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醫療器材管理

英國標準協會
醫療器材客戶經理　楊炎橙 (Leon Yang)

By Royal Charter

BSI 英國標準協會台灣分公司

楊炎橙 (Leon Yang)

醫療器材客戶經理
訓練課程講師

- 驗證經歷
  - BSI 英國標準協會: 醫療器材客戶經理/主導稽核員/訓練課程講師
- 業界經歷(醫療器材)
  - 研發部經理/品保部經理/風險管理小組召集人/臨床試驗小組組員/管理代表
  - 醫療器材產業11+年業界經驗
- 學歷
  - 台北醫學大學 牙醫學博士候選人
  - 台北醫學大學 牙醫學碩士
  - 中原大學 醫學工程學系
- 專長
  - 品質管理系統、風險管理、設計管制、醫材標準及法規、量測設備儀器管理、設計驗證及確校、流程確校、滅菌確校(gamma-ray)、植入式醫療器材，生醫材料設計及分析(降解性高分子/陶瓷/金屬)

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稽核員這款人

父母覺得稽核員是這樣

BSI 覺得稽核員是這樣

我還以為稽核員是這樣

實際上稽核員是這樣

即使稽核員打算這樣

受稽方常希望稽核員是這樣

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課程大綱

醫療器材品質管理系統標準簡介
品質管理系統(Sec.4)
管理階層責任(Sec.5)
資源管理(Sec.6)
產品實現(Sec.7)
量測、分析與改善(Sec.8)

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ISO 13485 品質管理系統的原則

- 在全球各地註冊醫療器材時，必須符合規定的品質管理系統要求。
- 客戶希望獲得符合其要求的產品
- 各項要求反映在產品規格中
- 要求變更及技術增進
- 組織必須持續維持其品質系統的有效性
- 品質管理系統需要有定義明確且在控制下的流程
- 提供產品符合要求的信心

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各國醫療器材管理

	美國	澳洲	日本	歐盟	加拿大
主管機關	美國食品藥物管理局 (FDA)	治療產品管理局 (TGA)	厚生勞動省 (MHLW)	歐盟會員國衛生主管機關 (CA)	加拿大衛生部 (HC)
品質管理系統標準	QSR 21CFR 820 based on ISO 13485:2003	ISO 13485:2003	Ministerial Ordinate No. 169	EN ISO 13485:2012	CMDCAS based on ISO 13485:2003
審查機構	美國食品藥物管理局 (FDA)	TGA 或 Notified Body	MHLW或第三認證機構	Notified Body	第三認證機構
產品上市前審查	FDA	TGA 或 Notified Body	MHLW	Notified Body	HC
產品上市後通報機關	FDA	TGA	MHLW	CA 和 Notified Body	HC

ISO9001 & ISO13485差異

法規要求	1.1/5.1(a)/7.2.1(c)/7.3.2(b)	16處提及
維持	Improvement 持續改進	Effectiveness 有效性
不同類型(產品)	Same 未區分	Implant..etc. 植入式..等等
客戶	Satisfaction 滿意	Focus 著重
風險管理	No 無	Yes 有
追溯	Less 較少	More 較多
滅菌, 清洗, 衛生, 環境	Not emphasized 未強調	Emphasized 強調
文件程序	6	29
文件記錄	Less 較少	More 較多
建議性通告	Not mentioned 未提及	Mentioned 有提及
主動	Not mentioned 未提及	PMS

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" Voluntary自願" "Regulatory法規強制"

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Fundamentals of Quality Management
品質管理基礎架構

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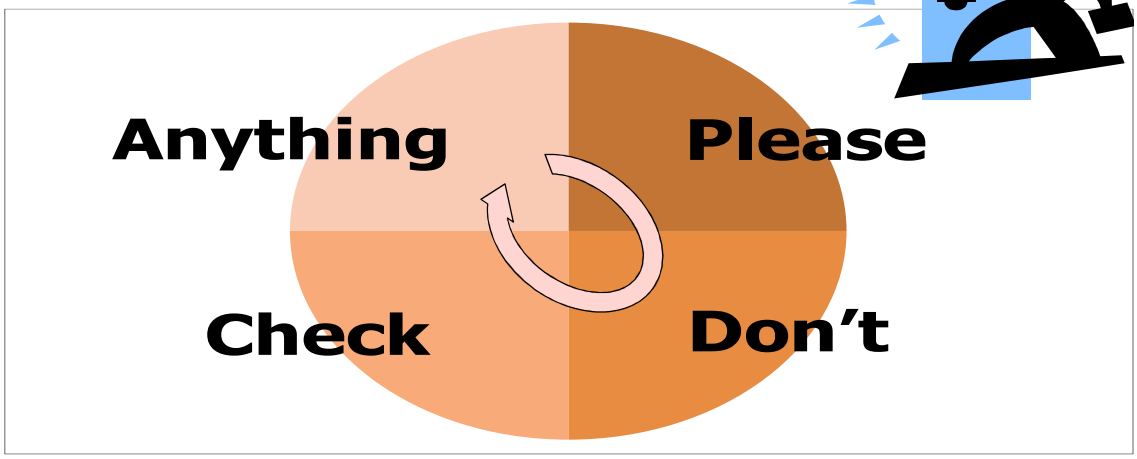
The "P-D-C-A" cycle?



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PDCA (Plan-Do-Check-Act)

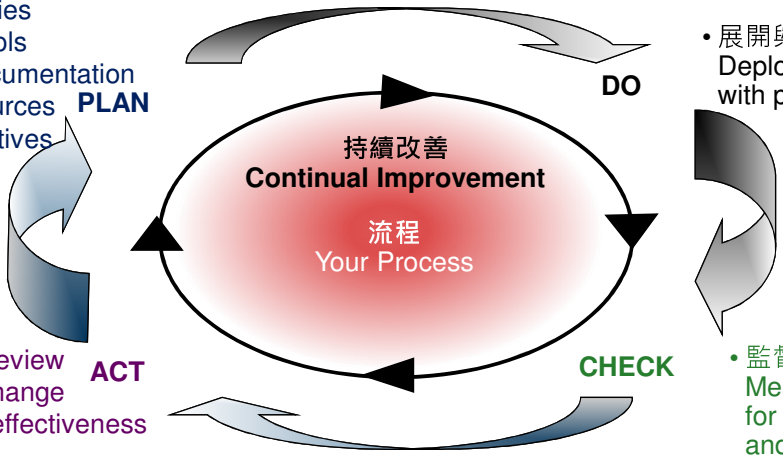
PDCA 方法論運用於所有的流程

- 活動 Activities
- 控制 Controls
- 文件化 Documentation
- 資源 Resources
- 目標 Objectives

PLAN

DO

- 展開與執行
  Deploy and conform with plan



CHECK

- 監督與量測
  Measure and monitor for conformity and effectiveness

ACT

- 分析 Analyze/review
- 決策 Decide/change
- 改善 Improve effectiveness

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八大管理原則

- Mutually Beneficial Supplier Relationship 供應商的互利關係
- Customer Focus 客戶焦點
- Leadership 領導統御
- Factual Approach to Decision Making 基於事實的決策
- Involvement of People 全員參與
- Continual Improvement 持續改善
- System Approach to Management 系統導向的管理
- Process Approach 流程導向

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Process Approach 流程導向

PROCEDURE 程序

(Specified way to carry out an activity or process – must be documented)

用特定的方式完成一個活動或流程 – 必須用文件化的方式

輸入-Input

資源-Resources

PROCESS 流程

(set of interrelated or interacting activities 一組相關聯或互相作用的活動)

輸出- Output

產品- Product

MONITORING & MEASUREMENT OPPORTUNITIES

(Before, during, and after the process)

監督和量測機會 (流程前、中、後端)

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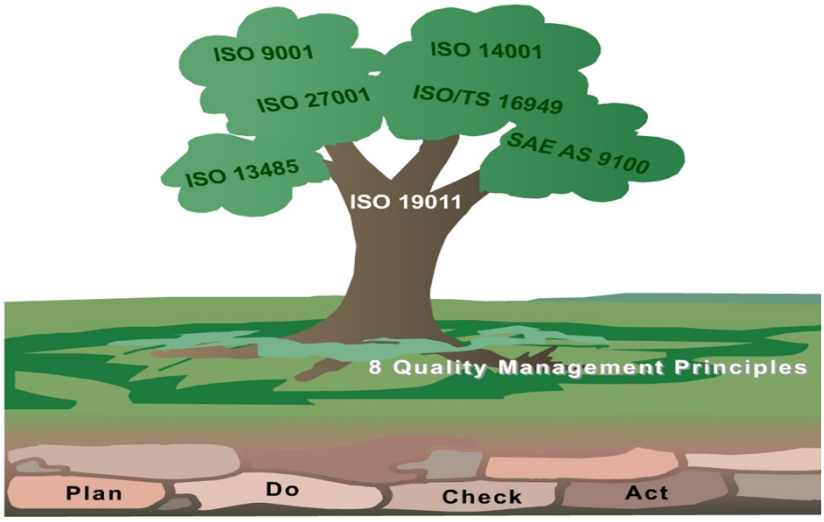
Structure of Quality Standards
品質標準的結構



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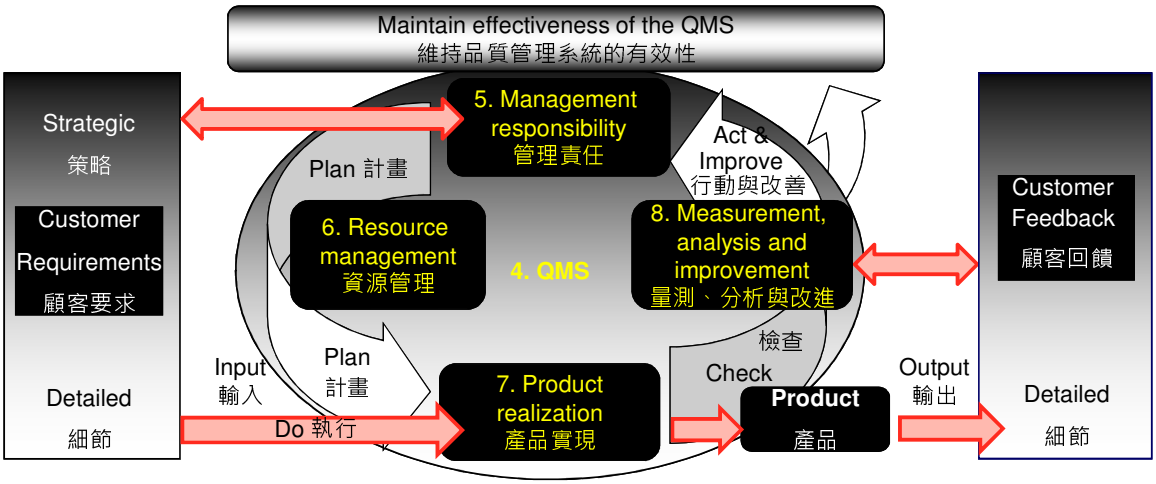
Process Model 流程模式



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4. Quality Management System
品質管理系統

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General Requirement
一般要求

4.2 Document Requirement 文件化要求

4.2.1 General 概述
4.2.2 Quality manual 品質手冊
4.2.3 Control of documents 文件管制
4.2.4 Control of records 紀錄管制

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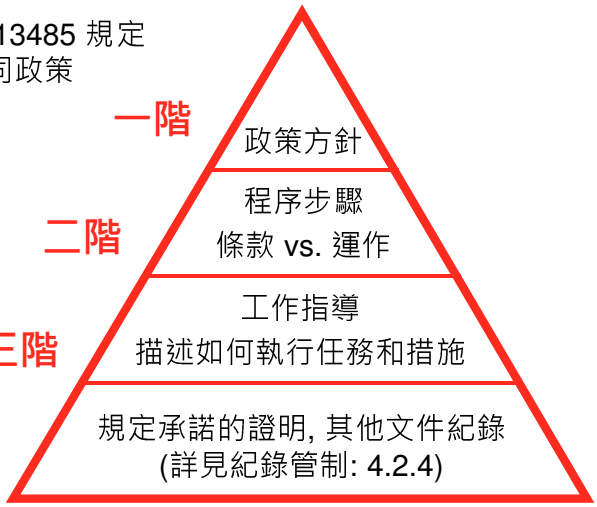
品質系統文件

描述 ISO 13485 規定
有關的公司政策



品質手冊
(為什麼)
↓
程序步驟
(誰、什麼、何時、何處)
↓
工作指導
(如何做)
↓
形狀、標籤等

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5. Management Responsibility
管理階層責任

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5. Management Responsibility
管理階層責任

5.1 Management Commitment 管理階層承諾
5.2 Customer Focus 顧客為重
5.3 Quality Policy 品質政策
5.4 Planning 規劃
5.5 Responsibility, Authority and Communication 責任、職權及溝通
5.6 Management Review 管理階層審查

Top management 最高管理階層

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Quality Policy 品質政策

- 好品質、好客戶、賺大錢
- 品質、創新、持續營運

Quality Policy

[redacted] Ltd is an Australian company developing technologies for wound healing.

[redacted] Ltd strives to be at the forefront of our industry, delivering cutting edge biomedical technologies to the healthcare profession. Our directors are committed to consistently achieving the highest quality products and services, through innovation and technical excellence, in a cost-effective and profitable manner, for both our company and our clients.

[redacted] Ltd has implemented a Quality Management System, tailored to its operations, to ensure accomplishment of our quality objectives, recognition and compliance with relevant statutory and regulatory requirements, and a continual desire for self-improvement, review and development.

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Quality Policy 品質政策

Company A:

- 取得驗證
- 取得專利
- 持續獲利

Company B:

- YTD +10%
- QTD +2.5%
- MTD +1%

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Responsibility and Authority 責任和權限

- 5.5.1All personnel who manage, perform and verify work affecting quality
  所有人員
- 5.5.2Management representative
  管理代表
  - Reporting the performance of QMS
    績效報告
  - Promotion of awareness of regulatory and customer requirements throughout the organization
    對內溝通法令法規、客戶要求
- 5.5.3Internal communication
  內部溝通

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Management Review
管理審查

Top management shall review QMS, at planned intervals, including opportunities for improvement, need for change to QMS, quality policy and objectives.
最高管理階層應在規劃期間內審查品質管理系統，包和改進的時機，系統、政策及目標變更的需求。

- 8 inputs
稽核結果、客戶回饋、過程績效/產品符合性、矯正預防措施、先前審查措施、可能影響系統的變更、改善建議、法規要求。
- 3 outputs
系統/流程有效性的改進、產品的改進、資源需求、

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6. Resource Management
資源管理

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6. Resource Management
資源管理

6.1 Provision of Resources 資源提供

Determine and provide resources needed to:

- *Implement QMS and maintain effectiveness*
  實施品質管理系統並維持其有效性
- *Meet regulatory and customer requirements*
  滿足法規與顧客要求

6.2 Human Resources 人力資源
6.3 Infrastructure 基礎設施
6.4 Work Environment 工作環境

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Work Environment
工作環境

- Health, cleanliness and clothing of personnel
  人員健康、清潔、衣著
- Work environment conditions
  工作環境條件
- Temporary personnel under special environment conditions
  特殊環境條件下的臨時人員
- Control of contaminated or potentially contaminated product
  汙染或潛在污染產品的控管

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7. Product realization
產品實現

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7.1 Planning of product realization

產品實現之規劃

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Reports that say that something hasn't happened are always interesting to me, because, as we know, there are known knowns; there are things we know we know.

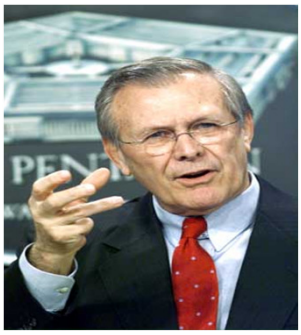
尚未發生的事對我們而言是很有趣的，因為我們知道，世上有已知的已知事物，亦即我們知道有些事情是我們知道的。

We also know there are known unknowns; that is to say we know there are some things we do not know.

我們也知道世上有已知的未知事物，亦即我們知道有些事情是我們不知道的。

But there are also unknown unknowns –the ones we don't know we don't know"

但是上也有未知的未知 – 亦即我們不知道有些事情是我們不知道的。



Donald Rumsfeld

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什麼時候進行風險管理?

- 實際設計開始前
- 當設計、流程、人員、材料、方法.....變化時
- 當新的數據/資料到達時

ISO14971:2007
EN ISO14971:2012
Medical devices - Application of risk management to medical devices
醫療器材風險管理

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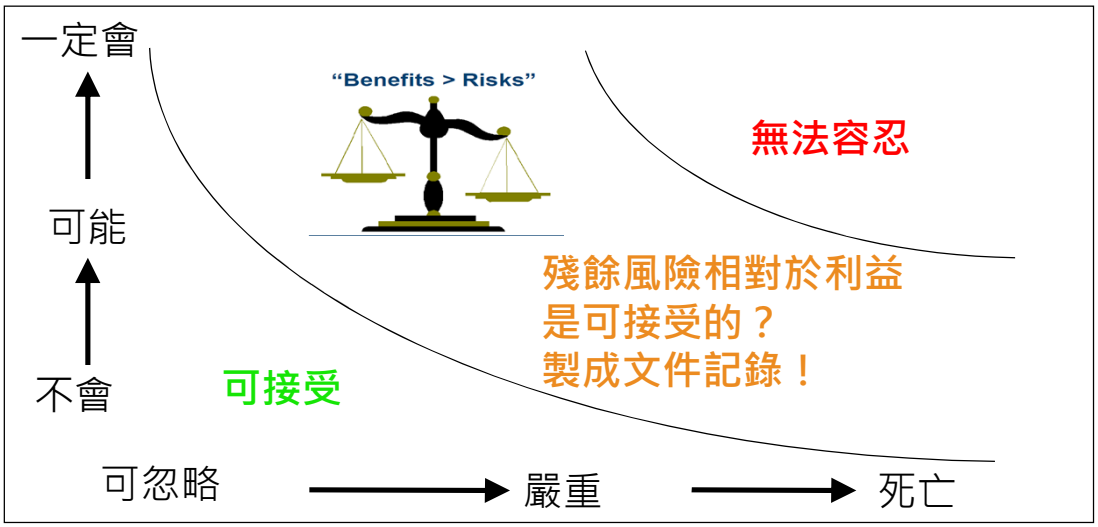
風險可接受度



不可接受風險的成本

- 設計前 before design $5,000
- 設計後 after design $50,000
- 生產後 after production $500,000
- 不良事件後 after vigilance $3,000,000
- 訴訟後 after litigation $20,000,000

- *更重要的是病人的成本！*

7.2 Customer related processes
顧客有關之過程

7.2.1 Determination of requirements related to the product 判定產品有關的要求

7.2.2 Review of requirements related to the product 審查產品有關的要求

7.2.3 Customer communication 客戶溝通

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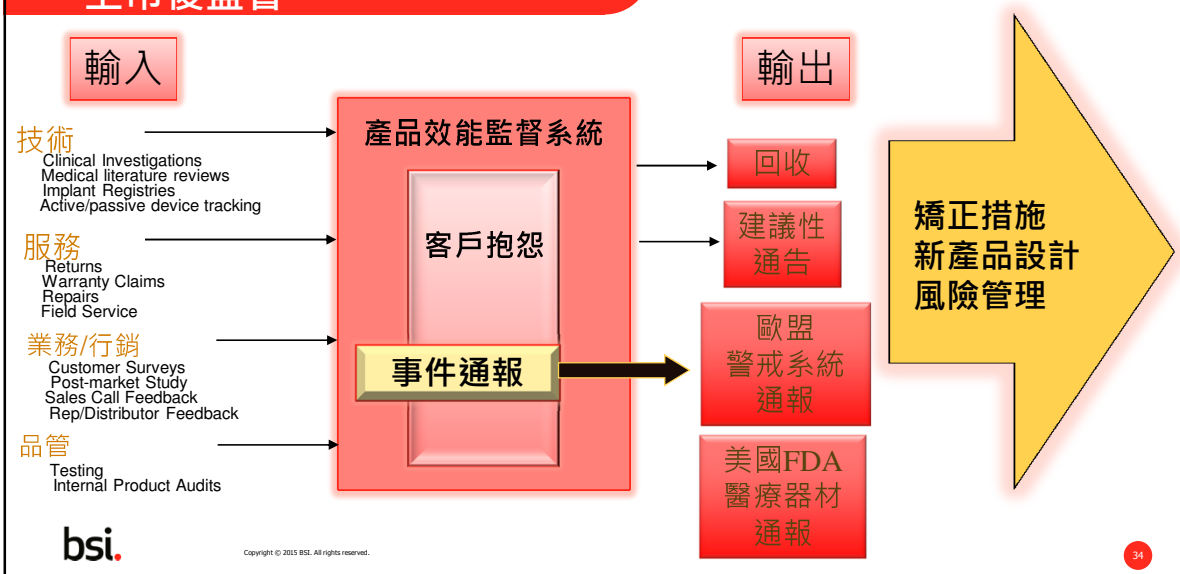
PMS– NBMed 2.12
上市後監督



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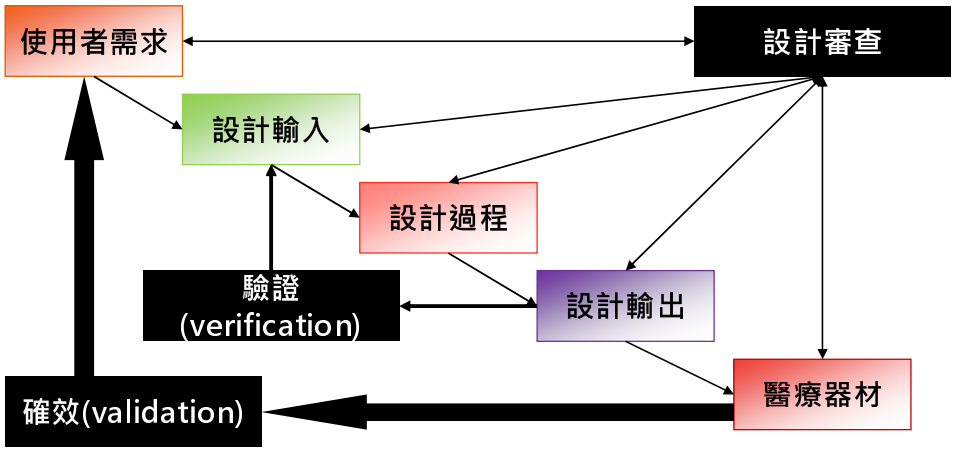
7.3 Design and development
設計與開發



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7.4.1 Purchasing Process
採購流程

- Documented procedures with specified purchase requirements.
  文件化程序定義採購要求
- Evaluate and select suppliers based on their ability
  評估並選擇供應商
- Criteria for selection, evaluation and re-evaluation shall be established.
  選擇、評估及再評估的準則
- Records
  紀錄

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7.4.2 Purchasing Information
採購資訊

- Purchasing information shall describe the product to be purchased, including where appropriate
  採購資訊應描述所採購之產品，適當時，包括：
  a) Requirements for approval of product, procedure, processes and equipment,
     產品、程序、流程及設備的核准之要求；
  a) Requirements for qualification of personnel, and
     人員資格之要求；及
  b) Quality management system requirements.
     品質管理系統之要求。

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7.4.3 Verification of purchased product
所採購產品之驗證

- Inspection or other activities necessary
  檢驗或其他必要的活動
- Perform verification at the supplier's premises, shall state the intended verification arrangements and method of product release in the purchasing information.
  在供應商的場所實施驗證時，應在採購資訊中規定驗證的安排與產品放行的方法
- Records
  紀錄

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7.5 Production and service provision

生產與服務提供

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Process Approach 流程導向

PROCEDURE 程序

(Specified way to carry out an activity or process – must be documented)

用特定的方式完成一個活動或流程 – 必須用文件化的方式

輸入-Input

資源-Resources

PROCESS 流程

(set of interrelated or interacting activities 一組相關聯或互相作用的活動)

輸出- Output

產品- Product

MONITORING & MEASUREMENT OPPORTUNITIES

(Before, during, and after the process)

監督和量測機會 (流程前、中、後端)

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Inputs 輸入

Operator 人員

Equipment 設備

Material 原/物料

Document 文件

Environment 環境

Monitoring 監督

Labelling and packaging
標示和包裝

Measurement 量測

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Outputs 輸出

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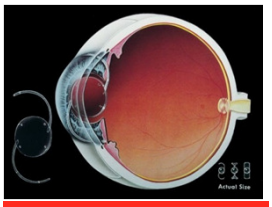
Question :

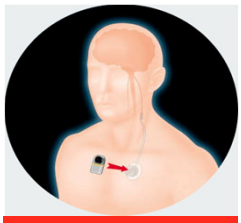
- 哪些產品需要清潔?

Orthopaedic & dental implants & instruments



Ophthalmic implants & instruments

Vascular surgery & cardiology



Active Implants

Reference: ISO 12891-1:2011

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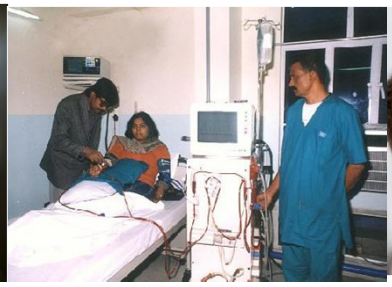
Does it "Installation" ?
這是「安裝」嗎?

MRI
put in location?



Dialysis machine
fit to patient ?

Dental implant
implant in patient ?

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Servicing activities
服務活動

- Repair 維修
- Maintenance 保養
- Training 訓練.....

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Methods of sterilization
滅菌

Ethylene Oxide
Radiation
Moist Heat
Aseptic processing
Low temperature steam and formaldehyde
Others
⋮

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Process Validation
流程確效

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Process Validation
流程確效

- Qualifications
  - Is it stalled correctly ? 是否正確被安裝? **IQ**
  - Is the process parameters challenged ? 有無過程參數極限? **OQ**
  - Will the process consistently produce acceptable product under normal operation conditions? 此過程能在一般的操作條件下持續產出可接受的產品嗎? **PQ**

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Process Validation
流程確效

7.5.2.1 … Software 軟體

The organization shall establish documented procedures for the validation of the application of computer software for production and service provision.

7.5.2.2 … Sterilization 滅菌

The organization shall establish documented procedures for the validation sterilization processes.

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- Identification 鑑別
- Traceability 追溯
- Status identification 狀態鑑別

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What are customer property ? 哪些是客戶財產?

- Raw materials or components supplied for inclusion in product.
  產品所使用的原料或組件
- Product supplied for repair, maintenance or upgrading.
  提供進行維修、保養或升級的產品
- Product supplied for further processing.
  提供進行後續加工的產品
- Services provided on behalf of the customer.
  以客戶角度進行的服務
- Customer intellectual property
  客戶智慧財產

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Internal processing 內部流程

- Identification 鑑別
- Handling 處理
- Packaging 包裝
- Storage 儲存
- Protection 保護

Delivery 運送

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7.6
Control of monitoring and measuring devices

量測與監督設備的管控

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電子秤標誌量(mg)		100	500	1000
砝碼秤重量(g)		0.110 0.095 0.098	0.501 0.497 0.504	1.008 1.006 0.999
量測的平均值	(g)	0.101	0.501	1.004
	(mg)	101	501	1004
平均值與標準值差異(%)	判定值	< 5%	< 2%	< 1%
	量測值	1%	0.2%	0.4%

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8. Measurement, analysis and improvement

量測, 分析和改善

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8.1
General
概述

8.1 General 概述

- The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed 組織應規劃與實施所需之監督、量測、分析及改善流程，以
  - a) To demonstrate conformity of the product
    顯示產品之符合性
  - b) To ensure conformity of the quality management system, and
    確保品質管理系統之符合性
  - c) To maintain the effectiveness of the quality management system
    維持品質管理系統之有效性

- This shall include determination of applicable methods, including statistical techniques, and the extent of their use.
  這應包括對統計技術在內的適用方法及其應用範圍之決定。
- NOTE: National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.
  備註： 國家或地區法規可能要求組織建立統計技術應用的實施與管制的文件化程序。

8.2
Monitoring
and
measurement

監督和量測

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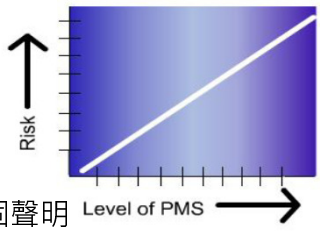
Feedback System回饋系統PMS



- Customer surveys 客户調查
- Customer complaints 客户抱怨
- Customer requirements and warranty claims 客户要求和保固聲明
- Announce and communication of regulations 法規的公告和溝通
- Literature reviews 文獻資料
- Experience with similar devices 同類產品的經驗
- Post CE-market clinical trials 上市後的臨床試驗
- Maintenance/service reports 维修/服務報告
- User reactions during training programmes 訓練方案中的使用者回饋
- User feed-back from sales force 業務端的使用者回饋

- Must be pro-active 必需為主動的

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Audit Types 稽核類型

- 1st Party - **WE** auditing **our own** system (Internal)
  第一方稽核-組織對自己的系統進行稽核 (內部)
- 2nd Party - **WE** auditing **our supplier** (External)
  第二方稽核-組織對其供應商的稽核(外部)
- 3rd Party - **WE** being audited by a **registration body** (External)
  第三方稽核-由獨立機構(如: BSI)對組織稽核(外部)

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8.3
Control of nonconforming product

不合格品的管制

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8.3 Control of nonconforming product
不合格品的管制

- The organization shall deal with nonconforming product by one or more of the following ways: 組織應藉由下列之一項或數項方法，處理不合格品：
  a) By taking action to eliminate the detected nonconformity
     採取措施消除所發現之不符合
  b) By authorizing its use, release or acceptance under concession
     以特採方式授權使用、放行或允收
  c) By taking action to preclude its original intended use or application
     採取措施以防止供作原意圖的使用或應用

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8.4
Analysis of data

資料分析

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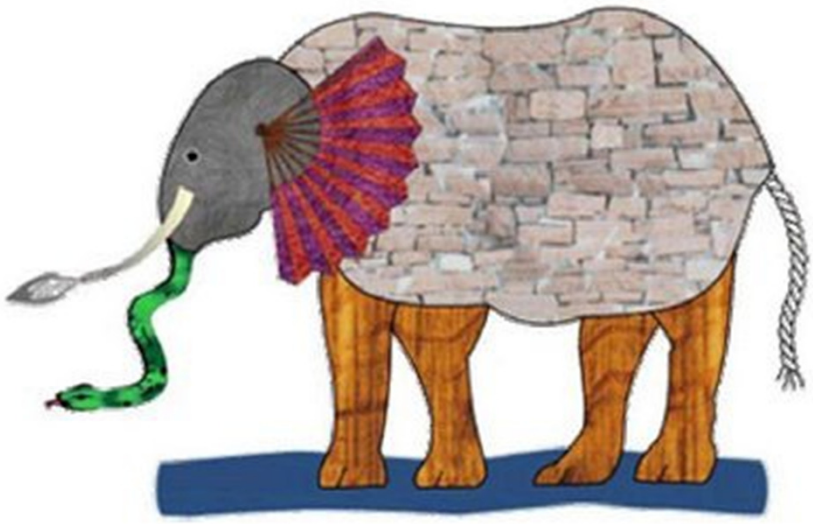

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8.5 Improvement

改善

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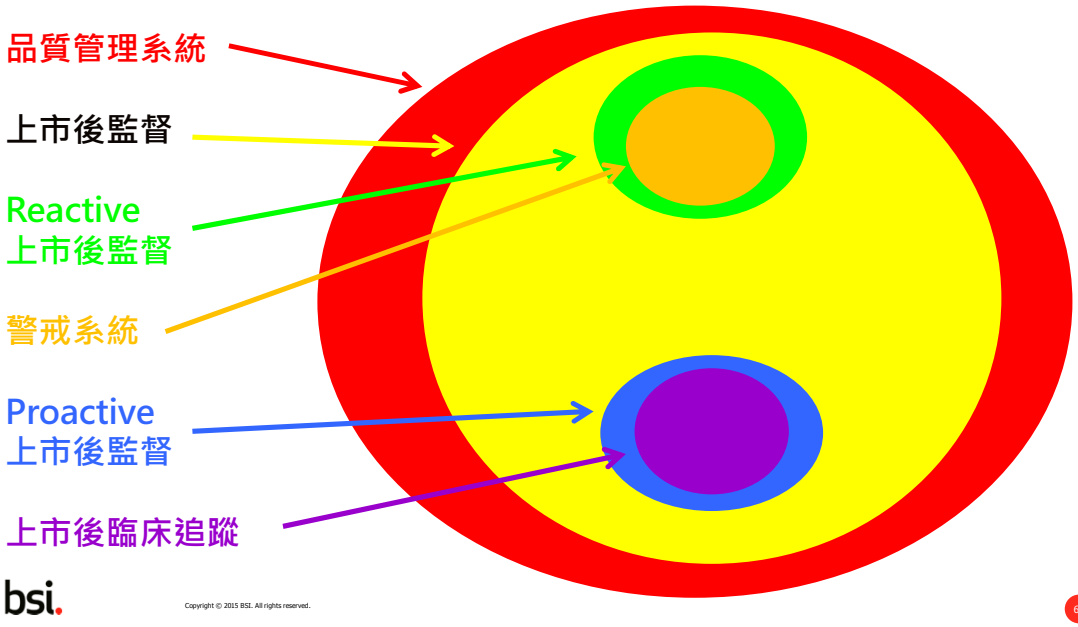

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8.5.2 Corrective action
矯正措施

- The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.
  組織應採取消除不符合原因的措施以防止其再發生。
- Corrective actions shall be appropriate to the effects of the nonconformities encountered.
  矯正措施應與不符合事項的影響程度相稱。

8.5.3 Preventative action 預防措施

- The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.
  組織必須決定措施以消除潛在不符合事項的原因，以預防其發生。
- Preventative actions shall be appropriate to the effects of the potential problems.
  預防措施必須應與潛在問題之影響相稱。

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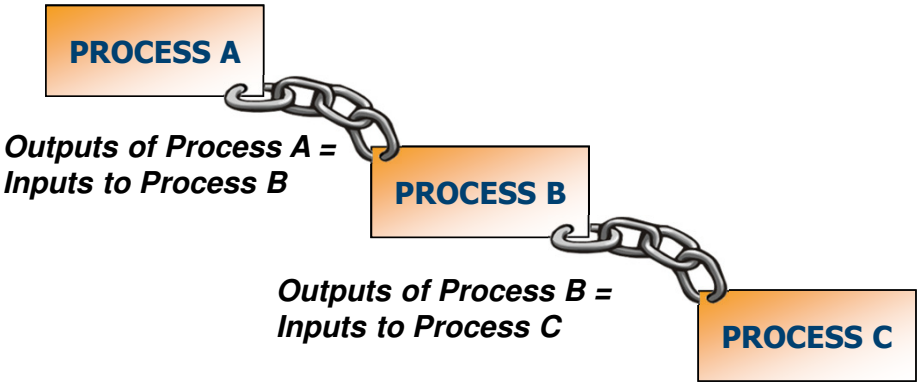
Process Approach
流程導向

Chain of Interrelated Processes 流程鏈:



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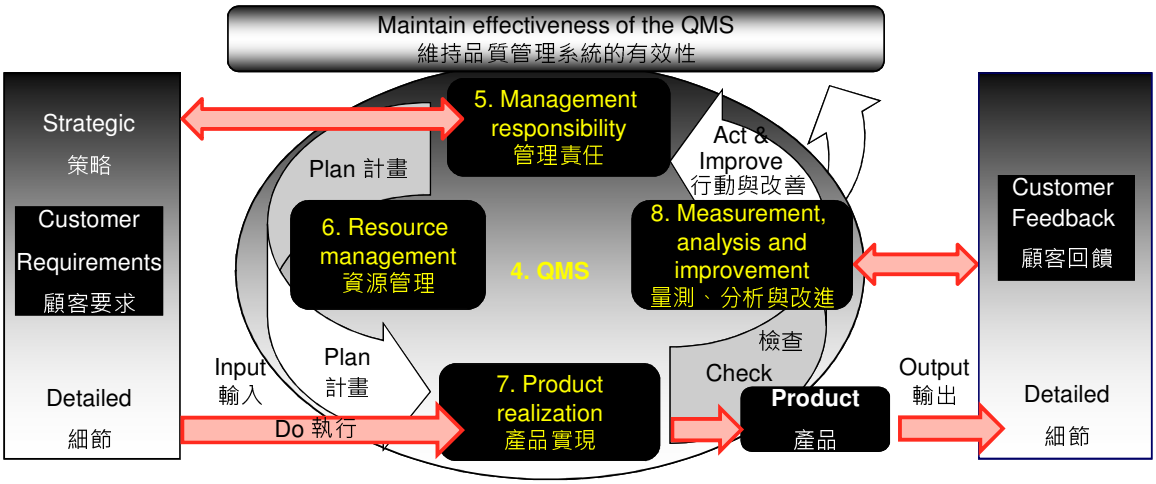
Process Model 流程模式



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Questions 問題?




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thank you and have a safe journey home
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