



委外作業之委/受託商 評估與管理要點

張富文

2015-Oct-21/22

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藥品供應鏈模型



藥品供應鏈模型

藥品GDP實施範圍

藥品之採購、儲存、供應、輸入或輸出的所有活動*：品質管理、人事、作業場所與設備、文件管理、作業、申訴、退回與回收、

委外作業、自我查核、
運輸及其他應遵行事項，
應符合優良運銷規範。

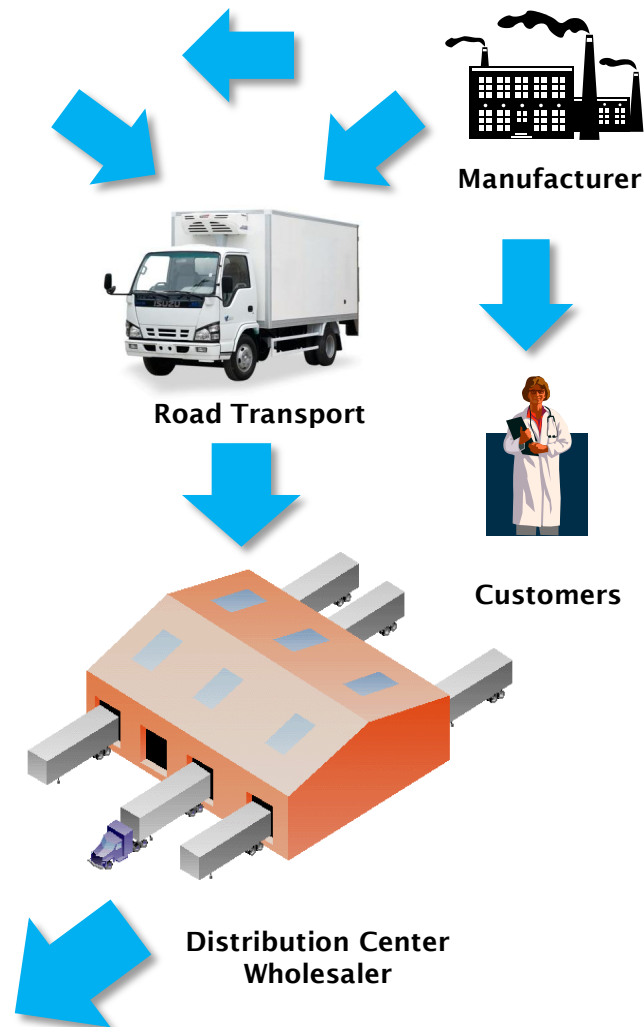
*不包含供應藥品給大眾



Customers
Pharmacy
Hospital
2nd Wholesaler



Dispatch



我國藥品GDP 規範

公告「西藥藥品優良運銷規範(第三部：運銷)」，自即日起生效。

衛生福利部 公告

發文日期：中華民國104年7月16日

發文字號：部授食字字第1041102778號

附件：「西藥藥品優良運銷規範(第三部：運銷)」中英文對照條文1份

主旨：公告「西藥藥品優良運銷規範(第三部：運銷)」，自即日起生效。

依據：藥物優良製造準則第三條。



我國藥品GDP 規範

1. 本規範係採PIC/S GDP (PE011-1)制訂，考量本國國情及現況，將部分條文酌修，以符合國內法令之規定，且本規範僅適用人用西藥藥品。

2. 本規範所指批發運銷商係進行藥事法中批發運銷相關活動之我國藥品販賣業者及藥品製造業者。

藥事法第15條:經營西藥批發、輸入及輸出之業者

藥事法第16條:經營藥品之製造、加工與其產品之批發、輸出之業者



我國藥品GDP 規範



第 7 章 委外作業(Chapter 7 Outsourced Activities)

7.1 原則 (PRINCIPLE)

任何本規範所涵蓋之委外作業應清楚界定、同意且管制，以避免發生可能影響產品完整性之誤解。委託者與受託者之間須有書面合約，合約中清楚訂定雙方責任歸屬。

7.2 委託者(Contract Giver)

7.2.1 委託者負責將作業外包。

7.2.2 委託者負責評估受託者確實履行要求之工作能力，確保本規範所闡述之藥品優良運銷規範的原則與指引受到遵循。委外作業開始前及有變更時，應進行受託者之稽核，稽核頻率應基於委外作業之風險予以規範，委託者應可隨時進行稽核。

7.2.3 委託者應提供受託者所有必要的資訊，以使其依照特定之產品要求 及任何其他相關要求，正確履行約定的作業。

7.3 受託者(Contract Acceptor)

7.3.1 受託者應負責GDP 涵蓋範圍及委託者委派之活動。

7.3.2 受託者應有適當的作業場所與設備、程序、知識與經驗及勝任人員，以執行委託者所託付的工作。

我國藥品GDP 規範



第 7 章 委外作業(Chapter 7 Outsourced Activities)

7.3.3 受託者未經委託者事先評估、核准該等安排及稽核第三方(由委託者或受託者執行)前，不得將契約所委託的任何工作轉託給第三方。受託者及任何第三方間所作的安排，應確保批發運銷提供之資料是依照委託者及受託者原約定的方式。

7.3.4 受託者應避免對受託處理之產品品質可能造成不良影響的任何活動。

7.3.5 受託者必須依照合約要求，向委託者提交任何可能影響產品品質之資訊。

➤ 藥品運銷相關活動之委/受託商其相關委託活動在雙方合作前，應依程序執行評估並核准，依風險考量對受託商執行稽核，且合格受託商需定期評估其作業是否符合法規與合約規範。

➤ 藥品品質管理涵蓋整個藥品生命週期，要確保藥品在儲存、運輸與配送的過程中之委/受託商保證藥品品質及維持包裝完整性。

我國藥品GDP 規範



委外作業之委/受託商評估核准與管理流程

Step 1

建立委外作業管理流程/SOP : GDP條文1.2, 1.3

Step 2

明瞭供應鏈委外需求

Step 3

收集相關資料

我國藥品GDP 規範



委外作業之委/受託商評估核准與管理流程



委/受託商評估核准與管理流程

Step 1

建立委外作業管理流程/SOP：品質系統應擴大到任何關於藥品採購、儲存、供應、輸入或輸出之委外作業的管制及審查。此流程/SOP應納入品質風險管理並包含：

- 評估受託者執行活動之適任性與能力、藥品保存之完整性與安全性及文件維護，必要時檢查許可及市場狀態；
- 定期監測及審查受託者的績效，並識別及執行任何必須改善之處。

Step 2

明瞭供應鏈委外需求：依需求執行全面/分段委託。

委/受託商評估核准與管理流程

Step 3

收集相關資料:

受託商的適當性、能力及可靠性: 營利事業登記項目/工廠登記/許可執照/相關證照(GxP/ISO...)/運銷許可、品質系統/人力配置/設施設備/作業程序、地理位置/周邊環境、特殊要求...

➤問卷評估(範例)或訪談

- 參照GDP條文設計
- 依委託內容設計

➤風險評估以選擇適當的受託商進一步評估。

委/受託商評估核准與管理流程

Good Distribution Practice Questionnaire

Name of Company	XXXX Inc.		
Address	XXXXXXXX, Taiwan, ROC		
Completed By	XXXXXX (Print Name)	(Signature)	
Title	XX Manager	Date	xxxx-xx-xx

1. Quality Management

General Requirements

		Yes	No
1	Hold required Business /Wholesale license for distribution of medicines/medical devices	v	
2	Hold other certification (e.g. ISO 9001)	V (ISO9001, ISO13485)	
3	Hold valid license as per local regulatory requirement for performing redressing of products (if required by country regulation)	V (GMP Certificate & Approval Letter)	
4	Hold a current commercial agreement with XXXXX.		v
5	Maintain a documented Quality Management System which covers storage, distribution and redressing (if applicable).	v	
6	System for managing Deviation	v	
7	System for managing Change Control	v	
8	System for managing Corrective Correction and Preventive Correction (CAPA)	v	
9	System for Product Complaint Handling	v	
10	System for facility and equipment validation/qualification	v	
11	System for managing contract service providers (e.g. audit of service provider, contract with service provider)	v	

Required Documents

		Yes	No
1	Current Business/Wholesale license	v	
2	Current ISO certificate	v	
3	Document control Standard Operating Procedure (SOP) and Record	V (SOP X105)	
4	Deviation Management SOP and Record	V	

Good Distribution Practice Questionnaire

		Yes	No
		(SOP E129)	
5	Change Control Management SOP and Record	V (SOP E119)	
6	CAPA Management SOP and Record	V (SOP X109)	
7	Complaint Handling SOP and Record	V (SOP W102)	
8	Validation SOP, Protocols and Reports, where appropriate	V (SOP E125)	

Comments: SOP number referred to XX SOP number(See attachment of SOP List).

2. Personnel and Training

General Requirements

		Yes	No
1	An adequate number of qualified, experienced personnel. How many staff in QA Department? <u>QA 5 staffs and QC 3 staffs</u>	v	
2	A nominated, named person responsible for the control and operation of the Quality System Name of Responsible Person (RP): Mr. Chang XXXX Job title: QA Manager	v	

Required Documents

		Yes	No
1	Organization chart	v	
2	Job descriptions including roles & responsibilities of the RP	v	
3	Training SOP and Records (inclusive of effectiveness assessment)	V (SOP X111)	

Comments: SOP number referred to XX SOP number(See attachment of SOP List).

3. Documentation and Record Retention

General Requirements

		Yes	No
1	System for control of Standard Operation Procedure (SOP), Form and Work Instruction	v	
2	Document controller responsible for managing the documentation system	v	
3	Computer records secure and protected from unauthorized access and changes to data	v	
4	Computer records with backup system	v	

委/受託商評估核准與管理流程

Good Distribution Practice Questionnaire

Name of Company	XXXX Inc.		
Address	XXXXXXXX, Taiwan, ROC		
Completed By	XXXXXX (Print Name)	(Signature)	
Title	XX Manager	Date	xxxx-xx-xx

1. Quality Management General Requirements

1	Hold required Business /Wholesale license for distribution of medicines/medical devices	Yes v	
2	Hold other certification (e.g. ISO 9001)	V (ISO9001, ISO13485)	
3	Hold valid license as per local regulatory requirement for performing redressing of products (if required by country regulation)	V (GMP Certificate & Approval Letter)	
4	Hold a current commercial agreement with XXXXX.		v
5	Maintain a documented Quality Management System which covers storage, distribution and redressing (if applicable).	v	
6	System for managing Deviation	v	
7	System for managing Change Control	v	
8	System for managing Corrective Correction and Preventive Correction (CAPA)	v	
9	System for Product Complaint Handling	v	
10	System for facility and equipment validation/qualification	v	
11	System for managing contract service providers (e.g. audit of service provider, contract with service provider)	v	

Required Documents

		Yes	No
1	Current Business/Wholesale license	v	
2	Current ISO certificate	v	
3	Document control Standard Operating Procedure (SOP) and Record	V (SOP X105)	
4	Deviation Management SOP and Record	V	

- Quality Management
- Personnel and Training
- Documentation and Record Retention
- Premises & Equipment
- Transport and Delivery
- Stock Management
- Returned Goods and Recall
- Third party management
- Self Inspection
- Counterfeit Products
- Product destruction
- Cold chain management
- Business continuity plan
- EHS compliance
- Controlled substance

委/受託商評估核准與管理流程

Good Distribution Practice Questionnaire

List of attachment

1	Current Business/Wholesale license(Sales Authorization, GMP Certificate & Approval Letter, GMP Certificate for Pharmaceutical products)
2	Current ISO certificate(ISO9001 & ISO13485)
3	Organization chart
4	Job descriptions including roles & responsibilities of the RP
5	Quality Manual
6	SOPs/Forms Master Index- SOP List
7	Map of storage areas- layout

Comments: It is our general policy that we do not share SOPs and pertaining records that may be considered as intellectual property. The SOPs and pertaining records are in place for your on-site inspection.

委/受託商評估核准與管理流程

Step 4

受託商之評估與核准:

- 委外作業開始前及有變更時，應進行受託者之稽核，稽核頻率應基於委外作業之風險予以規範。
- 品保單位核准所有可能影響符合本規範之轉委託作業。合約商核准評估表(範例)。
- 作業場所非直接由批發運銷商營運時，應具備書面委託合約。該合約委託之作業場所應符合國內法令之要求。除簽訂業務服務合約，另應包括品質合約(範例)。
- 建立合格商名單(範例)納入監測及審查; 分級分類管理。

Step 5

受託商執行受託作業:

- 委託商如有特殊指示或作業需求，執行作業前應對受託者完成特定訓練。
- 受託之作業有變更時，應有變更管制，經委託商核准。
- **Gemba Walk** 現場走動管理 (範例)。

委/受託商評估核准與管理流程

合約商核准評估表 (範例)

TAIWAN.1

Approval and Control Check List核准評估表 Contract Logistic Service Provider

#.1	Topic.1		Comment / Remarks / Answers (supporting docs).1
1.1	Company Overview.1	公司概述.1	
	Ownership.1	倉庫所有權.1	.1
	Sites, Facilities (addresses).1	場站.1	.1
	Other businesses.1	其他業務.1	.1
	(% of pharmaceuticals of total business).1	藥品佔所有業務的比例.1	.1
2.1	Organization.1	組織.1	
	# of personnel.1	員工.1	.1
	Organization chart.1	組織圖.1	.1
	Job descriptions.1	職務說明書.1	.1
	Working hours.1	配送服務時間.1	.1
	QA organization.1	品保組織.1	.1
3.1	Accreditations.1	任命.1	
	Government licenses (dates, copies).1	政府執照.1	.1
	ISO certified (dates, copies).1	國際標準組織認證.1	.1
	Last ZPI audit.1	上一次裕利公司的稽核.1	.1
	Other government audits (dates, copies).1	其他的政府機關稽核.1	.1
	GDP or GSDP certified?.1	是否有 GMP 或 GSDP 認證?.1	.1
	Quality Systems.1	品質系統.1	
	Quality manuals.1	品質手冊.1	.1

範例

由品保核准

委/受託商評估核准與管理流程

合格商名單(範例)

The Qualitified Supplier Catalogue 合格供應商名單

分級 Classification	狀態 Status	廠商 Supplier	聯絡資訊 Contact information	地址 Address	服務項目 Services/Products
I	A	Hs			運輸 Delivery A.C. Products+non-A.C. Products+Cold Chain Products (Pharma/OTC/Devices/Others)
I	A			123樓	運輸 Delivery A.C. Products+non-A.C. Products+Cold Chain Products (Pharma/OTC/Devices/Others)
II	A	Y			運輸 Delivery Cold Chain Products (CDC Vaccine)
II	A	F		樓	運輸 Delivery (Support type) A.C. Products+non-A.C. Products+Cold Chain Products
II	A				運輸 Delivery non-A.C. Products (Milk Powder)
II	A	Ti		1號3	溫度計校正 Temperature Calibartion
II	A				磅秤校正 Scale Calibartion
II				6號	保麗龍 Styrofoam Box
II					蓄冷劑 Coolant
II					蟲害管制 Pest Control
II					捕蚊燈 Mosquito Light Trap
II					機電設備統包商 Facilities Maintenance
II	A			1號	機電設備商/打點式記錄器校正 Facilities Maintenance / Dot Recorder Calibartion
II	A				貼紙 Sticker
II	A	Jye-Daw Human Resource Corp.		2號	臨時人力公司 Temporary Manpower

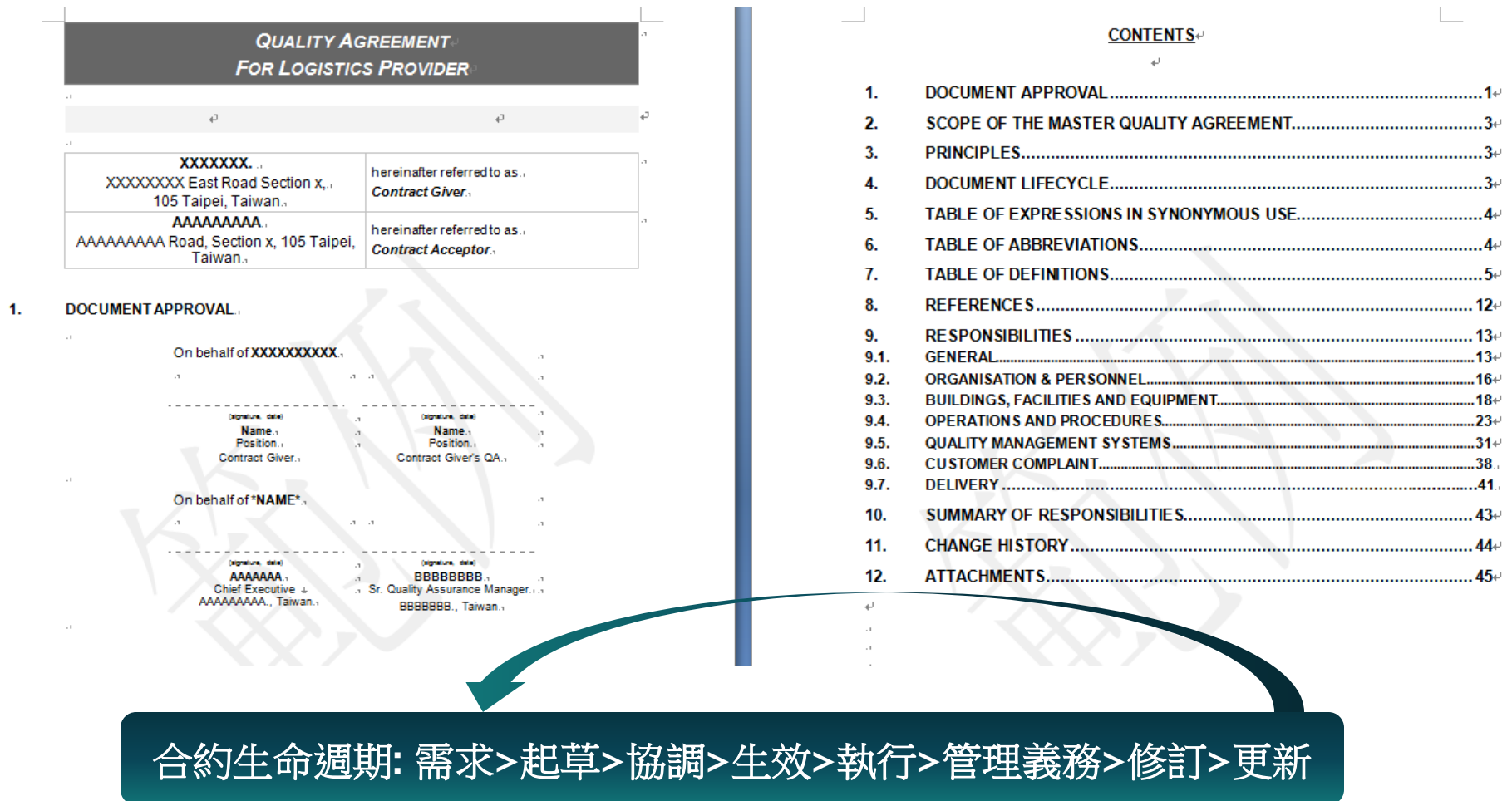
分級分類管理

範
例

Approved by/Date:

委/受託商評估核准與管理流程

物流品質合約(範例)



委/受託商評估核准與管理流程

運輸品質合約(範例)

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1. Purpose/Scope 主旨/範圍

Purpose 主旨

The purpose of the Quality Agreement is to ensure that the roles and responsibilities and expectations are clearly defined with respect to xxxxx Taiwan and Applicable Laws.

本品質協議書旨在明確規範與 xxxxxx 有關之職責、義務與期待及相關法律。

Scope 範圍

Parties to the agreement 協議書之簽約雙方

This Quality Agreement is by and between xxxxxxxx Taiwan with office at <10F- xxx, xxxxxxxx RD. Sec. 4, Taipei 105, Taiwan, R.O.C>, hereafter referred to as **Contract Giver** and <xxxxxxxxxx Service Co., Ltd> with office at <xxxxxxxxxxxxx, Sec. 2, Nankan RD., xxxxxx Township, xxxxx County xxx, Taiwan, R.O.C>, hereafter referred to as **Contract Acceptor**. Whereas, **Contract Acceptor is responsible for Quality in the services and provision of Quality products for Contract Giver.**

本份文件係公司地址位於 <xxxxxxxxxxxxx 號 10 樓> 之 xxxxxxxx，以下稱**合約給與者**；與公司地址位於 <xxxxxxxxxxxxx 號 1 樓> 之 <xxxxxxxxxxxxx 有限公司>，以下稱**合約接受者**，雙方簽訂之品質協議書。有鑑於此，合約接受者負責為合約給與者提供優質服務及優質產品。

