SPECIAL RISK INSURANCE MANAGERS

Suite 103, 8411 – 200th St. Langley BC. V2Y 0E7
Toll Free 800 993 6388 | Fax 604 888 1008 | WWW.SRIM.CA

LIFE SCIENCES APPLICATION

Applicant

1. Name of Applicant(s): _____
2. Address of applicant (include postal code): _____
   _____
3. Website address _____
4. In business since: _____

Underwriting Information

5. Type of entity: Corporation ☐ Partnership ☐ Joint Venture ☐ Limited Liability Company ☐
   Other (please describe): ☐ _____
6. Parent Company Name: _____
7. Parent Company Address: _____
8. Additional Insureds: _____
9. Brief description of operations: _____
   _____
10. Has the company filed for bankruptcy in the last 7 years? ☐ Yes ☐ No
11. Has the company had any mergers/acquisitions in the last 6 years and/or have any plans in the next 12 months? ☐ Yes ☐ No
    If yes, please explain: _____
12. Is the company/shareholders/directors/officers/partners/members thereof under any investigation for alleged criminal violations relating to business? ☐ Yes ☐ No
    If yes, please explain: _____
13. Has the company ever operated under a different name? ☐ Yes ☐ No
    If yes, please explain: _____

Coverage Information

14. Coverage Effective Dates: From (M/D/Y): _____ To (M/D/Y): _____
15. Prior insurance history:

Year	Coverage	Carrier	Limits	Deductible	Premium

16. Policy limits/Deductible/Retroactive dates request

	Limits	Deductible	Retroactive date
Errors and omissions liability			
Healthcare professional services			
Products/completed operations liability			
General liability			
Clinical trial medical expenses			
Clinical trials medical monitoring expenses			
Products medical expenses			
Products medical monitoring expenses			

17. Revenue History

	Canada	U.S.	Rest of World	Total
Projected				
Last year				
1st Prior				
2nd Prior				
3rd Prior				

Continue next page...

18. Please provide a breakdown of revenue by product/service for the current financial year as follows:
    The total must equal 100%.
    If these are Human Clinical Trials, complete the Clinical Trials section in the application.

Pharmaceuticals/ Biologics/Nutra	%	Medical Devices	%	Contracted Professionals	%
Injectable/Oral prescription		Analytical instruments		Contract research organization	
Benzodiazepine		Surgical instruments		Contract manufacturer	
SSRI's or SNRI's		Dental instruments		Academic medical institution	
Cannabinoids		Diagnostic kits		Site management organization	
Scheduled I or II Substance		Hospital Products/Supplies		Lab services	
Opioids		Mobility aides		Clinical staff recruitment/Training	
Fertility/Birth control		Monitoring devices		Database management/Regulatory filings/Medical writing	
Hormone replacement		Imaging devices		Distribution	
Drug delivery/Nanoparticles		Anesthesia/Respiratory		Assembly/Repackaging	
Generic Pharma		Pain pumps		Quality assurance/Control	
Imaging/Diagnostic agents		Implantable-Active		Sales/Marketing	
Nutri-pharmaceuticals		Metal-on-Metal implants		Sterilization	
Weight management		Breast implants			
Sexual enhancement		Implantable-Non active			
Topical prescription		Lasers			
Vaccines		Morcellators			
Food supplements/vitamins		Dialysis			
Cosmetics		Surgical mesh			
		IVC Filters			
		Cold therapy			
		IUD devices			
Other (specify):		Other (specify):		Other (specify):	
Total %	**100%**	**Total %**	**100%**	**Total %**	**100%**

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Products Completed Operations

19. Please list your company's products and indicate whether you are the manufacturer or distributor. If you are the manufacturer, please indicate whether you manufacture the entire product or only a part of it. For distributed products, please indicate the product's country of origin.

Product	% of Total Revenue	Manufacturer or Distributor	Whole or Part	Country of origin (for distribution only)

20. Please provide a breakdown of your revenues by class of device (as defined by Health Canada, the FDA in the U.S., or any other regulatory authority).

	Last Twelve (12) Months			Next Twelve (12) Months		
	Canada	U.S.	Other	Canada	U.S.	Other
Class 1:						
Class 2:						
Class 3:						
Class 4:						
Other:						
Total:						

