

# 110年醫療器材優良運銷準則 主題論壇 <自有倉儲規劃與管理>

Sysmex Taiwan Co., Ltd.  
2021, Jun 2<sup>nd</sup>

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## About Sysmex



# sysmex

Lighting the way **with diagnostics**



# Sysmex by the Numbers

This section uses numbers to introduce Sysmex's businesses,  
characteristics and strengths.

## Global NO.1 in Hematology

Sysmex holds the No. 1 share of the global market in the hematology field (the field of *in vitro* diagnostics that determines whether precise testing is necessary by analyzing the number, type and size of red, white and other blood cells). To ensure that accurate testing results are delivered swiftly, we provide products of high quality and high usability and offer extensive after-sales support.

► The Basics of Hematology

► About Blood





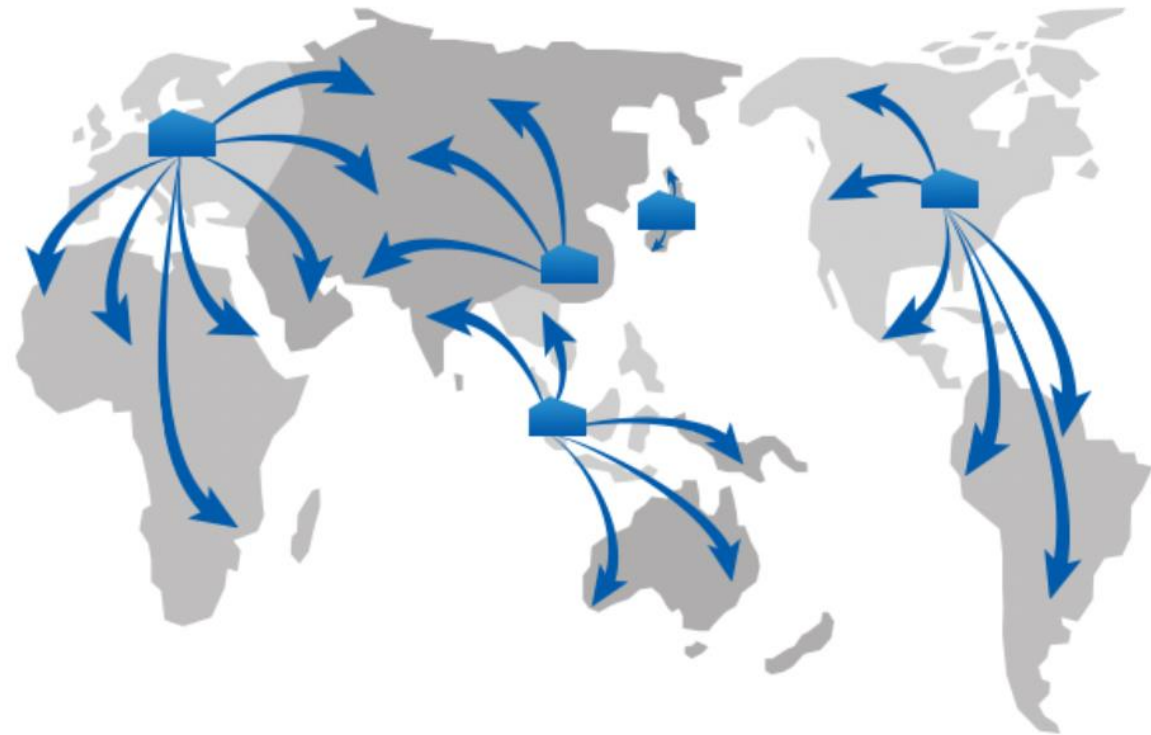
## More than 190

### Countries around the World

Sysmex's business is in the *in vitro* diagnostics field. We are an integrated manufacturer that conducts everything from R&D to manufacturing, sales and after-sales services on the instruments, reagents and software used to analyze blood, urine and cell specimens. We provide products and after-sales support to customers in more than 190 countries around the world.

► Introducing Our  
Business Activities

► Sysmex Near You



# 2 $\mu$ m

Circulating blood cells are too small to be seen with the naked eye. Sysmex helps people remain healthy through its technologies for measuring these blood cells, which have a diameter of around 2 micrometers. (One micrometer is one-millionth of a meter, or 0.001 millimeters.)

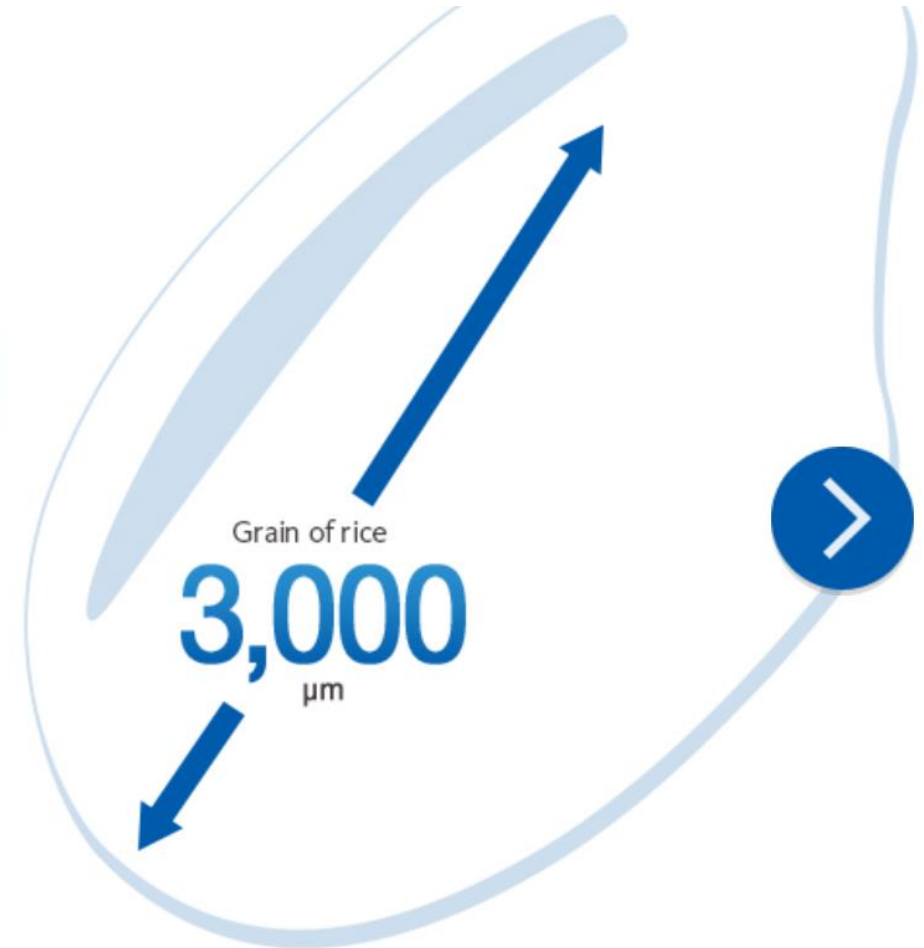
► Research and Development

► About Blood

Pollen  
30 $\mu$ m

Cross section  
of a human hair  
80 $\mu$ m

Blood cell  
2 $\mu$ m





# 100,000

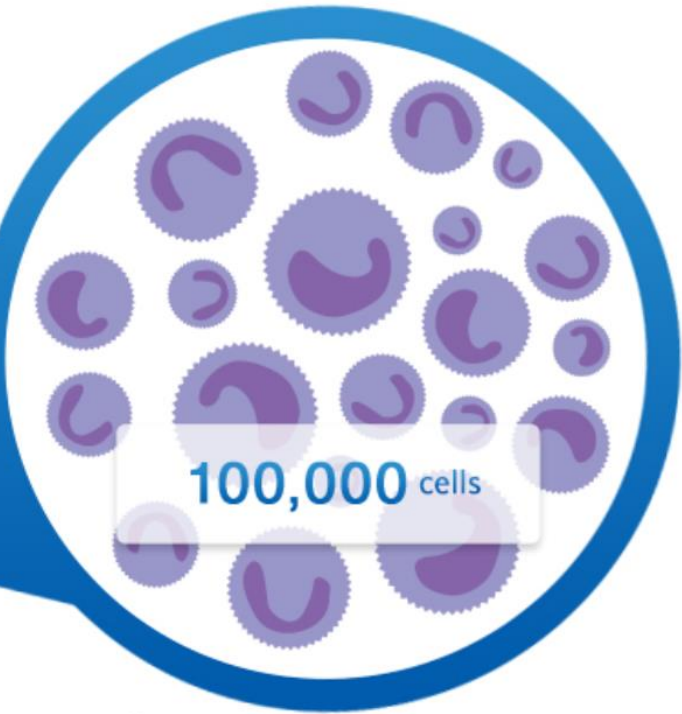
## Cells per Second

Nearly 100 years before automation in the field of hematology, healthcare professionals used microscopes to measure and count the number of blood cells. In 1963, Sysmex became the first company in Japan to achieve automation in hematology. Now, we have developed technology that allows for the automated counting of around 100,000 blood cells per second with higher testing precision and efficiency.

▶ The Basics of Hematology



Automated Measurement  
of Blood Cells



< Back to the top



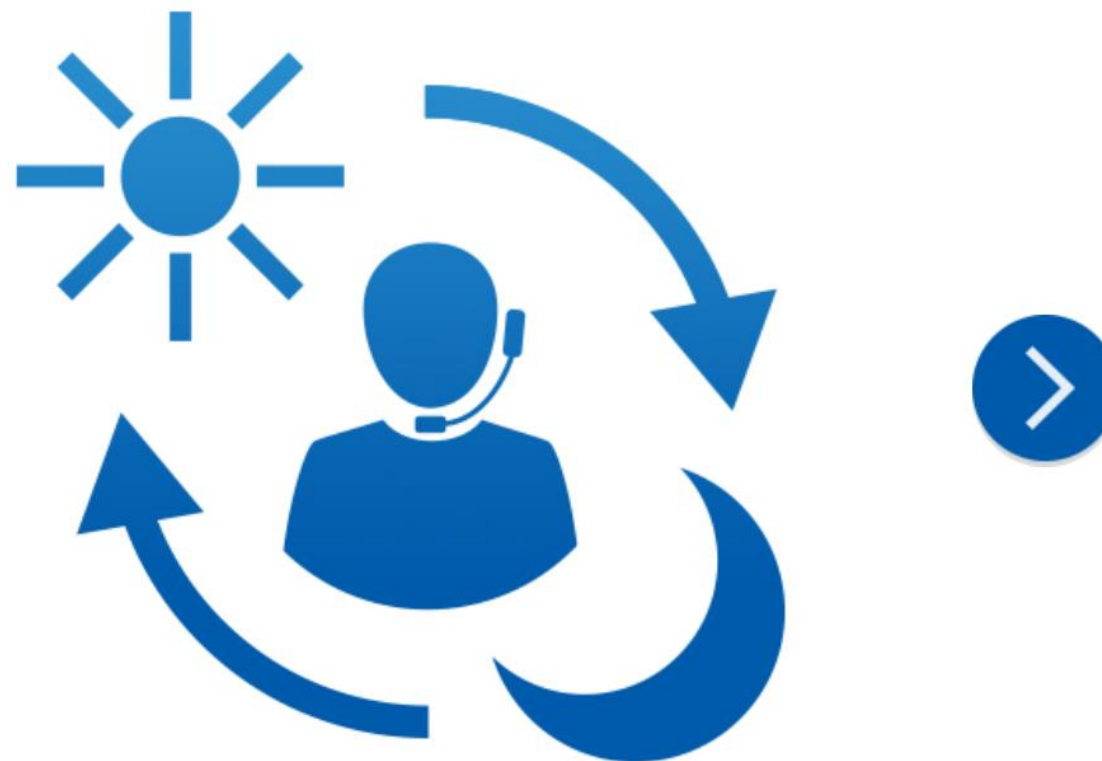
## Around the Clock, **365** Days a Year

Sysmex provides medical instruments that are closely connected with people's lives. For this reason, we have in place call centers for customer service contacts staffed with highly knowledgeable, dedicated staff that operate around the clock, 365 days a year<sup>\*1</sup>.

In Japan and at our regional headquarters overseas, we provide call center support to our customers. We also operate the Sysmex Network Communication Systems (SNCS<sup>\*2</sup>), which provides real-time monitoring and remote maintenance.

<sup>\*1</sup> A separate agreement is required.<sup>\*1</sup>

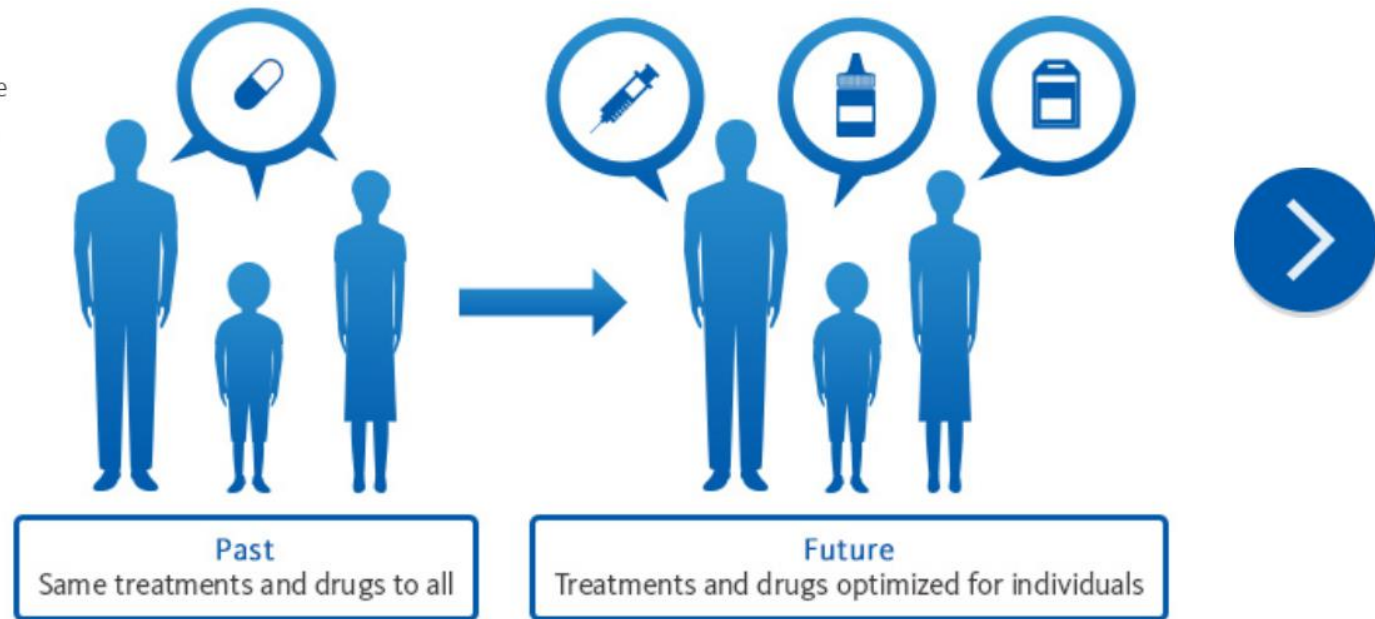
<sup>\*2</sup> SNCS is a support service for the online provision of remote instrument maintenance and quality control by connecting the Customer Support Center and customers' products via an online network.<sup>\*2</sup>



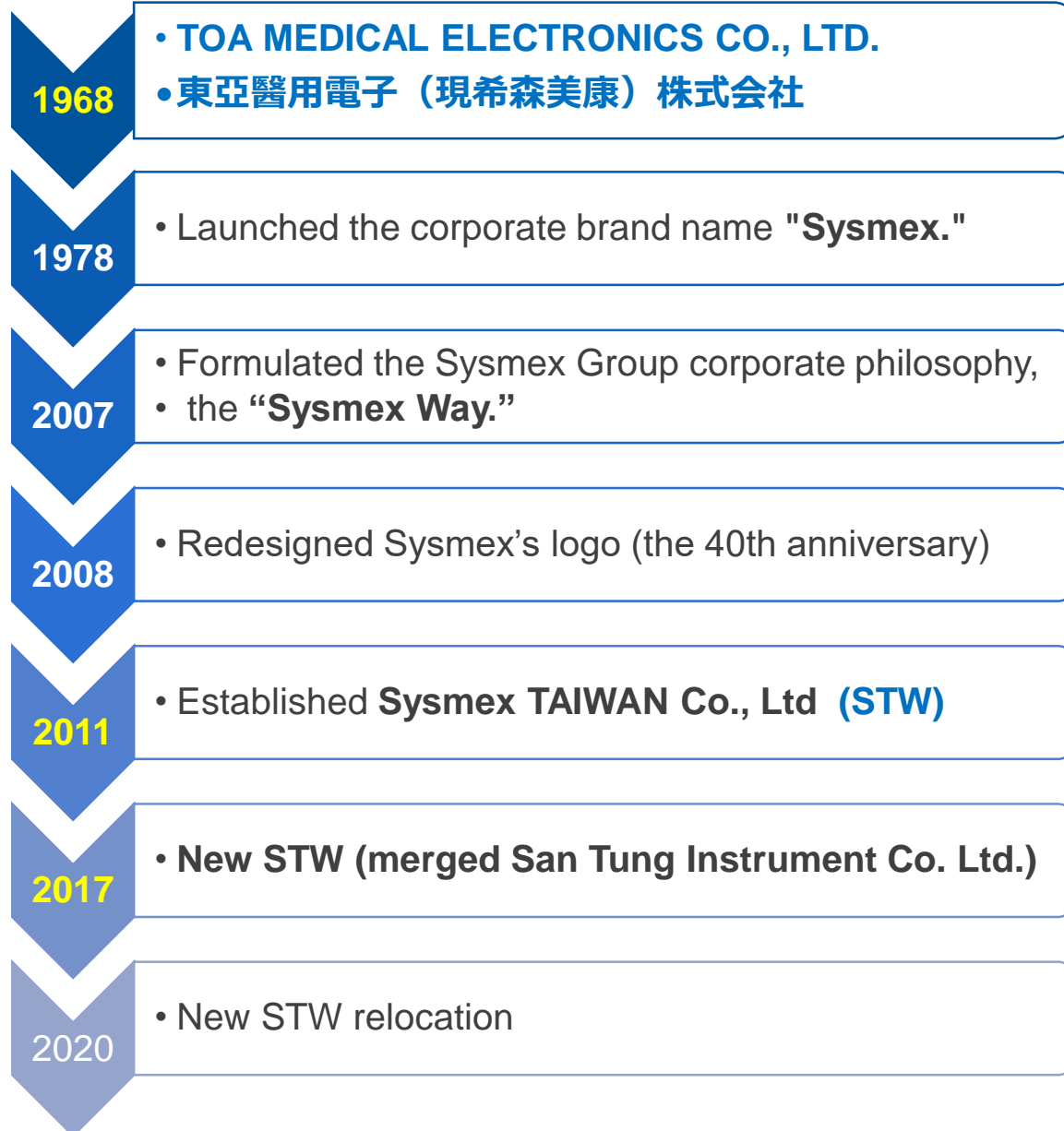
## 1 person, 1 treatment method

Disease states differ by person, so it is understood that the same treatment method may not be appropriate even for people with the same disease. In recent years, progress in genetic analysis technology has made it possible to determine optimal treatment methods for individual patients. Selecting the optimal treatment method can help reduce the physical burden on patients, as well as curtail medical expenses.

► About Personalized Medicine



# Sysmex's History



## Sysmex Way

- Mission**

Shaping the advancement of healthcare.
- Value**

We continue to create unique and innovative values, while building trust and confidence.
- Mind**

With passion and flexibility, we demonstrate our individual competence and unsurpassed teamwork.



The automated hematology analyzer CC-1001

## Mission

Shaping the advancement of healthcare.

實現發展保健醫療系統。

## Value

We continue to create unique and innovative values,  
while building trust and confidence.

我們持續追求獨創價值，以贏得客戶信賴。

## Mind

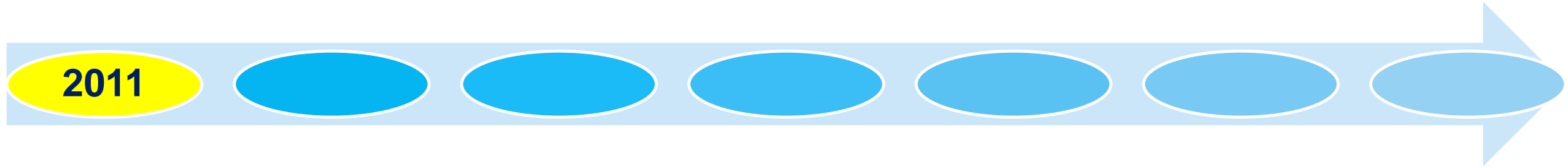
With passion and flexibility,  
we demonstrate our individual competence and unsurpassed teamwork.

我們透過熱忱及靈活的個人工作態度，以展現單一無二的卓越團隊。

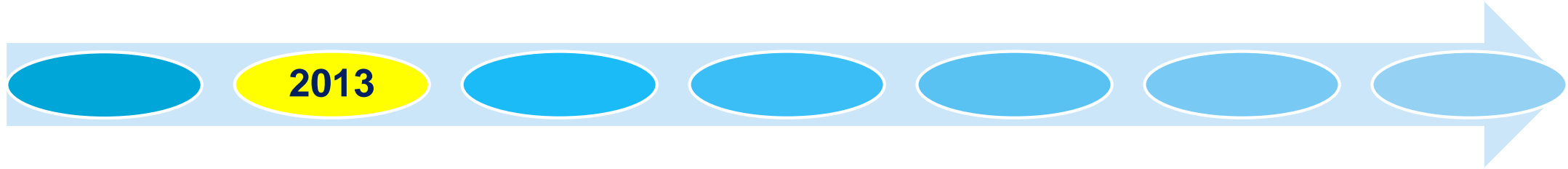


STW & GDP

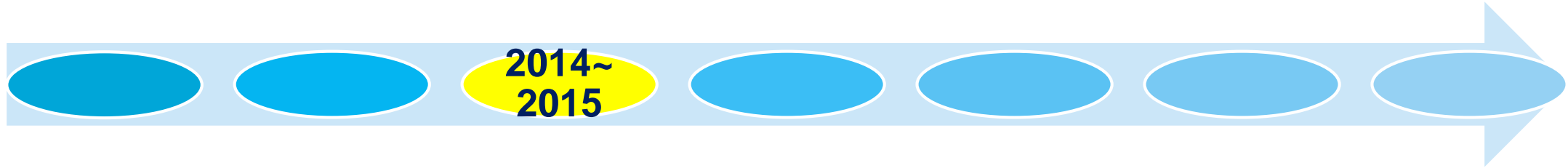




**STW established**



- MIRDC started GDP promotion
- STW participated in related seminars actively



- TFDA released GDP draft
- STW joined in GDP counselling plan

**STW**

Import  
輸入

**ST**

Storage  
儲存

Transportation  
運送

Distribution  
銷售

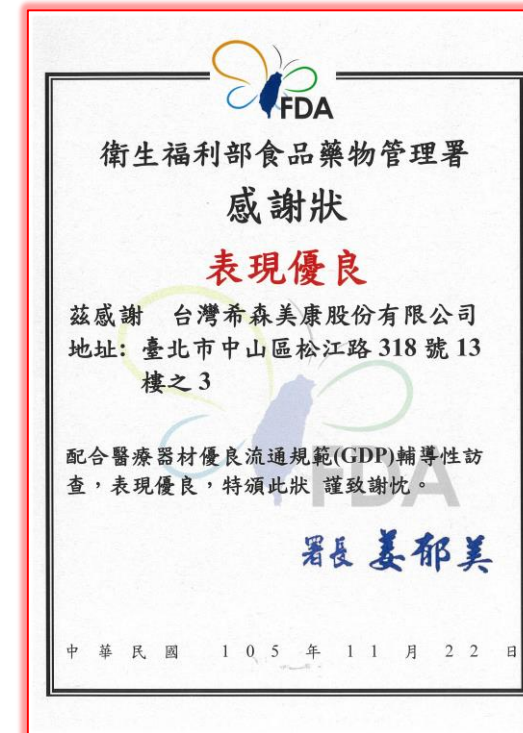
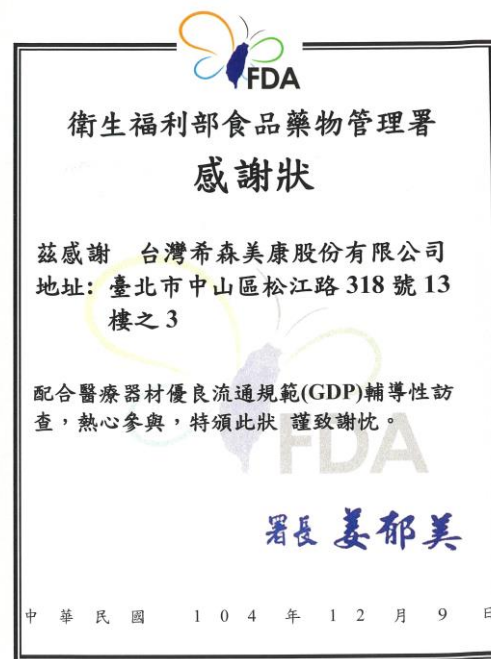
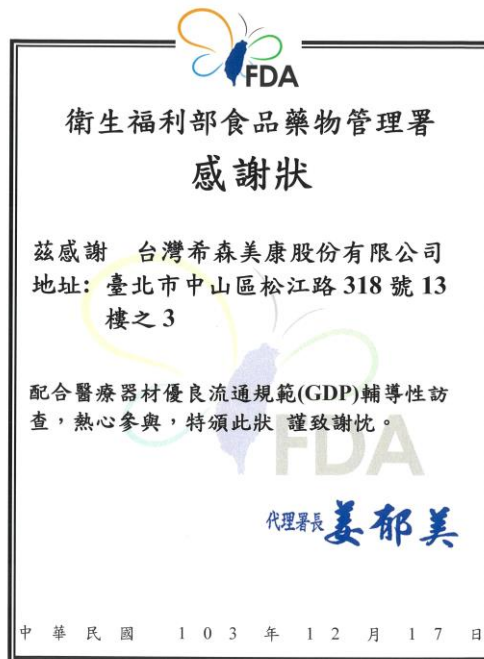
**We realized GDP is more important to our distributor than to STW.**

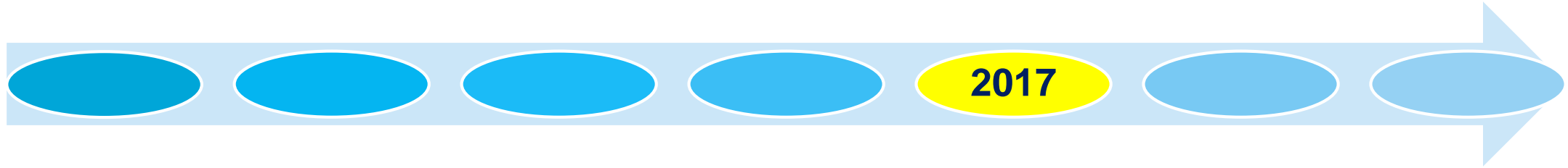
STW: License holder, importer

ST: Distributor, responsible for storage, transportation and distribution.

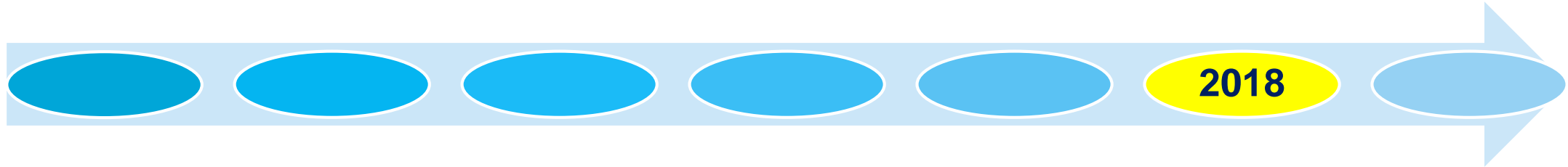
2016

- STW got "Good performance" of GDP in counselling plan





- **New STW was established**  
(merged SAN TUNG instrument Co. Ltd.)



## ● New Quality Management System released

STW
Quality management system
Management responsibility
Resource management
Product realization
Measurement, analysis and improvement
<b>SOP #20</b>

+

Distributor
Quality management system
Management responsibility
Resource management
Product realization
Measurement, analysis and improvement
<b>SOP #55</b>





New STW
Quality management system
Management responsibility
Resource management (human, environment, equipment)
Product realization
Measurement, analysis and improvement
<b>SOP #48</b>



2020

## ● New STW got qualification of Pilot Audit Program.

 衛生福利部食品藥物管理署  
食品藥物管理署  
109 年度「醫療器材優良運銷準則推廣計畫」項目二：醫療器材優良運銷準則試辦計畫

 ITRI  
Industrial Technology Research Institute

### 109 年度「醫療器材優良運銷準則(GDP 準則)試辦檢查方案」徵求參與廠商

一、目的：

衛生福利部食品藥物管理署因應「醫療器材管理法」公布，於 109 年預告「醫療器材優良運銷準則(GDP 準則)」草案。醫療器材管理法第 24 條已明定「經中央主管機關公告之醫療器材及其販賣業者，應建立醫療器材優良運銷系統，就產品之儲存、運銷、服務、人員配置及其他相關作業事項予以規範，並應符合醫療器材優良運銷準則。且醫療器材販賣業者依前項準則規定建立醫療器材優良運銷系統，並經中央主管機關檢查合格，取得運銷許可後，始得批發、輸入或輸出。」。為此，衛生福利部食品藥物管理署特別委託工業技術研究院量測技術發展中心辦理 109 年度「醫療器材優良運銷準則(GDP 準則)試辦檢查方案」，以協助醫療器材業者瞭解醫療器材新法之要求及相關規定，並建立更完善之醫療器材產管管理制度。

二、方案實施內容：

本計畫執行「醫療器材優良運銷準則(GDP 準則)試辦檢查方案」，協助廠商符合醫療器材優良運銷系統之法規要求，該方案實施內容如下：

項目	醫療器材符合「醫療器材優良運銷準則」試辦檢查(徵求 20 件)
參與資格	國內從事醫療器材輸入、儲存、運輸、銷售之醫療器材商
方案內容	1. 提交符合「醫療器材優良運銷準則」現場稽核。 2. 通過試辦檢查者，授予符合性證明文件，業者得向食藥署換發正式醫療器材運銷許可函。
備註	有志參與 GDP 準則試辦檢查之醫療器材商皆歡迎報名，若報名業者超過徵求件數，優先考量條件包括如： 1. 曾參與醫療器材優良運銷系統/醫療器材優良運銷準則(GDP)管理制度及推廣計畫之訓練或輔導性計畫者； 2. 第 3 等優良醫療器材/體外診斷醫療器材； 3. 具滅菌要求醫療器材； 4. 植入式醫療器材； 5. 儲存條件具現場管制要求醫療器材。
參與費用	免費

1

 衛生福利部食品藥物管理署  
食品藥物管理署  
109 年度「醫療器材優良運銷準則推廣計畫」項目二：醫療器材優良運銷準則試辦計畫

 ITRI  
Industrial Technology Research Institute

### 109 年醫療器材優良運銷準則試辦檢查方案 醫療器材業者 GDP 符合性證明文件

茲證明

醫療器材販賣業者名稱：台灣希森美康股份有限公司

醫療器材販賣業者地址：新北市板橋區深丘里中山路一段 156 號 18 樓

醫療器材貯存場所：\_\_\_\_\_

證明文件編號：\_\_\_\_\_

許可作業內容：  
醫療器材之輸入、儲存、銷售等作業。



工業技術研究院 量測技術發展中心  
新竹市 300 光復路二段 321 號 1 館 711 室  
證明文件核發日期：中華民國 109 年 12 月 31 日

第 1 頁/共 1 頁

本表單為 109 年度醫療器材業者「醫療器材優良運銷準則試辦檢查方案」表單，醫療器材優良運銷系統檢查文件以食藥署正式訂定版本為主。

A photograph of a sunset or sunrise over a calm ocean. The sun is a bright, glowing orb in the upper left, partially obscured by a few clouds. Its light reflects as a shimmering path across the water's surface. The sky is filled with soft, white clouds, and the horizon line is visible in the distance.

What STW did for GDP

# What STW did for GDP

- Top Management support on GDP establishment
- Cooperation with distributor to set up GDP system
- Warehouse visit to S-Corp in Japan to learn from their experience
- Internal audit training by Headquarter (S-Corp) in Japan



# Internal audit training

- **Lectures**  
Description of the audit outline using of ISO 19011
- **Training**  
Role playing
- **Site tour of a factory warehouse and moc audit**







**Sysmex Seishin**



**Sysmex i-Square**

## About STW's warehouse



# Factors considered for choosing a warehouse

- ✓ Location (Industrial Area)
- ✓ Capacity
- ✓ Workflow
- ✓ Expense



# Capacity & Product information

## Product information

- License: XX
- Product:
  - Medical device: XX
  - Non-Medical device: XX
- Storage conditions:
  - 2 ~ 8°C
  - 2 ~ 10°C
  - 2 ~ 30°C
  - 2 ~ 35°C
- Safety stock: XX months

Capacity

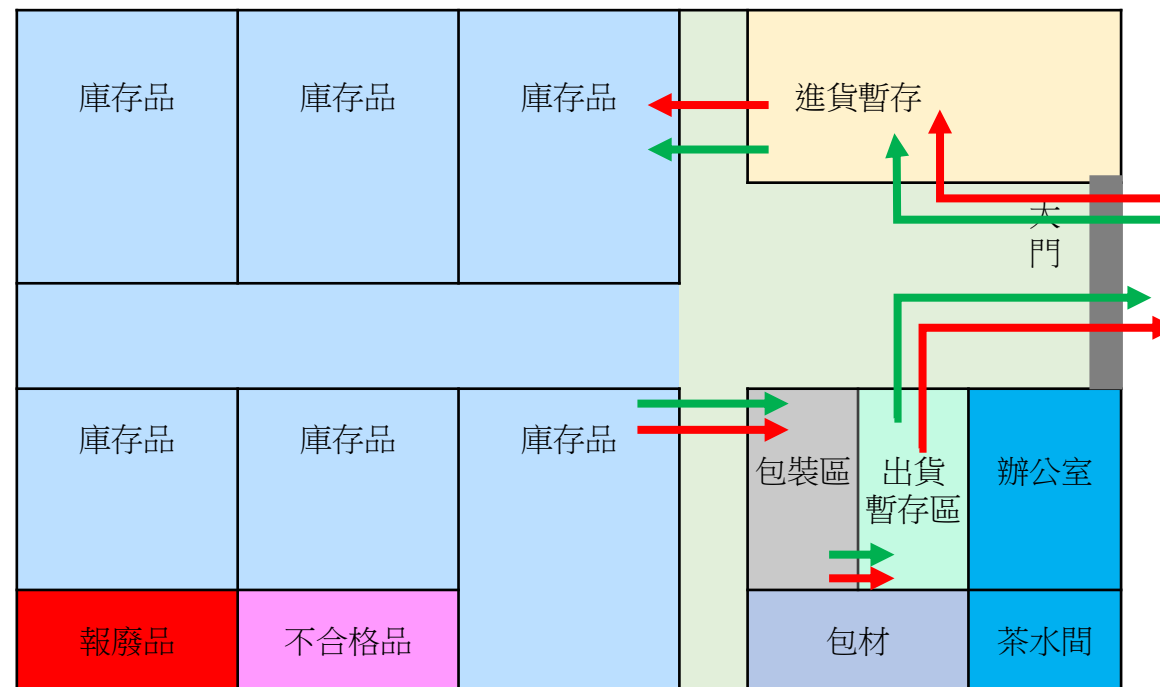
附件七、醫療器材清冊

編號	醫療器材名稱	分類分級代碼	醫材等級	許可證字號	許可證持有業者名稱	溫度條件	放置地點(倉庫名稱/地址)
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

# Layout & Workflow



- ✓ 進貨暫存區
- ✓ 庫存區
- ✓ 包裝區
- ✓ 出貨暫存區
- ✓ 不合格品區
- ✓ (報廢區)
- ✓ 短效期品區



圖例： → 人流  
→ 物流

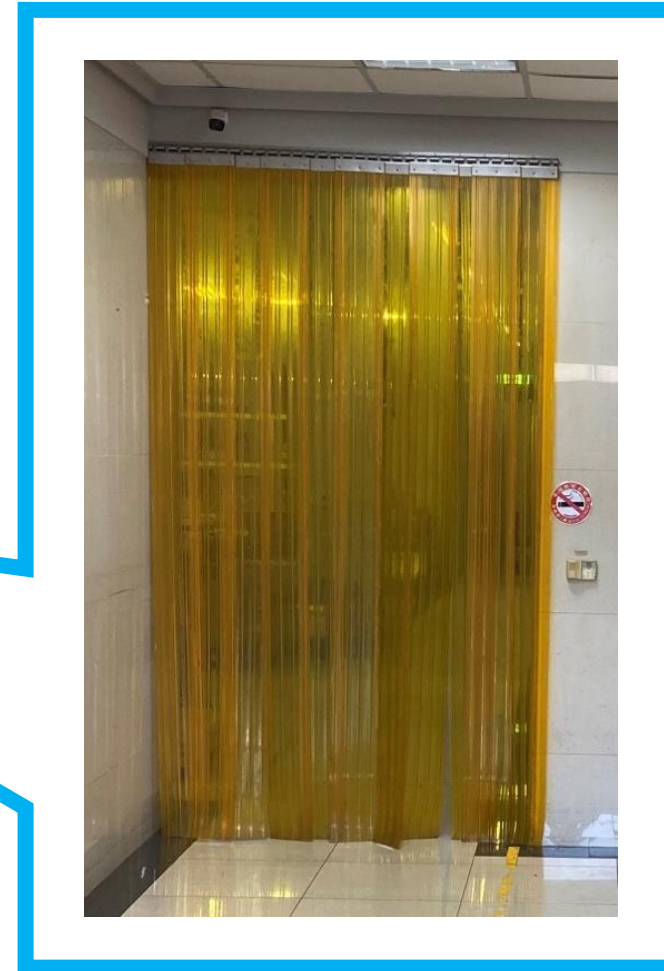
(僅供參考)



