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| • 計畫中文名稱 | 建構奈米化藥品法規審查與安全性評估機制                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |        |             |
| • 計畫英文名稱 | Establishment of the Regulatory Affair Mechanism and Safety Assessment Issues for the Nano Drug                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |        |             |
| • 系統編號   | PG9902-0314                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | • 研究性質 | 基礎研究        |
| • 計畫編號   | DOH99-TD-N-111-013                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | • 研究方式 | 補助(研究/辦理)   |
| • 主管機關   | 行政院衛生署                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | • 研究期間 | 9901 ~ 9912 |
| • 執行機構   | 台北醫學大學                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |        |             |
| • 年度     | 99 年                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | • 研究經費 | 3020 千元     |
| • 研究領域   | 藥學                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |        |             |
| • 研究人員   | 鄭慧文,鄭幼文                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |        |             |
| • 中文關鍵字  | 奈米藥品；奈米性；功能性/有效性；安全性；奈米科技法規；；；                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |        |             |
| • 英文關鍵字  | Nano medicines；Nano particle feature；functionality/validity；drug safety；nanometer technical laws and regulations；；；                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |        |             |
| • 中文摘要   | <p>本計劃之目標為成立奈米科技法規專家核心小組，以俾將來完善國內之審查機制之參考及促進國內相關法規之國際協合化，並研擬品質安全管理體系架構，研修產品審查相關法令規章之修正草案。成立奈米藥品科技法規專家核心小組。其中小組成員包含產、官、學、研界，產業界有藥技中心、財團法人醫藥品查驗中心、政府官界有衛生署(食品藥物管理局 TFDA)與工業局。研究單位包含中研院與工研院，學術界則包含藥學及法學界之專家等。所執行的工作則包括了，收集美國、歐盟、日本等國奈米藥品品質管控法規之資訊，擷取最新管理資料，與我國相關法規命令進行比較分析規劃。針對擬申請上市之奈米新藥物其產品之奈米顆粒特性對產品效能及安全性之評估，以及針對已核准上市之藥物(如 OTC 或第二、三等級醫材類似品)，改用奈米材料或奈米化製程，就產品效能及安全性之評估，並實地參訪一家奈米藥物研發公司(或製造廠)，確實掌握奈米藥物發展現況，建立安全性及有效性審查機制，並評估奈米藥物製程於現有藥物製造工廠及臨床試驗之相關規範，研擬具體管理法規之修正草案。邀請國外藥政管理專家與國內產、官、學界人士進行交流討論，對於初擬之品質安全管理體系架構、國內外法規協合及相關法令規章之修正條文內容，以及現行法規管理體制對國內產業發展之看法及意見，提出可行策略。最後邀請藥政管理及法律專家學者參與本研究，與奈米科技法規專家核心小組研議及產、官、學界專家進行討論交流，依據我國與各國之法規與基準協和方式及機制，提出相關奈米藥物產品之安全評估報告及審查管理架構之建議，並就現行「藥事法」、「藥品查驗登記審查準則」、「藥品優良臨床試驗準則」及「藥物製造工廠設廠標準」相關條文研擬修正條文草案，最後將提具總結報告，最終目標為成立成立奈米科技法規專家核心小組，以俾將來完善國內審察機制之參考及促進國內相關法規之</p> |        |             |

國際協和合化。

• 英文摘要

The goal of this plan is to establish a core technical group, including both nanotechnology science and pharmaceutical regulation experts, to draw up the quality and safety control regulation system and to discuss a draft for the product assurance related laws and regulations. The panel will consist members from industrial, government administrative and academic fields. The industrial representatives include PITDC (Medical and Pharmaceutical Industry Technology and Development Center) and Pharmaceutical Manufacturers Association. The government official circles include Technology Section of Department of Health, TFDA and CDE. The research unit consists of ITRI (Industrial of Technology Research Institute). The tasks of this project will include collection and review of the US, EU, Japan and other countries' nanotechnology drugs quality control regulatory measures and the latest management information in order to compare with Taiwan's current relevant laws and regulations for future planning. The intended for submission subjects include drug possesses nano particle features that may affect its efficacy and/or safety as well as some previously approved drug that changes its manufacturing process to nano process or adopts some nano materials during its production. We will visit one nano research or manufacturing company to familiarize with the manufacturing process and further work with them to develop a manufacturing safety assessment protocol. We intend to invite review experts from all fields to participate with our discussion panel members to propose a feasible strategy for both regulatory body and pharmaceutical industry. In accordance with Taiwanese laws and regulations and that of other advanced countries, we will initiate a suggestion of the draft amendments to drug products related to nanotechnology safety assessment and "Drugs Registration Criteria", "Good Laboratory for Clinical Laboratory Studies" and "Standard Drug Manufacturing Process". Organized seminars will be held to communicate with all stakeholders regarding the draft amendments to relevant laws and regulations and other provisions. A final report will be submitted to DOH with the ultimate goal to facilitate the domestic legislative process of nano medicine and to cope with the international legislative harmonization.