locked exits ◯ Video ◯ Other (describe)

Section 17— Hired and Non-Owned Auto (HNOA) (if requested)

Employees use personal vehicles for business? Yes ◯ No ◯

Total number of employees	
Number of employees who use personal vehicles for business	
Annual cost of hire (estimated)	
Annual mileage	

Describe vehicle use (types of trips, frequency, distances):

SECTION 18 — QBE renewal and exposure updates (If applicable)

Expiring policy number	
Expiring policy period (eff/exp)	

Revenue/exposure comparison (expiring vs. projected renewal):

Exposure	Expiring	Projected renewal
Domestic (U.S./Canada) $		
Foreign (rest of world) $		
Total $		

Changes since expiring term (check all that apply):

- ☐ Products/services – complete section 6
- ☐ Manufacturing/suppliers
- ☐ Distribution
- ☐ Recalls/field actions – complete section 14
- ☐ Regulatory findings – complete section 14
- ☐ Claims/incidents – complete section 4
- ☐ Have there been any material changes to your risk management or quality systems during the current policy period? Yes ◯ No ◯

If 'Yes', briefly describe:

Other details (if any):

Section 19 — Fraud warnings

The applicant must review the below notice to policyholders fraud warning. By signature below, the applicant acknowledges the notice to policyholders fraud warning provided by the insurer that is applicable to the applicant's state of residency.

Section 20 — Signature & representations

The undersigned authorized officer represents that the information provided is true, complete, and not misleading and acknowledges that QBE will rely upon it in underwriting. Signing does not bind coverage.

Authorized signature

Printed name/title

Date *(dd/mm/yyyy)*

Fraud warnings

Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

Notice to Alabama residents: "Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or who knowingly presents false information in an application for insurance is guilty of a crime and may be subject to restitution, fines, or confinement in prison, or any combination thereof."

Notice to Alaska residents: "A person who knowingly and with intent to injure, defraud, or deceive an insurance company files a claim containing false, incomplete, or misleading information may be prosecuted under state law."

Notice to Arizona residents: "For your protection Arizona law requires the following statement to appear on this form. Any person who knowingly presents a false or fraudulent claim for payment of a loss is subject to criminal and civil penalties."

Notice to Arkansas residents: "Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison."

Notice to California residents: "For your protection, California law requires the following to appear on this form. Any person who knowingly presents false or fraudulent information to obtain or amend insurance coverage or to make a claim for the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison."

Notice to Colorado residents: "It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance, and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete, or misleading facts or information to a policyholder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies."

Notice to Delaware residents: "Any person who knowingly, and with intent to injure, defraud or deceive any insurer, files a statement of claim containing any false, incomplete or misleading information is guilty of a felony."

Notice to District of Columbia residents: "WARNING: It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant."

Notice to Florida residents: "Any person who knowingly and with intent to injure, defraud, or deceive any insurer files a statement of claim or an application containing any false, incomplete, or misleading information is guilty of a felony of the third degree."

Notice to Idaho residents: "Any person who knowingly, and with intent to defraud or deceive any insurance company, files a statement of claim containing any false, incomplete, or misleading information is guilty of a felony."

Notice to Indiana residents: "A person who knowingly and with intent to defraud an insurer files a statement of claim containing any false, incomplete, or misleading information commits a felony."

Notice to Kansas residents: "Fraud is defined as: 'an act committed by any person who, knowingly and with intent to defraud, presents, causes to be presented or prepares with knowledge or belief that it will be presented to or by an insurer, purported insurer, broker or any agent thereof, any written, electronic, electronic impulse, facsimile, magnetic, oral or telephonic communication or statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance that such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto.'"

Notice to Kentucky residents: "Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any materially false information or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime."

Notice to Louisiana residents: "Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison."

Notice to Maine residents: "It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties may include imprisonment, fines or denial of insurance benefits."

Notice to Maryland residents: "Any person who knowingly or willfully presents a false or fraudulent claim for payment of a loss or benefit or who knowingly or willfully presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison."

Notice to Minnesota residents: "A person who files a claim with intent to defraud or helps commit a fraud against an insurer is guilty of a crime."

Notice to New Hampshire residents: "Any person who, with a purpose to injure, defraud or deceive any insurance company, files a statement of claim containing any false, incomplete or misleading information is subject to prosecution and punishment for insurance fraud, as provided in RSA 638:20."

Notice to New Jersey residents: "Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties." "Any person who knowingly files a statement of claim containing any false or misleading information is subject to criminal and civil penalties."

Notice to New Mexico residents: "Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to civil fines and criminal penalties."

Notice to New York residents: "Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime, and shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each such violation."

Notice to Ohio residents: "Any person who, with intent to defraud or knowing that he is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud."

Notice to Oklahoma residents: "WARNING: Any person who knowingly, and with intent to injure, defraud or deceive any insurer, makes any claim for the proceeds of an insurance policy containing any false, incomplete or misleading information is guilty of a felony."

Notice to Pennsylvania residents: "Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties."

Notice to Rhode Island residents: "Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison."

Notice to Tennessee residents: "It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits."

Notice to Texas residents: "Any person who knowingly presents a false or fraudulent claim for the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison."

Notice to Utah residents: "Any person who knowingly presents false or fraudulent underwriting information, files or causes to be filed a false or fraudulent claim for disability compensation or medical benefits, or submits a false or fraudulent report or billing for health care fees or other professional services is guilty of a crime and may be subject to fines and confinement in state prison."

Notice to Vermont residents: "Any person who knowingly presents a false statement in an application for insurance may be guilty of a criminal offense and subject to penalties under state law."

Notice to Virginia residents: "It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits."

Notice to West Virginia residents: "Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison."