

 **Scottsdale Insurance Company Scottsdale Surplus Lines Insurance Company**

Home Office: One Nationwide Plaza Adm. Office: 18700 North Hayden Road

Columbus, Ohio 43215 Scottsdale, Arizona 85255

Adm. Office: 18700 North Hayden Road
Scottsdale, Arizona 85255

 **Scottsdale Indemnity Company**

Home Office: One Nationwide Plaza

Columbus, Ohio 43215

Adm. Office: 18700 North Hayden Road

Scottsdale, Arizona 85255

**LIFE SCIENCE SPECIALTY LIABILITY APPLICATION**

THE POLICY FOR WHICH THIS APPLICATION IS MADE IS WRITTEN ON A **CLAIMS MADE** BASIS. THIS MEANS THAT THE COVERAGE AFFORDED BY THIS POLICY IS LIMITED TO CLAIMS FIRST MADE AGAINST THE INSURED DURING THE POLICY TERM IN ACCORDANCE WITH THE COMMON CONDITIONS. DEFENSE COSTS COVERED BY THIS POLICY ARE SUBJECT TO, WILL REDUCE AND MAY EXHAUST THE LIMITS OF INSURANCE.

Throughout this application “you” refers to the applicant seeking coverage. Prior to completing the application, please read and follow the instructions below. Please attach all required documentation so that we may review and process the Application in an efficient and timely manner. All questions in this application must be answered truthfully and completely for all persons or organizations applying for insurance under this application. If a question is not applicable, please answer “N/A.”

|  |  |
| --- | --- |
| **Requested Effective Date:**       | **Coverage Type:** [ ]  **New** [ ]  **Renewal** |
| **SUBMISSION REQUIREMENTS:**[ ]  A list of all current, proposed, and discontinued products with revenue and unit counts for each.[ ]  Most recent audited financial statement.[ ]  Five year currently valued (within 60 days) loss history.[ ]  Active clinical trial schedule, informed consent form and protocol documents.[ ]  Three largest manufacturing or service agreements.[ ]  Independent contractor, physician, hospitals, laboratories agreements.[ ]  Quality control, cGMP Compliance Procedures, Business Continuity Plans.[ ]  Complaint resolution, adverse event reporting policies.[ ]  Procedures for label change, doctor notification.[ ]  Provide copy of all marketing/sales brochures.[ ]  If previous insurance is in effect, submit the prior declarations page for limit and retroactive date validation. | **BROKER/AGENT CONTACT INFORMATION:** |
| Firm Name: |       |
| Address: |       |
| Broker Name: |       |
| Email: |       |
| Phone: |       |
| License No.: |       |
| Home State: |       |
| **Submit E&S License information with each submission.****New Jersey Broker Issued Applicant No.:**       |

**I. GENERAL APPLICANT INFORMATION**

Legal Name of First Named Insured:

Physical Address:

Mailing Address:

Insured Contact Name and Title:

Insured Contact Number and Email:

Website:

Company Type:       Date Established:

Parent Company (if any):

Parent Company Address:

|  |
| --- |
| Description of Operations:       |

|  |
| --- |
| List any other name(s) or DBA name(s) used in the past:       |

**1.** Are you aware of any active or pending criminal investigations related to your business, directors, officers, partners or members thereof? [ ]  Yes [ ]  No

If yes, please provide details:

**2.** Have you sold any companies and/or product lines in the past for which you maintain legal liability? [ ]  Yes [ ]  No

If yes, please provide details:

**3.** Will any of your products or services be insured or excluded from coverage during this requested policy term? [ ]  Yes [ ]  No

If yes, please provide details:

**4.** Have you filed for bankruptcy in the last seven years? [ ]  Yes [ ]  No

If yes, please provide details:

**5.** Please provide your top three competitors:

**II. ADDITIONAL NAMED INSURED INFORMATION**

Please provide **Additional Named Insureds** for all other legal entities that are intended for coverage to apply.

*Attach in a separate spreadsheet if more room is needed.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Entity Name** | **Description of Operations** | **% Owned/Status** | **Date Acquired** | **Retroactive Date** |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

Do you expect any acquisitions or mergers to close during this requested policy term? [ ]  Yes [ ]  No

If yes, please provide details:

**III. COVERAGE INFORMATION**

**1.** What coverages and limit options are you seeking?\*

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Coverage** | **Limit of InsuranceEach Claim/Aggregate** | **Deductible or Self-Insured RetentionEach Claim/Aggregate** | **Retroactive Date(s)\*** |
| [ ]  Product-Work Hazard Liability | Option 1: $      /$      | $      /$      | [ ]  Ded [ ]  SIR |       |
| Option 2: $      /$      | $      /$      | [ ]  Ded [ ]  SIR |       |
| [ ]  Life Science Professional Liability | Option 1: $      /$      | $      /$      | [ ]  Ded [ ]  SIR |       |
| Option 2: $      /$      | $      /$      | [ ]  Ded [ ]  SIR |       |

\* For more expansive options and multiple retroactive date needs, please attach a separate request with this application.

**2.** For each coverage you are seeking, provide details of coverage purchased in the past five years:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Policy Period** | **Carrier** | **Type of Coverage** | **Limit** | **Deductible/SIR** | **Premium** | **Claims Made (CM)—Retro Date/Occurrence (OCC)** |
|       |       |       | $      /$      | $      | $      | [ ]  CM       [ ]  OCC |
|       |       |       | $      /$      | $      | $      | [ ]  CM       [ ]  OCC |
|       |       |       | $      /$      | $      | $      | [ ]  CM       [ ]  OCC |
|       |       |       | $      /$      | $      | $      | [ ]  CM       [ ]  OCC |
|       |       |       | $      /$      | $      | $      | [ ]  CM       [ ]  OCC |

Have you had any insurance cancelled or nonrenewed in the past five years? [ ]  Yes [ ]  No

If yes, explain:

**IV. EXPOSURE INFORMATION**

|  |  |  |
| --- | --- | --- |
| **Income Source** | **Projected 12 Month Income** | **Prior 12 Month Gross Income** |
| **US** | **Foreign** | **US** | **Foreign** |
| Gross Sold Product Revenue | $      | $      | $      | $      |
| % Joint Venture Collaboration |      % |      % |      % |      % |
| Total Product Units |       |       |       |       |
| Gross Service Revenue | $      | $      | $      | $      |
| Royalty Revenue | $      | $      | $      | $      |
| Government Grants, Endowments, Investment | $      | $      | $      | $      |
| Clinical Trial Subjects |       |       |       |       |

**1. Pharmaceuticals** ([ ]  Check if N/A)

**a.** Indicate the projected annual gross revenue percentage and number of products sold of pharmaceuticals that are:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product** | **US Rev %** | **Unit Count** | **Foreign Rev %** | **Unit Count** | **Are any of these specific products or classes included in your portfolio? Check all that apply.** |
| Active pharmaceutical ingredient manufacturing |       |       |       |       | [ ]  Cannabis[ ]  Dexfenfluramine[ ]  Fenfluramine[ ]  Isotretinoin[ ]  Metoclopramide[ ]  Opioid Agonist[ ]  Opioid Antagonist[ ]  Phentermine[ ]  Phenylpropanolamine[ ]  Proton Pump Inhibitors | [ ]  Sibutramine[ ]  Testosterone[ ]  Thalidomide[ ]  Thimerosal**Drug Classes:**[ ]  Birth Control[ ]  Blood Pressure[ ]  Hormone Replacement[ ]  SSRI/SNRI |
| Contract manufacturing |       |       |       |       |
| Brand: Prescription |       |       |       |       |
| Brand: Over the Counter |       |       |       |       |
| Generic: Prescription |       |       |       |       |
| Generic: Over the Counter |       |       |       |       |
| Drug delivery |       |       |       |       |
| Veterinary Use |       |       |       |       |

**2. Biologics** ([ ]  Check if N/A)

**a.** Indicate the projected annual gross revenue percentage and number of products sold of biologics that are:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product** | **US Rev %** | **Unit Count** | **Foreign Rev %** | **Unit Count** | **Are any of these specific products or activities included in your portfolio/activities? Check all that apply.** |
| Contract manufacturing |       |       |       |       | [ ]  Swine Flu Vaccines[ ]  Pediatric Vaccines[ ]  Live Virus Vaccines[ ]  CAR-T Therapy[ ]  Organ procurement[ ]  Patient Consent | [ ]  Direct to Consumer Genomic/genetic testing[ ]  Ancestry Mapping[ ]  Tissue/Blood Analysis[ ]  Culture Library |
| Biopharmaceuticals |       |       |       |       |
| Biopharma Biosimilar |       |       |       |       |
| Tissue Processing |       |       |       |       |
| Vaccines |       |       |       |       |
| Gene therapy |       |       |       |       |

Do you manufacture any vaccines eligible under the National Vaccine Injury Compensation
Program? [ ]  Yes [ ]  No

If yes, explain:

**3. Medical Devices** ([ ]  Check if N/A) FDA Registration Number (if applicable):

**a.** Indicate the projected annual gross revenue percentage and number of medical devices sold for each class:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product** | **US Rev %** | **Unit Count** | **Foreign Rev %** | **Unit Count** | **Are any of these specific products or types included in your portfolio? Check all that apply.** |
| Contract Manufacturing |       |       |       |       | [ ]  Metal-on-metal joints[ ]  Mesh[ ]  Heather/Cooler[ ]  Gadolinium | [ ]  Uterine ablation[ ]  Power morcellator[ ]  Latex[ ]  IVC Filters |
| Class I Medical Devices |       |       |       |       |
| Class II Medical Devices |       |       |       |       |
| Class III Medical Devices |       |       |       |       |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product** | **US Rev %** | **Unit Count** | **Foreign Rev %** | **Unit Count** | **Are any of these specific products or types included in your portfolio? Check all that apply.** |
| Humanitarian Use Devices |       |       |       |       | [ ]  Birth control[ ]  Robotic surgery[ ]  Concussion testing[ ]  Duodenoscopes[ ]  Cold therapy[ ]  Consumer Diagnostic Kits[ ]  Pediatric use only | [ ]  Pain pumps[ ]  Radiation emitting[ ]  Cardiac life sustaining[ ]  Insulin infusion[ ]  InVivo WIFI enabled[ ]  Silicone |
| DeNovo Devices |       |       |       |       |
| Veterinary Use |       |       |       |       |
| PMA required devices |       |       |       |       |

**b.** Do you have any devices sold direct to the consumer that are not regulated by the FDA? [ ]  Yes [ ]  No

If yes, explain:

**4. Nutraceuticals/Dietary Supplements** ([ ]  Check if N/A)

**a.** Indicate the projected annual gross revenue percentage and number of products sold of nutraceuticals/dietary supplements that are:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product** | **US Rev %** | **Unit Count** | **Foreign Rev %** | **Unit Count** | **Are any of these specific ingredients included in your portfolio? Check all that apply.** |
| Contract Manufacturing |       |       |       |       | [ ]  1,3 demethylimination/1,3 DMAA, geranainine, methylhexanamine[ ]  Aconite[ ]  Bitter Melon[ ]  Caffeine/powder[ ]  Cannabis/Hemp[ ]  Celandine/Greater[ ]  Chaparral[ ]  Comfrey | [ ]  DMBA/DMHA[ ]  Ephedra/Germander[ ]  Hoodie Gordonil[ ]  Kava[ ]  Kratom[ ]  Methylhexanamine[ ]  Methylsynephrine[ ]  Organs and glandulars[ ]  Pennyroyal Oil |
| Vitamins |       |       |       |       |
| Minerals |       |       |       |       |
| Herbs |       |       |       |       |
| Botanicals |       |       |       |       |
| Amino Acids  |       |       |       |       |
| Other:       |       |       |       |       |

**b.** Do you manufacture any products that are NOT recognized by United States Pharmacopeia Certification? [ ]  Yes [ ]  No

If yes, explain:

**c.** Are all your products in compliance with the Dietary Supplement Health and Education Act? [ ]  Yes [ ]  No

If no, explain:

**d.** Do you have any products with ingredients that are NOT listed on the label? [ ]  Yes [ ]  No

If yes, explain:

**e.** Do you have any products that you resell without ingredient validation and/or re-label? [ ]  Yes [ ]  No

If yes, explain:

|  |
| --- |
| **f.** Provide details of how you control your materials to assure product purity and safety:       |

**5. General Product Questions**

**a.** Do you have any past, present, or planned products that do not have formal FDA approval for marketing (i.e., products subject to DESI, Prescription Drug Wrap-Up, or OTC drug review)? [ ]  Yes [ ]  No

If yes, explain:

**b.** Do you have any past, present, or planned products that you market for off-label use? [ ]  Yes [ ]  No

If yes, explain:

**c.** Do you have any discontinued products? [ ]  Yes [ ]  No

If yes, explain:

**d.** Are any of your products sold under another company’s labels? [ ]  Yes [ ]  No

Do you sell another company’s products under your label? (private labeling) [ ]  Yes [ ]  No

If yes, explain:

**e.** Are any products sold as components for other products? [ ]  Yes [ ]  No

If yes, explain:

**f.** Do you contract out any product development, manufacturing, training, sales or distribution? [ ]  Yes [ ]  No

If yes, explain:

|  |
| --- |
| Please provide a list of all contracted parties and the services they provide along with contracts:       |

|  |
| --- |
| **g.** If you are selling “direct to consumer” products, what is your return policy?       |

**h.** Do you have a standard operating and compliance procedures (SOCPs) for: (Check the box to indicate “Yes”)

[ ]  Label changes [ ]  Order validation [ ]  Supply chain redundancy [ ]  Expiration date tracking

[ ]  Flagging abnormal requests [ ]  Product recall [ ]  DEA compliance [ ]  Customer complaints

[ ]  Doctor and consumer warnings

|  |
| --- |
| If yes, please provide details or provide the SOCPs in a separate document:       |

 **i.** Do you repair, resell or lease used equipment? [ ]  Yes [ ]  No

Do you recondition or repair any equipment prior to resale? [ ]  Yes [ ]  No

Are employees trained by original manufacturer and original specification training? [ ]  Yes [ ]  No

If yes, please attach a list of equipment with corresponding company contracts.

 **j.** Are any of your employees/contractors present during patient procedures, surgeries or
examinations? [ ]  Yes [ ]  No

If yes, provide details:

**k.** Do you have any association with banned products? [ ]  Yes [ ]  No

 **l.** Where do you source Active Pharmaceutical Ingredients?

Please provide country and contract details or provide the summary in a separate document.

**6. Life Science Professional/Contract Services** ([ ]  Check if N/A)

**a.** Specifically describe each of the following types of contract services and projected annual revenue of each:

| **Type of Service Performed for Others** | **Description of Services** | **US Rev %** | **Foreign Rev %** |
| --- | --- | --- | --- |
| Pharmaceutical manufacturing |       |       |       |
| Biopharmaceutical manufacturing |       |       |       |
| Medical device manufacturing |       |       |       |
| R&D/lab instrument manufacturing |       |       |       |
| Active Pharmaceutical Ingredient manufacturing |       |       |       |
| Nutraceutical/Dietary Supplement manufacturing |       |       |       |

**b.** Specifically describe other types of contract services and projected annual revenue of each:

| **Type of Service Performed for Others** | **Description of Services** | **US Rev %** | **Foreign Rev %** |
| --- | --- | --- | --- |
| Repackaging/assembly |       |       |       |
| Repair/installation |       |       |       |
| Sterilization |       |       |       |
| Refurbishing |       |       |       |
| Clinical trial oversight |       |       |       |
| Protocol, Informed Consent design/development |       |       |       |
| General Consulting |       |       |       |
| DSMB, OSMB, IRB Board Formation/Credentialing |       |       |       |
| Laboratory |       |       |       |
| Pharmacovigilance/safety surveillance |       |       |       |
| Pre-clinical testing and development |       |       |       |
| Sales and marketing |       |       |       |
| Training |       |       |       |
| Site Investigator\* |       |       |       |
| Distribution\* |       |       |       |
| Trial Subject Recruitment\* |       |       |       |
| Others (describe):       |       |       |       |

**c.** How many contracts will be in effect during the requested policy term?

**d.** Have you discontinued any services in the past five years? [ ]  Yes [ ]  No

If yes, explain:

|  |
| --- |
| **e.** Please list the countries where services are performed:       |

**f.** What is the projected total value of personal property of others in your care, custody or
control? $

What is the LARGEST value of personal property of others under a single contract or
agreement? $

Do you purchase property coverage for this exposure? [ ]  Yes [ ]  No

|  |
| --- |
| Please provide limits, effective dates and the insurance company information:       |

\**Supplemental applications may be required.*

**7. Clinical Trials** ([ ]  Check if N/A)

**a.** Complete the following information and provide all trial documents applicable to each trial. Provide under separate cover if more room is necessary:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trial Product** | **Protocol Number** | **Trial Phase** | **Country** | **Number of Subjects Enrolled** | **Status:(Planned, Ongoing or Completed)** |
| **Projected Policy Period** | **Prior Policy Period** |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |

**Clinical Trials General Questions** ([ ]  Check if N/A)

**b.** Has any clinical trial been excluded, uninsured or self-insured from any previous coverage? [ ]  Yes [ ]  No

If yes, explain:

**c.** Are you currently in compliance with all applicable regulatory guidelines regarding clinical
trials? [ ]  Yes [ ]  No

**d.** How many total trial subjects are you expected to enroll this year and how many have you previously enrolled in the past three prior years:

Projected this year:

Prior Year 1:

Prior Year 2:

Prior Year 3:

**e.** Do any clinical trials involve the following trial subject categories?

**(1)** Persons under eighteen (18) years of age [ ]  Yes [ ]  No

**(2)** Pregnant women [ ]  Yes [ ]  No

**f.** Do you anticipate any expanded access/compassionate use or inmate subjects during the policy period? [ ]  Yes [ ]  No

**g.** Have there been any Severe Adverse Events Reported (SAER) including death in connection with your trials? [ ]  Yes [ ]  No

**h.** Have there been any trials involving your product which has been discontinued or placed on hold for safety reasons? [ ]  Yes [ ]  No

 **i.** Do you or any of your employees act as both trial sponsor and clinical investigator? [ ]  Yes [ ]  No

Do you have medical professionals as employees performing medical services? [ ]  Yes [ ]  No

 **j.** Do you operate any in-patient facility? [ ]  Yes [ ]  No

**k.** Do any of your employees provide direct patient care? [ ]  Yes [ ]  No

If yes, do you require them to carry their own individual medical malpractice insurance? [ ]  Yes [ ]  No

 **l.** What is the targeted reading grade level for your informed consent documents?

**m.** Is the IRB accredited by the Association for the Accreditation of Human Research Protection Programs? [ ]  Yes [ ]  No

**n.** Do you incorporate financial disclosures in the informed consent documents or process? [ ]  Yes [ ]  No

**o.** Do you have a formalized Clinical Trial Suspension standard operating procedure in place? [ ]  Yes [ ]  No

**p.** Do you audit your clinical investigators to ensure procedures are followed? [ ]  Yes [ ]  No

**q.** Have you or any clinical investigators been cited for regulatory violations in connection with your trials? [ ]  Yes [ ]  No

**V. REGULATORY COMPLIANCE**

**1.** Are you in compliance with FDA regulations or foreign agency equivalent? [ ]  Yes [ ]  No

**2.** Are you involved in the manufacturing, marketing, sale or distribution of any controlled substances as defined by the Controlled Substances Act or any other products requiring the DEA registration? [ ]  Yes [ ]  No

**3.** Are you registered with Attorney General as required by Title 21 USC Controlled Substance Act (CSA)? [ ]  Yes [ ]  No

**4.** Are you compliant with requirements to report inventories, acquisitions and dispositions of all controlled substance as required by Title 21 USC CSA using the ARCOS Online Reporting System? [ ]  Yes [ ]  No

**5.** Have there been any incidents of non-compliance with company SOPs or regulatory requirements regarding sales, marketing, advertising or labeling? [ ]  Yes [ ]  No

**6.** In the past five years, have you been cited for non-compliance with any Good Clinical Practice quality standards, Good Laboratory Practice quality controls or Current Good Manufacturing Practices? [ ]  Yes [ ]  No

**7.** Have you had any FDA, Federal Trade or Federal Communications Commission violations in the past policy term? [ ]  Yes [ ]  No

**8.** Have you been in violation of any consumer product safety act or any other federal or local
legislation? [ ]  Yes [ ]  No

If yes, provide complete details:

|  |
| --- |
| **9.** Provide any of your products requiring a black box warning:       |

|  |
| --- |
| **10.** Provide any products requiring a Risk Evaluation & Mitigation Strategy:       |

**11.** Please provide the date of your last FDA inspection?

**12.** Were you issued an FDA 483 form? [ ]  Yes [ ]  No

If yes, please provide a copy and your response.

**13.** Have you received any warning letters from the FDA? [ ]  Yes [ ]  No

If yes, please provide copies and your response.

**14.** Have you had any of the following:

Class 1 Product Recalls: [ ]  Yes [ ]  No

Other Class Product Recalls: [ ]  Yes [ ]  No

Voluntary Product Recalls: [ ]  Yes [ ]  No

|  |
| --- |
| Please provide an explanation:       |

**15.** Please provide product and adverse event report (AER) information along with a copy of the most recently completed safety report for your top three products:

|  |  |  |
| --- | --- | --- |
| **Product Name/Formulary** | **Severe Adverse Events** | **Total Number AERs** |
|       | [ ]  Death [ ]  Permanent Injury [ ]  Hospitalization |       |
| [ ]  Other:       |
|       | [ ]  Death [ ]  Permanent Injury [ ]  Hospitalization |       |
| [ ]  Other:       |
|       | [ ]  Death [ ]  Permanent Injury [ ]  Hospitalization |       |
| [ ]  Other:       |

**16.** Do you have safety recommendations or advisory requirements involving any remedial actions that have yet to be implemented or completed?

**a.** Healthcare professional letter? [ ]  Yes [ ]  No

**b.** Additional studies? [ ]  Yes [ ]  No

**c.** Expanded product monitoring or testing? [ ]  Yes [ ]  No

**d.** Product recall or withdrawal? [ ]  Yes [ ]  No

**VI. CONTRACT GOVERNANCE**

**1.** Do you require executed written documents with all of your customers before starting services? [ ]  Yes [ ]  No

**2.** Do you use a purchase order template with any customers? [ ]  Yes [ ]  No

If yes, please attach a sample.

**3.** Are all contracts and agreements reviewed by an attorney? [ ]  Yes [ ]  No

**4.** Do standard and agreed to contracts contain the following minimum provisions:

|  |  |
| --- | --- |
| [ ]  Duties and Responsibilities of Each Party | [ ]  Definitive Product or Service Final Acceptance |
| [ ]  Arbitration Clause | [ ]  Limitation of Liability |
| [ ]  Choice of Law or Jurisdiction | [ ]  Limitation of Consequential Damages |
| [ ]  Force Majeure | [ ]  Mutual Hold Harmless |
| [ ]  Disclaimer of Warranties | [ ]  Indemnification  |

**5.** Have you been involved in any contractual disputes? [ ]  Yes [ ]  No

If yes, please attach an explanation.

**6.** Do you have any contracts that are past due acceptance? [ ]  Yes [ ]  No

If yes, please attach an explanation.

|  |
| --- |
| **7.** How do you track or manage customer complaints or concerns on contract performance:       |

**8.** What is the largest projected value and the average value of your contracts?

Largest projected contractual value: $

Average projected contractual value: $

**VII. RISK MANAGEMENT**

**1.** Do you have an employed risk manager? [ ]  Yes [ ]  No

Please provide contact information:

**2.** Do you have a formal written quality control program? [ ]  Yes [ ]  No

**3.** Do you have a formal business continuity plan? [ ]  Yes [ ]  No

If applying for professional liability, please submit as an attachment.

**4.** Do you have formal written procedures for cGMP compliance? [ ]  Yes [ ]  No

**5.** How often are standard operating procedure, compliance and quality control documents reviewed, audited and updated:

**a.** Who conducts the audits?

**b.** Who receives the audit report?

|  |
| --- |
| **6.** How do you ensure the procedures are being followed?       |

|  |
| --- |
| **7.** How do you track or manage healthcare professional and consumer complaints or reports of product adverse events?       |

**VIII. CLAIMS/LOSS INFORMATION**

**Claim and Loss History**

**1.** Is any person or organization proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in a products-work hazard liability, life science professional liability or general liability claim or suit that would be included under the proposed insurance? [ ]  Yes [ ]  No

If yes, provide complete details:

**2.** Is any person or organization proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in a data breach liabilityclaim or suit or expense? [ ]  Yes [ ]  No

If yes, provide complete details:

**3.** Is any person or organization proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in property damage to your customer’s propertyinyour care, custody or control? [ ]  Yes [ ]  No

If yes, provide complete details:

**4.** Is any person or organization proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in aproduct recall? [ ]  Yes [ ]  No

If yes, provide complete details:

**5.** Complete the following for all claims (regardless of fault and whether or not insured) and circumstance that may give rise to claims for the past five years: [ ]  Check if none.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date of Circumstance** | **Line of Business** | **Description of Circumstance Or Claim** | **Date of Claim** | **Amount Paid** | **Amount Reserved** |
|       |       |       |       | $      | $      |
|       |       |       |       | $      | $      |
|       |       |       |       | $      | $      |
|       |       |       |       | $      | $      |
|       |       |       |       | $      | $      |

|  |
| --- |
| **6.** Provide the number and complete details of any customer complaints you have received concerning your products or services in the past five years:       |

**7.** Under any previous policy term, have you or any insurer declared a related claim or batch regarding similar allegations, injuries or wrongful acts? [ ]  Yes [ ]  No

|  |
| --- |
| If yes, provide complete details and provide a copy of the final agreed upon declaration letter:       |

**8.** Is there any active litigation or suits pertaining to your products or services? [ ]  Yes [ ]  No

**9.** If at any time during the requested retroactive date period you were self-insured, maintained a captive insurance program, had an insulated retention by another insurer or had a self-funded self-insured retention, please provide all loss information in addition to any carrier loss detail or summary. Any reserve represented with a $1 will require an explanation.

**IX. SIGNATURE, ACKNOWLEDGEMENT AND CERTIFICATION**

THE APPLICANT REPRESENTS THAT THE STATEMENTS AND FACTS MADE IN THIS APPLICATION ARE TRUE AND THAT NO MATERIAL FACTS HAVE BEEN SUPPRESSED OR MISSTATED.

Applicant acknowledges a continuing obligation to report to us as soon as practicable any material change in the facts and statements above, and in each supplementary application, for which applicant becomes aware after signing the application.

Completion of this form does not bind coverage. Applicant’s acceptance of Company’s quotation is required prior to binding coverage and policy issuance. It is agreed that this form shall be the basis of the contract should a policy be issued.

The Applicant hereby declares that the above statements and particulars are true and the Applicant agrees that this application shall be the basis of the contract with the insurance company.

I/We hereby declare that the above statements and particulars are true and I/We agree that this application shall be the basis of the contract with the insurance company.

**FRAUD WARNING:** 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. (Not applicable in AL, AR, CO, DC, FL, KS, KY, LA, ME, MD, MN, NE, NJ, NY, OH, OK, OR, RI, TN, VA, VT or WA.)

**NOTICE TO ALABAMA APPLICANTS:** 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 COLORADO APPLICANTS:** 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 policy holder or claimant for the purpose of defrauding or attempting to defraud the policy holder 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.

**WARNING TO DISTRICT OF COLUMBIA APPLICANTS:** 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 Applicants:** 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 KANSAS APPLICANTS:** 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 which 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, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

**NOTICE TO KENTUCKY APPLICANTS:** 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 Maine Applicants:** 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 a denial of insurance benefits.

**NOTICE TO MARYLAND APPLICANTS:** 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 APPLICANTS:** 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 JERSEY APPLICANTS:** Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

**NOTICE TO OHIO APPLICANTS:** 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 APPLICANTS:** 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.

**FRAUD WARNING (APPLICABLE IN ARKANSAS, LOUISIANA AND RHODE ISLAND):** 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.

**FRAUD WARNING (APPLICABLE IN VERMONT, NEBRASKA AND OREGON):** Any person who intentionally presents a materially false statement in an application for insurance may be guilty of a criminal offense and subject to penalties under state law.

**FRAUD WARNING (APPLICABLE IN TENNESSEE, VIRGINIA AND WASHINGTON):** 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.

**NEW YORK FRAUD WARNING:** 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.

APPLICANT’S NAME AND TITLE:

APPLICANT’S SIGNATURE: DATE:

PRODUCER’S SIGNATURE: DATE:

AGENT NAME:       AGENT LICENSE NUMBER: