Good Distribution Practice For Medical Devices (GDPMD) –

From Guideline To Implementation

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Agenda

- What?
- Why?
- Who?
- Where?
- When?
- How?
- What If?
- In a Nut Shell

What?

We are in a “X” industry……

GCP → Good Clinical Practice

GMP → Good Manufacturing Practice

GLP → Good Laboratory Practice

GSP → Good Storage Practice

GDP → Good Distribution Practice

What?

Now, what is GDPMD?

Good Distribution Practice
For Medical Device

Now, what is ISO?

Itu Susahkan Orang

ISO9001 & ISO13485 both have major similarity with GDP

Why?

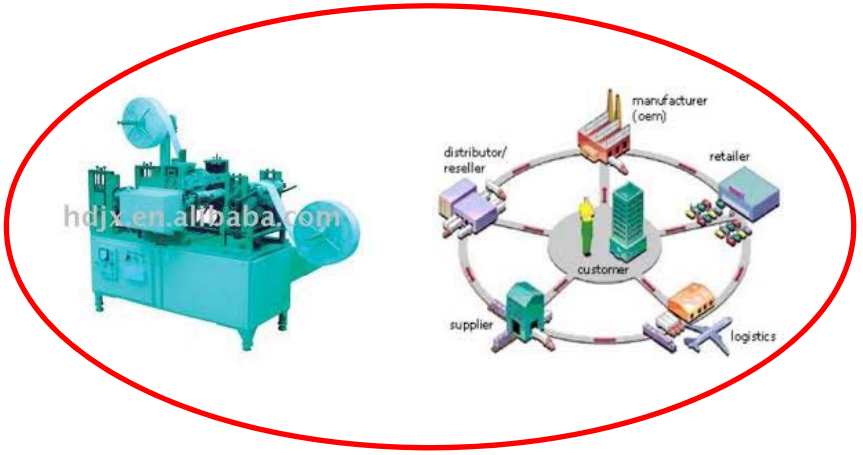
Business version:	so that my competitors will die flat
Supply Chain version:	stock take 10 minutes “kao dim”
Quality version:	nak susahkan orang lagi
Regulatory version:	I always have a job

Regulator’s version:

Ensure the quality, safety and performance of medical device during all aspects of medical device supply-chain, which include, but not limited to, product sourcing and procurement; transportation and delivery; storage; installation, commissioning, service and maintenance, calibration and after sales service; tracking, documentation and record-keeping practices.