21. Are products or parts manufactured outside of Canada? ☐ Yes ☐ No ☐ N/A
    If yes, what product(s) and where? _____
22. Are you aware of product(s) sold off-label? ☐ Yes ☐ No ☐ N/A
    If yes, are off-label products tracked? ☐ Yes ☐ No ☐ N/A
    Do you have procedures in place for inhibiting employees from off-label promotions? ☐ Yes ☐ No ☐ N/A
23. Are any products repackaged or relabeled? ☐ Yes ☐ No ☐ N/A
    If yes, which products? _____
24. Do product(s) have a Black Box or other significant safety warning? ☐ Yes ☐ No ☐ N/A
    If yes, which products? _____
25. Are product(s) sold as components of other products? ☐ Yes ☐ No ☐ N/A
    If yes, which products? _____
26. Have product(s) ever been associated with death/permanent injury or hospitalization? ☐ Yes ☐ No ☐ N/A
    If yes, please explain: _____
27. Has any product(s) been recalled in the past 5 years? ☐ Yes ☐ No ☐ N/A
    If yes, please explain: _____
28. Are you considering recalling any known or suspected defective products from the market? ☐ Yes ☐ No ☐ N/A

29. Are any products specifically approved for, and used by: minors, pregnant women, cognitively impaired and/or prisoners? ☐ Yes ☐ No ☐ N/A

30. Have you discontinued any products or services in the last 5 years? ☐ Yes ☐ No ☐ N/A

31. Are you considering discontinuing any product or service? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

32. Is applicant considering introducing any new products or services in the next 12 months? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

33. Do you rent/lease medical equipment? ☐ Yes ☐ No ☐ N/A
If yes, which products? _____

34. Do you repair/install/or service medical equipment? ☐ Yes ☐ No ☐ N/A
If yes, are you or your employees factory trained? ☐ Yes ☐ No ☐ N/A

35. Do you comply with the Health Canada's Good Manufacturing Practices (GMP) or equivalent manufacturing standards for your product(s)? ☐ Yes ☐ No ☐ N/A

36. Do you maintain the following records:
When and where product was manufactured? ☐ Yes ☐ No ☐ N/A
To whom the product was sold and date of sale? ☐ Yes ☐ No ☐ N/A
Who supplied the materials for the product? ☐ Yes ☐ No ☐ N/A
Change in design/change in advertising? ☐ Yes ☐ No ☐ N/A

37. Do any of your products contain the following (including any derivative thereof):
Aconite, Higenamine; Aegeline; Androstenedione; animal derived products, AMP Citrate, 1,3-dimethylbutylamine citrate,1,3-dimethylbutylamine HCL, methylpentanamine; Aristolochic Acid, BMPEA, B-Methylphenethylamine, Acacia rigidula; Butanediol, Chaparral, Comfrey (Pyrrolizidine alkaloids), Contraceptives or any other products intended to inhibit pregnancy or act as birth control; Chomper, Creatine, Dehydroepiandrosterone, Dendrobium; Dieter's Tea, Dienestrol, diethylstilbestrol, or DES, or which has the same chemical formulary, or which is a stilbene derivative, or any other product or substance having substantially similar formation, structure, or function by whatever name manufactured or marketed as DES; Diethylistbestrol, DMAA, 1,3-dimethylamylamine, dimethylamylamine, methylhexanamine; Ephedra, Ma huang, Ephedra sinica, Chinese Ephedra, ephedrine, ephedrine Alkaloids, pseudoephrine, norpseudoephredine, or any other product or substance having substantially similar formation, structure or function, by whatever name manufactured, grown or marketed; Ephedrine, Estazolam, Gamma Butyrolactone, Gamma Hydroxybutyric Acid, Germander, Germanium, Injectables and implants intended for cosmetic purposes, including but not limited to breast implants, bovine collagen based dermal fillers or implants, human collagen based dermal fillers or implants, hyaluronic acid based dermal fillers or implants, autologous fat transfer, cadaveric based products, and botulinum toxin injections; Isotretinoin, Accutane; Indinavire, Jin Bu huan; Kava, kava-kava and related derivatives; Lobelia; L-Tryptophan or products of any kind or nature which contain L-Tryptophan or any derivative thereof, regardless of whether the product is designated as L-Tryptophan or given any other appellation; Melatonin, oral contraceptives, Pennyroyal Oil; Phenolphthalein or NeoPrunex, or any derivative thereof; Phentermine, Phenylalanine, Phenylpropanolamine, Phenylpropanolamine Hydrochloride, PPA or any product or drug containing any of these substances; Picamilon, N-nicotinoyl-GABA, pycamilon, pikamilon; products that are know mutagens, products that are known teratogens, psychotropic products, SSRI (Selective Serotonin Reuptake Inhibitor) or SNRI (Selective Norepinephrine Reuptake Inhibitor); Stephania; St. John's Wort, Stephania or Magnolia, tobacco or any tobacco products (or ingredients of, or used in the manufacture or production of, such products); Thalidomide; Thimerosal, Tiractricol, Trix Metabolic Accelerator, Vaccines, toxoids, sera and other immunizing agents; Vinpocetine, Cavinton, Intelectol, ethyl apovincaminate; weight reduction products, Willow Bark, and Yohimbe arising out of any product used for the treatment of obesity, weight loss and/or weight management, including but not limited to suppressants containing fenfluramine (Ponderal, Ponderal Pacaps, Pondimin) or dexfenfluramine (Redux) or as part of a combined therapy known as fenphen (fenfluramine and phentermine); any product containing silicone or similar which is in any form implanted or injected in the body; ☐ Yes ☐ No ☐ N/A
If yes, please state which ones:

_____

Human Clinical Trials

38. Test subjects enrollment history

	Canada participants	U.S. participants	Rest of world participants	Number of minor participants	Total
Projected					
Last year					
Prior					

39. Schedule of human clinical trial(s):
Please provide copy of Protocol and Informed Consent Form for each sponsored trial (use attachment if necessary)

Product/Protocol Name & Number	Number of Test Subjects encolled last year	Number of Test Subjects Newly Enrolled this Year	Phase of Trial and Indication/ Disease tested	Country of Trials	Ongoing/ Completed

40. Are all of your clinical trials approved and subject to oversight by an institutional review board? ☐ Yes ☐ No ☐ N/A
If no, please explain: _____

41. Do you operate an in-patient facility? ☐ Yes ☐ No ☐ N/A
If yes, how many beds? _____

42. Do you or your employees ever act as both the Trial Sponsor and Clinical Investigator? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

43. Do your employees participate on an institutional review board? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

44. Has any of your trials been suspended/place on hold because of safety concerns? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

45. Are any of the following incentives provided to the Clinical Investigator? ☐ Money ☐ Stock ☐ Position ☐ Other ☐ None

46. Have any clinical investigators been cited for regulatory violations in connection with your trials?
If yes, please explain: _____

47. In the past 12 months, have there been any AER's or SAER's filed? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

48. Have any warning letters been issued against you or your investigators? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

49. Have there been any clinical trial "For Cause Audits" conducted in the last 5 years? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

50. Do any clinical trials involve minors (under the age of 18)? ☐ Yes ☐ No ☐ N/A

51. Are any of the subjects approved for expanded access/compassionate use? ☐ Yes ☐ No ☐ N/A
If yes, how many? _____

52. Do you publish all clinical trial results? ☐ Yes ☐ No ☐ N/A

53. Do you ever provide material/product for another organisation's clinical trial? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

Healthcare Professional Services

54. Healthcare Professional Staff:

Name	Specialty	Board certification	Hours worked	Full-time/ part time	Own malpractice Insurance? Limits

55. Has applicant or any of its staff's license to practice medicine or license to prescribe or dispense drugs ever been limited, suspended, revoked, placed on probation or been voluntarily surrendered in any province/territory? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

56. Are any of the above-listed physicians to be listed under applicant's policy? ☐ Yes ☐ No ☐ N/A
If yes, please provide CV for each physician.

57. Do any of the physicians have direct patient care responsibilities? ☐ Yes ☐ No ☐ N/A

58. Prior to hiring any employee, do you verify the following:
    - Education background/training? ☐ Yes ☐ No ☐ N/A
    - Employment references with at least two previous employers? ☐ Yes ☐ No ☐ N/A
    - Criminal record on Local/Provincial/Territorial/National? ☐ Yes ☐ No ☐ N/A
    - Driving record? ☐ Yes ☐ No ☐ N/A
    - Drug Test? ☐ Yes ☐ No ☐ N/A

59. Are all health professionals credentialed prior to hiring? ☐ Yes ☐ No ☐ N/A
If yes, how are often are physicians re-credentialed? _____

60. Has the applicant or any staff ever been the subject of disciplinary/investigative proceedings or reprimand by a governmental/administrative agency, hospital, or professional association? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

Errors and Omissions

61. Are any contracts past due, customers stopped payments or requested refunds? ☐ Yes ☐ No ☐ N/A
If yes, please explain: _____

62. Do you have formal written contracts/agreements in place with all clients/customers? ☐ Yes ☐ No ☐ N/A

63. Do you ever assume liability of others in your contract? ☐ Yes ☐ No ☐ N/A

64. Do the contracts include the following provisions?

All duties and responsibilities of each party	☐ Yes	☐ No	☐ N/A
Arbitration Clause	☐ Yes	☐ No	☐ N/A
Choice of Law or Jurisdiction	☐ Yes	☐ No	☐ N/A
Force Majeure	☐ Yes	☐ No	☐ N/A
Guarantee/Warranty Disclaimers	☐ Yes	☐ No	☐ N/A
Hold Harmless Agreements/Indemnification	☐ Yes	☐ No	☐ N/A
Limitation of Consequential Damages	☐ Yes	☐ No	☐ N/A
Limitation of Liabilities/Capping of Limits	☐ Yes	☐ No	☐ N/A

65. Does an attorney review all contracts or agreements including changes prior to use? ☐ Yes ☐ No ☐ N/A

66. Do you contract out product development, manufacturing, packaging, sales, distribution, sterilization and/or validation? ☐ Yes ☐ No ☐ N/A

67. Do you receive a hold harmless agreement from each contractor? ☐ Yes ☐ No ☐ N/A

68. Do you obtain Certificate of Insurance from all manufacturers/suppliers evidencing Product Liability insurance? ☐ Yes ☐ No ☐ N/A
    If yes, what are the minimum limits required? _____

69. What is the largest contract by revenue? $ _____

70. What is the longest contract by duration (month) _____

71. What is the average value and duration of contracts: $ _____ _____ Months

Regulatory/Risk Management

Note: UW may request to review copies of QC/QA, Product Recall, Contract Agreements as part of the submission)

72. To the best of your knowledge, are you in compliance with the Health Canada regulations and if applicable, the foreign agency equivalent? ☐ Yes ☐ No ☐ N/A

73. Have there been any incidents of non-compliance (including sales and marketing practices) in the past 5 years? ☐ Yes ☐ No ☐ N/A
    If yes, please explain: _____

74. Do you have a formal Quality Control program? ☐ Yes ☐ No ☐ N/A

75. Do you have a formal Loss Control/Risk Management program? ☐ Yes ☐ No ☐ N/A

76. Do you have a formal written Product Recall plan? ☐ Yes ☐ No ☐ N/A

77. Do you have a Records Retention Plan? ☐ Yes ☐ No ☐ N/A

78. Do you require all sales personnel to participate in a formal training program that instructs them on all applicable company policies and procedures? ☐ Yes ☐ No ☐ N/A

79. Do you have any products that do not have a formal Health Canada and if applicable, foreign agency equivalent approval for marketing? ☐ Yes ☐ No ☐ N/A
    If yes, please explain: _____

80. When was your last Health Canada inspection (if relevant)? _____
    Were you issued a notice as part of this inspection? ☐ Yes ☐ No ☐ N/A
    If 'Yes', please provide a copy along with your responses, if applicable

81. Do your product(s) require a Risk Evaluation & Mitigation Strategy (REMS)? ☐ Yes ☐ No ☐ N/A
    If yes, what product(s)? _____

Loss Information

82. Please provide details of applicant's total aggregate losses, from the 1st dollar, including expenses (and please also attach hard copy loss runs for the last 5 years):

Policy Period	Insurer	Number of Claims	Total Cost Incurred

83. Any claim(s)/known occurrence(s) not yet reported? ☐ Yes ☐ No ☐ N/A

84. Does the applicant handle claims in-house or utilize the services of a third-party administrator? ☐ Yes ☐ No ☐ N/A

85. Has any claim or suit for an error, omission or malpractice ever been made against applicant or any employees/staff working on its behalf? ☐ Yes ☐ No ☐ N/A

86. Any product or service has been/is involved with any certified/attempted class action or multi-national litigation? ☐ Yes ☐ No ☐ N/A

87. Has your insurance ever been cancelled or non-renewed by a carrier? ☐ Yes ☐ No ☐ N/A

88. If answered yes to any questions 83-87, please explain:

Please provide the following information:

1. Detailed Loss History for the last FIVE years. The loss runs should be updated within the last 30 days, and include a breakdown of total incurred losses (paid and reserves for both indemnity and expense), and a description of all losses, whether paid or outstanding.
2. Most recent AUDITED financial statements.
3. Copy of CONTRACTUAL AGREEMENT(S) in place with whom you enter into a service for a fee agreement.
4. Copy of Human Clinical Trial PROTOCOL(S) and INFORMED CONSENT FORM(S)
5. Copy of recently issued WARNING LETTERS/and RESPONSES
6. Most recent local and/or provincial/territorial accreditation agency reports.
7. Any marketing brochures or literature detailing services provided.

I/We declare and warrant that after enquiry all statements and particulars contained in this Proposal and addenda are true and that no information whatsoever has been withheld which might increase the risk of the Underwriters or influence the acceptance of this Proposal and should the above particulars alter in any way I/We will advise Underwriters as soon as practicable. I/We understand that failure to disclose any material facts that would be likely to influence the acceptance and assessment of the Proposal may result in the Underwriters refusing to provide indemnity or voiding the policy in every respect. I/We hereby agree and accept that this Declaration shall be the basis of the contract between both parties if entered into. I/We have been advised by the broker and consent to any information that may be perceived as personal information for collection, appropriate use, and disclosure of to third parties

Print name: _____ Position held (Owner, partner, authorised officer): _____

Signature: _____ Date: _____

Broker Name: _____ Broker Address: _____