

2002 年報

目錄 (Content)

前言(Preface).....	2
序(Introduction).....	4
成立背景(Establishment).....	6
願景/使命(Vision/ Mission).....	7
定位與功能(Role & Function).....	8
組織架構 & 人力配置(Organization & Human resource).....	11
主要業務及相關成果(Major Task & Performance).....	12
新藥查驗登記案審查(NDA Review).....	14
臨床試驗計畫書審查 (IND Review).....	16
銜接性試驗(Bridging Study Evaluation (BSE))	17
免除臨床試驗評估(Clinical Trial Waiving (CTW)).....	19
法規研擬(Guideline preparation).....	20
諮詢服務(Consultation Services).....	21
基因體計畫(National Genomic Project).....	24
中草藥計畫(Traditional Chinese Medicine Project).....	25
臨床試驗藥物不良反應評估(Clinical Trial ADR Evaluation).....	26
國際合作與法規協合化 (International Alliance & Regulation Harmonization).....	27
人員培訓(Training & Education).....	30
品質管理與作業電子化系統(Quality Management & e – system).....	31
未來展望(Prospective).....	33
2002 大事紀(A Summary of Minute).....	35

積極、主動 提昇競爭力 與國際接軌

本中心成立以來已屆滿四年，期許本中心能不斷精益求精，展現更堅強的團隊實力。回顧以往，除了在新藥、臨床試驗的審查上，本中心的表現可圈可點，在銜接性試驗議題上，中心在國際上亦扮演了相當重要的角色。

然而，隨著新興醫療科技的發展，醫藥衛生政策、健康保險制度以及疾病的型態等的改變，亞太地區各國發展生技產業的競爭更是不斷地上昇，本中心在此之際需運用當前優勢，不僅維持現有實力，更要提昇競爭力。因此，未來如何維持領先的地位？中心所擁有的最佳資源即是具有專業知能的同仁，所有同仁必須從案件審查及相關的事務中學習，除了增強專業的深度之外，更應拓展視野廣度，了解相關政策決策的背景，建立分析政策影響力的能力，同時觀察國際發展趨勢，思考與先進國家並駕齊驅的策略。

由於本中心屬於衛生署設立之法人團體，在接受衛生署委託辦理的審查業務之外，亟須以本中心的專業，主動積極地分析各項資訊，回饋衛生署決策單位，以建立完整的決策回饋支援系統，供決策者了解政策執行結果，並思考是否有必要加以調整。

本中心成立之初，衛生署即希望借助 FDA 的經驗，提昇我國藥物審查能力，並達國際水準。對本中心而言，最大的挑戰在於建立自行審查新藥的能力，這絕非一蹴可及，雖然，中心目前已漸漸步入與先進國家同步審查之作業方式，但如何使審查能力在國際間被認可，是我們未來五年應加倍努力之目標。



董事長 衛生署蕭美玲技監

Be Enthusiastic, take the initiative, enhance competitiveness, and keep up with global development

It has been four years since Center for Drug Evaluation (CDE) was established. The performance of CDE has been remarkable in the reviewing of clinical trial protocols and the New Drug applications. In the area of bridging studies, the Center has also played a very important role internationally. We will continue to strive for excellence and further strengthen teamwork.

However, with the advancement in medical technology, and changes in medical and health policies, health insurance system and the patterns of diseases, the competition between nations of Asian-Pacific region in the development of biotechnology industry has been heightened. CDE will have to utilize its current advantage, not only to maintain the strength of the present, but to enhance the competitiveness in the future. What do we have to do to maintain the Center's leading edge? The best resources of the Center are colleagues who possess professional knowledge and skills. Therefore, all colleagues have to try their best to learn from case reviewing and other relevant matters; increase the depth of their specialized fields and expand their horizons; understand the background of related policy decisions; develop the ability to analyze the influence of each policy; and, at the same time, observe the trend of international development, and formulate new strategy to keep up with the advanced nations.

Since CDE is a non-profit organization founded by the Department of Health (DOH), its responsibilities go beyond reviewing and evaluating cases contracted through the DOH. We should use our expertise to actively take the initiative in analyzing pertinent information, and share them with the decision-making body of the DOH, thereby establishing an integrated decision feedback support system to help the decision makers understand the results of policy implementation, and make necessary policy modifications.

When CDE was first established, the DOH hoped to introduce the experiences of the FDA to promote the capability in new drug evaluation in Taiwan and to upgrade the quality of the new evaluation process up to the international standard. The greatest challenge for the Center lies in developing the capability to independently evaluate the new drugs; and this goal certainly cannot be reached overnight. At the present, CDE is capable of reviewing new drug applications simultaneously with the other advanced nations. For the next five years, however, obtaining the recognition by the international communities of our capability in the evaluation of new drugs independently will be the utmost goal of CDE.

President,
Mei-Ling Hsiao
(Specialist-General of DOH)

序 (Introduction)

嚴謹審查機制 完善法規環境

時光飛逝，中心已邁入第五個年頭，回顧過去幾年，隨著業務的增加，人員及空間亦大幅成長，中心歷經了辦公室遷移的環境改變，然其間在新藥審查、法規草擬及產業推動等方面仍不遺餘力，奠基於已有的經驗，中心已制訂了相關審查作業之標準及機制，不僅為民眾的用藥安全做好把關的工作，更提供法規諮詢服務，協助新藥研發相關產業的發展。

回想一路走來雖然辛苦，看到中心現在穩健地成長則讓我倍感欣慰；本中心主要的業務之一為新藥審查，這項業務亟需要具有不同專業領域且專職的成員參與，而隨著近年來政府大力投入生物技術產業研發及生技製藥產業新興科技的發展，我們也配合趨勢延攬了各種醫藥專才投入，包括中醫師等各類科別的醫師，其中不乏醫師具有律師資格或博士學位者，還有藥師及其他專業之博碩士人員；除了審慎地網羅專業人員之外，中心亦相當重視人員的儲備、培訓以及經驗的傳承；此外，為符合國際審查要求的標準，我們亦積極地參與各項國際活動，與先進國家之法規單位交流，透過研討會及拜會活動，向國際介紹我國藥政管理法規之變革及相關成果，並建立良好的互動模式，適時地協助衛生署草擬並更新相關法規。

中心的審查人員已有能力進行全球未上市新藥的審查，亦致力於基因治療與臨床試驗環境的推動與改善，然而面對大環境的改變，我們不僅要維持現有之競爭力，更需要提昇專業的審查能力，逐步與國際審查標準並駕齊驅。未來本中心亦更應積極提供各項醫藥審查及專業諮詢服務，以建立高品質、高效率、高透明度及一致性之服務機制及專業審查，改善並完備我國法規環境以邁向國際化。



執行長 朱夢麟教授

Strict reviewing system, proficient regulatory environment

Time flies, and the Center has entered its fifth year .Past four years, with the increasing volume of our business, the Center has seen substantial growth in its personnel and office space. In spite of stressful environmental changes associated with office relocation, our colleagues continued to do their best in reviewing clinical trial protocols for investigational new drugs and evaluating new drug applications, in drafting guidelines, and in helping to promote the pharmaceutical industry. Building on to our early experiences, we have established standards and mechanisms for the evaluation of new drugs to safeguard public safety in drug usage, and provided consultation services to the industry on regulatory requirements to facilitate the research and development of new drugs.

It has not been an easy journey, but, it is gratifying for me to see the Center grow steadily. One of Center's principal tasks is to review the new drug applications, which requires the participation and expertise of many full-time faculty members in different specialty fields. In keeping with the government's efforts in promoting the research and development of the biotechnology industry, and the advancement in new technologies in the bio-pharmaceutical industry, we have recruited various experts into CDE, for example, Medical Doctors in different specialty fields (including physicians in traditional Chinese medicine and physicians with other advanced degrees such as J.D. or Ph.D.), as well as scientists with a Master's or a Ph.D. degree in statistics, chemistry, pharmacology, and other related fields. In addition to carefully recruiting professional members, we have also paid attention to important matters of training and passing of experiences. Furthermore, in order to keep up with the international standards in regulatory requirements, we have actively participated in various international events and communicated with the regulatory agencies in advanced nations. Through conferences and visits, we have introduced reforms in policies and laws by the Pharmaceutical Administration and the related achievements in Taiwan to other nations in the world, established good models for interactions, and provided timely assistance to the Department of Health in the drafting and updating of related guidelines and regulations.

At the present, reviewers at CDE are capable of reviewing the new drugs that are not yet approved for marketing in any countries in the world, and are also devoting their efforts to the promotion and improvement in gene therapy and clinical trial environment. However, in order to meet the challenge of the changing big environment we not only have to maintain the present competitiveness, but also to enhance the professional capability in reviewing to gradually keep up with the international standards. In the future, CDE will be actively in providing various evaluation and consultation services based on a professional review and service system with the best quality, high efficiency, transparency and consistency. Ultimately, CDE would like to improve and perfect our country's regulatory environment to move toward internationalization.

Executive Director,
Dr. Mong-Ling Chu

成立背景 (Establishment)

醫藥品關係國民健康至鉅，世界先進國家莫不重視並投入大量的人力、物力，建立最具專業技術水準之權責機關，以強化藥物查驗體系的功能及效率。我國政府為保障廣大消費者用藥安全，促進全民健康福祉，發展我國生技製藥產業，於八十六年修訂「加強生物技術產業推動方案」，在「健全法規體系」工作要項下，責成衛生署設立專職新藥審查機構。

衛生署為兼顧消費者保護與產業發展，且突破原有行政體系之限制，以根本解決專業審核人力不足之問題，乃於 1998 年 7 月 13 日成立財團法人醫藥品查驗中心，接受藥政處委託，協助其辦理新醫藥品及生物製劑之技術審查、訂定符合國際標準之審查法規，協助為新醫藥品上市前相關試驗之規劃提供諮詢及其他與醫藥品查驗登記相關之業務。

As drug products affect citizens' health greatly, advanced nations in the world all have considered it a priority and devoted a great deal of human and monetary resources to establish a regulatory agency with professional and technical proficiency, and to strengthen the function and efficiency of the drug review system. In order to ensure drug usage safety of the consumers, to promote public health and welfare, and to develop the nation's bio-pharmaceutical industry, our government amended Executive Yuan's "Promotion Program for Biotechnology Industry" in 1997 and directed the Department of Health to establish, under "sound statute system", a specific organization for the evaluation of new drugs.

To balance between consumer protection and industry development, and to bypass the constraint of the administrative system and solve the problem of lack of professional reviewers for drug evaluation, the DOH founded the Center for Drug Evaluation on July 13, 1998. The Center would be entrusted by the Bureau of Pharmaceutical Affairs to assist in the technical review of new drugs and new biological products, establish regulatory requirements that comply with international standards, provide consultations on plans of pertinent clinical trials for the purpose of new drug application and other matters related to new drug registration.

願景 *Vision* (TIGER)

- ✿ *Transparency* 透明公開
- ✿ *Integrity* 公正廉潔
- ✿ *Globalization* 全球化
- ✿ *Efficiency* 高效率
- ✿ *Responsiveness* 積極回應

使命 *Mission*

1. 建立透明、高效率、積極回應之新藥查驗申請機制

Establish a transparent, efficient and responsive system for regulatory applications in Taiwan

2. 臨床試驗與新藥審核相關法規國際化，促進台灣參與全球新藥之研發

Facilitate Taiwan's participation in global new drug development process by establishing guidelines in line with ICH requirements for clinical protocol and drug approvals

3. 建立法規專業並關注亞太地區特殊法規需求，扮演領導的角色

Play a leading role in building up regulatory expertise with educational efforts as well as examining the need for special regulatory requirements for the region

定位與功能 (Role & Function)

本中心之首要功能在協助衛生署藥政處建立專職、專業的審查制度與審核新藥之能力、協助衛生署建立法規輔導平台、提供產業界研發過程中所需之諮詢服務，並使我國有能力與國際同步審核未上市新藥或審核國內自行研發的新藥。另一方面，本中心屬非政府、非營利性機構，以參加或舉辦國際性研討會等多種方式，協助衛生署與國際衛生相關領域人員進行溝通與經驗交流，期能瞭解國際趨勢、促進國際對我國進步之瞭解，進而增進我國與國際合作之機會。

近年隨著基因密碼的解碼及各種生物技術快速的發展，相關研究已快速在全世界熱烈展開。我國政府不論對傳統製藥業升級或促進新興基因科技產品的研發，亦投注相當大的經費與資源，期能提振我國生技醫藥產業的研發與促成產業升級。已在全球引起廣泛注意與討論的基因治療、幹細胞治療、基因重組技術等相關新醫療技術與產品，亦成為現今衛生主管機關管理及審核極大的挑戰。本中心因此自 2002 年起協助衛生署醫政處，針對相關技術與產品審查的需求作良好規劃及建立相關配套措施，同時，亦提供國內外產業或研發單位必要之法規諮詢。值此貿易全球化時代，我國生技製藥產業之發展乃以全球市場為目標，生技製藥產品的研發，除需考量本地法規、兼顧醫藥品的品質、有效性、安全性及審查效率外，尚需努力使其符合國際醫藥品審核標準。

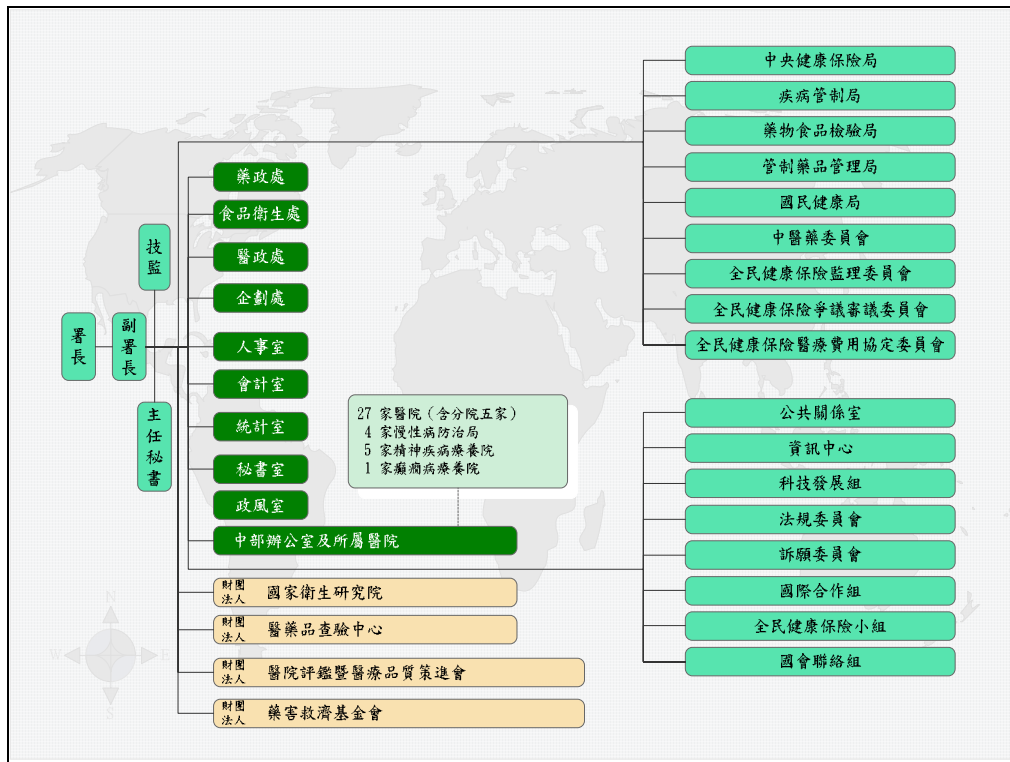
中醫藥為我國醫藥文化重要資源，歷經數千年而不衰，無論是臨床實際應用經驗或典籍文獻均累積豐碩的成果，這是其他國家研究中草藥者所不能及的，也是我國發展中草藥產業最大的優勢；然而，中藥之療效雖有數千年歷史為依據，但缺乏科學性驗證及科學化數據之支持，難以被國際認證體系所認同。一如其他的產業，中草藥產業必須要有夠大的市場，才能存活，進而發展，因此台灣要發展中草藥產業，「國際化」是一個無可替代的選擇。因此，為協助國內中草藥產業業者提昇產業競爭力面對國際市場的開拓及激烈的競爭，本中心亦協助衛生署中醫藥委員會，建立與國際接軌之中藥新藥臨床試驗及查驗登記法規環境，並彙整國際中草藥主要市場國家申請相關產品上市之法規及上市成功經驗，以建立中草藥國際化技術平台，對國內業者提供諮詢/輔導服務，以配合中藥在全球市場之快速成長及發展潛力，使未來台灣能真正成為中藥新藥的開發中心。

The principal functions of CDE are: to help Bureau of Pharmaceutical Affairs to set up the review system and enhance the ability to review new drug applications, to support DOH to establish a mechanism in drafting guidelines, and to provide consultation service to local bio-pharmaceutical industries, to upgrade Taiwan's ability to review the new drug applications of products developed domestically and those have not been approved in any other advanced countries. CDE is a non-governmental and non-profit organization, communication with worldwide regulatory agencies through active participation in international convention is

necessary. In order to keep path with current trends, CDE fascinates DOH to communicate and exchange experiences with international experts. In addition, other major functions of CDE include introduction of Taiwan's progress to international communities and further strengthen international cooperation.

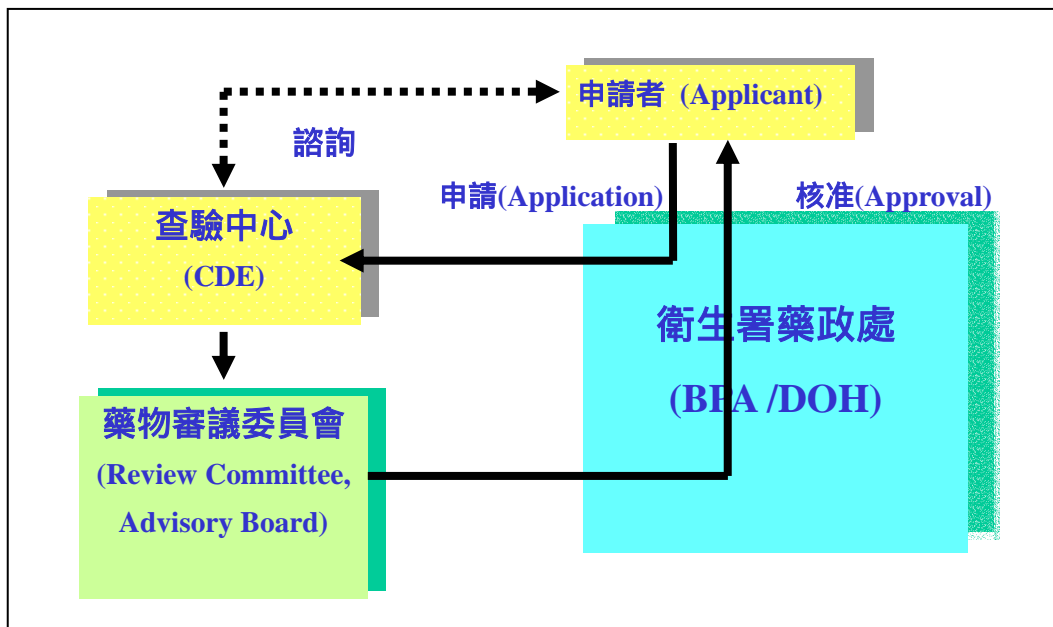
In recent years, through the development of biotechnology, the related research has been enthusiastically conducted. Our government devotes many resources and efforts to upgrading the pharmaceutical industry and the development of biotechnology. Gene therapy, stem cell therapy, and recombinant DNA technique that have been focused worldwide, have become a challenge for us. Because of these reasons, CDE began to plan and set up procedures to review biotechnology techniques and products. In the era of global trading, the goal of the development of biotechnology is to target global marketing, The development of biotechnology, in addition to the local guidelines, as well as the quality, efficacy and, safety, has to meet the international standard.

Chinese medicine is a very important resource in Taiwan. Because of thousands of years' of clinical experiences and vast documents, Taiwan has leading edge compared to other nations in conducting research of Chinese medicine. However, its value is difficult to be recognized internationally due to lacking of well-designed experiments and scientific data. Like other industry, Chinese medicine industry must have sufficient large market, in order to survive. If Taiwan intends to develop the Chinese medicine industry, "globalization" is the choice and no other alternative can be substituted. In order to enhance the competitiveness of domestic Chinese medicine industries, CDE cooperates with the Chinese Herbal Medicine Committee to establish a modernized mechanism in reviewing clinical trial protocols and new Chinese medicine registration. CDE aims to build up an innovative technology platform through integration of regulations and successful marketing experiences regarding Chinese medicine development worldwide. CDE provides consultation to sponsors in line with the rapid growth of Chinese medicine worldwide. The present government's goal is to promote Taiwan as a major research center for Chinese medicine.



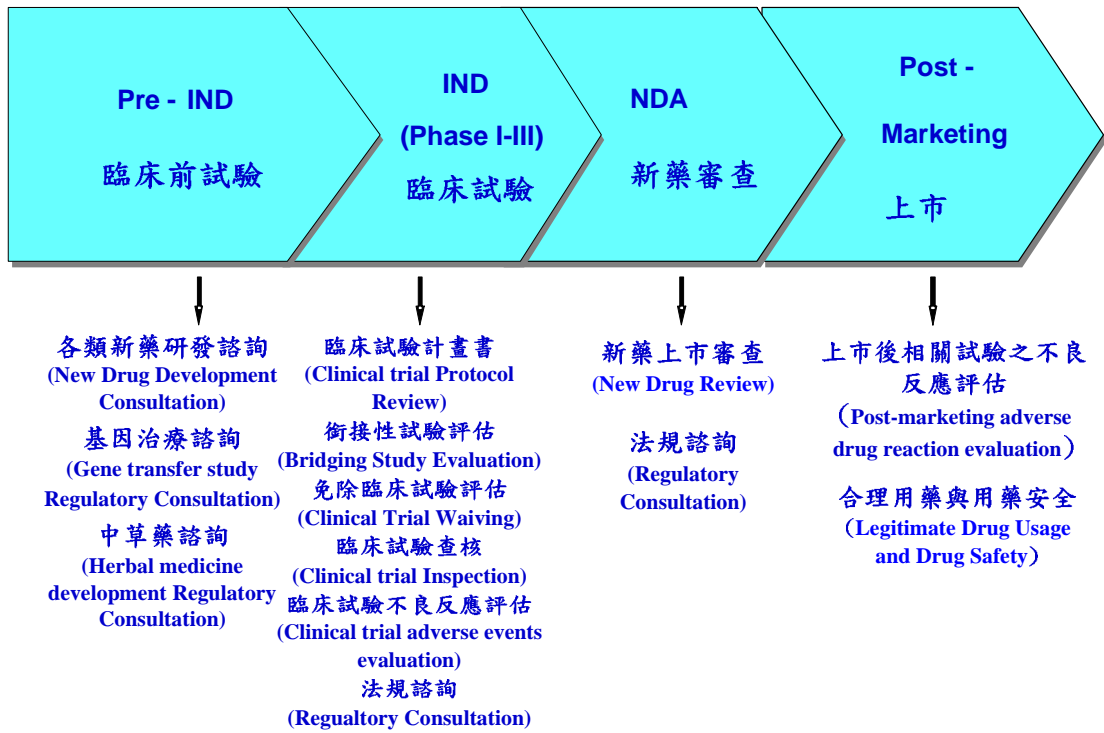
衛生署組織結構圖

(The Structure of Department of Health (DOH))



協助衛生署藥政處審查業務流程關係圖

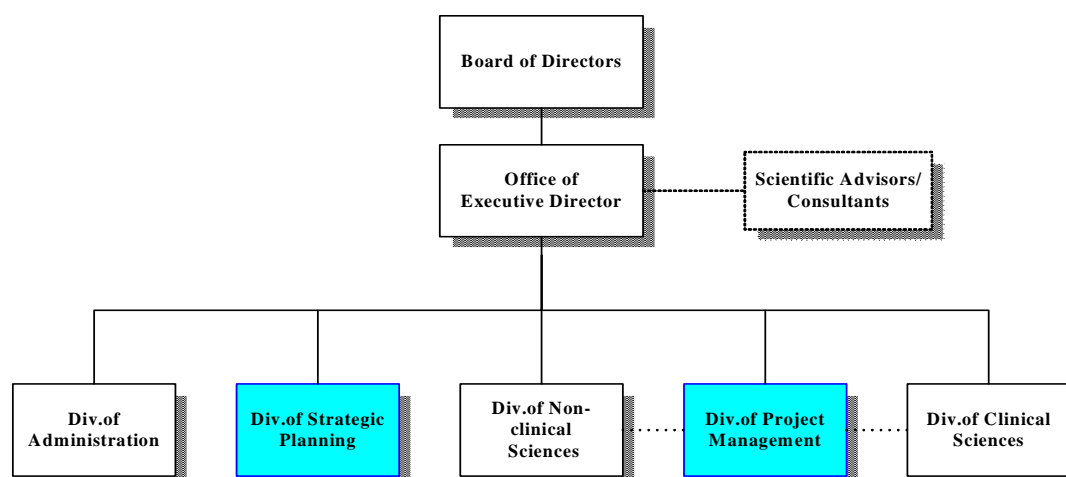
查驗中心之功能 (Function of CDE)



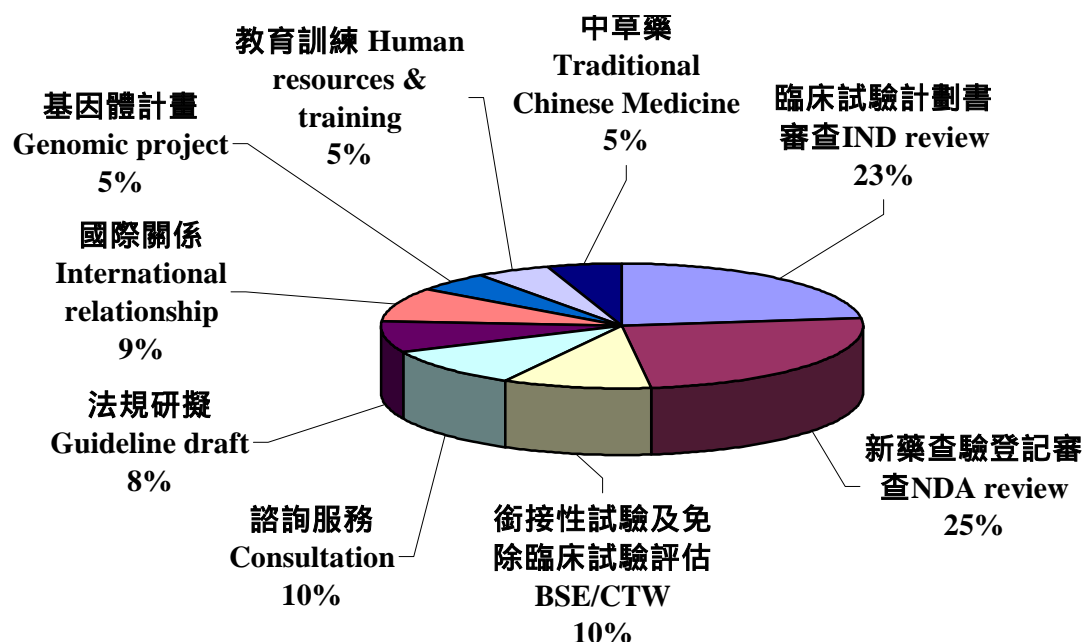
組織架構 & 人力配置 (Organization & Human resource)

本中心董事會由衛生署及國內醫藥相關領域十一位專家組成，指導中心業務，均為無給職。中心置正、副執行長各一人，下設行政、企劃、專案、臨床與基礎醫學等六組，延聘具有生物醫學、醫藥專業訓練背景之高科技人才，給予醫藥品審查法規相關訓練後擔任專職審查員，成為協助衛生主管機關執行技術性資料審查之主要專家群。本中心組織架構講求精簡，各組專業分工，期以「Regulatory Science」(法規科學)之精神，建立專業性、高效率的運作模式，協助衛生署建立公開，透明的審查流程，縮短審查時間，並有效提昇業界諮詢的服務品質。至2001年底已延聘臨床、藥理/毒理、化學製造及管制、生物製劑、藥政法規等專業人才，包括醫師(14)、博士(18)、碩士(18)、學士及其他專業(21)等總計71人。

CDE is governed by the board of directors which consists of eleven members with different expertise. The daily operation of the Center is overseeing by Executive and Deputy Executive directors. Underneath the Executive Office, CDE is supported by six different divisions. The organization structure of CDE is depicted in the following chart. CDE recruits professionals with biology, medicine and pharmacology backgrounds. With proper training, they become the reviewers and assume the responsibility in reviewing technical documents. They review drug applications based on regulatory science principles and they conduct business using professional and high efficient approaches. As of the end of 2001, CDE has recruited professionals with medicine, pharmacology/toxicology, chemistry, biologics and pharmaceutical regulations backgrounds. They include 14 physicians, 18 PhDs, 18 masters, 21 bachelors and professionals with other backgrounds.



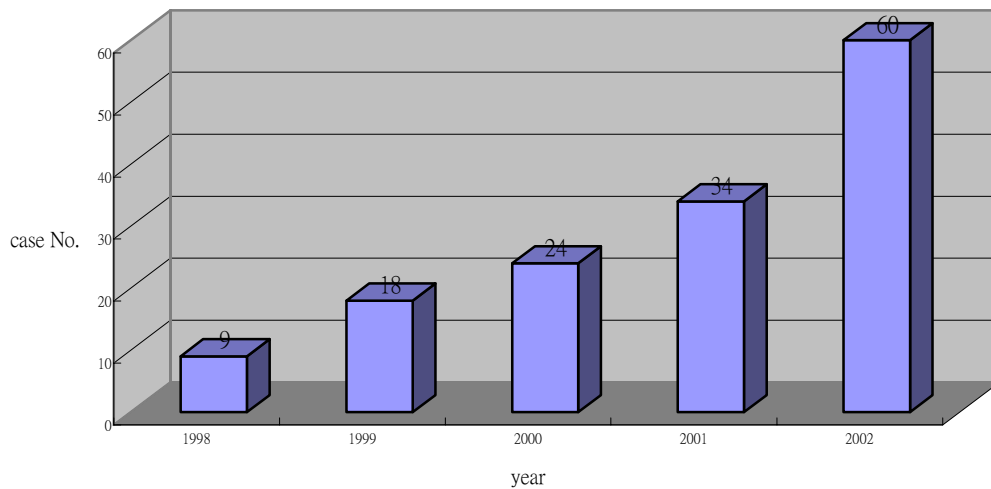
主要業務及相關成果(Major Task & Performance)



新藥查驗登記案審查 NDA Review

本中心接受藥政處委託審查新藥查驗登記案 (New Drug Application, NDA) 之技術性資料，以公正、透明的審查態度，遵循內部初審、複審機制以管控審查品質。隨著本中心業務的成長與經驗的累積，逐步增加查驗登記案之新藥類別，包括新成分、新複方、新劑型、新適應症與生物製劑；並提昇審查效率，案件之平均審查時間由 2001 年的 120 天進步為 100 天 (廠商補件時間除外)。

CDE reviews the technical information for the New Drug Application, entrusted by Bureau of Pharmaceutical Affairs, fairly and transparently. CDE evaluates cases through internal primary and secondary review to control the quality. By the accumulation of the review experience and the increasing number of cases reviewed, CDE gradually increases the categories of review, including new chemical entity, new combination, new formulation, new indication and biological products; and also increases the review efficiency by reducing the average review time from 120 days in 2001 to 100 days (sponsor time excluded).



● 新藥查驗登記案的審查機制

NDA Review system

- ◆ 新藥查驗登記案之審查流程分審查 (review) 與審議 (evaluation) 二層次。廠商原始資料於本中心完成初審 (primary review), 複審 (secondary review), 提出審查報告 (Assessment report), 再由衛生署藥物審議委員會採共識決審議。必要時, 本中心審查員於審查過程中可諮詢藥審會委員或其他專家。

The procedures for NDA Review can be divided into two parts, review and evaluation. CDE conducts the primary review, secondary review, internally, and presents the assessment report to the Drug Committee in DOH. A consensus is reached by discussing our assessment in the drug committee. When necessary, we consult the committee members or outside experts.

- ◆ 自 2001 年起, 配合衛生署新藥查驗登記法規鬆綁的政策, 本中心已受理審查四件尚未在任何一國上市 (Non-Free Sales Certificate) 之新成份新藥, 與先進國家同步審查, 對提昇本中心審查能力為一大挑戰。Effective in 2001, to comply with DOH's policy, we began to review and have evaluated four applications that have Non-Free Sales Certificate status. We review these applications concurrently with the advanced countries, which can be a great challenge for us.

● 補件、申覆輔導機制

Supplement, counseling the reply system

對於需要補件或申覆之案件，本中心提供廠商諮詢的機會。經由補件內容的解釋，輔導廠商了解補件要求，如有必要，亦可面對面的與審查員溝通與討論。

For applications requiring supplement of additional materials or counseling, we provide the opportunity to do consultation to the sponsors. Through explaining the required materials, we help the sponsors to provide what should be additionally submitted. If necessary, face-to-face communication and discussion with the reviewers will be arranged.

臨床試驗計畫書審查 IND Review

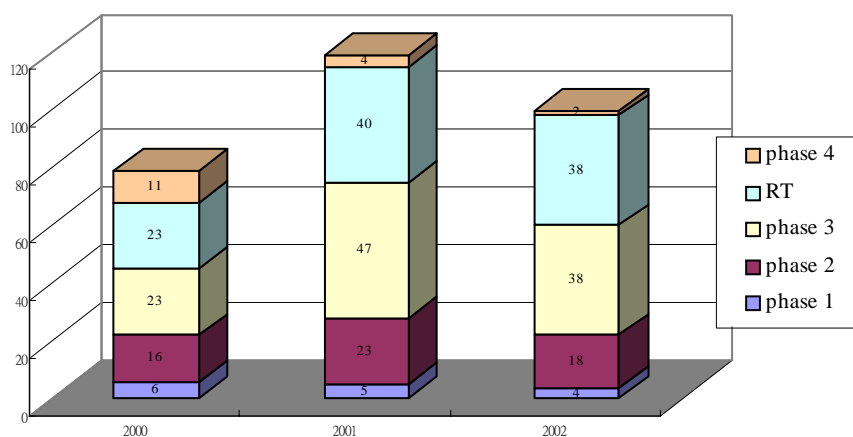
本中心以透明公開的審查機制受理所有衛生署委託之臨床試驗計畫書審查，經由召開廠商會議 (sponsor meeting)，使廠商或試驗主持人有機會與審查員面對面溝通，討論或修正試驗計畫書以釐清審查疑慮，以提高合理的案件核准率 (approval rate)。若將廠商時間除外，原則上臨床試驗計畫書之平均審查時間約 20 天。

資料顯示，2002 年本中心受理的多國性臨床試驗佔總案件數 36%，而早期臨床試驗計畫案 (含 phase 1、2、3a) 為總案件數 60%。台灣已逐漸增加早期臨床試驗比例並參與多國性臨床試驗，在亞太地區執行臨床試驗的能力獲得肯定，對於發展國內新藥研發環境亦是不可或缺的一環。

Through the transparent review mechanism, CDE reviews all the clinical trial protocols entrusted by DOH. By holding the sponsor meeting, there will be an opportunity for reviewers and sponsors or investigators to communicate, discuss, or revise the clinical trial protocols, face to face, to increase the approval rate. Excluding the sponsor time, the average review time for a clinical protocol is about 20 days.

In 2002, 36% of the cases evaluated by the CDE are multi-national clinical trials, and early phase trials (including phase 1, 2, 3a) constitute 60% of the cases. In Taiwan, the ratios of early phase trials have been increased and we participate in multi-national clinical trials. The ability to conduct clinical trials effectively and promptly in the Asia Pacific region has been recognized, which is an important part in the development of a new drug research environment in Taiwan.

於 2000 至 2002 年，本中心受理的臨床試驗計畫案件數類別統計，如下圖：



(Year)

● 銜接性試驗評估

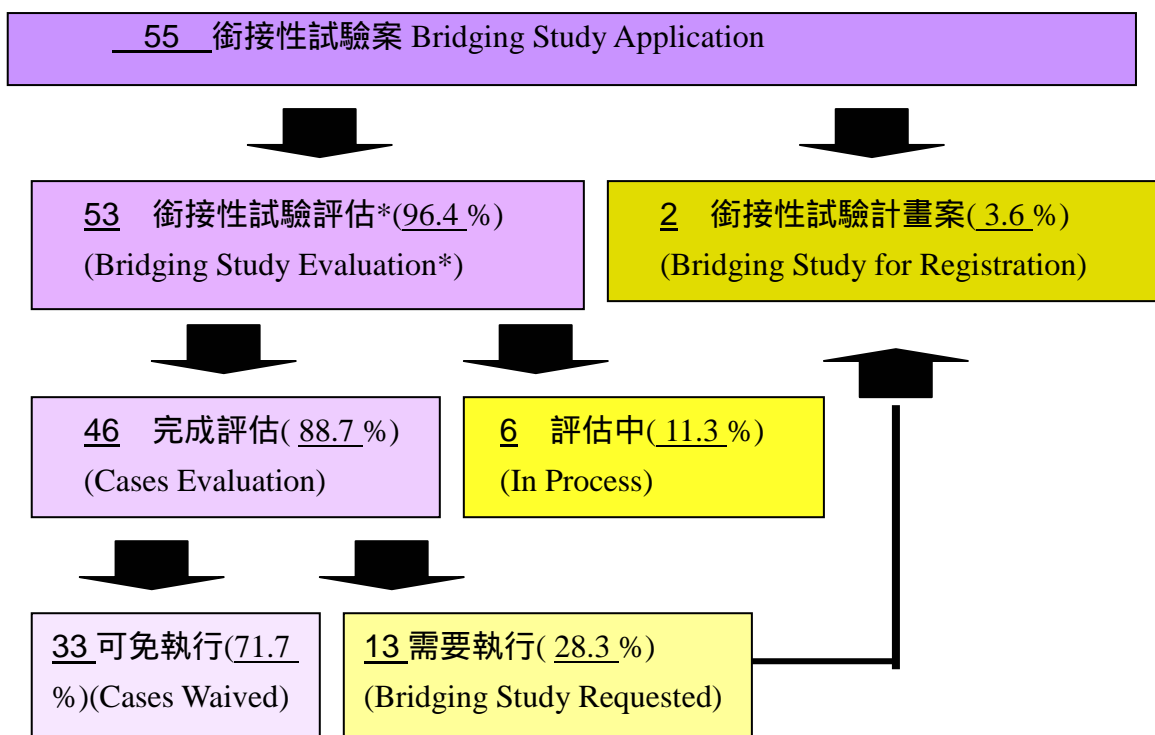
Review of Bridging Study Evaluation

銜接性試驗(bridging study)是提供國人相關療效、安全、用法用量等臨床試驗數據，使國外臨床試驗數據能外推至本國相關族群之試驗。以往亞洲許多國家在進行新藥查驗登記時，並未考慮藥品的作用是否會因人種而受影響，或直接接受國外的臨床數據。直到國際醫藥法規協會(The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, 簡稱 ICH)於 1998 年提出 E 5 (E 是 efficacy, 5 是裡面第五個基準)規範，以容易產生人種差異的十點考量作為科學根據，制定了評估族群對藥品作用的影響之相關內容，作為各國考慮以銜接性試驗或直接接受國外臨床試驗數據之參考。

台灣依循 ICH-E5 之精神，為減少新藥研發資源的浪費，以及提昇我國臨床試驗水準，由衛生署於 2000 年 12 月 12 日公告，自 2001 年 1 月 1 日起，以二年為緩衝期，在新藥查驗登記前，配合符合科學性之評估流程，逐步推動銜接性試驗將族群敏感性納入考量。本中心依據「雙十二(銜接性試驗)公告」，自 2001 年 3 月起受理「銜接性試驗案」的評估。目前受理件數已達 55 件，其中 53 件為銜接性試驗評估案，2 件為銜接性試驗計畫案。

The purpose of bridging study is to provide clinical trial data on the efficacy, safety, and drug use dosage so that foreign clinical data can be extrapolated to the Taiwanese populations. In the past, many Asian countries did not evaluate whether the drug efficacy is influenced by ethnic differences. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, abbreviated as ICH, in 1998, issued the E5 guideline, which consists of information on measures to review of the ethnic influence on drug efficacy, based on 10 scientific properties that are sensitive to ethnic differences. This guideline is used as a reference for the review of foreign clinical data.

In compliance with the E5 guideline, DOH announced that, effective on January 1, 2001, there was a gradual implementation of bridging study evaluation, which assessed ethnic sensitivity. CDE began to evaluate bridging study applications in March, 2001. As of March 2003, a total of 55 applications have been reviewed. Fifty three cases are bridging study evaluation and two cases are clinical trials fulfilling bridging purposes.



* Including one case withdrew by the sponsor. * 包括撤案者一件

完成審查之 46 件中有 33 件得免除銜接性試驗，可免除率為 71.7%

Of 46 applications that have been assessed, 33 (71.7%) were waived to conduct bridging study.

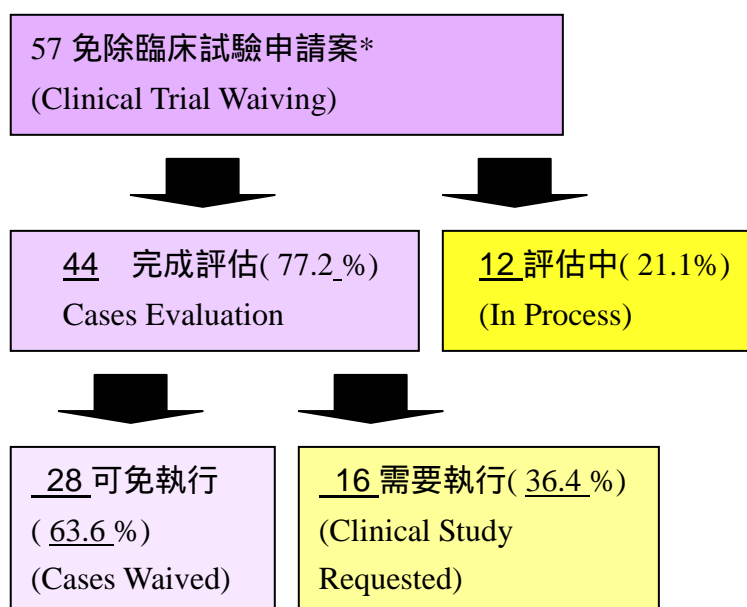
案件數 Number of cases	新成分 (New Chemical Entity)	新複方 (New Combination)	新使用途徑 (New Administration route)	新劑型 (New Dosage form)	共計 (Total)
已完成評估件數 (Cases Evaluation)	28	5	9	4	46
可免除件數 (Cases Waived)	21	3	5	4	33
不可免除件數 (Bridging Study Requested)	7	2	4	0	13
免除率 (The waived ratio)	75.0%	60.0%	55.6%	100.0%	71.7%

● 免除臨床試驗評估

Review of clinical trial waiving

為配合衛生署藥政處新藥查驗登記法規鬆綁政策，本中心自 2001 年 6 月起受理「免除臨床試驗評估案」。至 2002 年底，完成審查之 44 件中有 28 件得免除臨床試驗，可免除率為 63.6%。

In compliance of relaxing policy of new drug registration issued by the Bureau of Pharmaceutical Affairs, CDE began to evaluate “Clinical trial waiving” in June 2001. As of the end of 2002, a total of 44 applications have been evaluated and 28 cases were waived. The ratio for waiving was 63.6%.



* Including one withdrew case by the sponsor. * 包括撤案者一件

法規研擬(Guideline preparation)

本中心接受衛生署委託，研擬符合國際標準之相關醫藥品試驗基準或規範草案。已協助完成草擬，且衛生署於 2002 年公告之法規如下：

- (1) 「藥品優良臨床試驗規範」(2002 年 8 月公告)
- (2) 「腎功能不全病患的藥動學試驗基準」(2002 年 7 月公告)
- (3) 「小兒族群藥動學之評估基準」(2002 年 7 月公告)
- (4) 「藥品臨床試驗申請須知」(2002 年 6 月公告)
- (5) 「基因治療人體試驗申請與操作規範」(2002 年 9 月公告修正)

目前仍協助研擬/修訂中之法規

- (1) 研擬「試驗中新藥申請流程」草案
- (2) 修訂「臨床試驗報告之格式及內容基準」草案
- (3) 研擬「人體研究倫理規範」草案
- (4) 修訂「藥品非臨床試驗安全性規範」
- (5) 研擬「新藥查驗登記共通技術性資料」草案

Entrusted by DOH, CDE drafts guidance's and guidelines that are in line with international standards. Those that have been finished and have been implemented by DOH are as followed:

- (1) "Good clinical trial" guideline (Implemented August, 2002)
- (2) "Guideline on pharmacokinetics studies in patients with impaired kidney function" (Implemented July, 2002)
- (3) "Guideline on the evaluation of pharmacokinetics in pediatric populations" (Implemented July, 2002)
- (4) "Guideline on necessary documents to apply for the clinical trials" (Implemented June, 2002)
- (5) "Guideline on the application and operational standards for gene therapy" (Implemented September, 2002)

The guidelines that are currently still in the process of preparation and amendment are as follows:

- (1) "The investigational new drug (IND) process"
- (2) "The clinical trial report format and its content"
- (3) "The ethical standard for human research"
- (4) "The non-clinical safety guidelines for investigational new drug"
- (5) "The common technical document for new drug registration"

因應全球生物科技的蓬勃發展，本中心自成立以來，提供國內從事新藥(含中草藥、生技製藥)研發單位及相關業者，在研發過程中之法規諮詢服務，提昇國內臨床試驗執行的品質，及引進跨國性早期的臨床試驗至國內研究，進而帶動國內生技產業的蓬勃發展。

本中心受理之諮詢案的類別區分為新藥研發(包括化學藥、生物製劑、中草藥)、臨床試驗計畫書、銜接性試驗及一般法規諮詢等。

自 1999 年 1 月 1 日起至 2002 年 12 月 31 日止，中心受理諮詢案件共計 322 件。本中心鼓勵新藥及生技製藥業者於研發階段及早提出諮詢，並依諮詢需求的不同提供專業諮詢服務，面對面與業界溝通討論。目前已召開多次臨床試驗前會議(pre-IND meeting)，討論國產新藥或跨國性早期臨床試驗之諮詢案件。本中心對國產新藥研發，亦以輔導的角度提供專業的意見，目前已有 14 件進入下一個研發階段，3 件於諮詢後採取授權或技術移轉，2 件擱置評估，2 件決定放棄其投資策略。

透過中心的諮詢機制，廠商得以解決藥品研發上的瓶頸及法規方面的疑難，並有效地縮短業界的研發時間與投資成本，避免無謂或錯誤的投資。

For responding on the flourishing global development of biotechnology, the CDE, ever since her establishment, has provided the domestic R&D institutions and the related industries (including Chinese herbal medicine and biopharmaceutics) with the regulatory consultation service during their developing stage to improve the implementation quality in clinical trial, and has led multi-national trials of early phase into this country. Consequently, the prosperous development of biotech-industry in Taiwan has been motivated.

The consultations accepted by CDE can be categorized as: New Drug R&D (including small chemicals, bio-products, and Chinese herbal medicine), Clinical Trials, Bridging Study, and Regulatory Inquiry, etc.

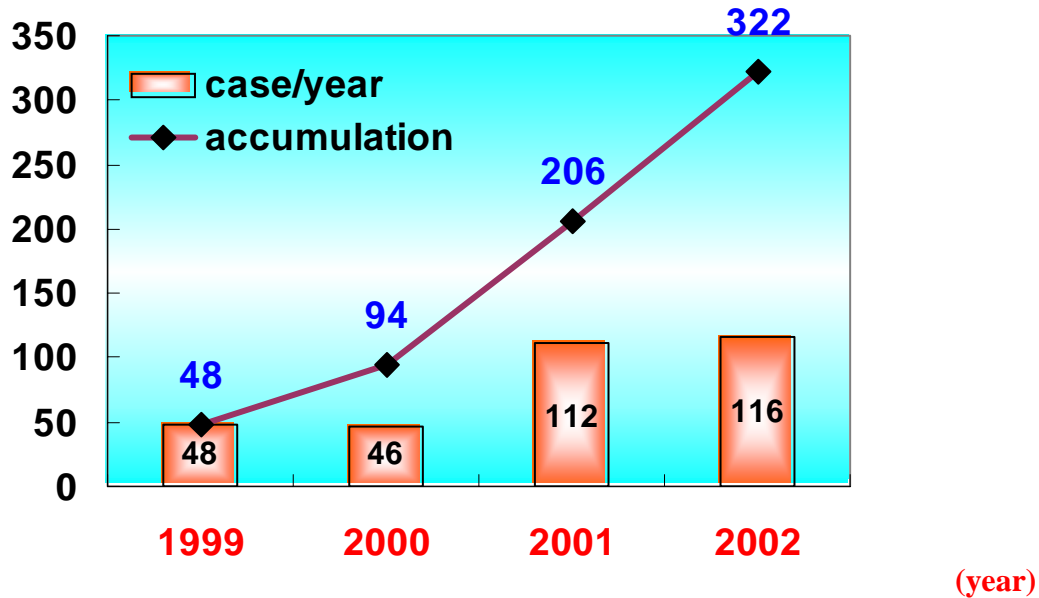
From January 1st, 1999 to December 31st 2002, CDE had consulted 322 cases. The sponsors of the pharmaceutical industry are encouraged to bring up inquiries earlier, and to discuss problems with us face to face throughout the R&D process. CDE provides the professional advice according the special need of each individual. Up to date we have already organized numerous pre-IND meetings regarding early phases of clinical trials for the domestic and multi-national new drugs. For domestic new drug development, CDE has provided professional opinions based on the regulatory point of view. After consultation, 14 cases are currently entering the next developing stage, 3 cases are seeking license-opportunity or technology transfer, and 2 cases are waiting for further evaluation, while 2 cases were terminated for further investment.

Through the consultation mechanism provided by CDE, the sponsors are able to resolve the bottleneck and regulatory problems raised during the R&D of the new products, both the time-span and the cost on R&D have been effectively cut down,

and indeed, initiation of unnecessary/wrong investments was therefore be avoided.

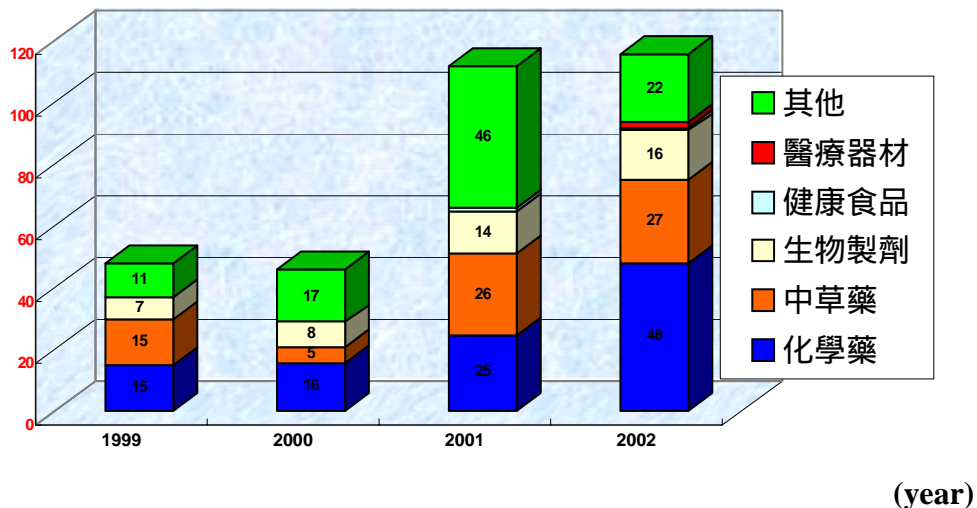
● 1999~2002 諮詢案件數累計圖

Case No.



● 1999~2002 諮詢案件分類圖(Classification of 1999~2002 consultations)

Case No.



此外，本中心為協助業者於新藥研發階段所面臨的法規問題提供溝通管道，使其瞭解政府推動生技製藥產業之政策與方針，乃針對不同業者與不同訴求，定期舉辦「臨床試驗」、「國產研發」、「生技研發」及「中草藥」四項產學會議。

行政院衛生署於 2001 年 10 月 25 日正式成立「生技產品諮詢單一窗口」，由本中心專案經理協助藥政處高科技小組同仁提供業界「一站到底」(one stop for all)

之全方位服務。其專業諮詢項目包括藥品、醫療器材、健康食品、化妝品及中草藥之研發、設廠、臨床試驗與上市管理等法規；諮詢服務的對象涵蓋了個人、國產藥品研發業者、外資藥廠、代理商、國內外生技研發公司、食品公司、醫療器材儀器公司、法律事務所、顧問公司、資訊公司與學界、育成中心以及政府相關單位等。

「生技產品諮詢單一窗口」未來的目標，期盼能整合產、官、學、研各方的資源與人力，協調建立國內研發環境，解決與排除國內生技發展困難，促成投資與國際合作。

Beside that, for the sake of assisting the sponsors who come across the regulatory problems during their R&D stage, CDE has provided communication channel to make them become awareness about the government's strategy and policy toward biopharmaceutical industry. With respect to the diversified inquiries raised by sponsors from various pharmaceutical fields, the joint industry-academia meetings, including "Clinical Trials", "Domestic R&D", "Biotechnology R&D" and "Chinese Herbal Medicine", have been scheduled and organized by CDE.

On October 25, 2001, the official "Single Window Consultation for Biotech-products" was established by the DOH, Executive Yuan. Program Managers of CDE have been working with the Hi-tech Group colleagues of the Bureau of Pharmaceutical Affairs (BPA) to provide the sponsors with the "one stop for all" service in all professional aspects, which include R&D of pharmaceuticals, medical devices, health foods, cosmetics, and Chinese herbal medicine, and the regulatory consideration about setting up factory, clinical trial, and marketing management, etc. The objects of this consultation service cover all individuals, the domestic pharmaceutical R&D sponsor, the foreign invested pharmaceutical factory, the dealer, the local/foreign biotechnology R&D company, the food company, the medical equipment apparatus company, the law/consultant firm, the information company, and the academic institutions, the incubation center and related division of the government.

The future goal of the "Single Window Consultation for Biotech-products" is being expected to integrate all resources and manpower from the industry, government, academia, and research institution, to coordinate and to establish the domestic research environment, to resolve potential development difficult for domestic biotech/pharmaceutical industry, eventually to promote investment and international cooperation in Taiwan.

隨著基因密碼的解碼及各種生物技術快速的發展，生技製藥產業已成為二十一世紀各國努力推動的目標；應用基因治療、幹細胞治療、基因重組等技術研發之新醫療技術與產品，均需要周延的法規政策及配套措施。

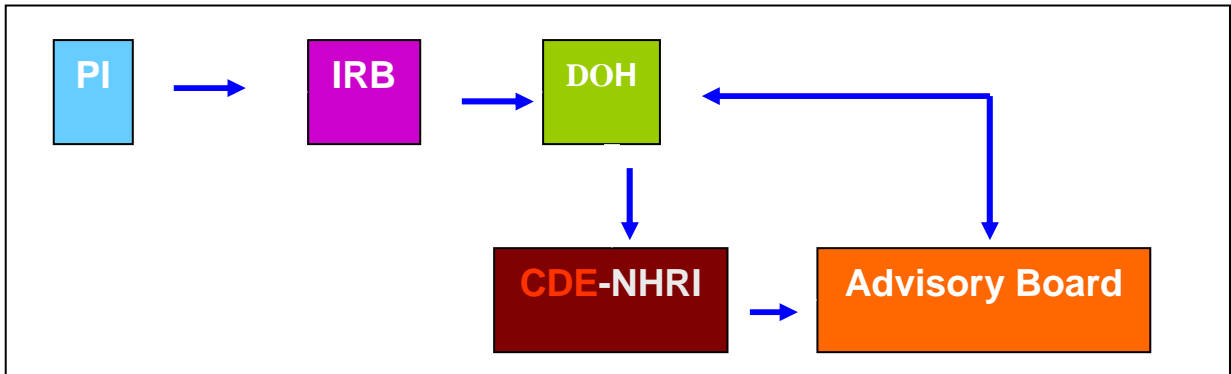
本中心深入了解國內外相關現況與需求，協助衛生署建立此新醫療技術與產品之相關管理機制。

本中心藉著參訪各國國際法規單位、藥廠及相關學術研發機構，如日本厚生省、美國食品藥物管理局(FDA)、國家衛生研究院(NHRI)、法國 Afssaps 及德國 PEI 等國際法規機構，深入瞭解國際基因治療之整體環境，積極協助衛生署研擬有關「基因治療人體試驗申請與操作規範」、「人體細胞組織優良操作規範」及「人體試驗委員會作業基準」等規範。同時建言衛生署醫政處，研擬基因治療人體臨床試驗計畫書審查流程；並與國衛院共同協助基因治療人體臨床試驗計畫書的初審。同時已提供 3 案件的諮詢輔導及舉辦多場相關座談會與研討會。

Followed by decoding of human gene and the expeditious development of the biotechnology, the biopharmaceutical industry has already become the worldwide endeavoring target of the 21st century. Such as the application of gene therapy, stem cell therapy, and the development of recombinant DNA, all these newly developed medical techniques and products need appropriate regulatory strategy and policy, and a corresponding management to follow up.

It has been realized in depth that the universal demanding and conditions on new medical techniques and products, the CDE has provided her support to the DOH to set up the administration mechanism with this regard.

By visiting international regulatory organizations, pharmaceutical companies and related academic/R&D institutions, such as the Koseishoo of Japan, the FDA and NIH of the U.S., the Afssaps of France, and the PEI of Germany, etc., we have been intensely aware of the entire environment of the gene therapy, and actively assisted the DOH in drafting guidelines, for example, “The Application and Implementation Guidelines for Gene Therapy Trial”, “Good Operation Practice for Somatic Cells and Tissues”, and “The Guidance for the Institutional Reviewing Board Operation”, etc. In the mean time, CDE has made suggestions to the Bureau of Medical Affair, DOH, to draft the reviewing procedure for the gene therapy trial proposal, and provided our assistance to the National Health Research Institutes (NHRI) in the primary reviewing for the gene therapy trial proposal. At the same time, CDE has provided the service of consultation for three cases, and has organized several related forums and seminars.



衛生署基因治療人體試驗申請及審查流程

The flow diagram of the DOH for the application and reviewing of the gene therapy trial.

中草藥計畫

(Traditional Chinese Medicine Project)

本中心自 2001 年起接受中醫藥委員會委託，審查中草藥臨床試驗計畫書申請案。至 2002 年 12 月 31 日止，共受理 14 件，經提中醫藥委員會討論，其中已有 6 件通過，准予執行。

本中心亦接受中醫藥委員會委託，參考歐美相關管理規定，並考量我國中藥新藥研發現況，協助研擬/修訂相關法規，包括：修訂「中藥新藥查驗登記申請須知」、研擬「骨質疏鬆症之中藥臨床試驗基準」；同時，亦受託與中醫藥委員會共同進行中草藥臨床試驗模擬查核，藉以提升中草藥臨床試驗之執行品質。

此外，亦藉著舉行「中草藥產學會議」，與業界及研發單位保持暢通之溝通管道；會議針對目前中草藥界關心的議題進行廣泛的討論，如：「中草藥研發選方的考慮與法規門檻」、「大陸執行的毒理學試驗台灣如何評估與採信」、及「有關中草藥 human experience 的認定」等；期能達到互動，及溝通暢通之目標。

Since 2001 CDE has commissioned for the Committee on Chinese Medicine and Pharmacy (CCMP), DOH, to review the clinical trial protocol for traditional Chinese medicine (TCM), including herbal remedies. Up to the end of 2002, a total of 14 clinical protocols had been evaluated by CDE and submitted the assessment reports to the board of the CCMP for final decision. Among these, 6 cases had been granted the permission to initiate the trials.

CDE also has commissioned by the CCMP to draft/revise related guidelines by consulting with the related management stipulations of the Europe and the U.S., and considering the current status of new drug R&D of TCM in this country as well. We have revised “The Guidance for New TCM Application”, and we have drafted “The TCM Trial Guideline in Osteoporosis Treatment”. Meantime, the joint CDE-CCMP team has carried out a simulating clinical inspection in order to enhance the implementation quality of TCM clinical trial.

In addition, CDE has been keeping a clear communication channel with sponsors and R&D institutions by holding regularly the “Joint Industry-Academia Meeting” focused on the topics, such as “the R&D consideration of singular TCM selection and regulatory restrictions”, “how to evaluate and interpret the toxicology data generated in China”, and “how to verify the TCM human experience”, etc., which are the current concerns of the TCM industry. Through these active meetings, mutual interaction and effective communication are anticipated to be achieved.

臨床試驗藥物不良反應評估 (Clinical Trial ADR Evaluation)

本中心協助全國藥品不良反應通報中心，辦理臨床試驗嚴重不良反應 (SAE) 報告之評估，依據通報中心通報之原始資料，完成「臨床試驗藥物不良反應」與「通報品質」之評估，回報該中心。

此外，本中心與全國藥物不良反應中心合作，協助衛生署更新「藥品不良反應通報表」中、英文版(包含中草藥臨床試驗 SAE)，希望藉由健全的通報制度提昇國內臨床試驗的嚴重不良反應之通報品質與時效。

To assist the National ADR Reporting Center, CDE has been in charge of evaluating the Clinical Trial SAE reports. According to the primary data provided by the Reporting Center, CDE completed the “Clinical Trial ADR” and “Reporting Quality” evaluation and the assessment report was forwarded to the ADR Reporting Center.

In addition, CDE has cooperated with the National ADR Reporting Center to assist the DOH to renew the Chinese and English versions of “ADR Reporting Form” (including TCM Trial SAE). Hopefully through such a well-organized responding system the reporting quality and time efficiency of the Clinical Trial SAE could be enhanced.

國際合作

International Alliance

為加強與國內外各醫藥法規相關單位之合作，本中心積極協助衛生署與美國食品藥物管理局 (U. S. Food and Drug Administration, FDA)、歐盟藥物評審委員會 (The European Agency for the Evaluation of Medicinal Products, EMEA) 及法國、德國、日本及澳洲等國際藥品審查法規單位之交流，並積極參與國際活動，期能建立法規對談與人員訓練管道。

In order to strengthen the cooperation among local and foreign regulatory agencies, CDE has actively assisted DOH in mutual communicating with the U.S. Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMA), and the regulatory organization/evaluation center of France, Germany, Japan, and Australia, etc., and CDE has enthusiastically participated in related international activities. Hopefully the channel of mutual regulatory dialogue and the training opportunity for the CDE staff could be established because of these efforts.

參加 38th DIA 年會--介紹我國生技製藥法規與臨床試驗環境

To participate 38th DIA Annual meeting—To introduce our pharmaceutical regulation system and clinical trial conduction environment

本中心於今年 6 月協助衛生署組團赴芝加哥參與「藥物資訊協會」 (Drug Information Association, DIA) 年會，於會中主持「IND/NDA Process in Asia」議題之討論，同時設立攤位展現台灣法規環境與執行早期臨床試驗之整體能力，獲得國際熱烈迴響。

返國後舉辦心得分享會，就臨床試驗亞洲製藥環境面對之挑戰，全球法規協化趨勢下的台灣對策，與國內產、官、學、研各界分享。

藉由此一系列活動，希望引進國外早期臨床試驗及藥品研發計畫，提高台灣參與國際生技醫藥研發之競爭力，進而帶動國內生技醫藥產業之發展。

In June, CDE assisted the DOH to lead a group of delegates to attend the Drug Information Association (DIA) Annual Meeting in Chicago, and hosted

the session of “IND/NDA Process in Asia” in the meeting. At exhibition booth, CDE displayed the regulatory environment and the integral ability in conducting early phase clinical trial in Taiwan, which has drawn enthusiastic feedback.

After convention, CDE has shared the DIA meeting experience with domestic industry, government officers, academia, and research institutions by providing the points regarding the challenge for the Asian pharmaceutical industry in clinical trial, and Taiwan’s response and strategy under the upcoming trend of global regulatory harmonization.

The efforts of these activities are intended to lead early phase of clinical trial or new drug development into this country, to enhance Taiwan’s competitiveness in participation of international biopharmaceutical R&D, and to promote local biopharmaceutical industry.

國際法規協合化與亞太經濟合作—亞太藥政法規聯絡網

Harmonized international guidelines to cooperate with Asian economic— Asia Pacific guideline of pharmaceutical affair contacting network

(ICH & APEC)

本中心基於參加 2000 年 ICH-5 會前會之經驗，建議於 ICH-6 會議中亦能納入非會員國家之意見；此項建議已於 2002 年 9 月初在美國華盛頓特區舉行的 ICH GCG meeting 中達成決議，並於 9 月 18 日在日本舉行之「2002 APEC Workshop on Bridging Study」會議中宣佈，將於 2003 年假大阪舉行之 ICH-6 會期前一天舉行非 ICH 會員國之會前會。

Based on the pre-meeting experience in the year 2000 ICH-5 meeting, CDE has suggested that non-membership nation’s opinion should be included in ICH-6 Meeting. This suggestion was derived from the decision in the ICH GCG Meeting, Washington DC, in the beginning of September, 2002. By September 18 the “2002 APEC Workshop on Bridging Study”, Japan, announced that the non-ICH membership nations pre-meeting would be held one day preceding ICH-6 Meeting (2003), Osaka Japan.

「APEC Network of Pharmaceutical Regulatory Science」

為擴大亞太地區會員國家醫藥品法規協合化之目的，本中心協助衛生署藥政處聯繫日本厚生勞動省，將台灣主導之「APEC Network of Pharmaceutical Regulatory Science」計畫移師至日本，於 2002 年 9 月 18

日在東京大學舉行「The 2nd APEC Workshop on Bridging Study」會議。該會議有來自 14 個國家之專家學者與會，針對 ICH E5 Guideline（如何接受國外臨床數據），交換實施「銜接性試驗」評估經驗，討論 E5 對亞太各國的臨床試驗之衝擊；亞太地區各會員國家並於會中報告該國之臨床試驗相關規範與銜接性試驗評估現況。本中心於會中介紹台灣實施銜接性試驗評估之方法與實際案例分析；台灣以科學性之角度評估「國外臨床試驗資料可接受性」的豐富經驗，獲得與會者一致肯定。會中舉辦 Regulatory dialogue，以建立各會員體間的對話機制並達成共識，下屆 APEC 會議將於 2003 年 11 月 17~18 日於台北舉行，以「ICH in APEC」為主要議題，希望能鼓勵非 ICH 會員國採用 ICH 相關規範，並進而加強亞太地區藥物審查法規單位間的互動。

For the purpose of expanding the harmonization of pharmaceutical guidelines in the Asia Pacific region, CDE has assisted the BPA, DOH, in establishing connection with Koseichoo, Japan, to transfer the “APEC Network of Pharmaceutical Regulatory Science” project led by Taiwan over to Japan. On September 18, 2002, “The 2nd APEC Workshop on Bridging Study” was held in Tokyo University. Professional scholars from 14 nations attended this meeting, which focused on ICH E5 Guideline (how to accept foreign clinical data) to exchange the experience in “bridging study” evaluation, and to discuss the impact of E5 on clinical trials conducted by Asian countries. In the meeting the Asia Pacific membership nations presented the current status of their clinical trial guidelines and bridging study evaluations. CDE reported the bridging study evaluation method and case study carried out in Taiwan. Our abundant experience based on the scientific point in evaluating “The Acceptability of Foreign Clinical Trial Data” has gained the consistent affirmation by all meeting members.

“Regulatory Dialogue” was discussed during the APEC meeting in order to construct the discussion mechanism as well as the consensus among members. The next APEC Meeting is going to be held in Taipei on November 17~18, 2003, with the main issue on “ICH in APEC”. Hopefully the utilization of the ICH guidelines would be encouraged in non-ICH members, which might further enhance interactions among the pharmaceutical regulatory organizations in the Asia Pacific region.

藥物審查人員除須具備其審查領域之專業背景（如：醫學/藥學/藥理/毒理/統計/生技/中草藥等）外，尤需藥物審查法規相關領域之知識及經驗累積，但因人才稀少，羅致不易；故本中心積極加強各項在職訓練。

- 新進人員教育訓練包括：綜合概述新藥發展流程 試驗中新藥申請流程(IND Process) 臨床試驗計畫書申請案、查驗登記申請案、中草藥及生技類產品、統計、以及上述各項相關法規之作業流程等。再針對不同之專業領域，提供進階之業務訓練。
- 在職訓練內容涵蓋藥政法規、中草藥發展、生物製劑、銜接性試驗、藥物動力學/藥效學、生物統計等審查業務相關課程。除了有許多機會聆聽國內外各專業領域資深及具審查經驗的專家之演講，或接受個案指導之外，亦有機會參與國內外研討會、接受跨國性大藥廠的新藥研發部門訓練、前往先進國家藥政法規單位受訓。
- 因應 2002 年度衛生署委託辦理基因治療等新興醫療技術相關業務，以及中藥新藥臨床試驗查核作業，故 2002 年教育訓練內容亦增加新興醫療技術及臨床試驗查核作業領域。

In addition to its own expertise (such as medical science, pharmaceuticals, pharmacology, toxicology, statistics, biotechnology, Chinese herbal medicine etc), an effective reviewer also needs knowledge and the accumulated experience in the related fields of drug review guidelines. Due to the talents are rare and difficult to recruit, CDE has taken efforts to provide on-job training in various areas of tasks.

- New coming members' orientation training includes: Comprehensive summary of new drug developmental process, IND Process, Application of clinical trial protocol, New Drug Application, Chinese herbal medicine and biotechnology categories products, statistic, and the review process with related guidelines as described above. Then focus on individual's discipline, CDE provides one to one advanced training.
- The courses of on-job training includes pharmaceutical regulatory guidelines, Development of Chinese herbal medicines, biological products, bridging study, pharmacokinetics / pharmacodynamics, biostatistics, and others related to the drug review. Reviewers at CDE also gained their training through invited speaker's lecture, attending domestic/international conference and taking short course at renowned international pharmaceutical companies.
- Driven by DOH commission to manage gene therapy and other advanced biotechnologies, as well as the GCP inspection of on Chinese herbal medicine, CDE is providing new training courses to meet the demand.

品質管理與作業電子化系統 (Quality Management & e – system)

為提昇審查與諮詢服務之作業品質與效率、落實廠商機密資料之有效管理，並配合衛生署電子化作業之推動，本中心已著手建立品質管理與電子化作業系統。

To enhance the quality and efficiency of drug review and consultation service, to effectively manage the confidential information of our sponsors, and to comply with the DOH-directed policy of implementing an electronic operation system, CDE has undertaken to set up a quality management and electronic system of operation.

● 品質管理

Quality Management

本中心品質管理內容如下：

1. 檔案管理

建立各種文件收發、資料傳遞與歸檔之電子化作業及資料庫管理系統。

2. 標準化作業

為確保各項審查作業之一致性、有效性與諮詢服務之品質，故建立本中心各項業務之標準作業程序(SOP)，包括審查作業流程、諮詢作業流程、查檢表、報告格式等。

3. 知識管理

利用知識管理系統，讓本中心同仁能有效掌握各項資訊，加強審查業務之經驗傳承，提昇工作效率與品質。

The Quality Management of CDE includes the following elements:

1. File management

To establish an e-operation and database management system to control the document's receiving, transfer, sending and filing.

2. Standardized operation

In order to ensure the consistency and effectiveness of drug review, and quality of our consultation service, CDE has set up standard operating procedures (SOP) for different itemized activities, including the review processes, consultation process, check list, and reporting format etc.

3. Knowledge management

This system aims to assist colleagues of CDE to assess information effectively, to share valuable reviewing experience and to enhance productivity and quality of

our services.

● 作業電子化

Operational e-system

為配合衛生署推動查驗登記電子化，本中心建立作業電子化系統之規劃重點如下：

1. 配合藥政處業務電子化的時程，建立電子資料交換系統。
2. 作業流程電子化，建構本中心品質管理系統所需之系統平台。
3. 資料庫管理電子化，落實本中心知識管理。
4. 強化資料安全維護與管理，建立電子資料存取之分權與授權制度。並擬訂配套之系統緊急應變措施，以加強本中心資訊系統管理之危機處理能力。

With an aim to comply with the DOH-directed policy to electronize the drug registration and reviewing system, CDE has outlined the following strategies:

1. Establishing an electronic information exchange system, according to the timeline defined by the Bureau of Pharmaceutical Affairs.
2. Electronizing the operating procedure by setting up a system platform in the Quality Management System of CDE.
3. Electronizing the database management, materializing the knowledge management of CDE.
4. Strengthening the security of data management by setting up a decentralizing and authorizing system in the access of e-information. Setting up emergency management procedure to increase the capabilities of coping with crisis.

本中心至今已成立四年並將邁入第五年，在此四年中，積極招募與培訓人才，並在台灣生技製藥推動、新藥上市審查與民眾用藥安全把關等方面，不但協助衛生署建立相關系統並與行政院相關部會間密切合作，致力推動台灣成為亞洲醫藥法規之主導者。

若將過去四年比喻為本中心的快速成長期，由於各方面努力的基礎及資深人員的培育訓練，團隊默契亦已建立，明年可望進入另一成熟穩定階段。基於整體大環境仍有許多改善空間，例如新藥上市後不良反應的預警制度及合理用藥觀念的推廣，正是本中心可積極貢獻，發揮團隊影響力之時。

若問及本中心未來有何挑戰？由於已建立法規科學之核心知識，並對趨勢、契機...均有全方位的瞭解，因此雖然大環境不斷變動，但我們有信心能隨時因應，掌握適當的方向及策略。此外，為使本中心能發揮最大功能，目前亦加強制度管理、績效考核及組織再造，並朝「使用者付費」方向規劃，以使本中心能持續成長。

本中心前一階段的努力已受到各界肯定，未來，各界的期許將更多，因此我們將懷抱感恩的心，以任重道遠、捨我其誰的使命感盡力而為。除了為民眾用藥安全及福祉把關，本中心亦謹記成立緣由，積極配合政府「加強生物技術產業推動方案」及「發展台灣成為亞太營運製造中心—生物技術與製藥工業推動計畫」所要達成之目標，以顧客服務導向之工作態度，推動產業升級與發展。

CDE has already been established for four years and striding into its fifth year. During the past four years, we have been actively recruiting and training talents. Regarding proactive support the development of pharmaceutical biotechnology, the review of the new drug application and ensuring safe usage of drug in Taiwan, CDE assisted DOH to establish related system, to cooperate closely with the related departments of the Executive Yuan, and to strive to promote Taiwan becoming the leader of regulatory sciences in Asian countries.

Considering the past four years as the rapid growing period of CDE, with the endeavor foundation of different areas, and the continuous training for the quality members, the unspoken consensus of the teamwork has already been established. Hopefully by the year 2004, we can enter another stage of maturity. On account of the entire large environment, which still has many rooms for improvement, CDE can actively contribute and develop the influence in the areas, such as the warning system of adverse events for the post-marketing surveillance, and the promotion of legitimate drug usage concept, etc.

As to the future challenge, because the core knowledge of the regulatory science has already been established, and its trend for revolution has been revealed, CDE has the confidence to grasp the opportunity to control suitable direction and strategy. Furthermore, in order for CDE to maximize its function, we will continue to strengthen system management, performance appraisal and organization restructure. For future continue growth, CDE is considering to implement the "User Fee".

The endeavor of CDE so far has already been recognized by public. In the future, the expectation from them will be even more. With gratitude, we will focus on our vision to fulfill the mission of CDE, that is, to ensure the safety and welfare of public health. CDE will

actively cooperate with government in “the Project for Strengthening the Biotechnology Industry” and “to develop Taiwan as an Asia-pacific operation and manufacturing center—the promotion plan for biotechnology and pharmaceutical industry” achieving the objective, based on customer-oriented attitude, to proactively support industry upgrade and development.

- 2002.1.27-2.1 副執行長參加 The 6th Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products , 並拜會 FDA CBER 和 NIH RAC 討論基因治療法規及審查流程。
The Deputy Executive Director attended “The 6th Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products”, and visited FDA CBER and NIH RAC for the regulation of gene therapy.
- 2002.2.8 查驗中心召開第二屆第一次董事會 , 審議 2001 年度成果與結算報告 , 並進行 2002 年度計畫與預算報告之審議。
CDE summoned the first board of directors for the second round, discussed the accomplishment & account settlement of the year 2001, and proceed with year 2002 project and discuss budget report.
- 2002.2.26 衛生署召開”2001 年 CDE 之 performance”會議 , 會中檢視查驗中心 2001 年成果 , 並討論 2002 年工作發展方向。
DOH summoned the meeting on “The performance of CDE in 2001”, to assess CDE’s performance in 2001, and to discuss the direction of the major tasks in 2002.
- 2002.5.31 新任藥政處處長王惠珀教授就任後 , 本中心進行首次業務簡報。
CDE held its first business briefing, after the newly appointed Director of General of Bureau of Pharmaceutical Affairs; Professor Hui-Po Wang has inaugurated.
- 2002.5.20-6.5 基礎醫學組審查員邱怡君博士派赴美國 FDA , 進行為期兩週之 OCPB 訓練 ; 並向 FDA 藥物動力學部門簡報"Implementation of ICH E5- Taiwan's Current Experience".
Dr. I-Chun Chiu, a pre-clinical reviewer, attended a two-week OCPB training session in FDA. She also gave a briefing on “The Implementation of ICH E5- Taiwan’s Current Experience” to the Pharmacokinetics Department of FDA.
- 2002.6.4 舉辦”Good Submission Workshop” , 針對各類案件之申辦送件與常見缺失與業界等溝通。
CDE held the “Good Submission Workshop”, aiming at application

process and common deficiencies in dossier submission.

2002.6.10-14 執行長率同仁拜訪美國 FDA 之 CDER、CBER 及 NIH 之 RAC 等單位，實地瞭解美國基因治療管理體系，吸取可資參考之經驗，並在 CDER 小兒用藥部門發表演說，介紹台灣兒科臨床試驗發展現況；同時亦參訪業界及知名大學，瞭解欲進行早期小型基因治療臨床試驗所需之設施及其概況。

The Executive Director led the colleagues to visit the CDER, CBER in FDA and the RAC in NIH, intending to draw experiences in the fields of gene therapy management. They also gave a speech in the pediatric division of CDER to introduce current status of clinical trials on pediatric patients in Taiwan. Besides, they visited industries and universities to realize the facilities required for early phase, small-scale clinical trials in gene therapy.

2002.6.16-20 協助衛生署組團參加第 38 屆 DIA 年會--「介紹我國生技製藥法規與臨床試驗環境」。

CDE assisted DOH to organize a team to participate 38th DIA annual meeting - To introduce regulatory requirements on biological and pharmaceutical products as well as the infrastructure of clinical trials in Taiwan.

2002.6.21 臨床組審查員張方直醫師在 FDA CDER 之"International Regulatory Science"論壇演講"Current Status of TCM Regulation in China and Taiwan"，頗受好評。

Dr. Fang-Chih Chang, a clinical reviewer, gave a speech on "The Current Status of TCM Regulation in China and Taiwan" in the Forum of "International Regulatory Science" in CDER of the U.S. FDA. The presentation was well recognized.

2002.7.19 舉行首次「生技研發產學溝通會議」。

CDE held the first communication meeting with Biotechnical Industries and Academic Institutions.

2002.7.22-26 朱夢麟執行長在「行政院2002年產業科技策略會議」中，代表法規單位報告「藥物研發法規國際協化-政府法規的制定與執行」。

The Executive Director, Dr. Mong-Ling Chu, reported on "The International harmonization of drug research & development - the issue & execution of government laws and regulations" in the Conference of "Executive Yuan 2002 Biotechnology Strategic Review Board".

2002.7.26 舉行首次「中草藥產學會議」。

CDE held the first communication meeting with Industries and Academic Institutions on “The Manufacturing and Academic Research on Chinese Herbal Medicine”.

2002.8.30-8.31 邀請Dr. Eric Abadie(歐盟醫藥品查驗總署專利醫藥品委員會副主席 /國際醫藥品法規協會常設委員會委員/法國藥政署查驗登記與臨床研究部主任) , 與本中心討論如何增加非ICH與ICH國家之互動 , 及未來我國與法國藥政主管機關合作之可行性。

Dr. Eric Abadie, M.D., MBA (EMEA/CPMP Vice Chairman/ICH Steering Committee Member/Director, Registration and Clinical Trials Department, French Bureau of Pharmaceutical Affairs, France), was invited to visit CDE, to discuss “ how to enhance the interaction between ICH and non-ICH countries, and the feasibility on the collaboration of the regulatory authorities between Taiwan and France in the future”.

2002.9.4 審理完成我國第一件Non-FSC新藥查驗登記申請案。

CDE completed the NDA review of first Non-FSC case in Taiwan.

2002.9.18 陪同藥政處王惠珀處長赴日本東京參加「The 2nd APEC Workshop on Bridging Study」。

CDE delegates accompanied Hui-Po Wang, the Director General of Bureau of Pharmaceutical Affairs, to attend “The 2nd APEC Workshop on Bridging Study” in Tokyo Japan.

2002.10.5-13 參加經濟部組團之「2002 Biotech Delegation to Europe」, 至德國與法國拜訪其藥政管理機關(PEI、BfArM、Afssaps), 針對歐洲中草藥及新醫療技術產品之最新管理法規及審查要點進行瞭解。

CDE took part of the group organized by the Ministry of Economic Affairs “the 2002 Biotech Delegation to Europe”. They visited the Regulatory Agencies of Pharmaceutical Affairs in Germany and France, such as PEI, BfArM, and Afssaps, concentrating their interests at the guidelines & points to review on herbal medicine and new technical products in Europe.

2002.11.3-4 舉辦“統計研討會”, 與產官學研各界討論臨床試驗相關統計議題。

CDE held a seminar on statistics with delegates from industries, government agencies, and academic institutions, in which statistics-related issues in clinical trials were discussed.