# STW's cold room

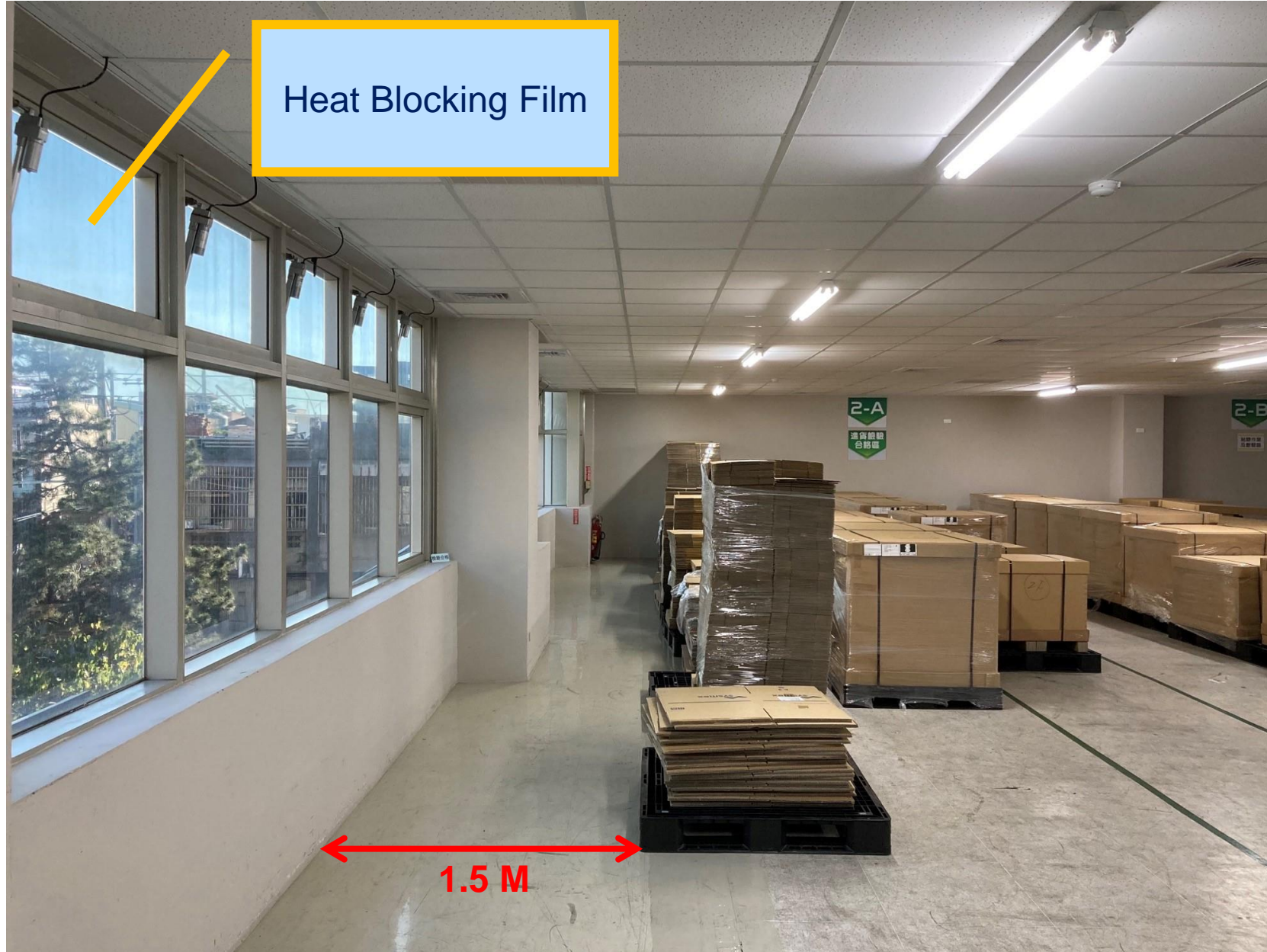


# Tips for energy conservation





# Tips for energy conservation





A photograph of a sunset or sunrise over a calm ocean. The sun is a bright, glowing orb in the upper left, partially obscured by a few wispy clouds. Its light reflects as a shimmering path across the water's surface. The sky is a gradient of blue and yellow, with a layer of soft, white clouds just above the horizon.

## What STW did for New GDP regulation

# Set up a Working Group

- **Qualified Team Members**
- **Well Experienced**

## **Management Representative**

- With more than 15 years of experience in QMS
- Medical Technologist
- ISO 15189 : 2012
- ISO 13485 : 2016

## **Quality Assurance Manager**

- With more than 5 years of experience in QMS
- ISO 13485 : 2016
- ISO 14971 : 2019

## **Supply Chain Management Manager**

- With more than 5 years of experience in GDP
- ISO 13485 : 2016

## **All STW members**

- Internal training of QMS and GDP

# Compare the difference between 2 versions

- ✓ Compare GDP draft & GDP regulation
- ✓ Check if the SOPs meet new regulation

GDP regulation	ISO 13485: 2016	SOP	Note
3	4.1.1~4.1.3	STW-001	O
4	4.1.4	STW-001	▲
5	4.1.5	STW-002	X
.....	.....	.....	
.....	.....	.....	
.....	.....	.....	
.....	.....	.....	
.....	.....	.....	

## 「醫療器材優良運銷準則」草案與 ISO 13485:2016

醫療器材優良運銷準則要求項目	ISO 13485:2016章節
第3條	4.1 General requirements (4.1.1 -4.1.3)
第4條	4.1 General requirements (4.1.4)
第5條	4.1 General requirements (4.1.5)
第6條	4.2.1 General, Documentation requirements
第7條	4.2.4 Control of documents
第8條	4.2.5 Control of records
第9條	5.5.2 Management representative
第10條	5.6.1 General, Management review 5.6.3 Review output

- GDP regulation is harmonized with ISO 13485: 2016

## Risk Management

**Supplier  
Management**

**Temperature  
Mapping**

**Software  
Validation**

**Evaluate the  
effectiveness of  
recall procedure  
every year**

# Strengthen supplier management (GDP #16-18)



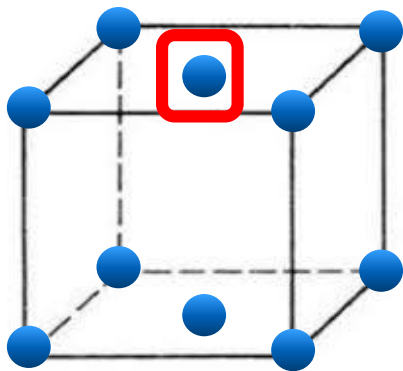
**\* Quality-related procedures or items**

<Note>

Supplier should send notification prior to implementation of any changes that affect the ability of purchased product.

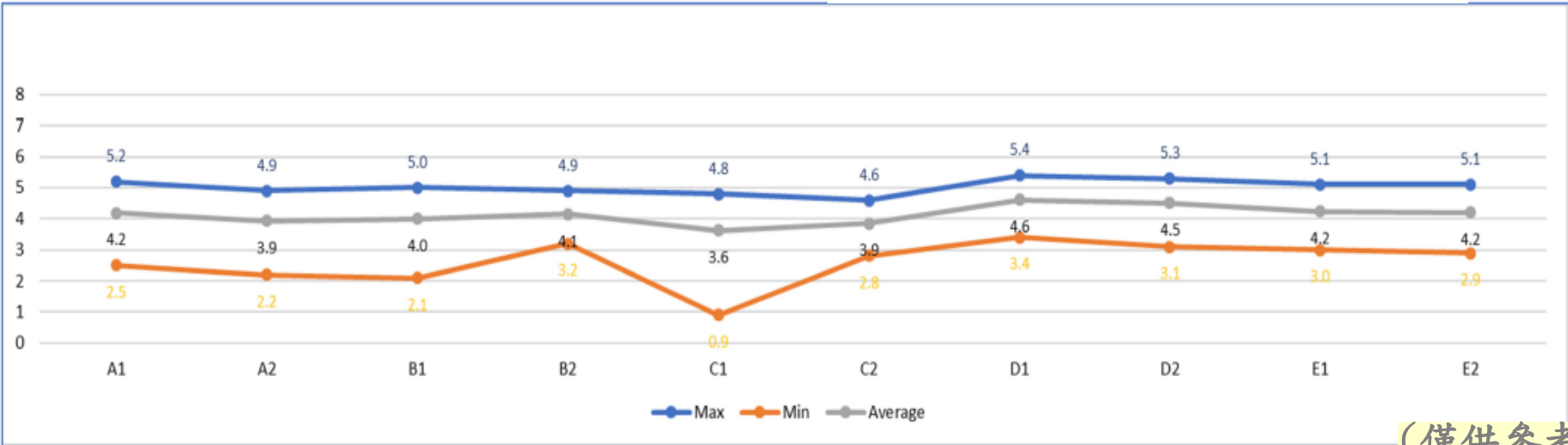
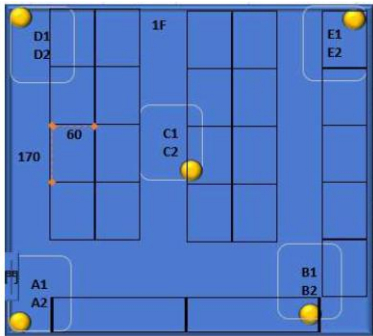
# Temperature Mapping (GDP #13)

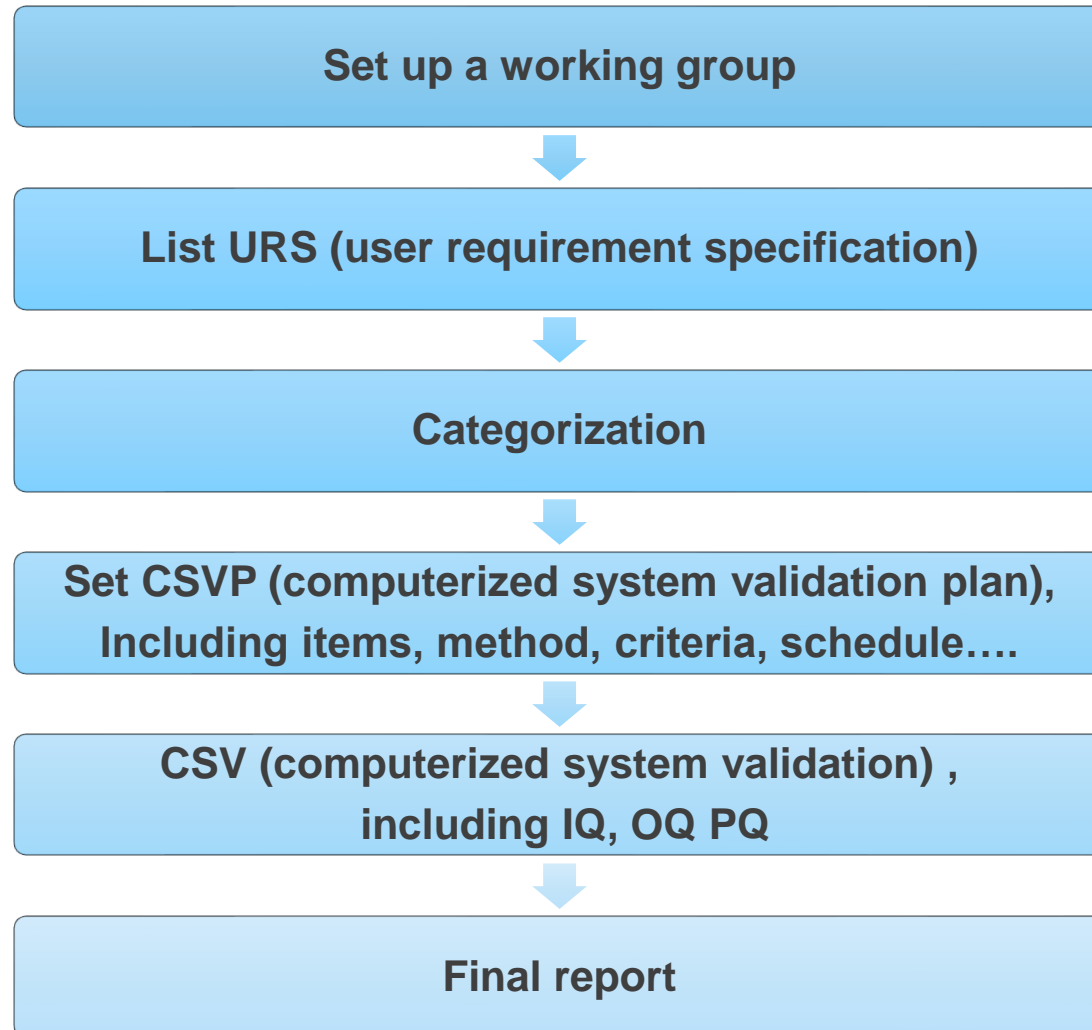
- ✓ Outsourced to qualified laboratory (ISO 17025)
- ✓ Conducted by qualified engineers
- ✓ Calibrated all sensors within 1 year



Point	Max	Min	Average
A1	5.2	2.5	4.2
A2	4.9	2.2	3.9
B1	5.0	2.1	4.0
B2	4.9	3.2	4.1
C1	4.8	0.9	3.6
C2	4.6	2.8	3.9
D1	5.4	3.4	4.6
D2	5.3	3.1	4.5
E1	5.1	3.0	4.2
E2	5.1	2.9	4.2

Term: 2021/3/9 00:00:00 AM~2021/3/16 00:00:00 AM  
Temperature Mapping





<Note>

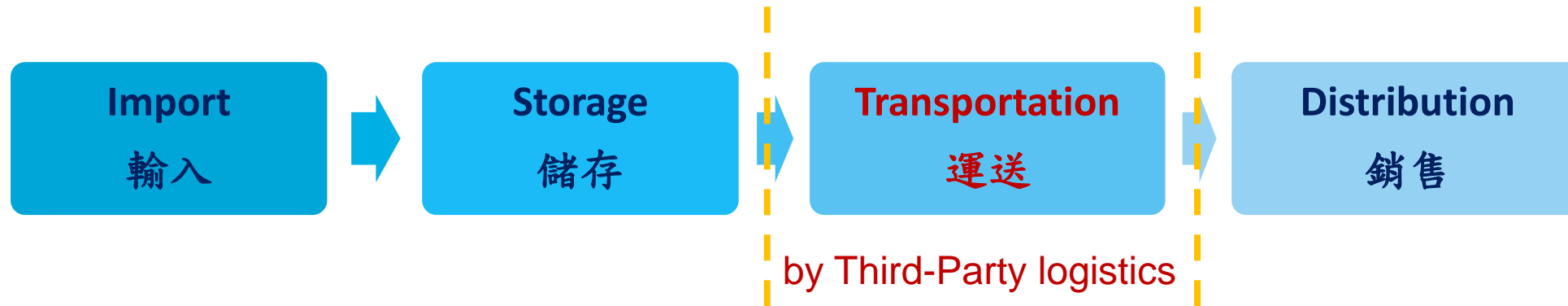
If any change to the computerized system, evaluate the impact of the change and decide whether validation is necessary.



# Visions of STW's warehouse



- Optimize the transportation monitoring process by strengthening cooperation with third party



- New ERP system
- ASRS, Automated Storage/Retrieval System

Lighting the way **with diagnostics**