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# 藥品**GDP**自我查核及矯正 預防措施-物流篇

BY **SEVEN CHANG**

2014-08-28

# CONTENTS

- 1. Self Inspection**
- 2. Corrective Action and Preventive Action(CAPA)**
- 3. Exercises**

## OBJECTIVES

- 1. To understand and develop self inspection program**
- 2. CAPA introduction**
- 3. Learn and share per exercise**

# SELF INSPECTION– Regulatory



PHARMACEUTICAL INSPECTION CONVENTION  
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

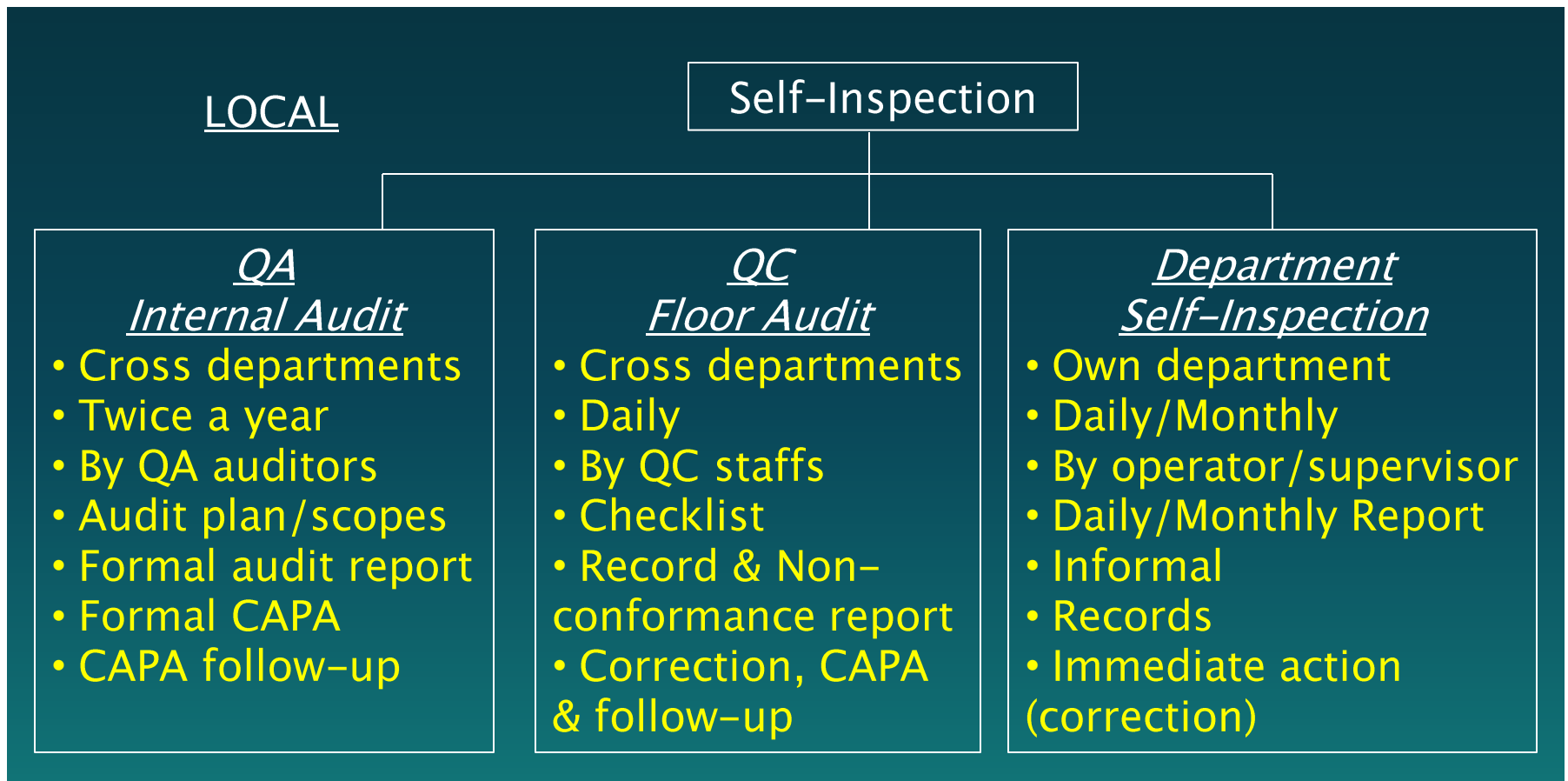
PE 011-1  
1 June 2014

## PIC/S GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS

# SELF INSPECTION– Regulatory

第八章 自我查核 (SELF INSPECTION)	
<p><b>原則 ( PRINCIPLE )</b></p> <p>Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures.</p>	<ul style="list-style-type: none"> <li>➤ 循規性</li> <li>➤ 與矯正預防措施相結合</li> </ul>
<p>8.2.1 A self-inspection programme should be implemented covering all aspects of GDP and compliance with the regulations, guidelines and procedures within a defined time frame. Self-inspections may be divided into several individual self-inspections of limited scope.</p>	<ul style="list-style-type: none"> <li>➤ 程序文件化</li> <li>➤ 訂定自我查核範圍</li> </ul>
<p>8.2.2 Self-inspections should be conducted in an impartial and detailed way by designated competent company personnel. Audits by independent external experts may also be useful but may not be used as a substitute for self-inspection.</p>	<ul style="list-style-type: none"> <li>➤ 適當的方法與人員執行</li> <li>➤ 外部稽核不能取代自我查核</li> </ul>
<p>8.2.3 All self-inspections should be recorded. Reports should contain all the observations made during the inspection. A copy of the report should be provided to the management and other relevant persons. In the event that irregularities and/or deficiencies are observed, their cause should be determined and the corrective and preventive actions (CAPA) should be documented and followed up.</p>	<ul style="list-style-type: none"> <li>➤ 文件記錄</li> <li>➤ 審核</li> <li>➤ 矯正預防措施與成效追蹤</li> </ul>

# SELF INSPECTION– Program



# SELF INSPECTION– Program

REGIONAL Audit  
by independent party

LOCAL

Self-Inspection

QA  
Internal Audit

- Cross departments
- Twice a year
- By QA auditors
- Audit plan/scopes
- Formal audit report
- Formal CAPA
- CAPA follow-up

QC  
Floor Audit

- Cross departments
- Daily
- By QC staffs
- Checklist
- Record & Non-conformance report
- Correction, CAPA & follow-up

Department  
Self-Inspection

- Own department
- Daily/Monthly
- By operator/supervisor
- Daily/Monthly Report
- Informal
- Records
- Immediate action (correction)

# SELF INSPECTION- Program

REGIONAL Audit  
by independent party



不能取代  
自我查核

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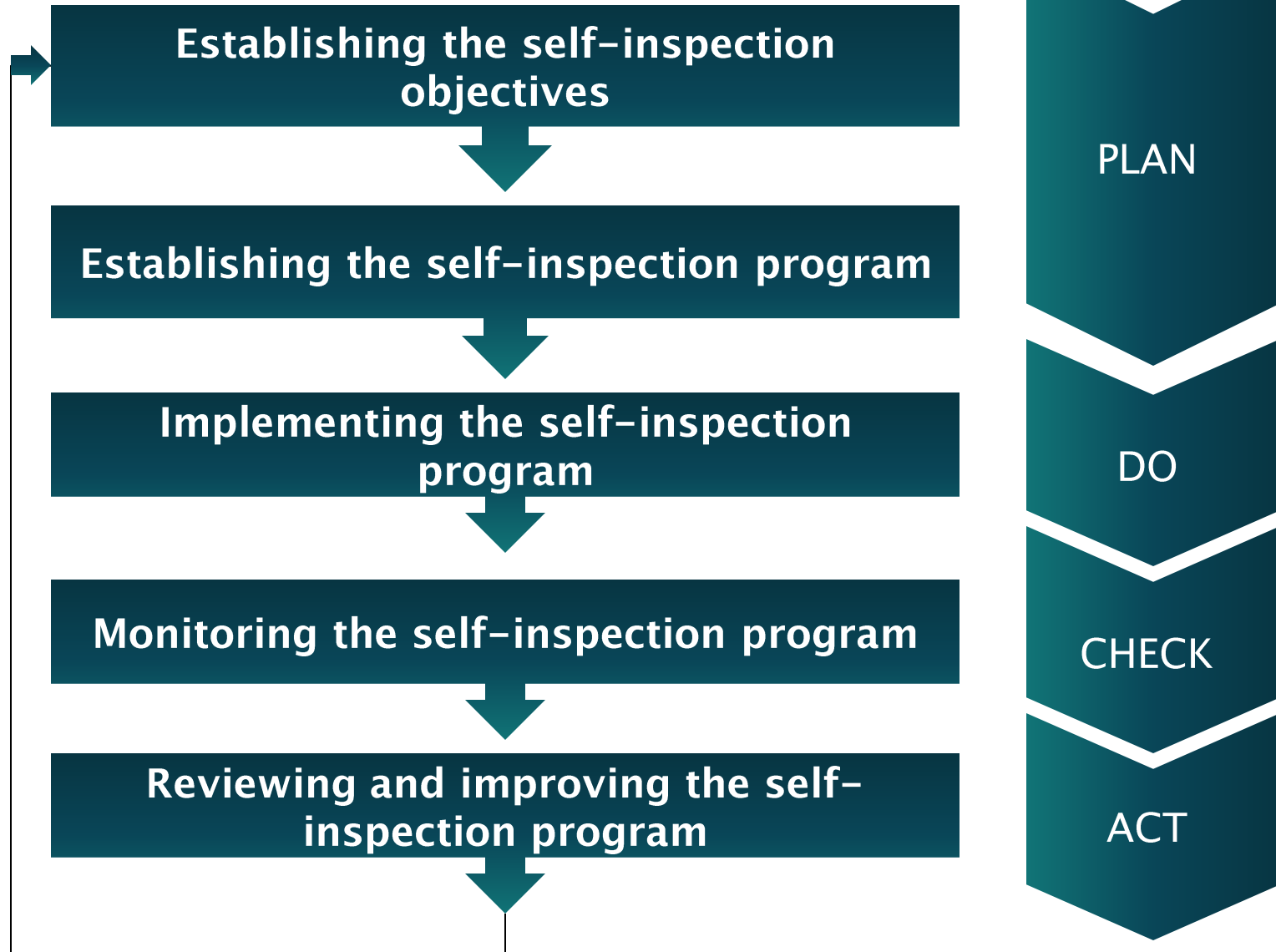
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# SELF INSPECTION– Program



# SELF INSPECTION– Program

Establishing the self-inspection objectives



Establishing the self-inspection program

- Roles and responsibilities of the person managing the program
- Competence of the person for the program
- Establishing the scope of the program
- Identifying and evaluating program risks
- Establishing procedures for the program
- Identifying program resources



PLAN

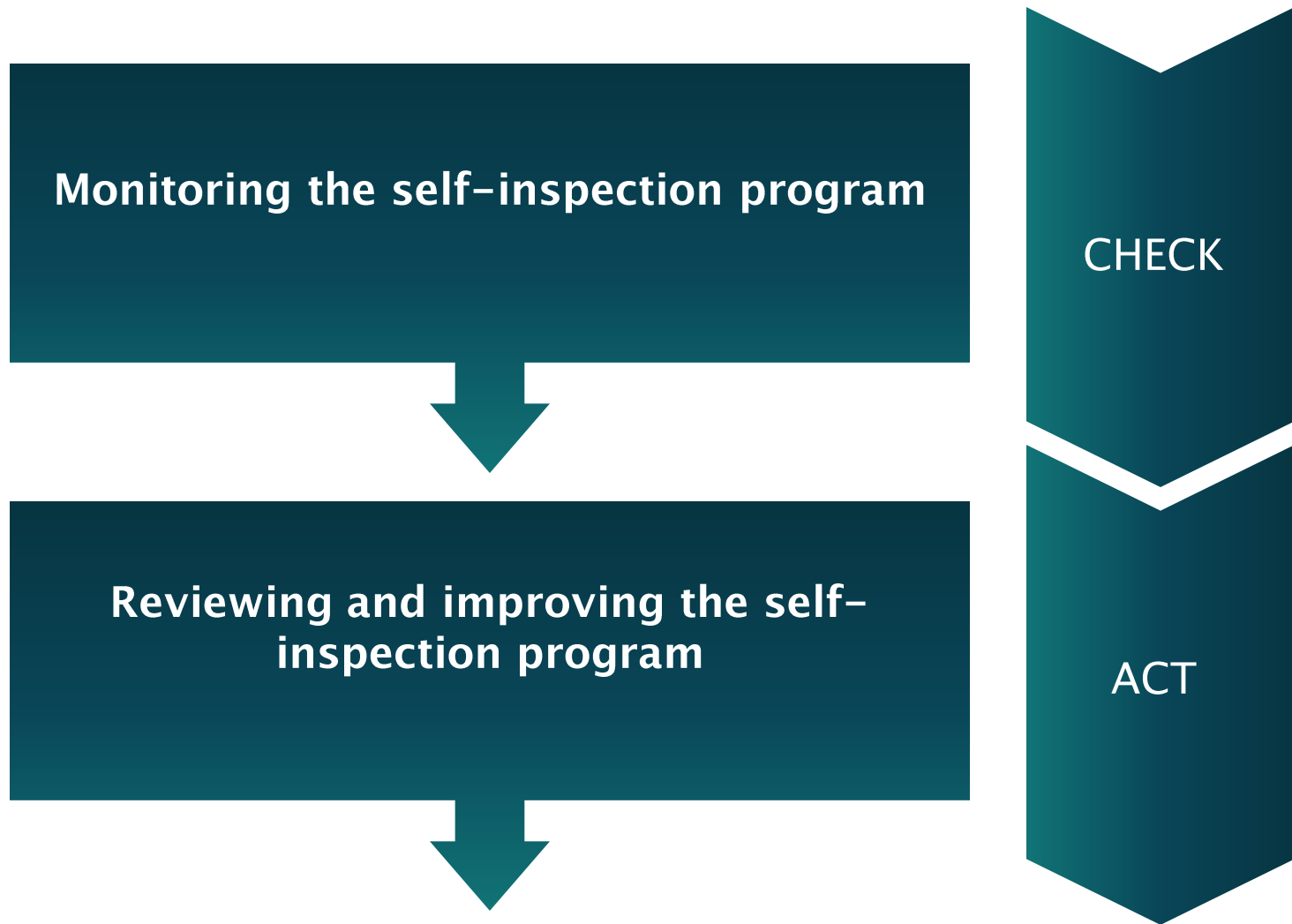
# SELF INSPECTION– Program

## Implementing the self-inspection program

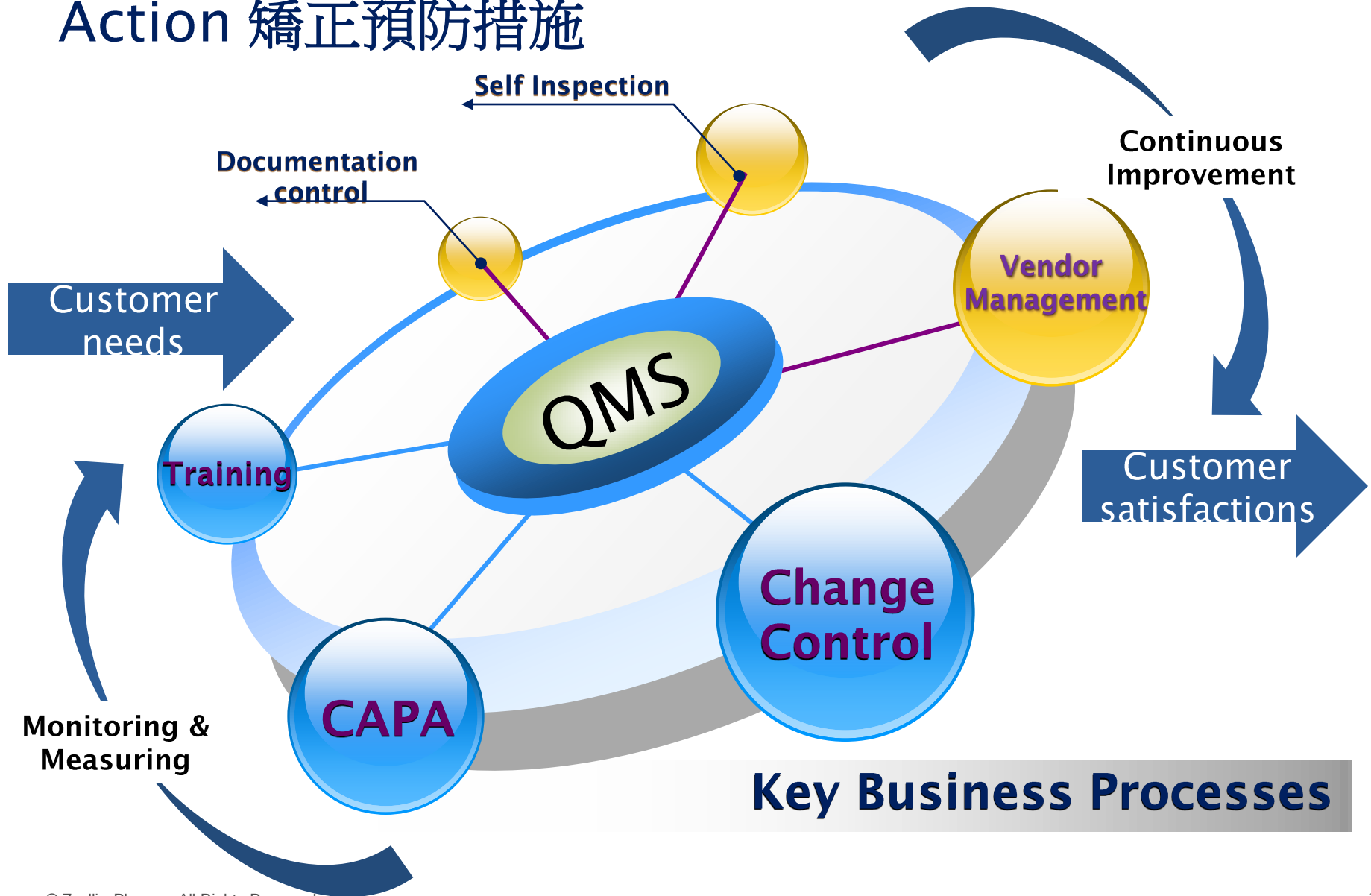
- General
- Defining the objectives, scope and criteria
- Selecting the methods
- Selecting the members
- Assigning responsibility
- Managing the program outcome
- Managing and maintaining program records

DO

# SELF INSPECTION– Program



# CAPA– Corrective Action and Preventive Action 矯正預防措施





**1.2.7** The quality system should ensure that:

vi. appropriate **corrective and preventive actions** (commonly known as CAPA) are taken to correct deviations and prevent them in line with the principles of quality risk management.

**2.3.5** The responsibilities of the designated responsible person(s) include but are not limited to:

viii. ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary **corrective measures** are put in place;



**3.6.3** Validation and qualification reports should be prepared summarising the results obtained and commenting on any observed deviations. Deviations from established procedures should be documented and further actions decided to correct deviations and avoid their reoccurrence (**corrective and preventive actions**). The principles of CAPA should be applied where necessary. Evidence of satisfactory validation and acceptance of a process or piece of equipment should be produced and approved by appropriate personnel.



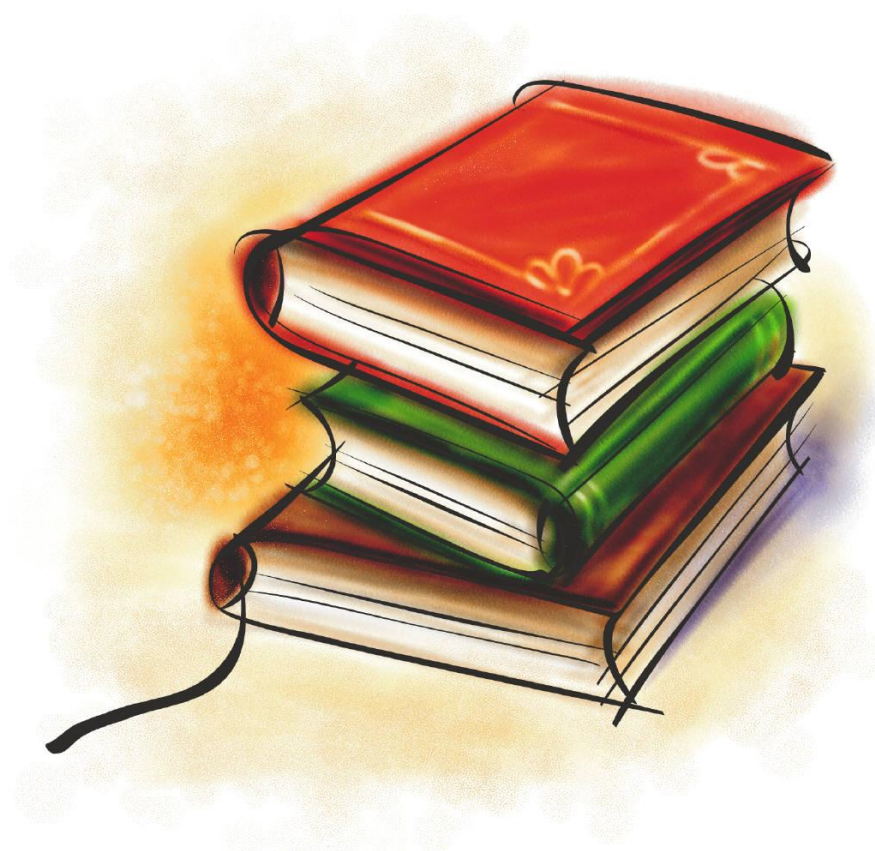
**8.2.3** All self-inspections should be recorded. Reports should contain all the observations made during the inspection. A copy of the report should be provided to the management and other relevant persons. In the event that irregularities and/or deficiencies are observed, their cause should be determined and the **corrective and preventive actions** (CAPA) should be documented and followed up.



CAPA

# Terms and Definitions

## 名詞解釋

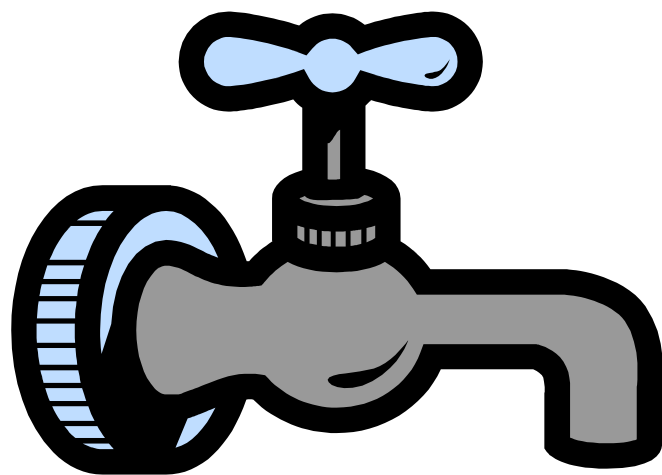


## Correction vs. Corrective Action

“Correction 矯正” refers to repair, rework, or adjustment and relates to the disposition of an **existing** nonconformity.

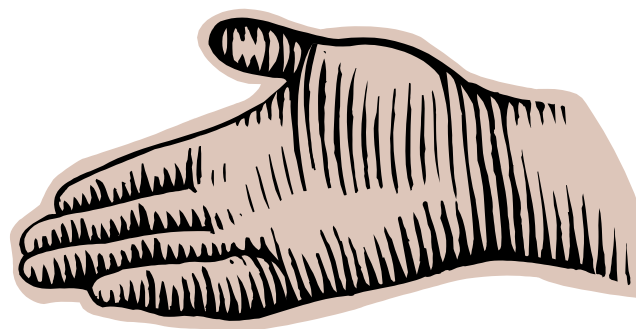
“Corrective action 矯正行動” relates to the **elimination of the causes of nonconformity**. [ISO]

# CAPA

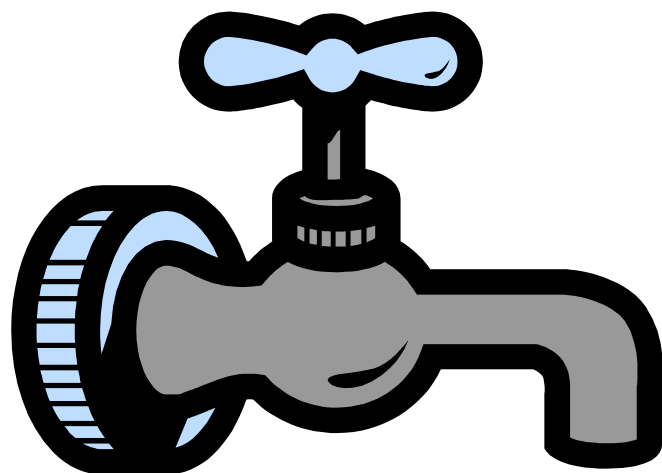


**DEVIATION,  
NON-  
CONFORMANCE**

**偏差**



# CAPA



DEVIATION,  
NON-  
CONFORMANCE

偏差



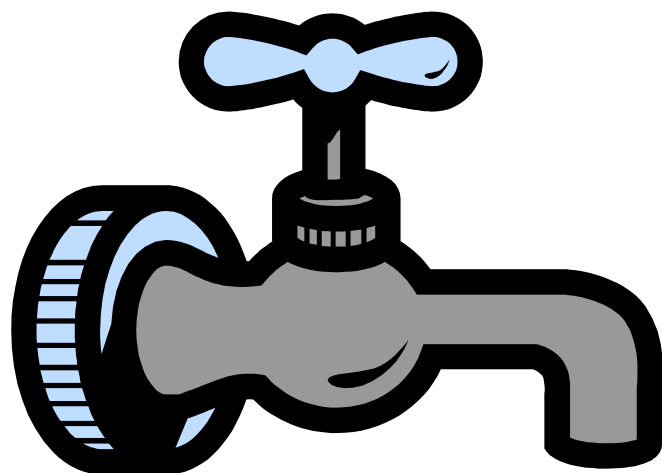
CORRECTION



CORRECTION

**RECURRENCE** 重覆

# CAPA



DEVIATION,  
NON-  
CONFORMANCE  
偏差



CORRECTIVE  
ACTION  
矯正行動

# CAPA

## Corrective Action 矯正行動

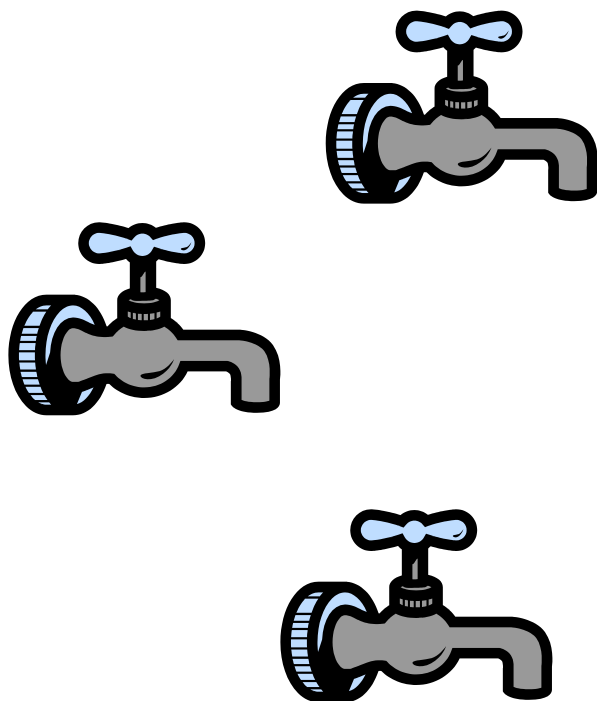
- ▶ Action taken to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to **prevent recurrence**(避免重覆發生). [ISO]

# CAPA

## Preventive Action 預防行動

- ▶ Action taken to eliminate the cause of a **potential** non-conformity, defect, or other undesirable situation in order to prevent occurrence [ISO]

# CAPA



**PREVENTIVE  
ACTION**

預防行動





# CAPA

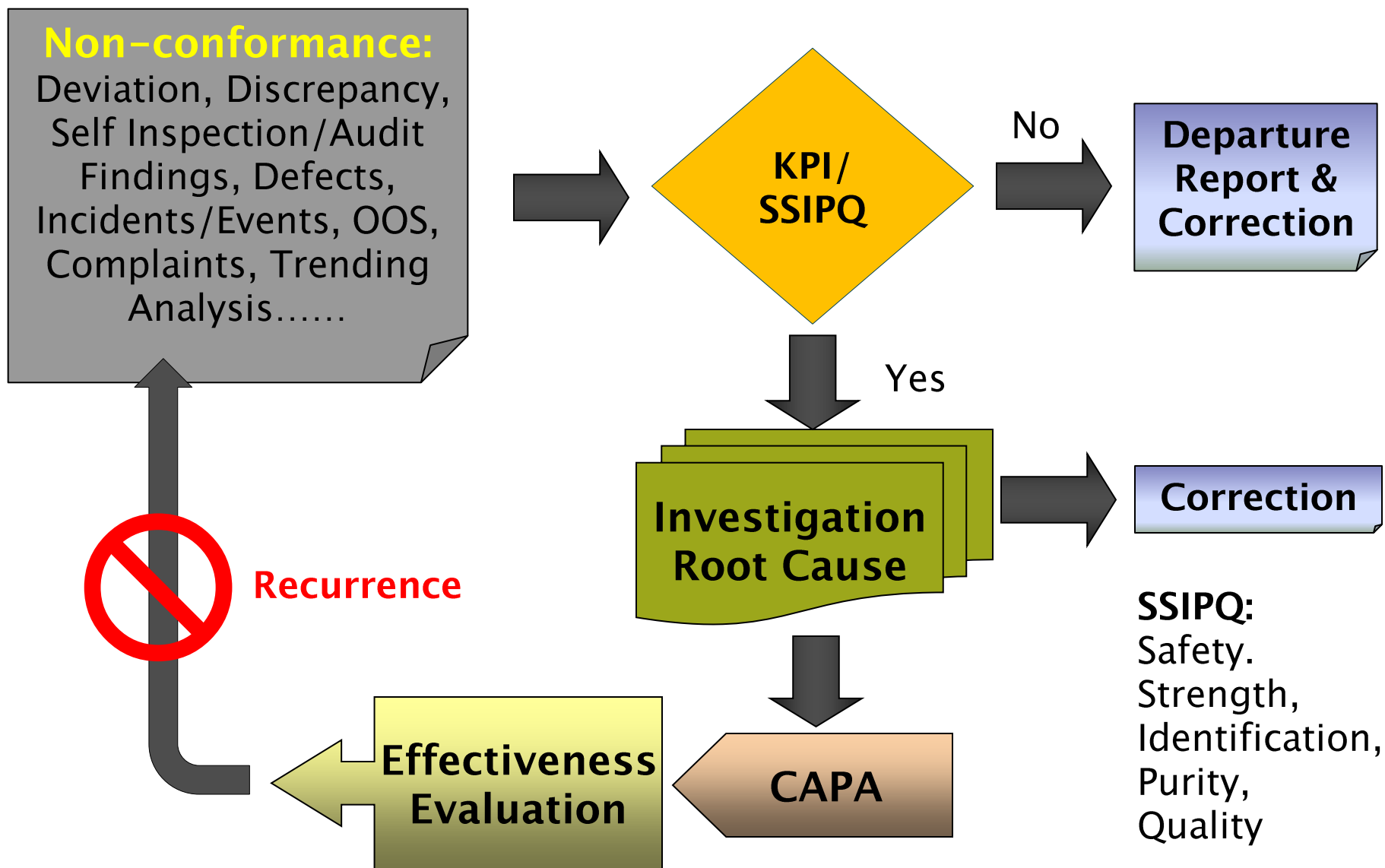
CAPA [21CFR 820.100]

Includes Actions Needed To:

- ▶ Correction 矯正 – 治標
- ▶ Corrective action (“prevent recurrence”)  
矯正行動 – 治本
- ▶ Preventive action 預防行動 – 預防勝於治療

Example:

# CAPA- Processes



# CAPA– Processes

- CAPA program is usually separate from deviation program. **CAPA**行動與偏差調查作業分開執行
- Implement corrective and preventative action(s) identified in the investigation report  
依調查結果執行**CAPA**
- Assign a responsible person to each action指定人員執行行動
- Assign a deadline訂定完成時間表
- Track and confirm completion of each action  
追蹤結果

# CAPA– Processes

## Summary

- Main Goal of an Investigation is to determine root cause of the failure/deviation. 調查找出根本原因
- Investigation Report should be written for outside auditors to read and understand. 相關報告便於閱讀
- Corrective Action/Preventative Actions should be based on information from the investigation report. 根據調查提出**CAPA**
- Goal of Corrective Action/Preventative Actions is to prevent reoccurrence of the deviation. **CAPA**的目的是預防偏差再發生
- Corrective Actions/Preventative Actions should be tracked to make sure that they are implemented. **CAPA**要持續追蹤

**Q & A**

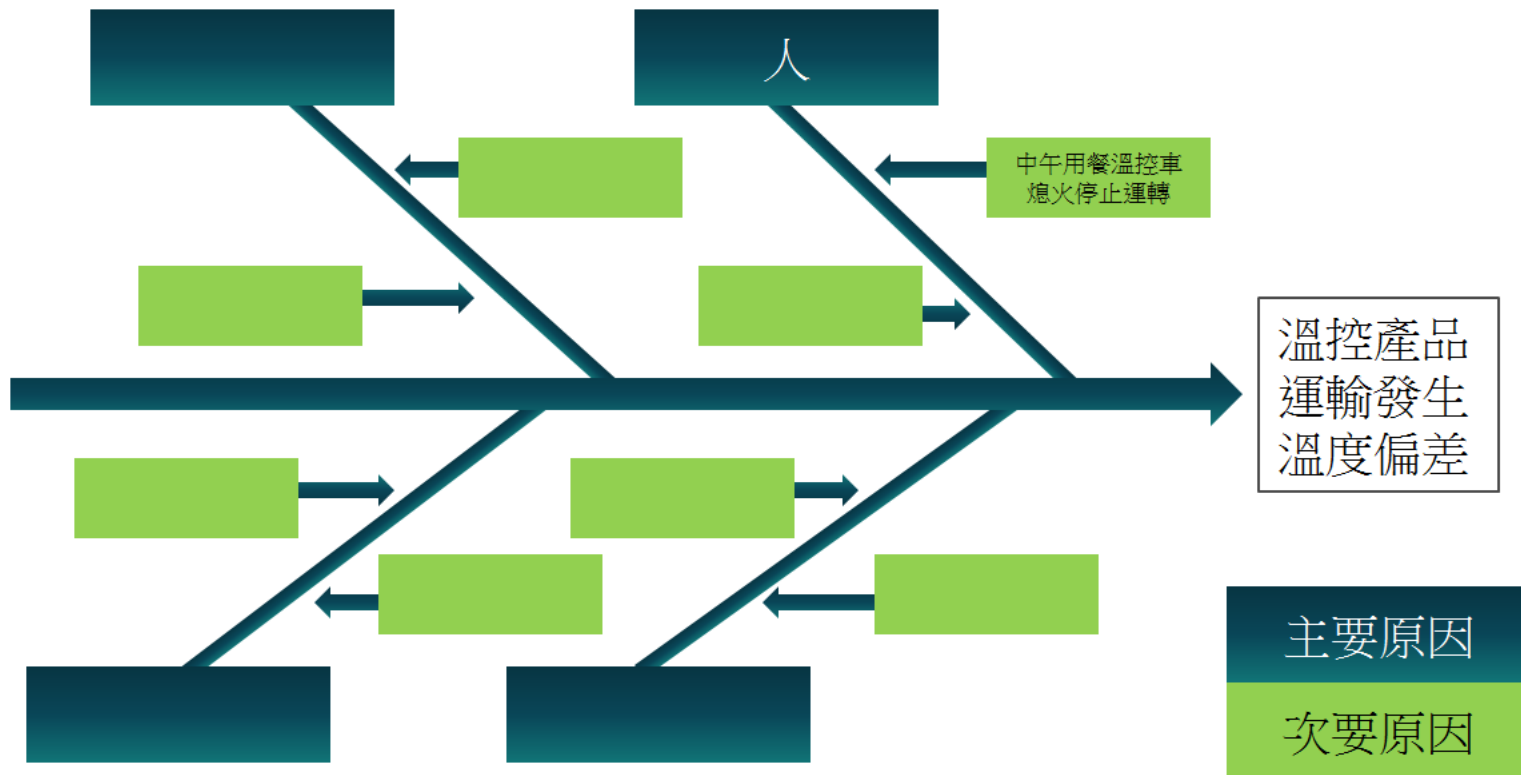
**Thank you**

# Exercise- I

## 小組討論:

1. 內部控制制度(例如、自我查核/內部稽核)增加許多手續要求，影響工作效率，甚至於喪失商機？
2. 自我查核/內部稽核的主要功能在於預防及揭發錯誤？
3. 自我查核/內部稽核之設計是內部稽核人員的職責？
4. 只要內部控制制度設計周全，有無設置品質/自我查核人員，並不重要？
5. 自我查核/內部稽核功能不彰，可改由外部稽核取代？
6. 內部稽核影響組織內部和諧？
7. 只要員工誠實又精明，自我查核/內部稽核便可有可無？
8. 欲建立一自我查核架構，你/妳會如何做？

## Exercise- II



司機小明於七月八日**01:00**由甲地出車配送一溫控產品內附溫度記錄器，到達乙地某診所時間為當日**15:10**。客戶於收貨當下檢視溫度記錄器發現異常警報訊號，因為完整溫度紀錄讀取需要適當設備所以小明將記錄器交付與你協助偏差調查：

1. 請利用魚骨分析找出偏差根本原因以訂定其矯正預防措施。
2. 矯正預防措施後續追蹤與成效確認如何執行？