

• 系統編號	RG9902-0211		
• 計畫中文名稱	建構奈米化藥品法規審查國際協合化與安全性評估機制		
• 計畫英文名稱	--		
• 主管機關	行政院衛生署藥政處	• 計畫編號	DOH98-PAB-1003
• 執行機構	台北醫學大學		
• 本期期間	9803 ~ 9902		
• 報告頁數	424 頁	• 使用語言	中文
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• 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	本計畫目的為成立奈米藥品科技法規專家核心小組，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。本計畫邀請產、官、學界成立奈米藥品科技法規專家核心小組，成員包含產、官、學、研界，產業界有藥技中心、生技中心，政府官界有衛生署(藥政處、財團法人醫藥品查驗中心)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。本計畫收集美國、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。針對奈米藥品之奈米顆粒特性對產品效能及安全性之評估，建立安全性及有效性審查機制，初擬品質安全管理體系架構，提出管理法規之建議。問卷調查產、官、學界專家對於初擬管理體系架構、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。本計畫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之建議，並對照現行「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」可能應予修正相關條文之建議，提供國內審查機制之參考。		
• 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 consists of 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 included 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. A questionnaire was developed by the panel experts to assess the future regulatory review mechanism on the safety/efficacy issues. A total of 145 questionnaires were distributed among the academic institution, pharmaceutical companies and government agencies with 29 responded. This survey results was communicated to the general public and will be used as a foundation for future development of the nano drug regulatory review mechanism. A draft amendment to the drug review mechanism specific on the nano drug was proposed to DOH and will be use for future discussion on 2010.