PSB Singapore

Distributing Safe and Effective Medical Devices:

A Certification Body's Perspective of Singapore's GDPMDS

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Introduction

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Good Distribution Practice for Medical Devices (GDPMDS): Background

- Part of Singapore's legislature for medical devices
- Quality Management system requirements
- Controls distribution phase
- Compliance determined via third party certification

Introduction

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GDPMDS: Objective

"…to assist in ensuring the quality and integrity of medical devices throughout the distribution process…"

Foreword
Health Sciences Authority publication, Good Distribution Practice – Requirements, TS-01-R2 effective October 15 2010

Introduction

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Processes subject to control:

- Handling
- Storage
- Delivery
- Installation
- Servicing
- Secondary assembly

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The 3rd Party Certification Body:

- Accreditation by Singapore Accreditation Council
- Recognition by Health Sciences Authority

The Requirements

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Clause 2: Quality Management System

- Required documents and records
- Control of documents
- Control of records

The Requirements

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Clause 2: Quality Management System

Requirements specific to GDPMDS

- Site Master File
- Retention period of distribution records

The Requirements

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Clause 3: Resource Management

- Personnel
- Facilities and Premises

The Requirements

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Clause 3: Resource Management

Requirements specific to GDPMDS

- Defined competence of key personnel in charge of warehouse operations
- Cleaning and pest control requirements

The Requirements

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Clause 4: Storage and stock handling

- Receipt of stock
- Calibration of equipment used
- Storage
- Distribution
- Installation and servicing

The Requirements

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Clause 4: Storage and stock handling

Requirements specific to GDPMDS

- Record of storage conditions
- Stock rotation

The Requirements

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Clause 5: Traceability

Requirement specific to GDPMDS

- Maintenance of distribution records for the lifetime of the device but not less than 2 years from the date of shipment.

The Requirements

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Clause 6: Medical device complaints

Requirements specific to GDPMDS

- Maintenance of records of complaints, investigation and subsequent action(s)
- Reporting of adverse events

The Requirements

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Clause 7: Field Safety Corrective Actions (FSCA)

Requirements specific to GDPMDS

- Documented procedures for handling of FSCA
- Recommendation to use ISO 14971

The Requirements

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Clause 8: Return of Medical Devices

Requirement specific to GDPMDS

- Establishment of criteria for re-evaluation of returned medical devices

The Requirements

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Clause 9: Disposal of Medical Devices

Requirement specific to GDPMDS

- Documented procedures for the disposal of medical devices

The Requirements

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Clause 10: Counterfeit, Adulterated, Unwholesome and Tampered Medical Devices

Requirements specific to GDPMDS

- Segregation of such medical devices once found
- Informing competent authority, registrant and product owner

The Requirements

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Clause 11: Internal Audit

Clause 12: Management Review

- Comparable to ISO 13485

The Requirements

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Clause 13: Outsourced processes

Requirement specific to GDPMDS

- Inclusion of supplier into internal audit unless supplier is GDPMDS certified

The Requirements

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Clause 14: Secondary Assembly

Comparable to Clause 7.5.1 of ISO 13485

- Requirements to be applied for processes which are considered to be secondary assembly i.e. a repackaging process which does not breach the primary packaging.

Conclusion

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Post GDPMDS Realities:

1. Quality Management system which is comparabe to ISO 13485 required for distribution of medical devices in Singapore

2. In addition to ISO 13485 requirements, compliance required for GDPMDS requirements specifically established by Singapore legislature.