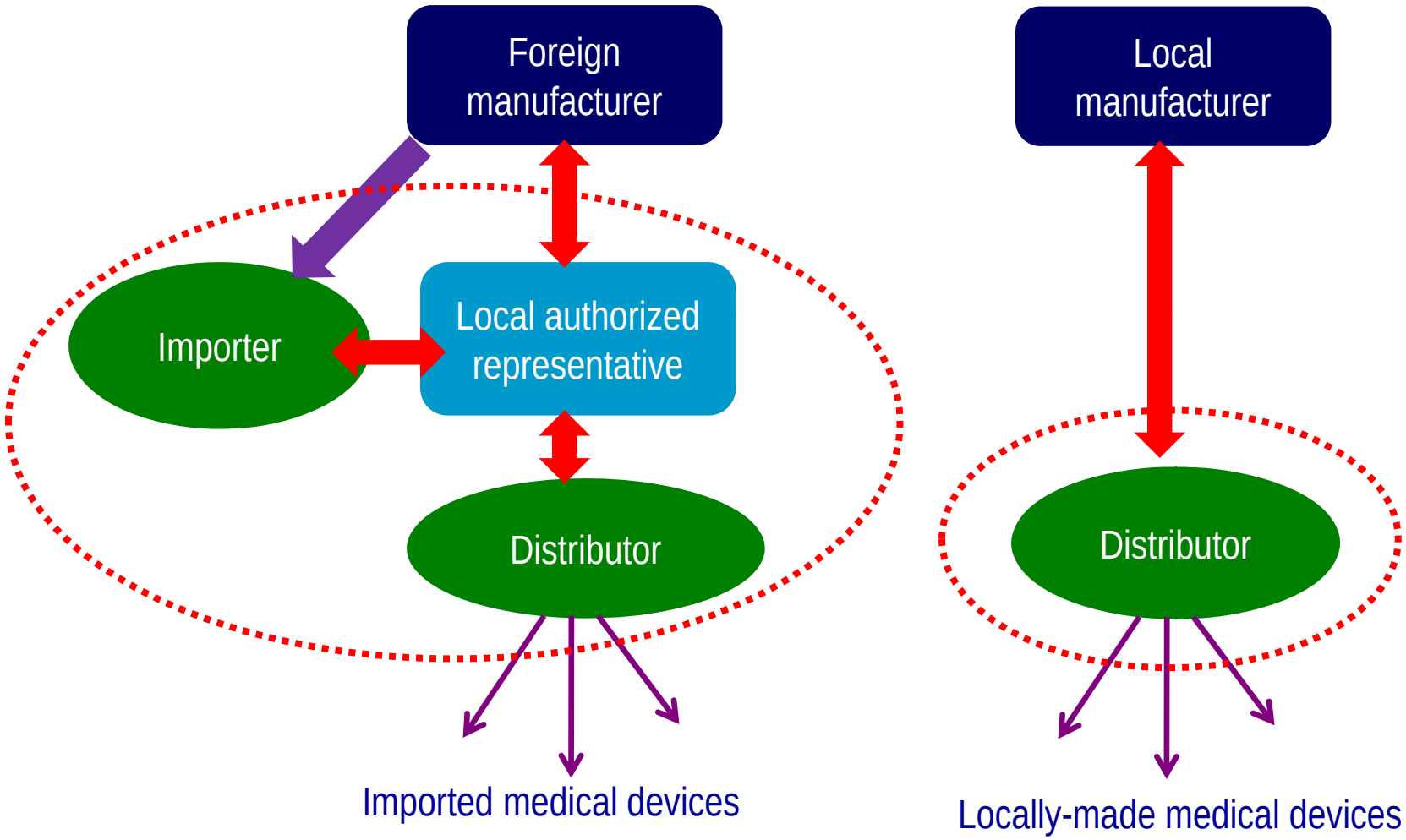
Malaysia GDPMD, version 1, July 2013

Who?



and everyone in the company that has involvement in supply chain activity of a medical device

Who?



Where?

LAR's office

Warehouse

Distributor

When?

MEDICAL DEVICE ACT 2012

APPOINTMENT OF DATE OF COMING INTO OPERATION

IN exercise of the powers conferred by subsection 1(2) of the Medical Device Act 2012 [*Act 737*], the Minister appoints 30 June 2013 as the date on which the Act comes into operation.

Dated 15 April 2013
[KK(R)-619(309) JLD. 4; PN(U2)2533/IV]

DATO' SRI LIOW TIONG LAI
Minister of Health

(2) A person who, prior to the appointed date, has been importing, exporting or placing in the market medical devices and intend to continue importing, exporting or placing in the market such medical devices shall, within twelve months from the appointed date, apply for an establishment ~~licence under section 16~~.

(3) A person referred to in subsection (1) or (2) may continue to import, export or place in the market the medical devices pending determination of its application for registration of a medical device or for an establishment licence, as the case may be.

How?

The organization shall establish, document, implement and maintain a QMS (quality management system) and maintain its effectiveness in accordance to the requirement of GDPMD (Good Distribution Practice for Medical Devices).

Where an organization choose to outsource any activities that may affect the quality of medical devices, the organization shall ensure control over such processes.

How?

Establish & document = documentation

Example: Standard Operation Procedure (SOP), Work Instruction (WI).

Implement & Maintain = record

Example: training record, distribution record.

Ensure control over such process =

- Responsibility segregation
- SOPs / WIs & record
- Verification / audit

How?

Do What You Say
Say What You Do

How?

1. Prepare:
    1. Interpret 251 clauses in GDPMD (Appendix 4 of Schedule 3 of Medical Device Regulation 2012)
    2. Map process internally
    3. Say what you will do → create documents (SOP, WI)
    4. Do what you have said → execute and maintain what is documented
2. Get audited by CAB (Conformity Assessment Body)
3. Submission to MDA (Medical Device Authority) via MedCast (Medical Device Centralized Online Application System)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
2					Organization and GDPMD Regulatory Compliance System		
2	4				Organization: The Establishment shall –		
2	4		i	HR	define the organization structure with the aid of an organizational chart and indicate the responsibility, authority and interrelationship of all key personnel;	Org chart	If organization has more than medical device (MDV) operation, limit this to MDV related only
2	4		ii	HR	define the duties and responsibilities with written job descriptions for every level of the organization;	JD, Responsibility & Authority	For every personnel involve in MDV operation
2	4		iii	HR	ensure managerial and technical personnel have the authority and resources needed to carry out their duties; and	JD, Responsibility & Authority	Have complete coverage on each and every role needed to support MDV operation, not leaving any role empty
2	4		iv	QA	set up and maintain a GDPMD regulatory compliance system and identify and correct deviations from the established system.	GDPMD Quality & Regulatory Manual	To specify entire QMS (Quality Management System) in supporting MDV operation
2	5				General: The Establishment shall –		
2	5		i	QA	establish, document and implement a GDPMD regulatory compliance system and maintain its compliance with the regulatory requirements;	GDPMD Quality & Regulatory Manual	To explain entire QMS (Quality Management System) correspond to GDPMD section / clauses.
2	5		ii	QA	identify the processes needed for the GDPMD regulatory compliance system and their application for all categories of medical devices, regardless of the type or size of the organization;	GDPMD Quality & Regulatory Manual	To address each process identified to support MDV operation

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
2	5		iii	QA	determine the sequence and interaction of these processes;	GDPMD Quality & Regulatory Manual	A map to clearly show interaction of processes
2	5		iv	QA	determine criteria and methods needed to ensure that both the operation and control of these processes are effective in ensuring compliance;	Document Management System	A Master Document List to show operation and control for each process is specified in certain document (SOP/WI/Std)
2	5		iv	QA	-ditto-	Change Control	To address procedure in managing change (document and process) including deviation of process
2	5		iv	QA	-ditto-	Internal Audit	Periodic internal audit to ensure processed are aligned to documents, internal auditors need to be trained and free from conflict of interest
2	5		v	HR	ensure the availability of resources and information necessary to support the operation and monitoring of these processes;	Training Needs Identification & Analysis	No empty role unfilled. Each role must be able to show training record that the PIC is clear and trained and provided with sufficient info
2	5		vi	QA	monitor, measure and analyze these processes;	Management Review	Periodic management review to analyse the effectiveness and efficiency of processes and compliance to GDPMP
2	5		vii	QA	implement actions necessary to achieve planned results and maintain the effectiveness of these processes to ensure compliance;	Records	Must be able to show records of execution of any process specified in any document, including duration for records keeping.

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
2	5		viii	QA	manage the processes in accordance with the regulatory requirements; and	Records	Same as Part 2, Sec 5 (vii)
2	5		ix	Sourcing	identify and control outsourced processes in accordance with the regulatory requirements.	Vendor Selection	To identify vendor qualifying process & criteria
2	6				Documentation		
2	6	1			The establishment shall establish and maintain a Regulatory Compliance Manual which shall include the following information—		
2	6	1	i	QA	establishment's profile, activities/operations, compliance to medical device regulatory requirements and obligations of the establishment, including those outsourced processes or activities/operations;	GDPMD Quality & Regulatory Manual	To specify entire QMS (Quality Management System) in supporting MDV operation
2	6	1	ii	QA	the scope of the GDPMD regulatory compliance system, including details of, and justification for any exclusion and/or non-application;	GDPMD Quality & Regulatory Manual	Specify exclusion clause from GDPMD.
2	6	1	iii	RA	the medical devices it deals with and their status of compliance;	Product Master List	Examples of info included in the List: Product name, Identifier (catalog #), SKU number, Pack size, Classification, Grouping, LAR, Registration# , validity & countries, Manufacturer info, Shelf life, Storage condition.

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
2	6	1	iv	QA	procedures required by GDPMD regulatory compliance system and reference to them;	All SOP/WI etc	Same as Part 2, Sec 5 (iv)
2	6	1	v	QA	documents needed by the establishment to ensure the effective planning, operation and control of processes for compliance; and	Records	Same as Part 2, Sec 5 (vii)
2	6	1	v	QA	-ditto-	Change Control	Same as Part 2, Sec 5 (iv)
2	6	1	v	QA	-ditto-	Internal Audit	Same as Part 2, Sec 5 (iv)
2	6	1	vi	QA	records required by the GDPMD regulatory compliance system;	Records Control	Records retention period must be inline with GDPMD requirement.
2	6	1	vii	RA	information regarding— - the premises where activities are conducted;	GDPMD Quality & Regulatory Manual	Premise address is to be included in the Manual
2	6	1	vii	RA	information regarding— - personnel conducting the activities; and	Organization chart	Same as Part 2, Sec 4 (i)
2	6	1	vii	RA	information regarding— - the medical device conformity assessment and the registration holder;	Product Master List	Same as Part 2, Sec 6 (i) (iii)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
2	6	1	viii	RA	detailed description on how the relevant and applicable regulatory requirements are addressed for each medical device specified in the scope of the GDPMD regulatory compliance system;	Product Master List	Same as Part 2, Sec 6 (1) (iii)
2	6	2			For each type of medical device it deals with, the establishment shall establish and maintain a file containing documents that define—		
2	6	2	i	RA	product specifications and installation qualifications (if applicable);	Product Standard / CSDT	LAR related only
2	6	2	ii	Engineering	-ditto-	Installation manual	
2	6	2	iii	Engineering & Supply Chain	complete distribution process and, if applicable, installation and servicing.	Distribution record	Refer GDPMD Part 6, Sec 39
2	7				Document Control: The Establishment shall –		
2	7	1	i	QA	control the documents required by GDPMD regulatory compliance system; and	Document Management System	Specify the handling of approval, release, distribution, storage, disposal, revision, training of document. Also specify handling of external document, control copy.
2	7	1	ii	QA	establish a documented procedure for the control of documents.	Document Management System	Refer Part 2, Sec 7 (1) (i)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
2	7	2		QA	All documents shall be prepared, approved, signed and dated by an authorized person.	Document Management System	Same as Part 2, Sec 7 (1) (i)
2	7	3		QA	The establishment shall give appropriate authorization on any change on authorized person permitted to carry out the task in sub-clause (2).	Document Management System	Same as Part 2, Sec 7 (1) (i)
2	7	4		QA	When a document has been revised, the control system shall prevent unintended use of the superseded version.	Document Management System	Same as Part 2, Sec 7 (1) (i)
2	7	5	i	QA	The establishment shall— (i) establish and maintain records of GDPMD regulatory compliance system that are legible, readily identifiable and retrievable;	Records Control	Note on the requirement of "legible, readily identifiable & retrievable"
2	7	5	ii	QA	The establishment shall— (ii) establish a documented procedure to define the controls for the identification, storage, protection, retrieval, retention time and disposition of records; and	Records Control	Same as Part 2, Sec 6 (1) (vi)
2	7	5	iii	QA	The establishment shall— (iii) retain the records for a period of time— - specified by relevant regulatory requirements; or - at least equivalent to the lifetime of the medical device product as defined by the product owner of the medical devices; or - no less than two years from the date that the medical device is shipped from the establishment, whichever is the longest.	Records Control	Address the retention time for each type of record. Example of record includes: distribution/inventory, installation, testing & commissioning, calibration, preventive maintenance, assembling process, complaint, recall, management review.

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
3					Establishment Responsibilities		
3	8				Responsibilities and authorities: : The Establishment shall –		
3	8		i	HR	ensure that responsibilities and authorities are defined, documented and communicated within the establishment; and	Job Description	
3	8		ii	HR	establish the interrelation between all personnel who manage, perform and verify works that affect quality, safety and performance of medical device and shall ensure the independence and authority to perform these tasks.	Organization chart	To demonstrate the “interrelation”
3	8		ii	HR	-ditto-	Responsibility & Authority	Should not have conflict of interest
3	9				Designated Person The establishment shall appoint a designated person who shall have the defined responsibility and authority that includes—		
3	9		i	QA	ensuring the GDPMD regulatory compliance system is established, implemented and maintained;	Management Representative (MR) Appointment Letter	A letter to appoint a person to be the MR for the total responsibility of GDPMD
3	9		ii	QA	reporting to top management on the performance of the GDPMD regulatory compliance system, as well as to identify and correct deviations from the established GDPMD regulatory compliance system;	MR Appointment Letter	Same as Part 3, Sec 9 (i)
3	9		iii	QA	ensuring the awareness on obligations to comply with regulatory requirements and any other applicable statutory requirements and any decision thereof made by top management throughout the establishment and supply chain; and	MR Appointment Letter	Same as Part 3, Sec 9 (i)
3	9		iv	QA	liaising with external parties on matters relating to the Malaysian medical device regulatory requirements.	MR Appointment Letter	Same as Part 3, Sec 9 (i)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
3	10				Management review. The management shall—		
3	10		i	QA	review its GDPMD regulatory compliance system at planned intervals, to ensure its compliance to Malaysian medical device regulatory requirements;	Management Review	Same as Part 2, Sec 5 (vi)
3	10		ii	QA	ensure the review includes assessment of the status of compliance and the need for changes; and	Management Review	Must have review conducted on "input" as specified in this clause, also same as Part 2, Sec 5 (vi)
3	10		iii	QA	maintain records of management reviews.	Records Control	Same as Part 2, Sec 6 (1) (vi)
3	11				Review input. The input for management review shall include—		
3	11		i	QA	results of internal and external audits;	Management Review	Including the closure of NCR
3	11		ii	QA	customer complaints/feedback;	Management Review	Complaint closure and trend analysis
3	11		iii	QA	GDPMD regulatory compliance system and medical device compliance;	Management Review	
3	11		iv	QA	surveillance and vigilance activities including field safety corrective actions, advisory notes, recalls and adverse event /incident reporting;	Management Review	Closure and trend analysis

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
3	11		v	QA	feedback from manufacturer;	Management Review	
3	11		vi	QA	feedback and directives from the Authority;	Management Review	
3	11		vii	QA	status of preventive and corrective actions;	Management Review	Closure and trend analysis
3	11		viii	QA	follow-up actions from previous management reviews;	Management Review	
3	11		ix	QA	changes that could affect the GDPMD regulatory compliance system; and	Management Review	
3	11		x	QA	recommendations for compliance.	Management Review	
3	12			QA	Review Output. The output from the management review shall include any decisions and actions related to—		
3	12		i	QA	the corrective and preventive actions required;	Management Review	
3	12		ii	QA	the effectiveness of the GDPMD regulatory compliance system and its compliance with the Malaysian medical device regulatory requirements; and	Management Review	
3	12		iii	QA	resource needs.	Management Review	

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
4					Resource Management		
4	13				Personnel		
4	13	1		HR	Key personnel in charge of managing activities/operations within the scope of the establishment including technical support shall be competent and possesses appropriate professional knowledge, education, training, skills and experience.	Training Needs Identification (TNI) & Training Needs Analysis (TNA)	Must also maintain training records, also same as Part 2, Sec 5 (v)
4	13	2		Sourcing	Skills of personnel providing post market technical support for active medical devices shall conform to the requirements and/or standards recognized by the Authority.	Qualifying specification for Installation, Testing & Commissioning, Calibration & Preventive Maintenance.	Specify the criteria to qualify this vendor.
4	13	3		Sourcing	The establishment shall possess an adequate number of competent personnel involved in all activities/operations in the supply chain of the medical devices in order to ensure the quality, safety and performance of the medical device are maintained.	Qualifying specification for Warehouse & Distribution	Specify the criteria to qualify this vendor.
4	14				Training, competency and awareness. The establishment shall –		
4	14		i	HR	determine the necessary competence for the key personnel;	JD	Specify requirement in JD for the position.
4	14		ii	HR	provide training to satisfy these needs;	TNI	
4	14		iii	HR	evaluate the effectiveness of the training; and	TNA	
4	14		iv	HR	maintain records of education, training, skills and experience.	Records Control	Same as Part 2, Sec 6 (1) (vi)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
4	15				Infrastructure		
4	15	1			The establishment shall determine, provide and maintain the infrastructure needed to achieve conformity to specified requirements which includes, as applicable—		
4	15	1	i	QA	buildings, workspace, workshop and associated utilities;	Environmental Control and Practices	To ensure the environment and facility meets requirement, e.g.: cleanliness, storage condition, dedicated area etc.
4	15	1	ii	Maintenance	tools, measuring and test equipment; and	Preventive Maintenance & Calibration	To ensure tools and equipment used meet the performance requirement by maintaining it and perform calibration if needed
4	15	1	iii	Supply Chain	supporting services (such as transport or communication).	Warehouse & Shipping	To ensure specification affects device performance, safety & quality is communicated, e.g.: specific transportation condition is being communicated to transporter
4	15	2			The establishment shall, as applicable—		
4	15	2	i	QA	ensure that the premises and equipment used are suitable , secure, safe and adequate in accordance with the manufacturer and regulatory requirements to ensure proper conservation and distribution of medical devices;	Environmental Control and Practices	Same as Part 3, Sec 15 1 (i)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
4	15	2	ii	Maintenance	establish documented requirements for maintaining the premises and equipment, including their frequencies; and	Cleaning and Maintenance	Specific instruction to address the cleaning and maintenance needed.
4	15	2	iii	Maintenance	maintain records of such maintenance activities.	Records Control	Maintain cleaning and maintenance record
4	16				Work environment. The establishment shall, as applicable—		
4	16		i	QA	determine and manage the work environment needed to achieve conformity to regulatory requirements;	Environmental Control and Practices	Same as Part 3, Sec 15 1 (i)
4	16		ii	Relevant Dept	establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the medical devices or work environment could adversely affect quality of the medical devices;	Personal Hygiene	Specify clothing and cleaning instruction for personnel prior to products handling
4	16		iii	Supply Chain	establish documented procedures or work instructions to monitor and control the conditions for work environment that could adversely affect quality of the medical devices;	Storage Condition Monitoring	Specify schedule, method, recording of storage condition and alert for deviation
4	16		iii	Supply Chain	-ditto-	Pest Control	Specify schedule, method, recording of pest control and alert for deviation

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
4	16		iv		ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person; and	Training Needs Identification (TNI)	Must also maintain training records, also same as Part 2, Sec 5 (v)
4	16		v		establish special arrangements and document the control of contaminated or potentially contaminated medical devices, work environment or personnel.	Handling of Nonconforming Material	Procedure to handle materials/products found to be non conforming, either at receiving / returned products etc
4	17				Cleaning and pest control		
4	17	1			The establishment shall, as applicable—		
4	17	1	i	Maintenance	establish documented requirements for the cleaning of premises, including frequency and methods; and	Cleaning and Maintenance	Same as Part 3, Sec 15 2 (ii)
4	17	1	ii	Maintenance	maintain records of cleaning.	Records Control	Maintain cleaning and maintenance record
4	17	2			The establishment shall, as applicable—		
4	17	2	i	Supply Chain	establish a pest control program to identify and prevent pest infestation; and	Pest Control	Same as Part 3, Sec 16 (iii)
4	17	2	ii	Maintenance	maintain records of pest control program.	Records Control	Maintain cleaning and maintenance record

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5					Supply Chain and Device Specific		
5	18				The establishment shall—		
5	18		i	Business/ Sourcing	obtain appropriate authorization from the relevant party to become authorized representative, importer or distributor of medical devices; and	Distributor Authorization Letter	Type of devices are to be specified in the letter
5	18		ii	Business/ Sourcing	establish and maintain written agreement with the relevant party pertaining to supply of information required for regulatory matters relating to medical devices it deals with.	Distributor Agreement	To specify information on flow of information from principal to distributor as per outlined in SOP
5	19				Communication Channels. The establishment shall—		
5	19		i	RA	establish and maintain communication channels and feedback mechanisms with the relevant party such that all relevant and updated medical device information can be disseminated to the related parties effectively;	Product Regulatory Information	To specify flow of regulatory information from manufacturing plant to LAR, from LAR to Importer, warehouse and distributors or any party that manage the device in supply chain.
5	19		ii	RA and Supply Chain	be responsible to manage and to communicate with users, public and Authority on matters pertaining to medical devices it deals with;	Field Safety Corrective Action	To specify the procedure of FCA, FSN (advisory notice), Recall and its reporting to Authority
5	19		ii	QA	-ditto-	Complaint Handling	To specify the procedure of complaint handling and its reporting to Authority

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	19		iii	RA	establish and maintain efficient communication channels with the manufacturers, such that all relevant medical device information and updated device information can be disseminated to the related parties effectively;	Product Regulatory Information	Focus on change management (ECO/Variation).
5	19		iv	QA	establish feedback mechanism for collecting comments and complaints from users and public, to be forwarded to the relevant party as applicable;	Complaint Handling	Same as Part 5, Sec 19 (ii)
5	19		V	Engineering	as applicable, establish mechanism to provide information on maintenance services, including calibration, provision of spare parts and other services, to the users.	Calibration and Maintenance Schedule	To be provided to customer as reference
5	20				Receipt of Stock. The establishment shall—		
5	20		i	QA and Supply Chain	establish and implement inspection or other activities necessary to ensure that medical devices received meets the specified requirements; and	Incoming inspection	To specify specification to check upon goods receiving, e.g.: packaging integrity.
5	20		ii	Supply chain	maintain records of verification.	Records Control	Maintain record of inspection

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	21				Storage and Stock Handling.		
5	21	1			The establishment shall—		
5	21	1	i	RA and Supply Chain	identify storage measures for specific medical devices and stored in accordance with the manufacturer's instructions;	Product Master List	Same as Part 2, Sec 6 (1) (iii)
5	21	1	ii	QA and Supply Chain	provide suitable and adequate storage to ensure proper conservation of the medical devices; and	Environmental Control and Practices	Same as Part 3, Sec 15 1 (i)
5	21	1	iii	Supply Chain	maintain an updated distribution records of medical devices it deals with, including the make, model, batch number, serial number, and quantity of the devices, as appropriate.	Inventory record	Example of information to be included in distribution record:: 1. Product Name 2. Catalog Number 3. Lot number 4. Expiry date (If any) 5. Manufacturer's name, address, e-mail, tel# 6. Supplier name, address 7. Customer name and address 8. Date customer purchase the product 9. Balance quantity in warehouse 10. Storage condition
5	21	1	iv	QA and Supply Chain	establish adequate precautions and control to prevent deterioration or damage of the medical devices;	Environmental Control and Practices	Same as Part 3, Sec 15 1 (i)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	21	2		QA	Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel.	Handling of Nonconforming Material	Specify quarantine area, also refer Part 4, Sec 16 (v)
5	21	3		QA	Any system replacing physical quarantine should provide equivalent security.	Handling of Nonconforming Material	Specify clear procedure should designated physical quarantine procedure is not available
5	21	4		Supply Chain	Medical device presenting special risks of abuse, fire or explosion (such as combustible/flammable liquids and solids and pressurized gases) should be stored in a dedicated area(s) that is subject to appropriate additional safety and security measures.	Special storage master list	Specify products that required special storage condition
5	21	5		QA	Broken or damaged medical device should be identified and withdrawn from usable stock and stored separately.	Handling of Nonconforming Material	Refer Part 4, Sec 16 (v)
5	22				Stock Rotation. The establishment shall—		
5	22		i	Supply Chain	establish a system to ensure stock rotation;	Warehouse & Shipping	To specify stock rotation system (FIFO or FEFO)
5	22		ii	Supply Chain	separate medical devices beyond their expiry date or shelf life from usable stock and clearly labeled ; and	Warehouse & Shipping	To specify segregation for expired products
5	22		iii	Supply Chain	dispose the expired medical devices in accordance with clause 25.	Warehouse & Shipping	To specify disposal procedure for expired products

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	23				Delivery To Customers. The establishment shall—		
5	23		i	Supply Chain	verify that the registered medical device is accompanied by certificate of registration and license and other applicable documents and instructions for use;	Warehouse & Shipping	
5	23		ii	Supply Chain	ensure that the medical device bears a type, batch or lot number, model and serial number or other elements of identification as well as name, trade name and address of the manufacturer and/or distributor organization;	Warehouse & Shipping	To specify the checking of incoming products to ensure it has batch/lot/serial number (if any), product name for identification purpose.
5	23		iii	Supply Chain	ensure the designated medical devices should only be sold and/or distributed to persons or entities that are entitled to acquire such medical devices as specified by the regulatory requirements by obtaining the proof of such authority prior to the distribution of medical devices to such person;	Warehouse & Shipping	

