品質文件管理

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生達製藥　品質系統總監

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Type of document

Manual (Policy)

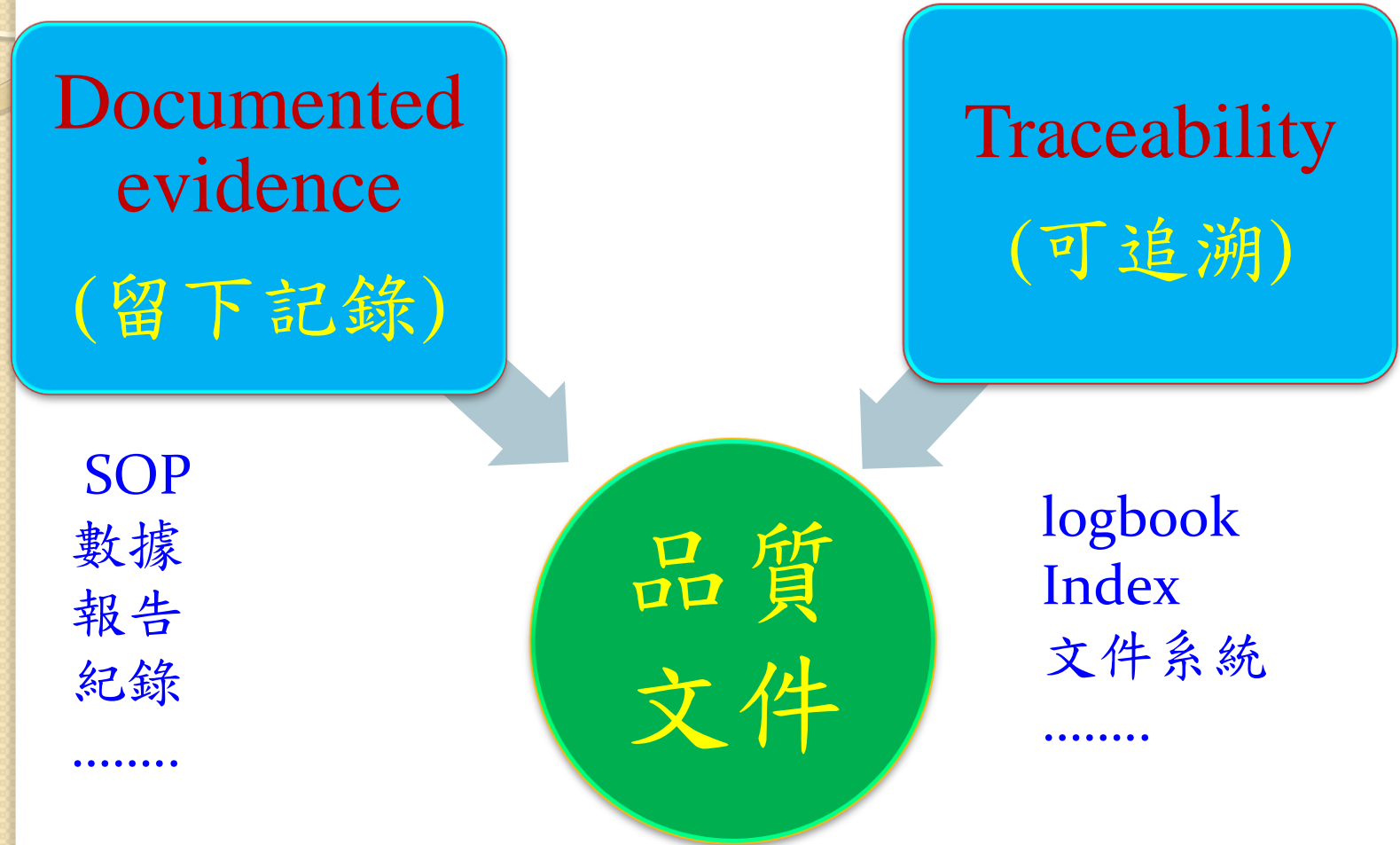**Instruction**

Procedure

- SOP, Protocol

Record

- Datasheet, Logbook

Quality Document - Definition

Documented evidence
(留下記錄)

Traceability
(可追溯)

SOP
數據
報告
紀錄
....

品質
文件

logbook
Index
文件系統
....

Context of SOP

Purpose	• Why
Application	• When/where
Responsibility	• Who
Reference	• Device, Document

Procedure	• How
	  • Step by step approach
	  • Data recording form

Flow chart	• Decision Tree

Organization of a document

1. **Purpose of the document**
   - Presentation of the objectives pursued by the document

2. **Definitions/abbreviations:**
   - Explanation of terms and abbr. that are central to providing an understanding if the document

3. **Responsibilities**
   - Presentation of the responsibilities for carry out and participating in the procedure described.
   - Responsibility of ongoing maintenance of this document in term of the revision, checking and approval of content
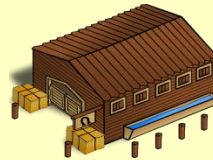
4. **Procedure**
   - Description of the objective and the task
   - Specifications for the materials and equipment to be used
   - Acceptance criteria
   - If required, information on the action to be taken in the event that deviations occur when the process is underway

5. **Appendix**

Scope of GDP
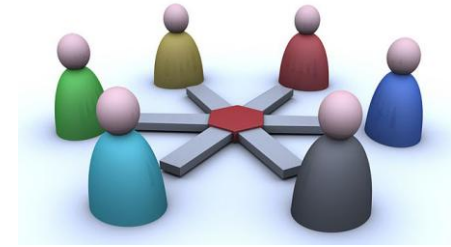
Finished
Product

Warehouse

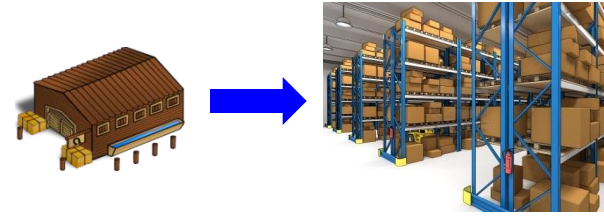Storage area
(Transit area)

Distribution/
Transportation

Customer

Storage/Transit Area

Receiving information
- Quantity/ check/ examination

Inventory
- Each Transaction

SOPs
- All related procedure in storage area/Transit area

Records
- Access/ Temp/ Humidity

Protocol/Report
- DQ/IQ/OQ/PQ
- Mapping, Computerized system

Calibration
- Reference gauges

Storage/Transit Area

Pest Control
- Procedure/drawing

Alarm system
- Check/ setting rationale

Deviation Procedure

FEFO mechanism

Picking/Packing

Limited Assessment area
- Special attention
- Local regulation/ law

Vehicle management

Hygiene

SOPs

Logbook

- Usage, quantity, Customer information

Record

- Temp, Humidity, Route

Training

Hardware

- DQ/IQ/OQ/PQ
- Mapping, RM/PM, Alarm

Cold Chain Supply

- **Maintain specified condition all the way**
  - Temp. monitoring device
  - Data logger
  - Alarm system

- **Ensure transportation condition**

| Manufacturer | WH | Sub-constractor | Customer |

Cold Chain Supply (2)

- Temp controlled vehicle
  ◦ Temp mapping
  ◦ Monitoring device
  ◦ Calibration

- Cold-Packs
  ◦ Disposition in package box
  ◦ Reuse evaluation
  ◦ Distinction of incomplete vs. chilled packs

Cold Chain Logistics interactive system

- Data mining
- On-line analysis

Management System

| Supply Chain structure | Standard / Specification |
| Warehouse Temperature management | Transportation surveillance management | Delivery & Acceptance quality management |

Quality control Status control

- quality pedigree
- Box temp.
- Car temp.
- Accept goods temp.
- Delivery status
- Warehouse temp.

Hardware

GPS Satellite

Temp. information cable

Temp. Sensor

cryobox

Communication equipment

Wireless (LAN/WAN)

Base station

GPS

RFID

Humidity / Temperature Sensor

GPS

software

GIS database

Map Location Analysis Others

Plate Information

No Break
In Cold Chain

Documentation (1)

- Quality manual/ Policy (or eg. Docket)
- Instructions
- Procedures
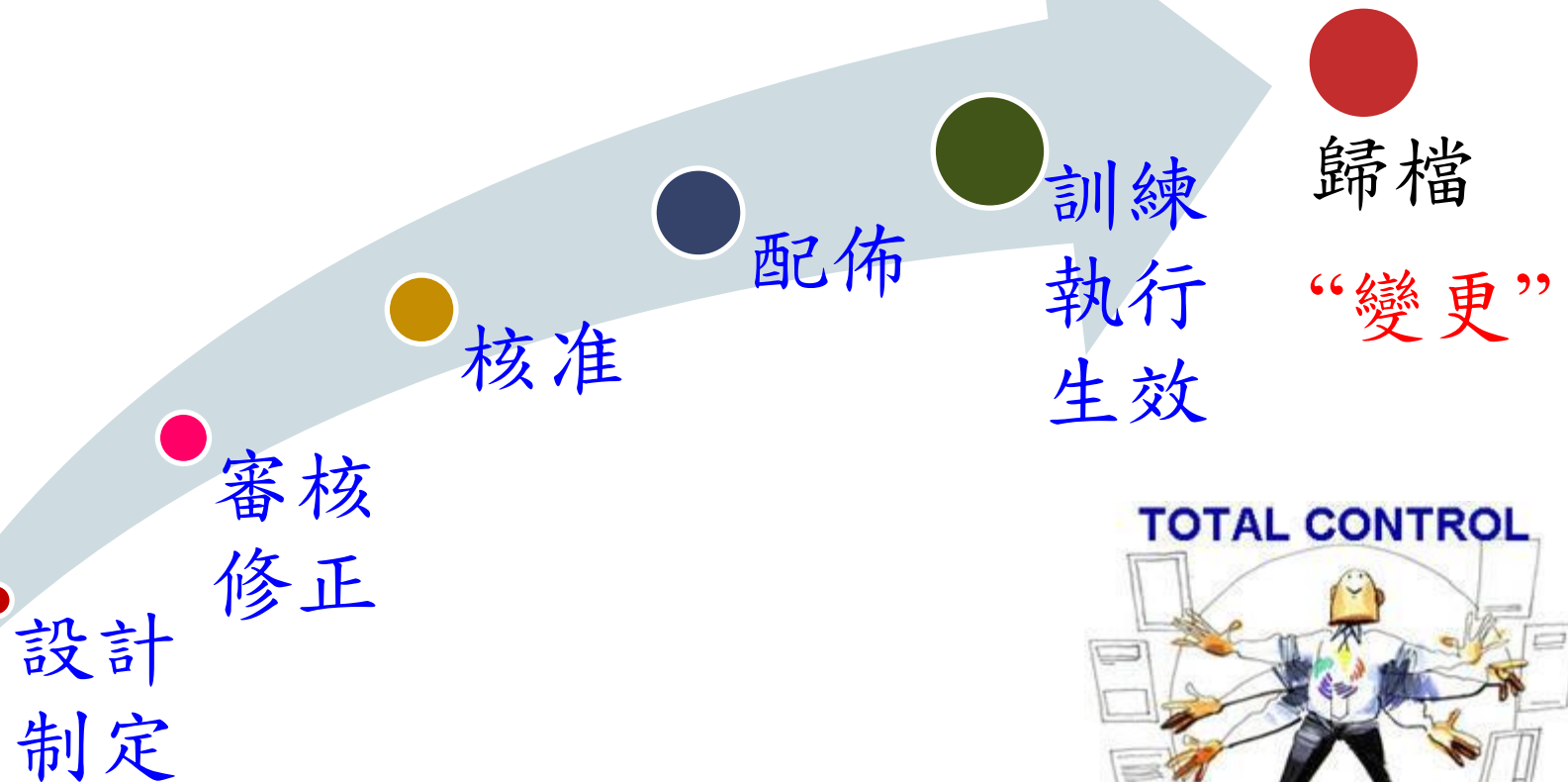- Records

Documentation

- In form of:
  - SOP
  - Protocol/Report
  - Datasheet
  - Layout/Drawing

- Approving Process
  - Preparation → Reviewing → Approval
  - Periodical review

- Retain Period

Documentation
(3)

- 文件制定流程

訓練
執行
生效

歸檔

"變更"

配佈

核准

審核
修正

設計
制定

TOTAL CONTROL

**Document Generation,
Output and Distribution**

Documentation

- 變更管制程序

Change
- 依需求提出文件修訂

Review
- 傳送相關單位審核
- 提出評估資料

Approval
- 經由品保部門做最終核准

Replacement
- 版本版次變更，取代原版本

Training

Organization Chart

Job Description

Training Program

- Initial/ OJT/Special handle

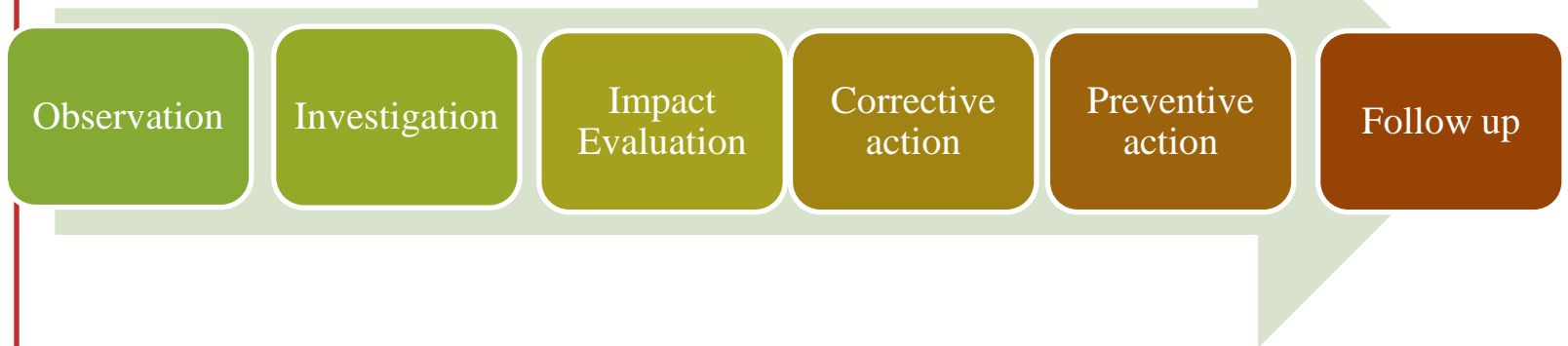**Training Material**

- GDP/ Procedure/ Hygiene

Effectiveness evaluation

Documents

- SOP
- Training Schedule
- Training Record

Handle of Deviation/Complaint/Non-Conformity

- ## SOP (procedure)

Observation	Investigation	Impact Evaluation	Corrective action	Preventive action	Follow up

- ## Records

- ## Logbook (Index)

Quality-Related Issues
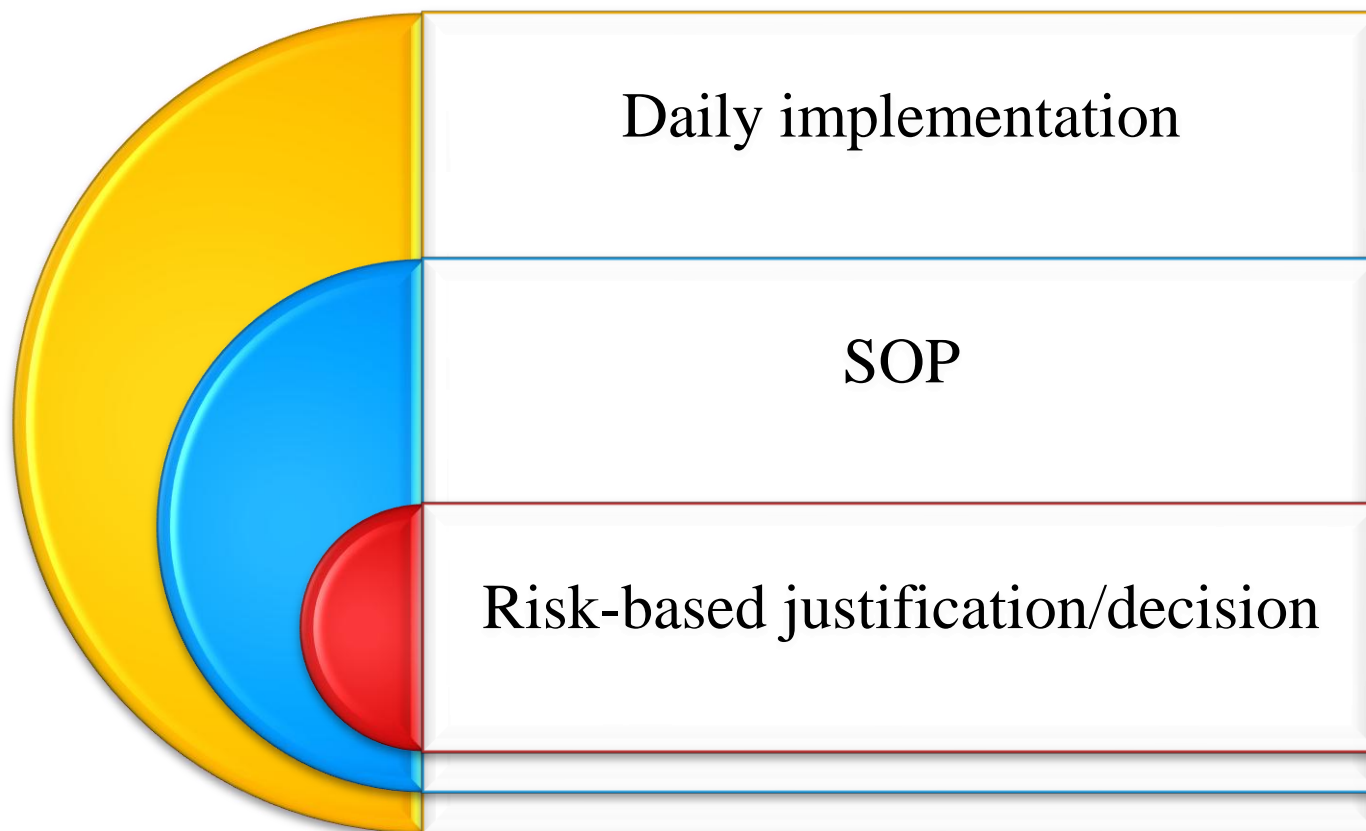
Returned Medicine, Recalls

SOP: Procedure

Returned →Re-inspection

- Quality evaluation
- Professional justification
- FEFO

Effectiveness of recall arrangement

- Periodical evaluation

Risk Management

Daily implementation

SOP

Risk-based justification/decision

# Risk Management
Annex1: Tools (Basic Method)

- **Basic risk management facilitation methods**
  - ✓ **Flowchart**
  - ✓ **Check Sheets**
  - ✓ **Process mapping**
  - ✓ **Cause and Effect Diagrams (Ishikawa / fish bone)**

They might be helpful to support risk identification

Justification

- Reports containing scientific data and expert professional judgment to substantiate decisions.

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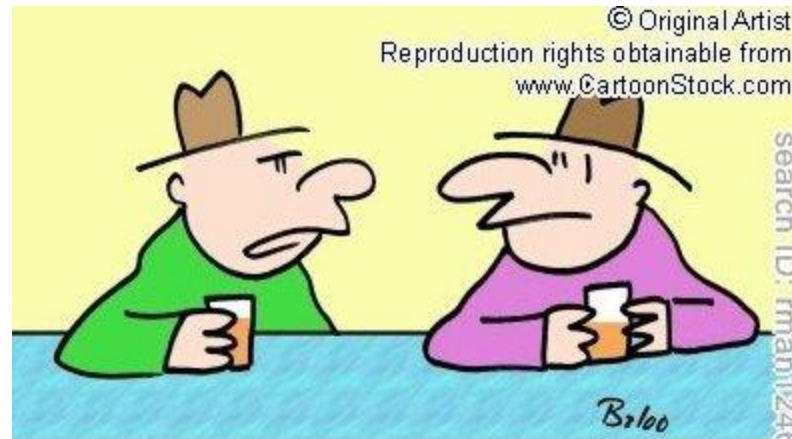
"If you can't make ends meet, how can they justify the means?"

THANK YOU FOR YOUR ATTENTION!