CHUBB®
美商安達產物保險股份有限公司台灣分公司
Insurance Company of North America, Taiwan Branch
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安達產物生命科學綜合責任保險要保書
CHUBB LIFE SCIENCE LIABILITY INSURANCE APPLICATION FORM

105.11.22 安達商字第 1050665 號函送保險商品資料庫

有關本公司公開資訊，請見本公司網址：http://www.chubb.com/tw

本商品經本公司合格簽署人員檢視其內容業已符合保險精算原則及保險法令，惟為確保權益，基於保險業與消費者衡平對等原則，消費者仍應詳加閱讀保險單條款與相關文件，審慎選擇保險商品。本商品如有虛偽不實或違法情事，應由本公司及負責人依法負責。

請您務必在本要保書充分並如實揭露您所知曉的或應當知曉的所有資訊，以免影響您基於本保險契約的權益。
YOU ARE TO DISCLOSE IN THIS FORM FULLY AND FAITHFULLY ALL FACTS WHICH YOU KNOW OR OUGHT TO KNOW, OTHERWISE YOUR RIGHTS UNDER THIS INSURANCE CONTRACT MAY BE PREJUDICED.

注意：這是一份以賠償請求報案制為部分承保範圍基礎的保險的要保書。依據本要保書所簽發的任何保險單的責任限額，根據保險單的相關定義，應包括對賠償請求的賠償金額和保險單所定義的理賠與辯護費用的給付。
NOTICE: This is an application for a policy with part of the coverage on claims made and reported basis and that the limit of liability under any policy to be issued in response hereto shall include both indemnity payments for claims and payment of claim and defense expenses, as defined in the policy.

茲經同意，本保險應由列名第一位的列名被保險人要保。列名第一位的列名被保險人應負責繳付保險費或接受退還的保險費，提出或接受終止的通知，協商、同意並接受附加條款，提出或接受本保險單規定的任何通知（申請延長報案期間的通知除外）。列名第一位的列名被保險人應取得各被保險人授權其代表所有被保險人提出或接受賠償請求的通知。
It is agreed that the Applicant shall be the first Named Insured of this insurance. The first Named Insured shall be responsible for the payment of premiums, receiving of premium refund, giving and receiving of notice of termination, negotiation on, consent to, and acceptance of endorsements, and giving and receiving of any notice provided for in this policy (except the giving of notice of applying for an Extended Reporting Period) and shall, with the authority from all Insureds, act on behalf of all Insureds with respect to the giving and receiving of notice of Claim.

請注意保險單的辯護費用條款規定責任限額可因給付訴訟費用而用盡。任何自負額或自留額均適用於賠償金以及調查費用和辯護費用。
Please note that the defense cost provision of the policy stipulates that the limits of liability may be completely exhausted by the cost of legal defense. Any deductible or retention shall apply to investigation expense and defense costs as well as indemnity.

所有根據本要保書投保的個人或組織都應當如實、完整地回答本要保書所列的所有問題。對於不適用的問題或欄目，請用“不適用”回答。如果一個問題的答案是無，請寫明“無”或者“0”。如果需要更多的空間填寫問題的完整答案，請另以附頁填寫，並註明其所回答的問題。
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 OR SECTION IS NOT APPLICABLE, PLEASE ANSWER "NA". IF THE ANSWER TO A QUESTION IS NONE, STATE "NONE" OR "0". IF MORE SPACE IS REQUIRED TO ANSWER A QUESTION COMPLETELY, PLEASE PROVIDE A SEPARATE ATTACHMENT AND IDENTIFY THE QUESTION IT RESPONDS TO.

本要保書是一份word文檔，要保人可以在相應的空白欄處填寫資訊，但請絕對勿對本要保書進行任何修改（除非為答案而保留的欄位）。本檔所設置的格式可以根據填入的內容而相應調整欄位元的空間大小。在要保書每一主項的末尾都留有空白欄位，可加註詳細的說明。
This application is a word document that allows applicant to enter information in the empty sections. Any alteration of this application (other than sections reserved for answers) is expressly prohibited. This document is configured so that each data entry section will expand to accommodate the information. A box for detailed commentary has been provided below each major section of the application.

填表前，請提供以下文件的影本作為本申請表的附件：
BEFORE CONTINUING, PLEASE ATTACH COPIES OF THE FOLLOWING WITH THIS APPLICATION:

1. 最近5年所發生的損失的詳細資訊
   Detailed loss information for the last 5 years
2. 銷售、服務和許可契約或協議的標準格式以及3份最大金額的銷售、服務和許可契約或協議

Copies of standard and 3 largest sales, service & license contracts or agreements

3. 如果為民營企業，最近一次財務報表
   If private, most recent financial statement
4. 現行主辦的臨床試驗計劃書以及相關受試者同意書
   Protocols and Informed Consent documents for active sponsored clinical trials
5. 其他可提供的材料
   Other materials as applicable

一般資訊
GENERAL INFORMATION

1. 要保人： Applicant:	
2. 請提供您經營業務的簡介： Please provide brief description of your operations:	
3. 地址： Address:	
4. 郵寄位址（如不同）： Mailing Address: *(if different)*	
5. 網址： Web Site Address:	
6. 其他地址（如不同於上述者）： Locations: *(if other than above)*	
7. 所有列名被保險人： All Named Insureds:	
8. 附加被保險人（說明關係）： Additional Insureds: *(explain relationship)*	
9. 最近5年內收購的任何子公司？*（如有，請寫明公司的名稱和收購日期）* Any acquired subsidiaries in the last 5 years? *(if yes, please provide entity name and date acquired)*	
10. 要保人是： Applicant is:	個 人 Individual ☐ 合 夥 Partnership ☐ 法 人 Corporation ☐ 合資企業 Joint Venture ☐ 有限責任公司 LLC ☐ 其他 Other ☐（說明）(describe)
11. 已營業期間： Years in business?	
12. 要保人是否有母公司？*（如有，請寫明母公司名稱）* Does applicant have a parent company? *(if yes, provide name)*	
13. 要保人是否以其他名稱經營業務？*（如有，請寫明詳細資訊）* Has applicant operated under another name? *(if yes, provide full details)*	
14. 要保人的競爭者中前3名？ Who are applicant's top 3 competitors?	
15. 要保人在最近七年內有否申請過破產？*（如有，寫明詳細資訊，包括申請破產理由的簡要介紹，破產管轄地，法院編號和破產管理人的身份和聯繫方式）* Has the applicant filed for bankruptcy in the last seven years? *(if yes, provide full details, including a brief description of the reason for filing, bankruptcy jurisdiction, court number and identity and contact information of the trustee)*	
16. 要保人或其任何股東、董事、經理人、合夥人或合資企業成員是否涉及任何與您業務有關的刑事犯罪調查？ Is the applicant or any shareholders, directors, officers, partners, or members thereof under any investigation for alleged criminal violations relating to your business?	
17. 要保人是否遵守所有的適用的法規指引？*（如果沒有，具體寫明）* Is applicant in compliance with all applicable regulatory guidelines? *(if no, provide details)*	
18. 要保人在最近3年內有否因任何違規原因被傳喚？*（如有，具體寫明）* Has applicant been cited for any regulatory violations in the last 3 years? *(if yes, provide details)*	
19. 預計國內銷售總額？ Total projected domestic gross sales?	
20. 預計國外銷售總額？ Total projected non-domestic gross sales?	
21. 上一年度銷售總額？ Previous year gross sales?	

22. 請從下列項目中勾選所投保的承保範圍 Please advise what coverage you would like to choose. (　)身體傷害與財物損失，公共意外責任 Bodily Injury And Property Damage, Premises/Operations Liability (　)身體傷害與財物損失，產品-完工危險責任(賠償請求報案制) Bodily Injury And Property Damage, Products-Completed Operations Hazard Liability, Claims-Made And Reported (　)廣告傷害與個人傷害責任 Advertising Injury And Personal Injury Liability (　)錯誤或疏漏責任(賠償請求報案制) Errors Or Omissions Liability, Claims-Made and Reported	

醫藥/生物製劑研發或產品收入比率。*如果不適用請在此註明：* ☐
DRUGS/BIOLOGICS R&D OR PRODUCT REVENUE PERCENTAGES. *If N/A, indicate here:* ☐

單一來源處方 Single Source Prescription		單一來源非處方 Single Source Over the Counter	
多源/一般處方 Multi-Source/Generic Prescription		多源/一般非處方 Multi-Source/Generic Over the Counter	

專業分類
SPECIALTY BREAKDOWN

心臟/血管疾病 Cardiology/Vascular Diseases		腫瘤 Oncology	
齒科/頜面外科 Dental/Maxillofacial Surgery		眼科 Ophthalmology	
皮膚科/整形外科 Dermatology/Plastic Surgery		耳鼻喉科 Otolaryngology	
內分泌科 Endocrinology		兒科/新生兒科 Pediatrics/Neonatology	
腸胃科 Gastroenterology		藥理科/毒理科 Pharmacology/Toxicology	
血液科 Hematology		精神病科/心理學科 Psychiatry/Psychology	
免疫/傳染病 Immunology/Infectious Diseases		肺/呼吸道疾病 Pulmonary/Respiratory Diseases	
骨科 Musculoskeletal		風濕科 Rheumatology	
腎臟/泌尿科 Nephrology/Urology		外科/急症科 Trauma/Emergency Medicine	
神經科 Neurology		其他 Other	
產科/婦科 Obstetrics/Gynecology			

1. 要保人是否曾經、正在或即將涉及任何下列類別的物質：*（如有，具體寫明）*
Does applicant have any past, present or planned association with substances in any of the following categories: *(if yes, provide details)*

