

# 研發與創新



## 內容大綱

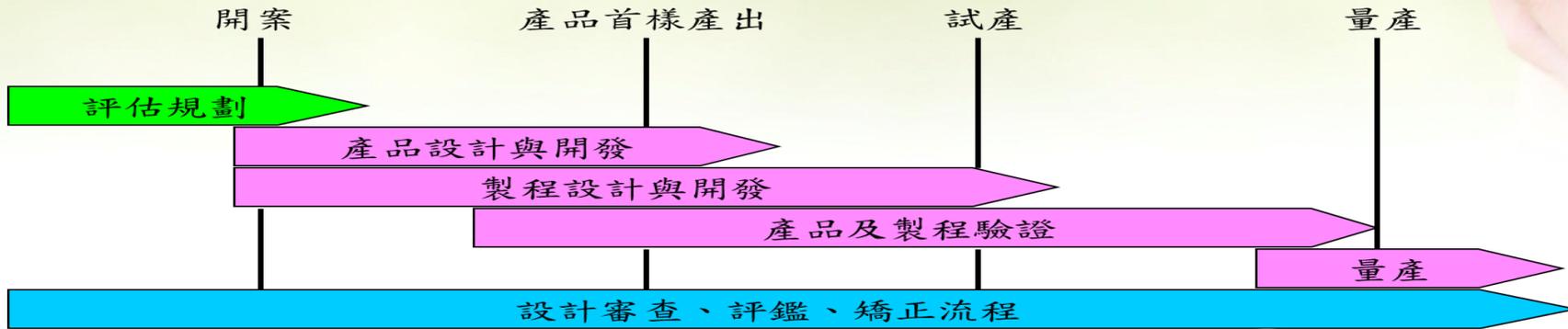
- 研發與創新策略及流程
- 研發與創新的投入
- 研發與創新成果衡量



# 研發與創新策略及流程

創新產品開發流程—醫療級APQP：

以先期產品品質計畫(APQP)的概念制定產品開發流程



顧客需求  
醫療法規  
醫療慣性  
市場定位  
**OEM/ODM**  
**OBM**



設計創新  
結構改善  
功能精進  
製程優化  
材料搜尋



**P**  
**醫療級 APQP**  
風險管理  
產品差異化

**D**  
**C**  
**A**

**醫療級 先期產品品質計畫**  
**Medical Advanced Product Quality Planning**

# 研發與創新策略及流程

先期產品品質計畫 → 醫療級先期產品品質計畫 → 風險管理 → 審查 → 驗證&驗收

風險管理：  
由風險角度  
所出發之產  
品開發設計  
流程

- 風險管理
- 審查
- 驗證&驗收

## 包裝測試 Package Test

DEANTRONICS Ltd. Product Verification Protocol  
Covidien Reliant II Pencil Packaging Transit Test  
Gamma Sterile, VL2600DB

- Purpose:**  
This protocol verifies the design of the Reliant II (RAD Project No. R956) packaging withstand the abusive handling induced during shipping transit.
- Scope/History Background:**
  - The Reliant Pencil was first introduced in 1998. Reliant II incorporate improvements internal to the pencil. The outside shape and packaging are not change.
  - This Protocol applies to VL2600DB, gamma sterilized, packaged prod.
- Responsibility:**
  - Sample Manufacturing and Assembly: R & D and Operation Depart
  - Quality Inspector: Quality Control Division of the Operation Depart
  - Quality Assurance: R & D and Quality Assurance
  - Operators executing this protocol must have documented records sho processes, tooling and equipment.
  - Approval: ND project leaders and Covidien assigned project person
- Equipment and Material used:**
  - Sample Quantity:
    - Three cases of VL2600DB pencils gamma sterilized at 52 °
  - Pencils will be produced and packaged by processes that meet OQ/PV
  - Equipment:
    - Framat Conditioning Equipment as required in section 5.
    - ESU: Generator, Valleylab Force FX.
    - Digital Multimeter
    - Hi-pot tester.
- Verification Process:**  
The transit conditioning shall be performed in the sequence listed. If a tes package validation, a repeat of the entire test sequence will be required unt supporting repeat testing of only a specific section of the test.
  - Expose the test samples to the following temperature/humidity condi:
    - The Ramp time between set points shall be controlled at a ra or condensation on the test samples.
    - After exposure, inspect outer package for visible damage and report.

Step #	Description	Temperature (°C)	Relative Hum (%)
1	Start	22 ± 3	ambient

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## 置架期測試 Shelf Life

DEANTRONICS Ltd. Product Verification Protocol  
Covidien Reliant II Pencil Accelerated Age Test E  
Sterile, VL2600DB

- Purpose:**  
This protocol verifies the Reliant II (RAD Project No. R95012) electro functional, quality and safety requirements for up to five years after EIT testing. This supports the Reliant II expiration date labeling with a five
- Scope/History Background:**
  - The Reliant Pencil was first introduced in 1998. Reliant II incorporate improvements internal to the pencil. The outside shape and packagi
  - This Protocol applies to VL2600DB, EIT sterilized, packaged prod
  - The activation force requirement for cut and cog button with positi grams per the Product Verification Protocol # P080707-E.
- Responsibility:**
  - Sample Manufacturing and Assembly: R & D and Operation Depa
  - Quality Inspector: Quality Control Division of the Operation Dep
  - Quality Assurance: R & D and Quality Assurance
  - Operators executing this protocol must have documented records r applicable processes, tooling and equipment.
  - Approval: ND project leaders and Covidien assigned project perso
- Equipment and Material used:**
  - Sample quantity and preparation:
    - Pencils will be produced and packaged by processes that
    - Ten cases (500 pc) of the VL2600DB will be EIT steriliz
    - Because some tests are destructive, testing will be condac Sample Group A and B, each containing 10 samples. The each test.
  - Equipment:
    - Force gauge tester, Grip fixtures.
    - ESU: Generator, Valleylab Force FX.
    - Burst test fixture.
    - Hi-pot tester.
    - Controlled Temperature Chamber
- Verification Process:**
  - Testing will be completed at the following age intervals. A Test Re age interval documenting the test results. Addendum's will be addo the test results for each remaining age interval.
    - Age intervals for testing
 

Days at Accelerated	Equivalent Real Time

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## 滅菌確效 Sterilization

DEANTRONICS Ltd. Sterilization Validation Protocol  
Covidien Reliant-II pencil sterilization validation

- Purpose:**  
This study will be performed to establish a radiation dose and validate the effectiveness of gamma irradiation for sterilization of the Reliant-II ESU pencil. The study will be based on practices recommended by the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO 11137-2:2006). Sterilization of health care products - Radiation -Part 2: Establishing the appropriate verification dose for this product. Recommendations for a routine minimum sterilization dose will be based on evaluation of microbial survivors following exposure of products to the verification dose. The recommended full process dose will be designed to provide a Sterility Assurance Level (SAL) of 10<sup>-6</sup> or no more than one nonsterile unit for each one million units exposure to the minimum required dose could be demonstrated by the use of calibrated dosimeters and without post-exposure sterility testing of each lot.
- Scope:**
  - If the Reliant II ESU pencil is considered similar to and be adopted into the "Pencil and Cords" gamma sterilization product family at New Deantronics, the aerobic Bioburden data from 3 lots of pencil will be compared to E0509. When the aerobic Bioburden is equal to or less than E0509, the sterilization dose would be the same with this family. Otherwise the Bioburden count is more than E0509, the full validation should be designed to provide a SAL of 10<sup>-6</sup>.
  - If the Reliant II ESU pencil is not considered similar to and be adopted into the "Pencil and Cords" gamma sterilization product family at New Deantronics, the full validation should be designed to provide a SAL of 10<sup>-6</sup>.
  - The representative model should be determined by considering weight and complexity in shape and in structure. The table below suggests that the model "VL2600DB" is the heaviest and has relatively complex structure. Therefore, this particular model will be used for the study.

Item	Model	Total Weight of a Complete Set (g)
1	VL2600 (10.5Fl)	59g
2	VL2600DB (15Fl)	69g
3	VL2600E (10.5Fl)	69g

- Responsibility:**
  - Sample Preparation: NDT Production Department.
  - Product Bioburden Testing, Bioburden Recovery Factor Testing, Sterility Testing: NDT Biological Laboratory

OR-450-4

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醫療級  
APQP

風險管理

產品  
差異化



# 研發與創新策略及流程

產品差異化：

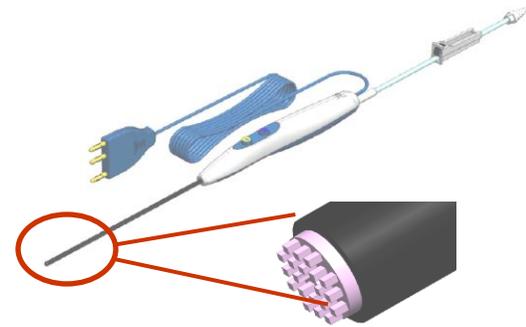
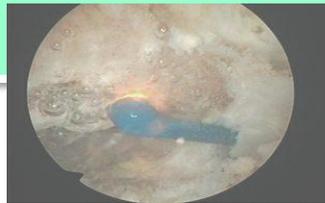
產品經由製程精實及設計優化提供客戶多元的產品

• 具價格成本競爭優勢(經濟型)：

- ✓ 一般外科手術拋棄式單極電燒刀創新自動化設計，致力於降低成本。

• 高附加價值產品：

- ✓ 應用國內精密加工技術導入醫療器材製程，產生高附加價值產品。
- ✓ 與國內專業共同開發精密鐳射焊接及彎管縮管技術。



P

醫療級  
APQP

風險管理

產品  
差異化

D

C

A

# 研發與創新策略及流程



技術全面提升：透過自動化設計、製程技術改良以及綠色設計，將現有技術全面提升

### 自動化設計

- 電線裁切+端子鉗壓 (K機)
- 電燒刀筆桿自動組裝機 (P機)
- 電線繞整自動機 (H機)
- 電燒刀全線自動組裝機

### 精實化製程

- 電燒刀核心控制單元  
製程需求人數:5人  
PCB+端子鉗壓+彈片+膠帶+射出包覆
- 製程需求人數:1人  
M2-switch  
上下蓋組裝

### 精密化技術

- 雷射焊接  
LASER WELDING
- 雙液型矽橡膠射出  
LSR
- 金屬粉末射出MIM  
陶瓷粉末射出CIM
- 臥式射出機  
特殊材料射出

### 綠色化產品

- E-GREEN
- 原設計  
材料重覆使用率0%
- 新設計  
材料重覆使用率88%

P  
D

技術全面化  
製程能力提升  
精密技術應用  
專業領域多元化  
研發資源投入

C  
A

# 研發與創新投入

製程能力提升：

透過不斷的導入自動化製程，有效的提升製程能力

電燒刀自有品牌-全線自動化製程  
為自動化而設計的產品 (Design for Automation)



全自動

半自動

手動

手型

製程提升 生產流程

Caring ~ 共好 幸福 傳承 永續經營

P

D

技術  
全面化

製程能力  
提升

精密技術  
應用

專業領域  
多元化

研發資源  
投入

C

A

# 研發與創新投入

精密化技術：導入各式不同的精密加工技術，有效提升產品品質



雙  
Liqu

金屬/非  
MI

臥式射出機

• 特殊材料射出

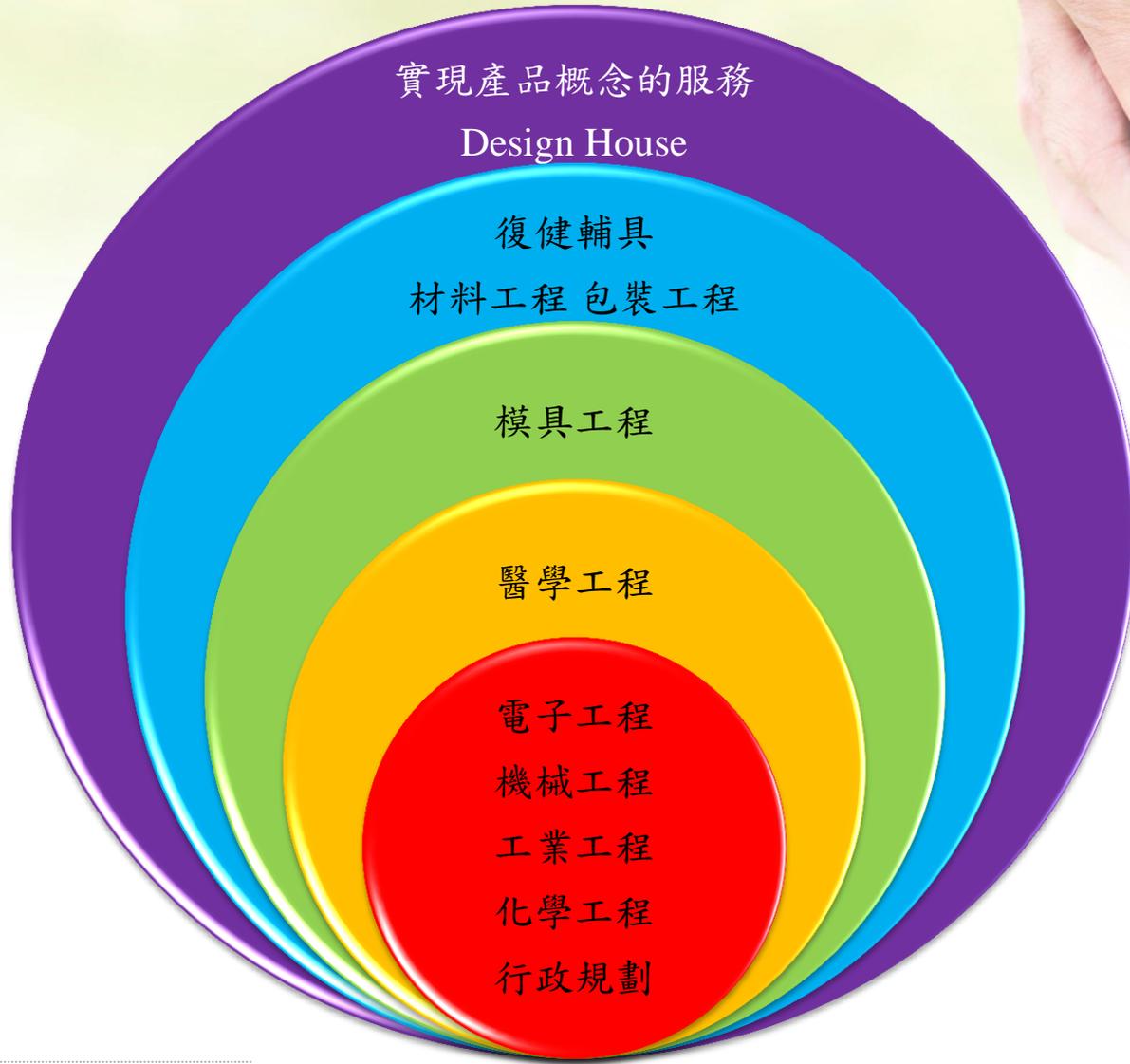
P  
D

技術  
全面化  
製程能力  
提升  
精密技術  
應用  
專業領域  
多元化  
研發資源  
投入

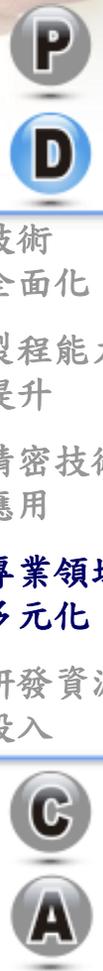
C  
A

# 研發與創新投入

專業領域多元化：  
 逐步增加各項專業領域人才，以達成實現產品概念的服務(Design House)之目標



- 技術全面化
- 製程能力提升
- 精密技術應用
- 專業領域多元化
- 研發資源投入



# 研發與創新投入

研發資源的投入：透過軟、硬體資源的投入，以期能達到更有效率的研發成果

軟體：

繪圖軟體: SolidWorks

分析軟體

FEA(預計投入)

資訊管理軟體:PDM

硬體：

雷射金屬焊接機

剝皮機

3D快速成型機(預計投入)

臥式射出機(預計投入)

以未來的Design House為目標不斷的投入人力、軟體、硬體等研發資源



- 技術全面化
- 製程能力提升
- 精密技術應用
- 專業領域多元化
- 研發資源投入



# 研發與創新成果衡量

創新成果實績-OEM產品

全球大廠C客戶  
電燒刀 + 迴流護片

射出包覆 改為  
自動化設計之上下蓋組裝

PHP產品

原供應量95%  
降為40%

創新為自動化設計

唯一供應商

策略夥伴

OEM  
實績  
ODM  
實績  
創新成果  
實績

P  
D  
C

A

# 研發與創新成果衡量

創新成果實績-ODM產品

國際大廠P客戶

共同開發  
AED磁鎖

創新設計概念

防偽功能

降低成本

唯一供應商

P

D

C

OEM  
實績

ODM  
實績

創新成果  
實績

A

# 研發與創新成果衡量

創新成果實績

國際原物料  
成本上漲

一般廠商  
因應手法

產  
以

研究創新

對策

提升品質 + 擴大產能 + 降低成本

創新的技術將  
電燒刀核心控制  
元件改良

研發技術進步

生產製程提升為全自動

開發自有品牌

產品成本

根留台灣，以研發與生產為本，不斷提昇市場佔有率

# 持續改善

開發流程之持續改善—以產品設計之模流分析為例：  
 依據不同階段之模流分析結果，確保零件設計符合實際成型需求，並可持續提升模擬結果與實際成型狀況之準確度



P  
D  
C  
A

開發流程  
持續改善  
研發知識  
分享傳承

# 持續改善

研發知識分享與傳承：

透過各式不同方式將產品開發歷程的相關經驗與知識，進行分享及傳承



P  
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開發流程  
持續改善  
研發知識  
分享傳承

# 持續改善

期許高瞻遠矚的觀察力，  
追求卓越，永續經營。

**Don't Look at Where we are,  
Look at Where We Need to Be and  
“Keep Moving Ahead”.**

