Introduction of Biomedical Engineering

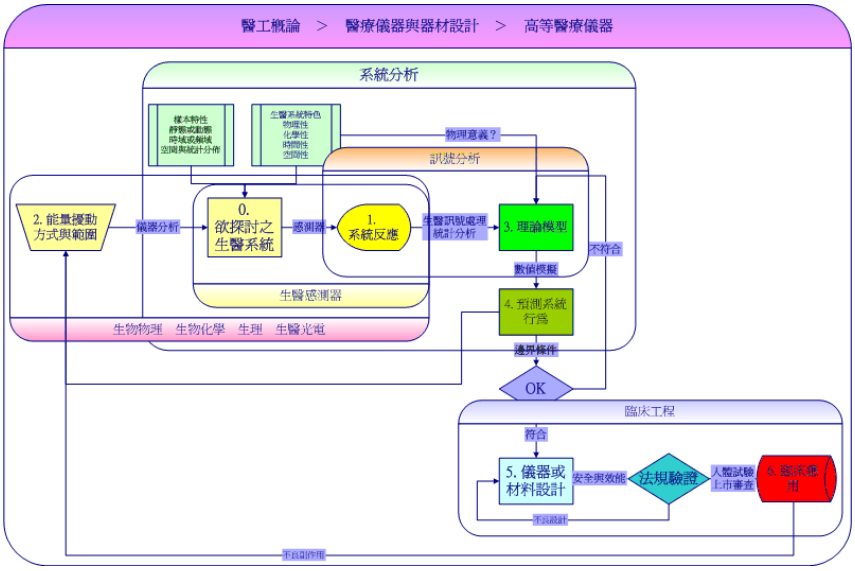
上課時間: 週四6、7、 8
(14:20~15:20)
上課地點: 電機二館 101教室

Course Schedule

09/22(四)	課程簡介與醫工生涯規劃 (林啟萬)
09/29(四)	分子生物與醫學工程(莊曜宇)
10/06(四)	生醫感測器(林啟萬)
10/13(四)	生物晶片與生物資訊(莊曜宇)
10/20(四)	微奈光電製程(管傑雄)
10/27(四)	人體潛能與撓場(李嗣涔)
11/03(四)	生醫訊號處理 (曹建和)
	期中考
11/17(四)	磁振造影 (陳志宏)
11/24(四)	磁振造影 (陳志宏)
12/01(四)	生醫超音波技術 (李百祺)
12/08(四)	生醫超音波技術 (李百祺)
12/15(四)	電腦斷層、核醫 (鍾孝文)
12/22(四)	電腦斷層、核醫 (鍾孝文)
12/29(四)	生醫光電 (孫啟光)
01/05(四)	生醫光電 (孫啟光)
	期末考

評分方式：作業 40% 報告 30% 期末考試 30%
課程網站：http://land.ee.ntu.edu.tw → 課程→ 醫學工程導論

Course Idea



Levels of Studies

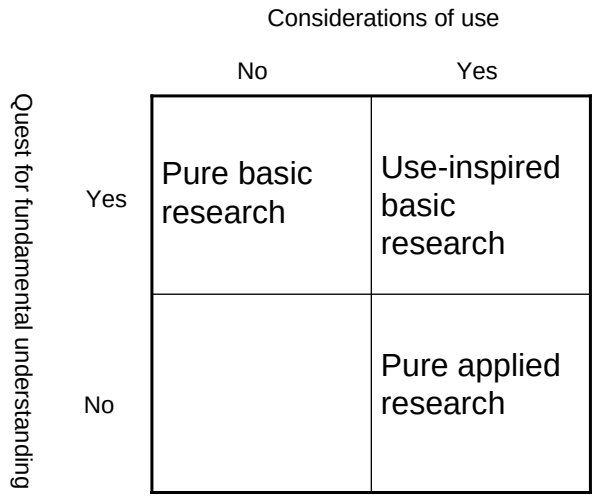
- Physiology
  - Molecular level
  - Cellular level
  - Tissue level
  - Organ level
- Biophysics
  - Principles
  - Theories
  - Models
- Engineering (Safe, Fast, Cheap)
  - Ethical issues
  - Design (materials, devices, functions)
  - Fabrication
  - Risk factors vs Benefit
  - Cost

“Charity in the broad spiritual sense – the desire to relieve suffering…. Is the most precious possession of medicine
-- Dr. Churchill, 1947”

- “His frustration at being unable to fulfill his childhood ambition of following his father into medicine only heightened his fascination with every aspect of the medical sciences” – commentary of Bradfor Hill’s achievements on Biostatistics
- “It may have been the fascination of an outsider, but this was only to his advantage. From this Olympian vantage point he was able to take a detached and critical view of medical developments” …

From The rise and fall of Modern Medicine, by James Le Fanu (p32)

Stokes' Quadrant Model of Scientific Research



The twelve Definitive Moments of Modern Medicine

- 1941 Penicillin
- 1949 Cortisone
- 1950 Smoking identified as the cause of lung cancer
  - Tuberculoisis cured with streptomycin and PAS
- 1952 The Copenhagen polio epidemic and the birth of intensive care
  - Chlorpromazine in the treatment of schizophrenia
- 1955 Open-heart surgery
- 1961 Charnley's hip replacement
- 1963 Kidney transplantation
- 1964 Prevention of strokes
- 1971 Cure of childhood cancer
- 1978 First test-tube baby
- 1984 Helicobacter as the cause of peptic ulcer

BME and Medical Devices

醫療器材的法源與定義

- 藥事法第四條
  - 本法所稱藥物，係指藥品及醫療器材。
- 藥事法第十三條
  - 本法所稱醫療器材，係包括診斷、治療、減輕或直接預防人類疾病，或足以影響人類身體結構及機能之儀器、器械、用具及其附件、配件、零件。
- 藥事法施行細則第二十六條
  - 醫療器材應予管理之範圍及其種類，由中央衛生主管機關視實際情形公告之。

Source: DOH

醫療器材之管理方式

一. 產品 → 醫療器材 → 須辦理查驗登記
醫療器材 → 無須辦理查驗登記
一. 產品 → 非屬醫療器材

二. 品質系統 → 須申請GMP
二. 品質系統 → 無須申請GMP

一等級（Class I）	二等級（Class II）	三等級（Class III）
醫療器材優良製造規範（GMP）（部份品項無須實施）	醫療器材優良製造規範（GMP）	醫療器材優良製造規範（GMP）
無須辦理查驗登記	查驗登記（部份品項無須辦理查驗登記）	查驗登記 + 臨床相關資料

Source: DOH

Medical Devices [21 U.S.C. 201 (h)]

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease, or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or intended to affect the structure or any function of the body of humans or other animals; and which does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals, and which is not dependent on being metabolized for the achievement of any of its principal intended purpose
- By Design

Source: FDA/CDRH

Drugs [21 U.S.C. 321 (g)]

- "An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; and an article (other than food) and other articles intended to affect the structure or any function of the body of humans or other animals"
- By discovery

Source: FDA/CDRH

Biological ? [41 U.S.C. 262(a)]

- "Any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man"

Source: FDA/CDRH

醫療器材的本質與特性

- 快速發展
  - 6500 Firms in 1980... over 20,500 in 1993
  - 4000 Product Submissions in 1980 ... 11,000 in 1993
- 高科技
  - Lasers, Artificial Hearts & Lungs, Pacemakers, Lithotripters, MRI
- 多樣化
  - 1800 Types of Products
  - 60-80,000 Brands and Models
  - Wide Spectrum of Risk (Bandages vs. Heart Valves)
- 資金導向中小企業
  - 95% of Device Firms Have 500 or Less Employees ("Small Business")
  - 60-65% Have 50 or Less Employees

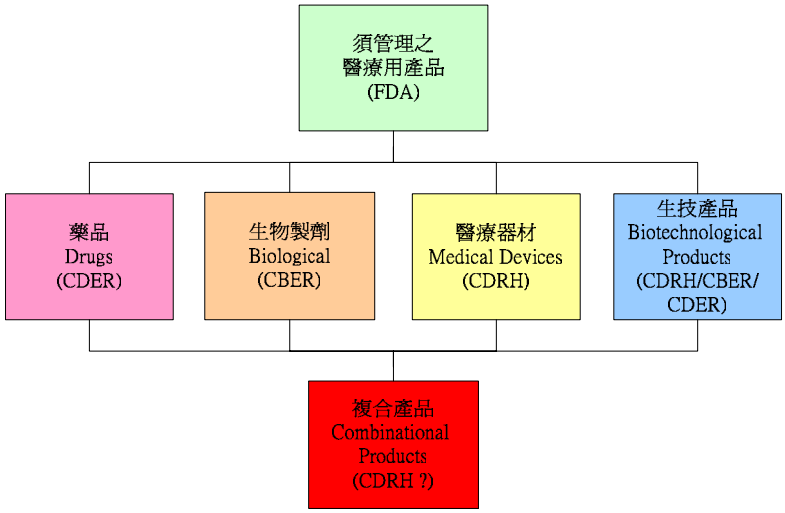
Source: FDA/CDRH

醫療器材與藥

- 醫療器材　by Design
  - 10% Clinical trials
  - Feasibility, Safety and Effectiveness
- 藥　by Discovery
  - 100% Clinical trials
  - Dose limiting toxicity trials (phase I)
  - Safety and efficacy (phase II, III, & IV)

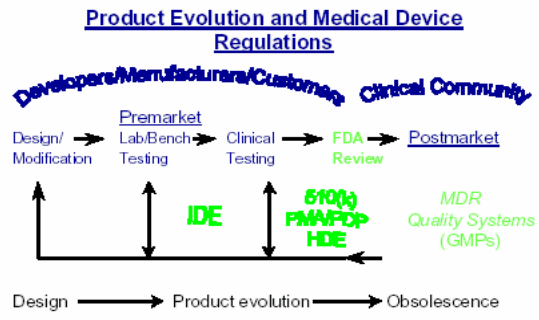
Source: FDA/CDRH

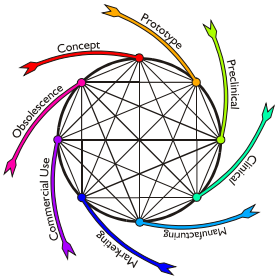
Categories of Medical Products



產品生命週期全程品質管理

想法 > 原形 > 前臨床 > 臨床 > 製造 > 市場 >商業使用 >下市





Source: FDA/CDRH

Premarket submission & Review

- Drugs/Devices (FD&C Act): requires demonstration of ***safety*** and ***efficacy*** for new drugs and devices prior to marketing.
  - IND/IDE
  - NDA/PMA/510(k)
- Biologics (PHS Act): requires demonstration of ***safety***, ***purity***, **and** ***potency*** for biological products before marketing.
  - IND
  - Biologics License Application (BLA)
- The sponsors (manufacturers) do the testing (preclinical and clinical), not FDA, to demonstrate that its product is ***safe***, and ***effective*** for the intended use.
- FDA evaluates the test results by assuring the safety and effectiveness of the product.

Source: FDA/CDRH

FDA預測未來十年六大主要技術趨勢

- Computer-related technology
- Molecular medicine
- Home- and self-care products
- Minimally invasive procedures
- Combination device/drug products
- Organ substitute and assist devices

醫療器材 vs 生物技術 產品

Source: FDA/CDRH

New Robotic Surgery Device

Da Vinci Surgical System

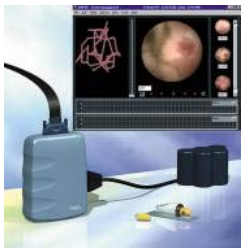
- Approved July 11, 2000
- Enable a surgeon to perform laparoscopic gall bladder and gastroesophageal reflux disease (severe heartburn) surgery while seated at a console with a computer and video monitor

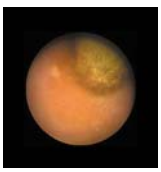
http://www.intuitivesurgical.com

Swallowable Camera Pill

Given Diagnostic Imaging System

- Approved August 1, 2001
- A swallowable capsule containing a tiny camera that snaps picture twice a second as it glides through the small intestine.
- A technological advance in methods of examining GI tract by visualizing inside of small intestine to detect polys, cancer, or causes of bleeding and anemia.





http://www.givenimaging.com/

GlucoWatch Biographer

- Approved August 7, 2001
- A disposable component for a wristwatch-like device designed to provide diabetics a noninvasive method to test glucose levels.
- Can alert users when glucose levels are too high or too low.
- It is intended to supplement, not replacement of standard finger-stick blood tests diabetics perform daily.

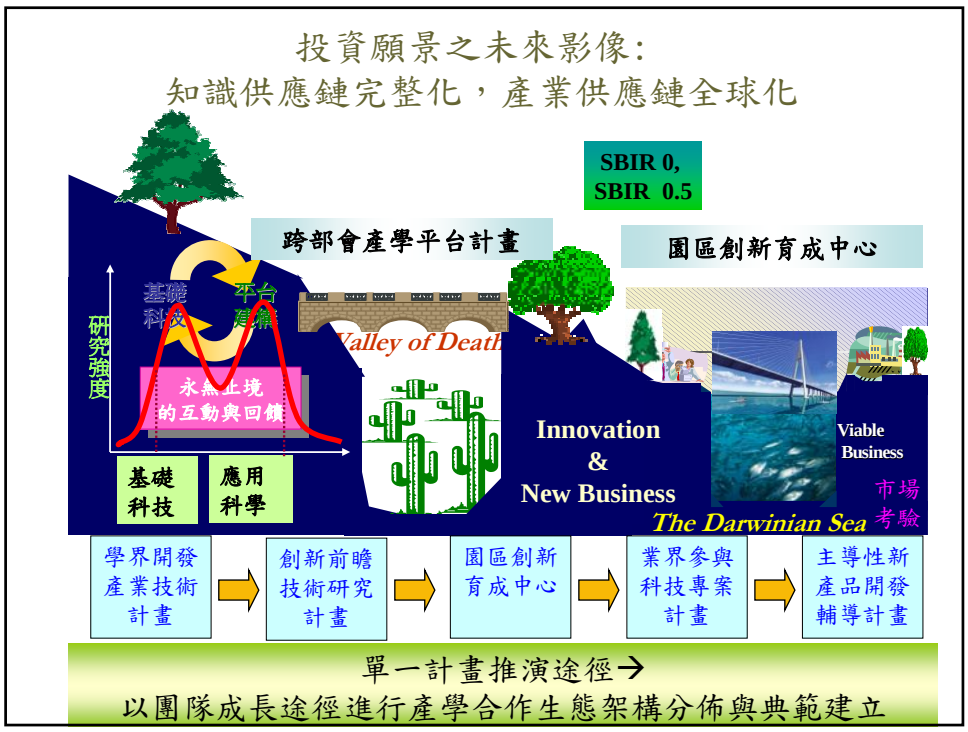
http://www.glucowatch.com/

BME Career

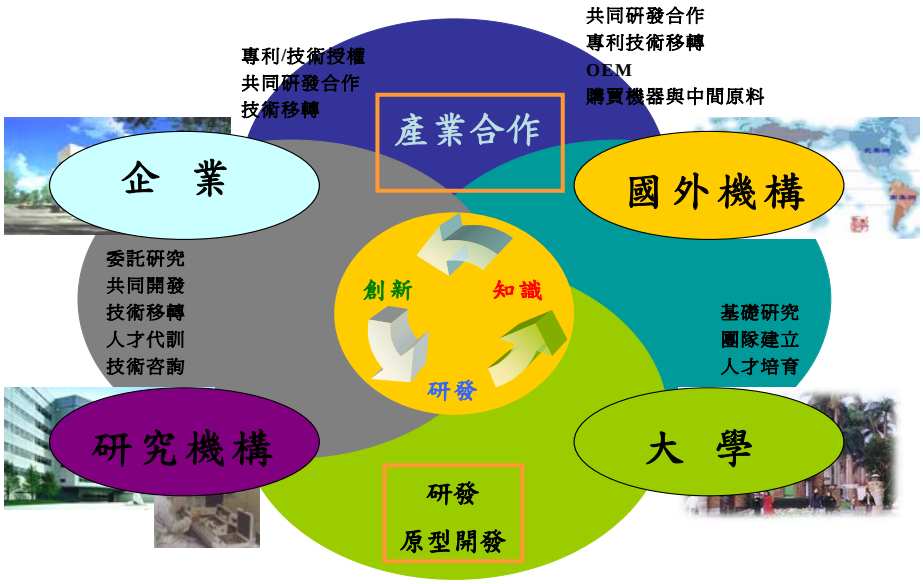
1. IEEE Career Guide
2. Keepers of the Technology – The clinical Engineering's role in Healthcare Delivery

Resources

- ***Where do I get more information about biomedical engineering programs?***
  - www.embs.org
  - www.bmenet.org
  - National Institute of Biomedical Imaging and Bioengineering www.nibib.nih.gov
- *Journals*
  - *IEEE Engineering in Medicine and Biology Magazine*
  - *IEEE Transactions on Biomedical Engineering*
- Societies
  - IEEE Engineering in Medicine and Biology (IEEE-EMBS),
  - The Biomedical Engineering Society (BMES),
  - The European Alliance for Medical and Biological Engineering and Science (EAMBES), and
  - The International Federation for Medical and Biological Engineering (IFMBE).



知識供應互動鍊



扶植台灣生醫產業SWOT分析

優勢 Strength

- 優勢ICT產業
- 優質醫療體系
- 醫療器材研發潛力
- 技術整合經驗豐富
- 台大團隊品質保證

劣勢 Weakness

- 跨領域生醫人才缺乏
- 認證驗證能量分散
- 法規修訂腳步緩慢
- 跨部會合作機制不全
- 未與國外相關機構接軌
- 缺乏長期資金投入

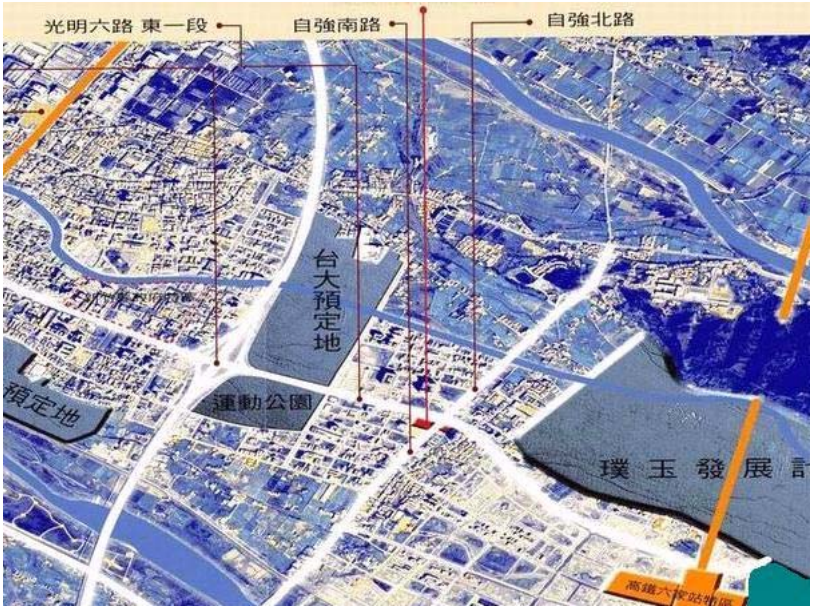
機會 Opportunity

- 世界潮流－醫療照護產業
- 國內環境－產官學研整合
- 跨領域整合介面－生醫園區
- 美國FDA全力支持
- 歐盟e-Health發展
- TCCLS / ITRI / III …

威脅 Threat

- 國際競爭-韓國…
- 2008政績展現
- 人才外移
- 經濟產值

園區週邊圖



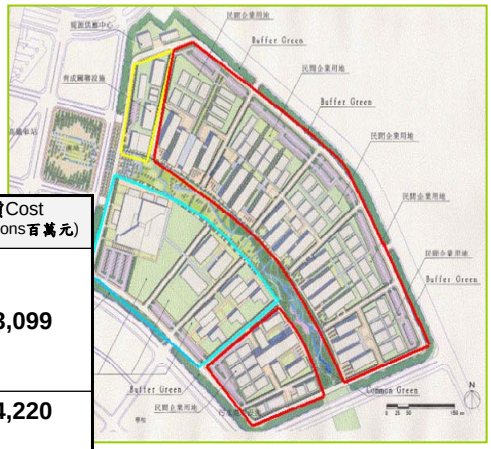
台灣生醫產業的港口

The Port of Biomedical Industry in Taiwan

Hsinchu Biomedical Science Park 新竹生物醫學園區

新竹生醫園區區域劃分

新竹生物醫學園區 主要計畫基地面積



	面積Area (ha公頃)	造價Cost (NT$ millions百萬元)
◆育成研發用地 Incubation/R&D Area	18.42	$ 13,099
◆醫學中心用地 Medical Center Area		
◆產業發展用地 Enterprise Area	19.87	$ 14,220
總面積 Total Area	38.29	$ 27,319

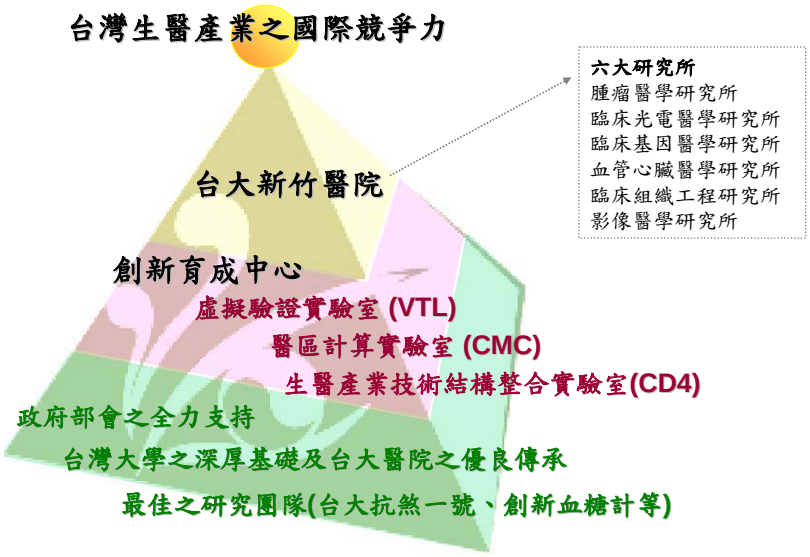
“以人為本 – e-Health”

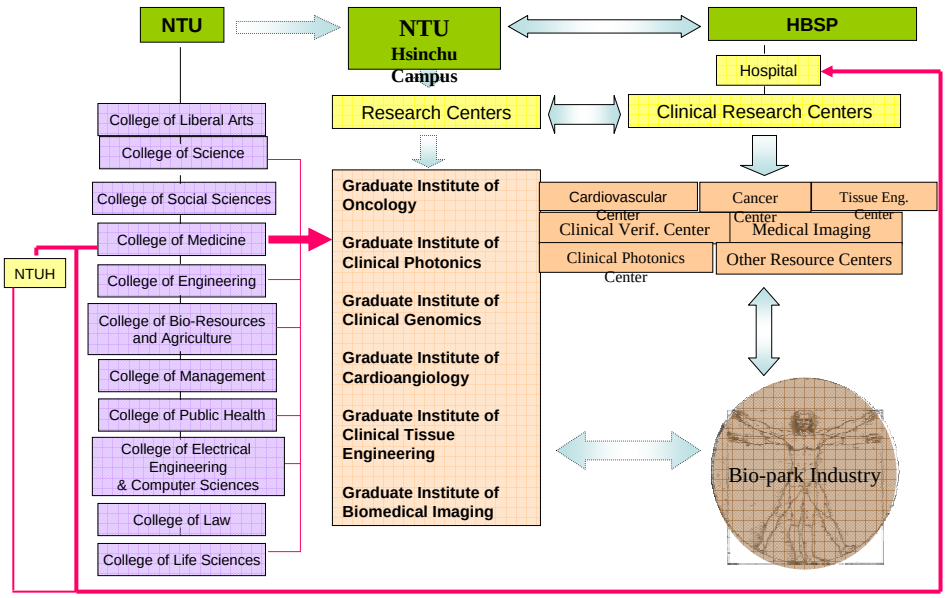
- **e-Health/i-Health**
  - **e-Purchasing**
  - **e-Trial (CRO/SMO)**
  - **e-Care (Telemedicine/Homecare)**
  - **e-Detailing (Mobile/Digital MD)**
  - **e-Learning/HIN**
  - **e-Pharmacy**
  - **e-Device/e-System/e-Home/e-Safety**
  - **e-Inclusion/e-Learning for elderly**
  - **e-Medicine (Clinical genomics)**

生命力、健康、再生力

- 古埃及Horus荷魯斯神的眼睛
- 兩片竹葉 — 新竹
- 眼球 — 陰陽太極
- 含苞花兒 — 開花結果
- 金字塔 —
  天、地、人之間的合作，為共同的目標而努力

HBSP核心組織與研發架構

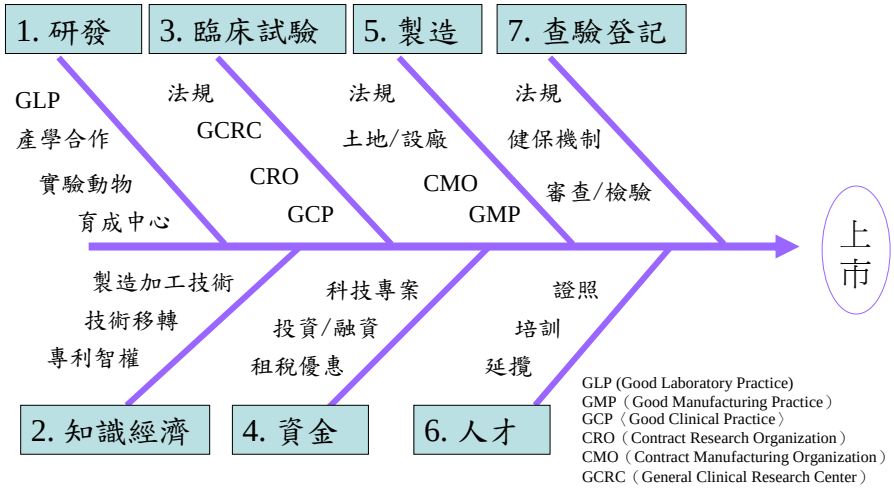




Innovation & Incubation

- 創新育成中心
- 生醫產業技術結構整合實驗室 (Centre of Drug, Device, & Diagnostic Development, CD4)
- 園區計算實驗室（Computational Medicine Centre, CMC）
- 知識管理教學中心
- 園區營運管理中心

國內生醫新產品研發上市之瓶頸



GLP (Good Laboratory Practice)
GMP（Good Manufacturing Practice）
GCP（Good Clinical Practice）
CRO（Contract Research Organization）
CMO（Contract Manufacturing Organization）
GCRC（General Clinical Research Center）

亞洲各國生技產業現況比較

	台灣	韓國	新加坡	印度	日本
企業	缺乏大企業支持，以中小企業爲主	LG Life Science及其他大公司投入及支持	近三十家知名國際生技/藥廠設立亞洲據點	共有170家廠商，其中約60家具現代化設備	中小企業爲主，大型藥廠及食品公司投入及支持
研發	國內自行研發、技術引進、國際合作、設立研發中心	在國外設立研發中心(美、英、德皆有)	經費直接投入美國公司後技術移轉至新加坡、國際合作	廠商自行研發、技術引進、國際合作、廠商研究單位合作	國內自行研發、國際合作、設立研發中心
政府	行政院與生技產業發展相關的國科會、經濟部、衛生署及農委會整合困難。院長已指示行政院政務委員負責整合	技術移轉於國外政府大力支持，由總統親任生技策略會議主席	由政府單一機構EDB統籌, 往下執行，簡單而有系統	生物科技國家委員會(NBTB)是生技發展的最高政府單位	主要部門：經濟產業省(METI)、厚生勞働省(MHLW)、農林水產省(MAFF)、環境省(MOE)等
人才	國外人才逐漸回國參與產業發展	藉重國外研發人才配合內部研發人才	大批人才由國外引進	技術人力充沛，大量高學歷人才國外學成歸國	國內人才培育計畫
專利	醫藥類美國專利數目逐漸落後於韓國(1999-2003年132件)	(277件)	(10件)	(239件)	(24,703件)

高鐵站區整合 一致之設計理念

醫學中心大樓 透視意象圖

門診棟入口

中央診療棟救護車•急診入口

醫學中心大樓 透視意象圖

醫學中心大樓　透視意象夜景圖

研究大樓 － 透視意象圖

環境 – 創造高度舒適的綠色環境

環境–創造高度舒適的室外環境

高鐵站區整合 一致之設計理念

Reading assignments

- Please read any one articles in the special issue of Science for Bionic Man
  - SCIENCE VOL 295 8 FEBRUARY 20