已知致畸物質 Known Teratogen		疫苗 Vaccines		植物源 Plant Derived		抗憂鬱症物質 Anti-Depressant	
已知致突變物質 Known Mutagen		動物源 Animal Derived		節育 Birth Control		荷爾蒙 Hormone	
已知致癌物質 Known Carcinogen		人類源 Human Derived		減輕體重 Weight Reduction		致癮物質 Addictive Substances	
詳細資訊： Details:							

醫藥設備研發或產品收入比率。*如果不適用請在此註明：* ☐
MEDICAL DEVICES R&D OR PRODUCT REVENUE PERCENTAGES. *If N/A, indicate here:* ☐

麻醉科 Anesthesiology		血液科和病理科 Hematology and Pathology	
心血管科 Cardiovascular		免疫科和微生物科 Immunology and Microbiology	
臨床化學科和臨床毒理科 Clinical Chemistry and Clinical Toxicology		神經科 Neurology	
齒科 Dental		助產科和婦產科 Obstetrical and Gynecological	
耳鼻喉科 Ear, Nose, and Throat		眼科 Ophthalmic	
腸胃科和泌尿科 Gastroenterology and Urology		整形外科 Orthopedic	
綜合整形外科 General and Plastic Surgery		物理治療 Physical Medicine	
綜合醫院和個人自用 General Hospital and Personal Use		放射科 Radiology	
		其他 Other	

1. 要保人是否曾經、正在或即將涉及任何下列類別的產品：*（如有，具體寫明）*
   Does applicant have any past, present, or planned association with any of the following products: *(if yes, provide details)*

隆胸 Breast Implants		脊椎類裝置 Spinal Devices		橡膠手套 Latex Gloves		
宮內節育器 IUD Devices		動物源 Animal Derived		增塑劑 DEHP		
椎弓根螺釘 Pedicle Screws		人類源 Human Derived				
詳細資訊： Details:						

營養補充品產品收入比率。如果不適用請在此註明： ☐
DIETARY SUPPLEMENT PRODUCT REVENUE PERCENTAGES. *If N/A, indicate here:* ☐

維生素 Vitamin		濃縮物，代謝物，成份物或提煉物 Concentrate, metabolite, constituent or extract	
礦物質 Mineral		酶 Enzymes	
草藥或其他植物性藥材 Herb or other botanical		藥類食物（需處方） Medical foods (prescription required)	
氨基酸 Amino acid		其他 Other	

1. 請寫明目前被列入美國食品及藥物管理局營養補充品警告及安全資訊網站 (http://www.cfsan.fda.gov/~dms/ds-warn.html)或類似的監督管理資料名錄中任何您的產品類別。 Please identify any of your product categories currently listed on the FDA's Dietary Supplement Warnings and Safety Information Site (http://www.cfsan.fda.gov/~dms/ds-warn.html) or similar regulatory database.	
2. 您的產品是否包含任何動物源物質？ Do any of your products contain any animal derived substances?	
3. 您的產品是否有過保健聲明？如有，是哪些產品？這些產品是否在同儕審評的專業刊物中出現過？ Do any of your products make health claims? If yes, which ones and have they been published in peer review publications?	
4. 您的產品是否符合任何新膳食成份的定義？如果是，是否根據規定進行過上市前的安全審查？ Have any of your products ever fit the definition of a new dietary ingredient? If so, have pre-market safety reviews been conducted per regulations?	
5. 您的產品中是否含有任何一項活性成份可能會被相關管理機構認定為藥物？如有，他們是什麼？ Have any of your products ever had an active ingredient that would be defined as a drug by a regulatory agency? If so, what are they?	
詳細資訊： Details:	

專業服務收入比率。*如果不適用請在此註明：* ☐
PROFESSIONAL SERVICE REVENUE PERCENTAGES. *If N/A, indicate here:* ☐

符合臨床檢驗改進修正案標準認證的實驗室服務（說明實驗室服務的類別） CLIA Certified Lab Services (indicate type of lab services)		產品回收/撤回 Product Recall/Withdrawal	
一期臨床試驗中心服務 Phase 1 Site Services		臨床試驗中心管理 Clinical Site Management	
臨床試驗產品包裝 Clinical Trials Packaging		設備安裝/維護/殺菌消毒 Equipment Installation/Maintenance/Sterilization	
臨床試驗中心選擇、訓練、監測 Clinical Site Selection, Training, Monitoring		品管系統和法令遵循 Quality Systems & Regulatory Compliance	
聯絡溝通和成果發表 Communications & Publications		銷售和市場推廣 Sales & Marketing	
健康管理、經濟和政策研究 Health Management, Economic, & Policy Research		軟體開發和產品設計 Software Development or Product Design	
資訊服務/資料庫 Information Services/Databases		生產/分銷/包裝/混合/標籤 Manuf./Distribution/Packaging/Mixing/Labeling	
臨床試驗審查委員會 Institutional Review Board		藥物監測/安全監督 Pharmacovigilance/Safety Surveillance	
臨床前服務 Pre-clinical Services		倉儲 Warehouse storage	
財務服務（請寫明） Financial Services (please describe)		其他（請解釋） Other (please explain)	

1. 要保人是否已制定專案計畫綱要和操作程序？ Does applicant have formalized project-planning policies and procedures?	
2. 要保人是否已制定客戶投訴解決方案和操作程序？ Does applicant have formalized client complaint resolution policies and procedures?	
3. 在最近3年內是否有任何過期契約，或有客戶停止付款或要求退款或賒帳？*（如有，具體寫明）* Are any contracts past due or has a client stopped paying or asked for a refund or credit in the last 3 years? *(if yes, provide details)*	
4. 現在有效契約的總數？ Total # of current contracts?	
5. 近10年內任何中途停止的服務？*（如有，具體寫明）* Any discontinued services within the last 10 years? *(if yes, provide details)*	
6. 要保人契約的平均契約價款？要保人契約的平均期限？ Average dollar value of applicant's contracts? Average duration of applicant's contracts?	
7. 請指明下一保險年度最大的客戶，以及相關契約的金額/數量和期限： Indicate largest client for upcoming policy year, and include contract amount/volume and duration:	
8. 要保人機構內其他人的動產總值？ What is the total value of the personal property of others at applicant's facilities?	
詳細資訊： Details:	

藥物發明技術研發或產品收入比率。*如果不適用請在此註明：* ☐
DRUG DISCOVERY TECHNOLOGY R&D OR PRODUCT REVENUE PERCENTAGES. *If N/A, indicate here:* ☐

生物資訊 Bioinformatics		蛋白質組 Proteomic		基因體 Genomics	
• 軟體： • Software:		• 軟體： • Software:		• 軟體： • Software:	
• 硬體： • Hardware:		• 硬體： • Hardware:		• 硬體： • Hardware:	
• 數據： • Data:		• 數據： • Data:		• 數據： • Data:	
其他： Other:					

詳細資訊： Details:

研究機構收入/基金。*如果不適用請在此註明：* ☐
RESEARCH INSTITUTIONS REVENUES/FUNDING. *If N/A, indicate here:* ☐

產品許可 Product Licensing		產品的商業化 Product Commercialization	
基礎研究 Basic Research		醫藥產品研究 Medical Product Research	
臨床前測試 Pre-clinical Testing		非醫藥產品研究 Non Medical Product Research	
臨床測試 Clinical Testing		其他 Other	

詳細資訊： Details:

供應商及/或批發分銷商收入比率。*如果不適用請在此註明：* ☐
SUPPLIER AND/OR WHOLESALE DISTRIBUTOR REVENUE PERCENTAGES. *If N/A, indicate here:* ☐

醫藥/生物製劑 Drugs/Biologics		醫療設備零配件/軟體 Medical Device Component Parts/Software	
醫療設備 Medical Devices		醫藥/生物製劑成分 Drugs/Biologic Ingredients	
營養補充品 Dietary Supplements		醫藥產品生產設備 Medical Products Manufacturing Equipment	
活性成份 Active Ingredients		醫藥產品研發設備 Medical Products R&D Equipment	
		其他 Other	

1. 是否有零配件或成分的供應商，或其他人產品的分銷商，要求成為產品許可持有者之產品責任保單的附加被保險人？您是否需要包括辯護費用在內的損害賠償保障？ If a supplier of components or ingredients, or a distributor for the products of others, do require additional insured status on the product license holder's products liability policy? Do you require indemnification for damages including defense cost?	
詳細資訊： Details:	

人體臨床試驗。*如果不適用請在此註明：* ☐
HUMAN CLINICAL TRIALS. *If N/A, indicate here:* ☐

目前主辦的試驗（包括第四期臨床試驗）
Active Trials Currently Being Sponsored. (include phase 4)

產品名稱及計畫書編號 Product Name & Protocol Number	在下一保險期間的新登記受試者人數 # of New Enrollees Over Next Policy Period	描述 Indication	試驗階段 Trial Phase	國家 Country(ies)	試驗場地數 Number of sites

1. 即將到來的保險期間內預計的擴大獲得/自願參加試驗者的數目？ Number of expanded access/compassionate use participants anticipated in the coming policy term?	
2. 最近3年內要保人主辦的人體臨床試驗已完成的總數： Total number of completed human clinical trials applicant sponsored in last 3 years:	
3. 最近3年內試驗收案總數： Total number of human participants enrolled in the last 3 years:	

4. 任何過去、現在或計畫涉及未成年人的臨床試驗？ Any clinical trials past, present, or planned involving minors?	
5. 任何因安全原因而中斷或暫停的臨床試驗？*（如有，具體寫明）* Any clinical trials discontinued or suspended due to safety reasons? *(if yes, provide details)*	
6. 有關挑選臨床試驗主持人的最低要求標準是什麼？ What are the minimum standards for Clinical Investigator selection requirements?	
7. 是否有臨床試驗主持人在從事與您試驗相關的活動時被登記違規？*（如有，具體寫明）* Have any Clinical Investigators been cited for regulatory violations in connection with your trials? *(if yes, provide details)*	
8. 要保人是否持有過去5年內臨床試驗主持人在從事與您的試驗有關的活動時嚴重違規或欺詐行為的證據？*（如有，具體寫明）* Has applicant had any evidence of serious regulatory non-compliance or fraud by Clinical Investigators in connection with your trials in the past 5 years? *(if yes, provide details)*	
9. 最近5年由要保人或監管機構對臨床試驗進行"因故稽查"的次數： Number of clinical trial "For Cause Audits" conducted by applicant or regulatory agency in the last 5 years?	
10. 您是否向臨床試驗主持人提供除了提供特定服務的費用以外的其他報酬，例如登記獎金、股權等等？ Do you provide Clinical Investigators with compensation other than charges for specific services rendered, such as enrollment bonuses, equity interest, etc.?	
11. 您的受試者同意書的目標閱讀級別為何？ What is the targeted reading grade level for your informed consent documents?	
12. 要保人是否要求臨床試驗主持人測試受試者對受試者同意書的理解程度？ Does applicant require Clinical Investigators to test participants on their understanding of the informed consent document?	
13. 要保人是否在受試者同意書中或相關過程中包含財務揭露的內容？ Does applicant incorporate financial disclosures in the informed consent documents or process?	
14. 要保人提供給受試者補助補償額的最高記錄是多少？ What has been the maximum compensation applicant has offered trial participants?	
15. 誰負責監督有關遵守國家的臨床試驗法律法規的情形？ Who monitors compliance with the individual state and country clinical trial regulations?	
16. 要保人有否制定實施臨床試驗中止的標準操作規程？ Does applicant have formalized Clinical Trial Suspension SOP's in place?	
17. 要保人的雇員或次承包商是否以要保人的名義提供直接病患照護服務？他們是否已投保其自身的醫藥專業責任保險？ Do any of applicant's employees or sub-contractors provide direct patient care on applicant's behalf? Do they carry their own medical malpractice insurance?	
18. 要保人是否曾同時作為試驗試驗委託人和臨床試驗主持人？ Does applicant ever act as both trial sponsor and clinical investigator?	
19. 要保人是否為非由您委託的臨床試驗提供原料和/或產品？ Does applicant provide material/product, or both, for clinical trials for trials you do not sponsor?	
20. 要保人是否經營住院醫療機構？如有，要保人是否具備合格認證的急救護理設備？ Does applicant operate an in-patient facility? If so, does applicant have an accredited emergency care facility?	
21. 在最近3年內要保人是否發表過任何研究成果，但未納入其他亦由要保人所作但結果不同的研究？*（如有，具體寫明）* In the last 3 years have applicant published any study results without including other studies that were conducted by applicant that did not support the same findings? *(if yes, provide details)*	
22. 要保人是否發表所有臨床試驗成果？ Does the applicant publish all clinical trial results?	
23. 要保人是否遵守所有應適用的法規指引？*（如沒有，具體寫明）* Is applicant in compliance with all applicable regulatory guidelines? *(if no, provide details)*	
24. 在最近3年內要保人有否因任何違規行為被登錄？*（如有，具體寫明）* Has applicant been cited for any regulatory violations in the last 3 years? *(if yes, provide details)*	
詳細資訊： Details:	

醫療人員簡況。*如果不適用請在此註明：* ☐
MEDICAL STAFF PROFILE. *If N/A, indicate here:* ☐

醫務人員 Health professionals	專科 Specialty	估計每年直接護理病人的小時數 Est. hours of direct patient interactions annually	要保人雇員人數 # Applicant Employees	獨立契約工人數 # Independent Contractors
醫師 Physicians				
註冊護士 RN's				
職業護士 LPN's				
藥劑師 Pharmacist				
醫療技士 Medical Technician				
急救醫療技士 EMT's				
其他（請寫明） Others (please describe)				
詳細資訊： Details:				

法律
LEGAL

1. 要保人是否有下列情況的契約：*（如有，請解釋）* Does applicant have any contracts that: *(if so, please explain)*	
a. 承擔第三人的侵權責任 Assume the tort liability of another party	
b. 沒有將賠償責任限制在直接損害範圍內 Does not limit damages to direct damages only	
c. 沒有將任何或全部非要保人所能控制的事項列入不可抗力範圍 Does not extend Force Majeure to any and all events outside applicant's control	
d. 沒有包含相互免責協議 Does not indicate a mutual hold harmless agreement	
2. 要保人是否與所有的客戶訂立書面的契約或協議（包括任何變更）？ Does applicant use a written contract or agreement with all clients, including changes?	
3. 所有的契約或協議（包括任何變更）在使用前是否經過要保人律師的審查？ Does applicant's attorney review all contracts or agreements including changes prior to use?	
4. 是否有正式的事故和賠償請求處理程序？ Are there formal incidents and claims escalation procedures in place?	
5. 是否有關於訴訟文件控管的正式程序？ Are there formal procedures in place regarding litigation document control?	
6. 是否有關於對內對外聯繫政策和程序的正式訓練？ Is there formal training on internal and external communication policies and procedures?	
詳細資訊： Details:	

產品銷售和市場推廣。如果不適用請在此註明： ☐
PRODUCT SALES & MARKETING. *If N/A, indicate here:* ☐

1. 預計年度處方/設備銷售量？ Projected annual prescriptions/units to be sold?	
2. 預計年度產品使用者數量？ Projected # of annual products users?	
3. 是否進口任何產品成分/零配件？*（如有，具體寫明）* Any product ingredients/components imported? *(if yes, provide details)*	
4. 是否生產任何以其他人商標銷售的產品？*（如有，具體寫明）* Any products manufactured sold under others' labels? *(if yes, provide details)*	

5.	是否有任何作為其他產品成份或零配件的產品銷售？*（如有，具體寫明）* Any products sold as ingredients/components for other products? *(if yes, provide details)*	
6.	是否有產品在國外生產？*（如有，具體寫明）* Any products manufactured outside the domestic country? *(if yes, provide details)*	
7.	是否有任何已獲准可供未成年人使用的產品？ Any products approved for use by minors?	
8.	是否有任何因安全原因而終止生產的產品？*（如有，具體寫明）* Any products discontinued for safety reasons? *(if yes, provide details)*	
9.	是否涉及任何被禁產品？*（如有，具體寫明）* Any association with banned products? *(if yes, provide details)*	
10.	在過去的3年內要保人回收產品的次數？詳細說明任何第1類回收的情況？ How many product recalls has applicant had in the past 3 years? Describe in detail any Class 1 recalls?	
11.	對涉及死亡、永久性傷殘或住院治療的產品，列出其不良事件報告次數位於前3項產品？請提供與這些產品相關的最新完成的安全報告的影本。 Indicate the top 3 products in terms of number of Adverse Event Reports where the product was associated with a death, permanent injury, or hospitalization outcome? Please provide copy of most recently completed Safety Report associated with these products.	
12.	列出最近3年內被要求在其現有標籤上或使用說明書中標明黑盒警告訊息或其他重大的安全警告的任何產品。 Identify any product requiring the addition of a black box or other significant safety warning to existing labeling or instruction manuals in the last 3 years?	
13.	列出有關任何安全監督團隊提出過下列形式的（尚在進行中的或已完成的）救濟措施的相關建議：產品回收/撤回，黑盒警告訊息標籤，"致保健專家"信函，進行額外試驗研究，或擴大產品監測。 Identify any safety surveillance team recommendations involving any of the following forms of remedial actions that have yet to be implemented or completed: product recall/withdrawal, black box warning label, "Healthcare Professional" letter, additional studies, or expanded product monitoring.	
14.	如果要保人發現其產品普遍地被使用於適應症以外的用途，公司將會採取何種措施？ What steps if any would the company take if applicant became aware of a pervasive off-label use of applicant's products?	
15.	請寫明已知的有關您從產品用於適應症以外用途所得的收入？ Please indicate known revenues from off-label use of your products.	
16.	公司是否允許散佈任何適應症以外的用途的相關資訊？ Does the company allow any off-label information dissemination?	
17.	是否曾有任何內部或外部產品銷售人員違反銷售和市場推廣法規的情況？ Have there been any incidents of non-compliance regarding regulations concerning sales and marketing practices by either internal or external product sales personnel?	
18.	有關您內部和外部銷售人員的法令遵循審查的間隔期有多久？ How often are compliance audits performed on your internal and external sales staff?	
19.	法令遵循審查是否包含與醫師的追蹤討論？ Do compliance audits include follow-up discussions with physicians?	
20.	公司廣告預算中有多少百分比是用於直接針對消費者的廣告？ What % of the company's advertising budget is allocated to Direct to Consumer advertising?	
21.	在產品推出後到進行直接針對消費者的廣告之間是否要求一段等待期？ Is there a required waiting period after product launch before DTC is conducted?	
22.	要保人提供給醫師的前三個最貴的補貼是什麼？ What are the top 3 most expensive perks applicant provides to physicians?	
23.	要保人對於禁止內部及外部產品銷售人員與患者的直接接觸是否有正式的特別規定？在最近3年內是否出現過任何違規情況？ Does applicant have formal policy specifically prohibiting physical patient contact by internal and external product sales personnel? Have there been any incidents of non-compliance in the last 3 years?	
24.	有關您內部和外部銷售團隊的定期正式且有書面記錄的法令遵循訓練的間隔期有多久？ How often is formal and documented compliance training required of your internal and external sales force?	

經營風險管理和損失控制

OPERATIONS RISK MANAGEMENT & LOSS CONTROL

1.	要保人是否已制定企業風險/安全制度？*（如有，請提供該制度的負責人姓名）* Does applicant have a formalized Enterprise Risk/Safety Program? *(if yes, please provide name of person in charge of program)*	

2.	您的企業風險/安全制度的重點範圍是什麼？*（範圍可以包括行為準則，隱私，生物危險，災難復原等等）* What are the main focal areas of your Enterprise Risk/Safety Program? *(Areas might include Code of Conduct, Privacy, Biohazards, Disaster Recovery, etc.)*	
3.	要保人是否要求所有新員工參與有關公司所有現行規章制度的指導訓練？ Does applicant require all new employees participate in training program that instructs them on all applicable company policies and procedures?	
4.	要保人是否要求其所有的供應商或次承包商提供保險憑證？要保人要求的保險責任限額和條款是什麼？ Does applicant require Certificates of Insurance from all of applicants' suppliers and sub-contractors? What limits and terms does applicant require?	
5.	是否每年都對所有的風險管理制度和標準操作規程進行審查？ Are all risk management programs and SOP's audited annually?	
6.	請說明任何由獨立的非政府機構/個人進行審查的風險管理制度和標準操作規程？ Please indicate any risk management programs and SOP's that are audited by independent non-governmental organizations/individuals?	
7.	說明行業協會會員資格情況。 Indicate Industry Trade Associations Memberships.	
8.	要保人是否配有應急處理團隊？ Does applicant have a crisis management team in place?	
9.	要保人是否有全職的風險管理人員？ Does applicant have a full time risk manager on staff?	
詳細資訊： Details:		

辦公場所/營運。如果不適用請在此註明： ☐
PREMISES/OPERATIONS. *If N/A, indicate here:* ☐

1.	指出下列哪些情況適用要保人的辦公場所：只有用磁卡才可以進入及/或經授權的員工可以進入，必需前臺登記方可進入，或沒有進入限制。 Indicate which of the following applies to applicant's premises: access is not allowed without card and/or authorized employee, front desk registration only, or no restricted access.	
2.	指出下列哪些情況適用要保人的辦公場所：危險物質不得進入，或分隔裝入許可的容器內，或僅在定時供應級別，或裝入非許可的容器的分隔區域。 Indicate which of the following applies: hazardous substances are kept outdoors or in a cut-off within approved containers, just in time supply levels, cut-off area with unapproved containers.	
3.	指出辦公場所內現存有多少加侖的危險物質？ Indicate how many gallons of hazardous substances are kept on site?	
4.	生物危險實驗室級別（如適用）？ Biohazard Lab Rating if applicable?	
5.	您是否有動物實驗設施或飼養動物？ Do you have an animal facility or house animals?	
6.	要保人是否遵守危險物質法規（如適用）？ If applicable is the applicant in compliance with Hazardous Materials Regulations?	
7.	要保人是否曾從直接競爭者處聘用重要雇員？ Has applicant ever hired key employees from direct competitors?	
8.	要保人是否曾進行和競爭者產品的直接產品比較？ Does applicant ever do direct product comparisons against competitors' products?	
9.	要保人是否有與其生產相似產品的競爭者？ Does applicant have any competitors making similar products?	
10.	要保人是否有正式的隱私規定？該規定最近一次更新和審查是在何時？ Does applicant have a formalized Privacy Policy in place? When was it last updated and audited?	
詳細資訊： Details:		

損失記錄和潛在損失
LOSS HISTORY & POTENTIAL LOSS

保險期間 Policy Period	保險人 Insurer	賠償請求次數 # of Claims	已發生損失總額 Total Incurred	賠付總額 Total Paid	賠付率 Loss Ratio

*總額是指最近五年內的賠款支付總額（全部的損失包括辯護費用、自負額和自留額）。
*Total aggregate cost (losses from ground up including defense, deductibles, and SIR's) for last five years
*另附前保險人承保的損失狀況
*Attach previous carrier loss runs

1. 說明所有已發生而損失金額等於或超過為10,000美元的損失： Describe all incurred losses of US$10,000 or more:	
2. 尚未申報的賠償請求？*（如有，具體寫明）* Any claims not yet reported? *(if yes, provide details)*	
3. 列明過去或現在涉及任何已證實的或試圖進行的集體訴訟或多地區訴訟的任何產品或服務？ Indicate any product or service past or present that has been involved with any certified, or attempted, class action or multi-district litigation?	
4. 要保人是否知道任何人會合理預期將導致本保險範圍內的賠償請求的任何事實、情況或情形？*（如有，具體寫明）* Is the Applicant aware of any fact, circumstance, or situation which one might reasonably expect could give rise to a claim that would fall within the scope of the insurance being requested? *(if yes, provide details)*	

本要保書所要求提供的資訊僅用於保險業務之目的，並不構成根據任何保險單對本公司的賠償請求或潛在賠償請求的通知。
The information requested in this Application is for underwriting purposes only and does not constitute notice to the Company under any policy of a Claim or potential Claim.

承保歷史記錄
COVERAGE HISTORY

保險期間 Policy Period	基層和超額責任限額 Primary & Excess Limits	保險人 Carriers	事故/賠償請求 Occurrence/Claims Made	追溯日 Retro Date

1. 要保人是否有任何由現在的保險人提出而尚未履行的損失控制建議？*（如有，具體寫明）* Does applicant have any outstanding loss control recommendations with applicant's current carrier? *(if yes, provide details)*	
2. 要保人是否有任何經保險人取消或未續保的保險？*（如有，具體寫明）* Has applicant's insurance ever been canceled or non-renewed by a carrier? *(if yes, provide details)*	
3. 您的產品、臨床試驗，或服務中是否有任何項目被特別排除在您的現行有效保險單之外？*（如有，具體寫明）* Any of your products, clinical trials, or services specifically excluded on your existing policy? *(if yes, provide details)*	
4. 您對於要求追溯至您指定的追溯日的本項保險是否同時持有重複的賠償請求發生制保險？ Have you had concurrent claims made insurance for the insurance you are requesting back to your stated retro date?	
詳細資訊： Details:	

INSURANCE REQUESTED

承保範圍 Coverage	投保限額 Limits Requested	自負額/自留額度要求 Deductible/SIR Requested
公共意外責任 Premises & Operations Liability		
產品和完工責任 Products & Completed Operations Liability		
專業責任（錯誤與疏忽的財務損害） Professional Liability (E&O Financial Injury)		
財產 Property		
其他 Other		
詳細資訊： Details:		

本要保書中所包含的資訊或資料或根據本要保書所提供的資訊或數據所提供的與核保程序有關的任何資訊或資料並不構成就任何意外事故、錯誤行為、賠償請求、訴訟或其他情況而作出的通知，也不構成任何保險單有關任何通知或其他任何條款所要求的條件。所有此類通知都必須根據適用的保險單條款分別提出。

INFORMATION OR DATA CONTAINED IN OR SUBMITTED IN CONNECTION WITH THIS APPLICATION DOES NOT CONSTITUTE NOTICE OF AN OCCURRENCE, WRONGFUL ACT, CLAIM, SUIT OR OTHER CIRCUMSTANCE AND DOES NOT SATISFY ANY OF THE REPORTING NOTIFICATION OR OTHER PROVISIONS OF ANY POLICY. ALL SUCH NOTICES MUST BE GIVEN SEPARATELY IN ACCORDANCE WITH THE APPLICABLE POLICY CONDITIONS.

為本要保書之目的，擬購買本保險的所有個人或組織的下列簽署主管就簽署本要保書聲明並承諾其未對本要保書作任何更改（除非為回答問題而保留的欄目），並且已經與其執行長、財務長、營運長和其他同類職務的負責人一同審閱過本要保書以及其中所包含的陳述，此外，盡他們所知和所信，經合理的詢問後，本要保書中的陳述和其他附件中的陳述對於所有依據此要保書提出保險申請的個人和組織而言，是真實和完整的。本公司獲得授權進行與本要保書有關的詢問。簽署本要保書並不對本公司構成約束或使本公司有義務提供本要保書所申請的保險，但各方同意本要保書的填寫和簽署是可能簽發的保險單的基礎。若本要保書中的陳述和其他附件中的陳述在擬簽發的保險單生效日之前發生實質性變更，要保人必須通知本公司，而本公司可以更改或撤回任何報價。

For the purposes of this application, the above-signed officer of all person(s) and organization(s) proposed for this insurance declares and acknowledges by executing this application that, no alterations were made to this application (other than sections reserved for answers), he/she has reviewed this application and the statements contained therein with his/her Chief Executive Officer, Chief Financial Officer, Chief Operating Officer or their equivalents, and that to the best of their knowledge and belief, after reasonable inquiry, the statements in this application, and in any attachments, are true and complete for all persons or organizations applying for insurance under this application. The Company is authorized to make any inquiry in connection with this application. Signing this application shall not constitute a binder or obligate the Company to complete this insurance, but it is agreed this application shall be the basis upon which a policy may be issued. If the statements in this application or in any attachment change materially before the effective date of any proposed policy, the applicant must notify the Company, and the Company may modify or withdraw any quotation.

要保人的授權簽字 Authorized Signature of Applicant	日期 Date
姓名 Print Name	職務 Title
要保人 Applicant	

■以下由保險公司及保險經紀人/代理人填寫：The following is filled by broker/agent and insurance company:

核保人 簽章 Underwriter's Signature		保險經紀/代理簽署人簽章 Signature of Broker's/Agent's Signatory		保險業務員 Insurance Salesperson	
				登錄證號： Registration ID No.:	簽章： Signature: