



TAIWAN

GDP Experience Sharing

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AGENDA

- **Abbott Overview**
- **Warehousing Management**
- **PMS Management**



1. GDP輔導性查核
2. 歷年說明會及課程講義 - 醫療器材優良運銷準則(GDP)專區 - 醫療器材 - 業務專區 - 衛生福利部食品藥物管理署
(fda.gov.tw)

Abbott Core Dx Products Overview

Product Scope

- **A, B and C (IVD only)**
- **Professional use**

Product Line

- **Immunoassay**
- **Clinical Chemistry**
- **Hematology**

Certification

- **QMS and GDP have been certified for Taiwan Core Dx**

Product Characteristic

- **Temperature Sensitivity Product(Assays)**

Topics Sharing for Temperature Sensitivity Product

TFDA GDP Requirement	ISO 13485:2016 Requirement
資源管理	
Article 13 基礎設施 (Infrastructure)	基礎設施 (6.3 Infrastructure)
Article 14 工作環境條件 (Work environment and contamination control)	工作環境 (6.4.1 Work environment) & 汙染管制 (6.4.2 Contamination control)
產品實現	
Article 19 產品防護程序 (Preservation of product)	產品防護 (7.5.11 Preservation of product)
Article 20 監管與量測設備 (Control of monitoring and measuring equipment)	監管與量測設備之管制 (7.6 Control of monitoring and measuring equipment)
量測、分析及改進	
Article 23 通報、回收及通告發布 (Reporting to regulatory authorities)	通報、回收及通告發布 (8.2.3 Reporting to regulatory authorities)
Article 25 鑑別及管制不符合產品 (Control of nonconforming product)	不合格產品之管制概述 (8.3.1 Control of nonconforming product)
Article 26 不符合產品處理方式 (Actions in response to nonconforming product detected before delivery)	產品放行前發現之不合格產品之行動 (8.3.2 Actions in response to nonconforming product detected before delivery)
Article 27 產品放行後之不符合產品管制 (Actions in response to nonconforming product detected after delivery)	產品放行後發現之不合格產品之行動 (8.3.3 Actions in response to nonconforming product detected after delivery)

Warehousing-1/2

Equipment Establishment for Storage of Temperature sensitivity products (such as IQ, OQ, PQ)

- **Equipment establishment (cooler, freezer or room temperature etc....)**
 1. Temperature range
- **Temperature mapping (cold spot & hot spot)**
 1. outsourcing or self
- **Equipment for Temperature Alarming and monitoring**
- **Calibration Procedure**
 1. outsourcing or self
- **Software Validation (Commercial software) for relevant equipment**
 1. IQ & OQ & PQ



Warehousing-2/2

Basic Maintenance for relevant storage Equipment (e.g., cooler, freezer or room temperature, thermometer, UPS system...)

- **Equipment maintenance**
 1. Equipment maintenance frequency
 2. Situation for RE-Verification & RE- Validation
- **Temperature mapping**
 1. Protocol and mapping frequency
 2. Situation for Re-verification & Re-validation
- **Temperature Alarming and monitoring**
- **Calibration**
 1. Frequency & Protocol
- **software validation (Commercial software)**
 1. IQ & OQ & PQ
 2. maintenance frequency
 3. Re-verification & RE- validation



Packaging Establishment-1/3

Example for Packaging Establishment

e.g.

Frozen Product:

https://www.youtube.com/watch?v=kg_hTzzhEHI (Source : ThermoSafe)

Packaging Establishment-2/3

Packaging Establishment (such as IQ, OQ & PQ)

- Packaging condition Choosing
 1. Temperature sensitivity product
 2. Active or passive shipping systems
- Passive shipping system establishment (cooler, freezer or room temperature ...)
 1. Packaging condition establishment
- Active shipping system: outsourcing
- Equipment for Temperature monitoring
- Calibration
 1. Purpose
 2. Frequency & Protocol
- software validation (Commercial software)
 1. IQ & OQ & PQ

保麗龍箱寸	small	Medium	Large
冷藏-保冷劑	?	?	?
冷凍-乾冰	?	?	?



Packaging Condition Maintenance & Monitoring -3/3

Packaging Condition Maintenance & Monitoring

- Passive shipping system Maintenance & Monitoring (cooler, freezer or room temperature ...)
 1. validation frequency
 2. Situation for RE-Verification & RE-Validation
- Calibration procedure for relevant equipment
 1. Frequency & Protocol
- Software Validation (Commercial software) for relevant equipment
 1. Maintenance Frequency
 2. Situation for RE-Verification & RE- Validation



鑑別及管制不符合產品 (Control of nonconforming product)

●Source

- Receiving Goods from manufacturer or locally purchasing
- Goods (Temperature sensitivity products) returned by customer

●Action-(Abbott Policy)

- Isolation depending on product specificity temperature and waiting for site decision
- Product is in quarantine area and waiting destruction

不符合產品處理方式

(Action for Nonconforming product detected before delivery)

●Source:

- Manufacturer's information or Customer information

●Action(Abbott Policy):

- Isolation depends on product specificity temperature and waiting for site decision
- Or Product is in quarantine area and waiting destruction

產品放行後之不符合產品管制

(Action for Nonconforming product detected after delivery)

●Source and Action

➤ Manufacturer information

- » Inventory product : Product destroyed, or product released
- » Product is in customer site: product destroy at customer site or delivery product correction info to customer.

➤ Locally Medical Incident or Customer information

- » Products hold to stop shipments and await manufacturer's decision

模擬回收 (Mock Recall)

- **Purpose**

- Annual Effectiveness check & verify PMS handling Procedure and Product traceability
- To ensure all procedure and process are effectiveness in managing product recall
- To ensure continually process improvement

- **Source :**

- Manufacturer product information (high-risk products , high-volume products.....)....

- **When**

- No product recalls have occurred in 1 year

- **Responsibility**

- Depends on relevant teams described in the SOPs



Abbott