

訪查前準備重點及經驗分享-專業物流



Distribution Centre of DKSH Taiwan
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DKSH

Agenda

- Introduction of DKSH
- Responsibility of PIC/s GDP Execution
- How to Prepare PIC/s GDP Inspection
- Experiences Sharing for Actual Practices
- Conclusion

Introduction of DKSH

A culture of quality, integrity and trust



Swiss reliability...



...and Asian can-do attitude

Publicly listed with a focus on long-term sustainable growth

High compliance, transparency and reporting requirements

Committed to quality through dedicated teams and regular audits

We are a professional partner for the long run

Warehousing and Transportation



Distance



Capability of Controlling Temperature

Storage



Picking



Packing



Delivery

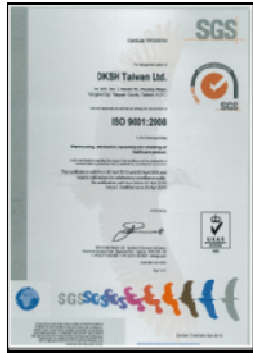


Customer



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Quality is embedded in all DKSH HEC DKSH



ISO 9001:2008



ISO 13485:2003



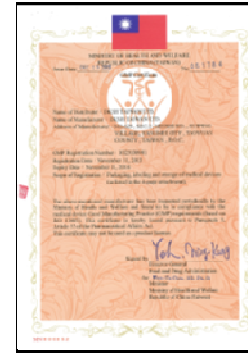
WHO GDP



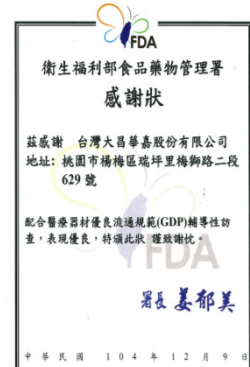
TFDA PICS GDP



TFDA PICS GMP



TFDA MD GMP



TFDA MD GDP

Before 2008

- cGMP Certified by TFDA

2009

- WHO GDP/GMP certified by SGS

2010

- TFDA cGMP renewal certification
- ISO 9001:2008 certified by SGS
- ISO 13485:2003 certified by SGS

2012

- PICS/GMP certified by TFDA
- PICS GDP audit by TFDA for LTDC

2013

- Medical Device GMP certified by TFDA

2014

- PIC/S GDP audit by TFDA for Depots

2015

- Medical Device GDP certified by TFDA

Responsibility of PIC/s GDP Execution

PIC/s GDP Responsibility



- Not Only **License Holder** but also **Distributor** should be Compliant with PIC/s GDP.

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主旨：有關**持有西藥製劑藥品許可證之販賣業藥商**應符合「西藥藥品優良製造規範（第三部：運銷）」，詳如說明段，請查照。

How to Prepare PIC/s GDP Inspection

PIC/s GMP Part I vs PIC/s GDP



Chap	PIC/s GMP Part I	PIC/s GDP
1.	Quality Management	Quality Management
2.	Personnel	Personnel
3.	Premises and Equipment	Premises and Equipment
4.	Documentation	Documentation
5.	Production	Operations
6.	Quality Control	Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls
7.	Contract Manufacture and Analysis	Outsourced Activities
8.	Complaints and Product Recall	Self-Inspections
9.	Self-Inspection	Transportation

Methodology for PIC/s GDP Inspection DKSH

- Gap Analysis of PIC/s GDP Guideline Adaptation
- Schedule for Preparing PIC/s GDP Inspection

Experiences Sharing for Actual Practices

For Contract Giver (License Holder)

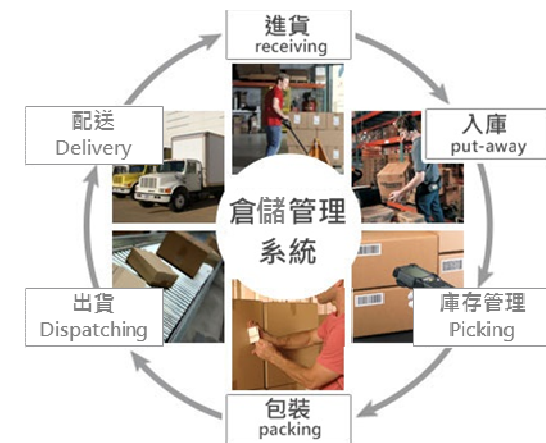


- PIC/s GDP Management System (Refer to PIC/s GMP)
- Vendor/Supplier Qualification
- Contract

For Contract Acceptor (i.e. DKSH)



- PIC/s GDP Management System (Refer to PIC/s GMP)
- Contract
- Hardware Construction
- Warehousing
- Transportation



Conclusion



- Not Only **License Holder** but also **Distributor** should be Compliant with PIC/s GDP.
- Selected the Suitable, Reliable and **Qualified Distributor** when Outsourced Activities Needs.
- Besides Jesus, All Things Bring Data.

Thank you for your attention

150
YEARS OF MARKET
EXPANSION
SERVICES



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