Specify Services and Products covered by agreement
協議包含之特定服務與產品

This agreement pertains to the following < Delivery > hereafter referred to as Services and Products: <list or see attachment>.
與本協議書相關之下列 <貨品運輸>，以下通稱服務及產品：<參閱清單或附件>。

明定績效指標

委/受託商評估核准與管理流程

Gemba Walk現場走動管理(範例)- 檢查表

Warehouse Inspection Checklist		Page 1
FACILITY INFORMATION		Date: 2015-mmm-dd
Name of Warehouse: XXXXXXXXXXXXXXXXXX	Country: Taiwan	Location: xxxxx
INSPECTED BY:		
xxxx staff: (name)	Warehouse Rep: (name): Mr Wang	
ELEMENT	Y/N/NA	COMMENTS / HAZARD
Y = Up to standard (adequate), N = Below standard (action required), NA = Not Applicable		
1 LAYOUT		
1.1 Area is tidy and well kept (designated areas for storage of stock and equipment, trip hazards removed, rubbish bins provided, walkways clear).	Y	5S are implemented SOP# 4130 Warehouse Cleaning
1.2 Adequate storage space is provided	Y	
1.3 Floor is free of obstructions and in good condition, trip hazards such as (not tripped over) (floor in removal from walkways, etc)	Y	
1.4 Any opening in the floor are guarded or covered (manhole and drain covers in place)	N	
1.5 Aisles are sufficiently wide for vehicular traffic and clearly marked (signage indicating direction of travel, traffic management safety messages such as speed limits, fixed safety	Y	Comments by XXXXX 1. Aisles are occupied by stocks in receiving/staging

Gemba Walks denote the action of going to see the actual process, understand the work, ask questions, and learn.

委/受託商評估核准與管理流程

Step 6

受託商之監督與管理:

- 定期報表
- 定期會議/會議記錄
- 定期盤點
- 定期監控報告(範例)
- 績效(KPI)評估(範例)
- 委託商自我查核
- 定期/不定期稽核受託商與 CAPA成效追蹤
- 定期審閱委/受託合約

委/受託商評估核准與管理流程

定期監控報告(範例)- 冷鏈運輸

DELIVERY MONTHLY MONITORING TEST

Description of the temperature-recording device:

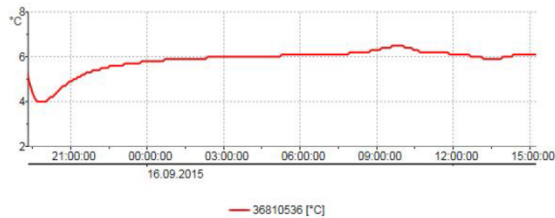
Brand	Device serial number	Next calibration due on:
TESTO	36810536	2016 April

Temperature put in time	1
Put in person	2

Test information	Test date	1
	P/S number	5
	Delivery by	2
	Location being monitored:	4
	Customer	6
	Time of departure	1
Products arrive time	1	

範
例

TEMPERATURE

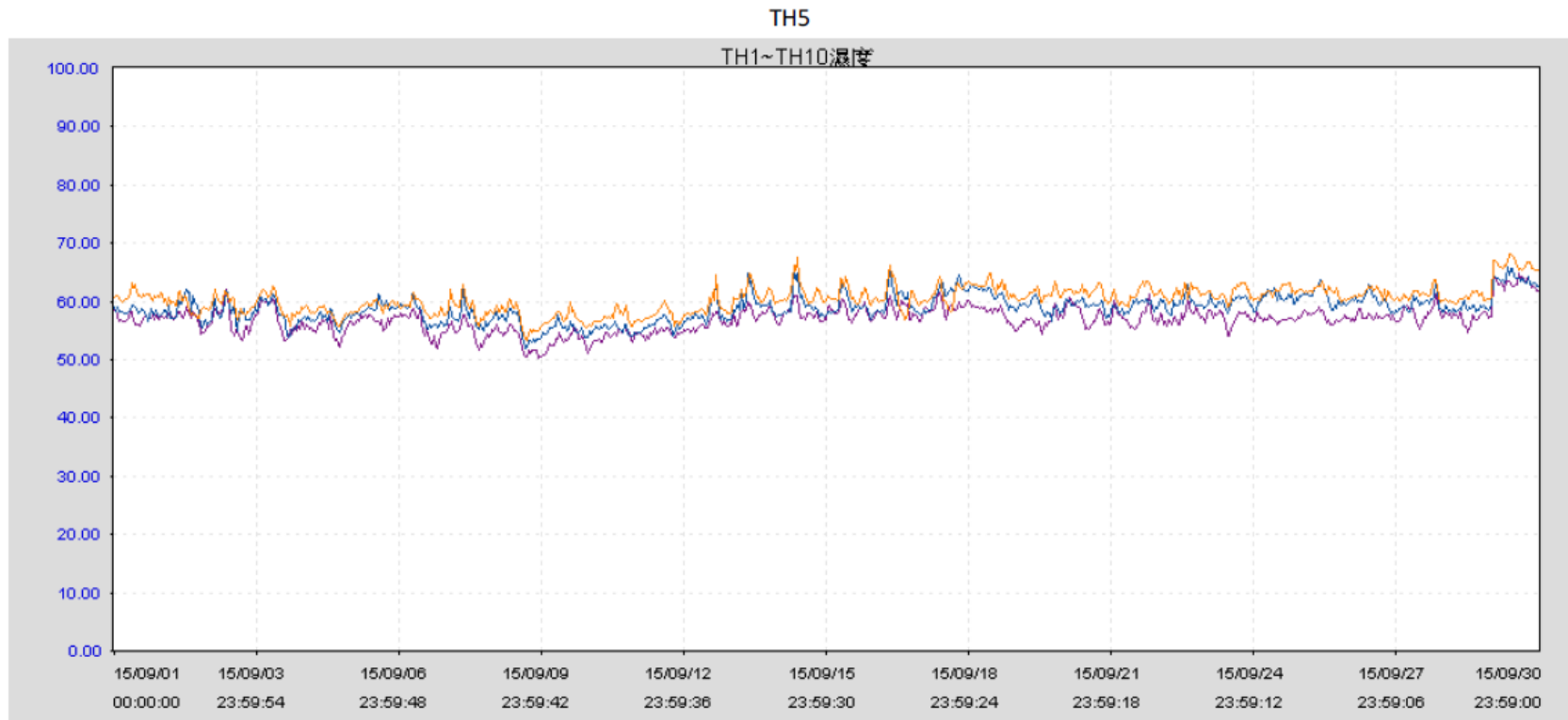


日期/时间	36810536 [°C]
2015/9/15 下午 07:22:00	4.9
2015/9/15 下午 07:27:00	4.6
2015/9/15 下午 07:32:00	4.3
2015/9/15 下午 07:37:00	4.1
2015/9/15 下午 07:42:00	4
2015/9/15 下午 07:47:00	4
2015/9/15 下午 07:52:00	4
2015/9/15 下午 07:57:00	4
2015/9/15 下午 08:02:00	4
2015/9/15 下午 08:07:00	4.1
2015/9/15 下午 08:12:00	4.2
2015/9/15 下午 08:17:00	4.2
2015/9/15 下午 08:22:00	4.3

2015/9/15 下午 08:27:00	4.4
2015/9/15 下午 08:32:00	4.5
2015/9/15 下午 08:37:00	4.6
2015/9/15 下午 08:42:00	4.7
2015/9/15 下午 08:47:00	4.7
2015/9/15 下午 08:52:00	4.8
2015/9/15 下午 08:57:00	4.9
2015/9/15 下午 09:02:00	4.9
2015/9/15 下午 09:07:00	5
2015/9/15 下午 09:12:00	5
2015/9/15 下午 09:17:00	5.1
2015/9/15 下午 09:22:00	5.1
2015/9/15 下午 09:27:00	5.2
2015/9/15 下午 09:32:00	5.2
2015/9/15 下午 09:37:00	5.3
2015/9/15 下午 09:42:00	5.3
2015/9/15 下午 09:47:00	5.3
2015/9/15 下午 09:52:00	5.4
2015/9/15 下午 09:57:00	5.4
2015/9/15 下午 10:02:00	5.4
2015/9/15 下午 10:07:00	5.4
2015/9/15 下午 10:12:00	5.5
2015/9/15 下午 10:17:00	5.5
2015/9/15 下午 10:22:00	5.5
2015/9/15 下午 10:27:00	5.5
2015/9/15 下午 10:32:00	5.6
2015/9/15 下午 10:37:00	5.6
2015/9/15 下午 10:42:00	5.6
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2015/9/15 下午 10:52:00	5.6
2015/9/15 下午 10:57:00	5.6
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2015/9/15 下午 11:47:00	5.8
2015/9/15 下午 11:52:00	5.8
2015/9/15 下午 11:57:00	5.8
2015/9/16 上午 12:02:00	5.8
2015/9/16 上午 12:07:00	5.8
2015/9/16 上午 12:12:00	5.8
2015/9/16 上午 12:17:00	5.8
2015/9/16 上午 12:22:00	5.8
2015/9/16 上午 12:27:00	5.8
2015/9/16 上午 12:32:00	5.8
2015/9/16 上午 12:37:00	5.8

委/受託商評估核准與管理流程

定期監控報告(範例)- 倉儲環境



委/受託商評估核准與管理流程

運輸品質KPI(範例)

Contract acceptor

受託者

No	KEY PERFORMANCE INDICATOR		Target	MM-YY	MM-YY	MM-YY	MM-YY	MM-YY	MM-YY	MM-YY	MM-YY	MM-YY
編號	關鍵績效指標		目標	2013年/1月	2013年/2月	2013年/3月	2013年/4月	2013年/5月	2013年/6月	2013年/7月	2013年/8月	2013年/9月
1	Delivery Achieving Rate 運送達成率	Packages must be delivered by the next day to customers based in major towns. Delivery to remote areas must be completed by day 3. 包裹必須在次日送交至主要城鎮的客戶。偏遠地區必須在第三日送交。	99%	99.8%	99.6%	99.6%	99.6%	99.7%	99.5%	99.6%	99.6%	99.7%
2	Delivery Error 運送錯誤	Measures delivery accuracy>Orders delivered to correct customers 評鑑運送準確率>訂單送交正確客戶。	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	0.0%
3	Submission KPI 提交KPI	Must be submitted before 7 th each month 必須每月七號前提交KPI。	100%	0.0%	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
4	Cold Room 冷藏室	Transit condition of cold chain product: maintain at 2-8 C 冷鏈產品的運輸情況：維持攝氏2-8度。	100%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
5	QA Report 品質管制(QA)報告	Monthly delivering temperature monitoring report for cold chain products delivered to north, central, south, and east of Taiwan during transportation must be submitted before 7th next month 運送至台灣北、中、南及東部的冷鏈品運輸途中的月份運送溫度監測報告，必須在每月七號前	100%	0.0%	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
6	Change Control 變更控制	Must inform Contract giver QA prior to changes potentially affecting GDP or product quality 變更可能影響GDP或產品品質的措施，變更之前必須先行告知委託者品質部。	100%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

範例

委/受託商評估核准與管理流程

物流服務KPI(範例)

				DISTRIBUTION PERFORMANCE INDICATOR 2015											
3	Order Entry Accuracy	Complaint cases	99.6%	100.0%	100.0%	100.0%	100.0%	100.0%	99.99%	100.00%					100.0%
		XX error		99.96%	99.94%	99.9%	99.99%	99.99%	99.97%	99.975%				100.0%	
4	Picking Accuracy		99.5%	99.99%	100.0%	99.99%	100.00%	100.00%	100.00%	100.00%					100.00%
5	Delivery Performance														
5.1	Urgent orders (Including, but not limited to Onco/Transplant)- within 24 hours upon receipt of order or as per specific time required by customer		98.0%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%					100.00%
5.2	With Taiwan Island (exclusive of Remote Area) - 1-2 working days upon receipt of order			100.00%	100.0%	100.00%	100.00%	100.0%	100.0%	100.0%					100.00%
5.3	Outside of Taiwan island and remote area - 3-4 working days upon receipt of order			100.00%	100.0%	100.0%	100.0%	99.9%	100.0%	99.9%					99.98%
6	Flat file accuracy		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%					100.00%
7	Monthly Reconciliation of inventory balances		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%					100.00%
8	Customer Complaints														
8.1	1st response to Customers - within 2 days after the customer complaint is received by XX.		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%					100.0%
8.2	Problem solved/clarified - within 5 days after the customer complaint is received by XX.		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%					100.0%

問題與討論

Q & A

- The End -