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	23		iv	Supply Chain	provide documentation of all medical devices supplied to customers to ascertain the date, the name of the medical device, the quantity supplied, the batch or lot number and/or model and serial number and the name and address of the distributor and addressee;	Warehouse & Shipping	To specify document accompany products and deliver to customer. Info on the document should have: 1. Product Name 2. Date of Delivery, 3. Quantity Supplied 4. Batch/Lot/Serial number (if any) 5. Name and Address of Distributor 6. Name and Address of Receiver.
5	23		v	Supply Chain	keep the record of delivery transactions as the proof of medical devices supplied to customers;	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	23		vi	RA	obtain all relevant conditions for storage and transportation, installation, testing and commissioning requirements, user and service manuals, spare parts list and relevant certificates from the manufacturer and provide to the customer ;	Product Master List	Refer Part 2, Sec 6 1 (iii)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	23		Vi	Engineering	-ditto-	Installation, Testing & Commissioning, Calibration & Preventive Maintenance.	Refer Part 2, Sec 6 2 (ii)
5	23		vii	Supply Chain	ensure the delivery of medical devices adhere to the conditions specified by the manufacturer;	Warehouse & Shipping	Refer Part 4, Sec 15 1 (iii)
5	23		viii	Supply Chain	establish adequate and specialized methods of delivery to achieve safe and secure delivery of medical device from the point of collection to the point of delivery; and	Warehouse & Shipping	Specify clear procedure should specialized method of delivery (other than temperature control) for certain devices are required.
5	23		ix	Supply Chain	ensure the delivery of medical devices which present special risks of abuse, fire or explosion are stored in safe, dedicated and secure areas, and transported in safe, dedicated and secure containers and vehicles, and shall comply with the applicable regulatory and/or statutory requirements.	Warehouse & Shipping	Refer Part 5, Sec 23 (viii)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	24				Control of nonconforming medical devices including returned medical devices . The establishment shall—		
5	24		i	QA	establish documented procedures for handling of returned medical device and shall be treated as a non-conforming medical device;	Handling of Nonconforming Material	Refer Part 4, Sec 16 (v)
5	24		ii	QA	ensure that medical device which does not conform to essential principles of safety and performance as stipulated in Act 737 and its subsidiary legislations, is identified and controlled to prevent its unintended delivery and use;	Handling of Nonconforming Material	Specify procedure for handling of non-conforming medical devices (upon receiving or some time after storage). Also refer Part 4, Sec 16 (v)
5	24		iii	QA	define the controls and related responsibilities and authorities for dealing with nonconforming medical device in a documented procedure;	Handling of Nonconforming Material	Define control and responsibility (particularly between LAR and distributors)
5	24		iv	QA	deal with nonconforming product by one or more of the following ways— - by taking action to eliminate the detected nonconformity; and - by authorizing its delivery and use under concession;	Handling of Nonconforming Material	Specify the process flow and decision possibilities of non-conforming products (dispose or use with concession)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	24		v	QA	ensure that nonconforming medical device is delivered and used by concession only if the regulatory requirements are met;	Handling of Nonconforming Material	Specify authorization procedure should a non-conforming products are decided to be used with concession
5	24		vi	QA	maintain records of the justification and identity of the person(s) authorizing the concession;	Handling of Nonconforming Material	Maintain record of decision for handling non-conforming devices, must include nature of non-conformance, PIC for authorization & justification from principal/manufacturer and /or authority
5	24		vii	QA	maintain records of the nature of nonconformities and any subsequent actions taken, including concessions obtained from the manufacturer and the Authority; and	Records Control	Refer Part 5, Sec 24 (vi)
5	24		viii	QA	take action appropriate to the effects, or potential effects, of the nonconformity, when nonconforming product is detected after delivery.	Handling of Nonconforming Material	Specify the process flow and decision possibilities of non-conforming products (dispose or use with concession), including if a recall is required

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	25				Disposal of medical devices . The establishment shall—		
5	25		i	Supply Chain	establish a documented procedure for the disposal of medical devices in accordance with regulatory requirements and any other applicable statutory requriemetns;	Disposal	Specify procedure in handling of devices disposal, including authorization from principal/manufacturer and /or authority
5	25		ii	Supply Chain	ensure, if the medical device have not been immediately sent for disposal, they shall be kept in a clearly segregated, safe and secured area and identified in accordance with regulatory requirements and any other applicable statutory requirement; and	Disposal	Specify segregation procedure and location for devices to be disposed off
5	25		iii	Supply Chain	maintain records of the disposal.	Records Control	Maintain disposal record
5	26				Traceability.		
5	26	1			The establishment shall—		
5	26	1	i	Supply Chain	maintain an updated records providing traceability of medical devices throughout the supply chain being dealt with, which include the make, model, batch number, serial number, and quantity of devices, as appropriate;	Inventory record	Refer Part 5, Sec 21 1 (iii)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	26	1	ii	QA	retain the records for a period of time— - specified by relevant regulatory requirements; or - at least equivalent to the lifetime of the medical device as defined by the manufacturer of the medical devices; or - no less than two years from the date that the medical device is shipped from the establishment, whichever is the longest;	Records Control	For easier management, take the longest lifetime as retention period.
5	26	1	iii	HR	ensure all parties involved in the supply chain shall be identifiable; and	JD, Responsibility & Authority	Refer Part 2, Sec 4 (ii)
5	26	1	iv	Supply Chain	establish measures to ensure traceability of the medical device throughout distribution channels from the manufacturer/importer to the customer and to the patient.	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	26	2		QA	Records including expiry dates and batch records shall be part of a secure distribution documentation enabling traceability.	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	27				Specific traceability requirements for implantable medical devices		
5	27	1			The establishment shall establish a tracking record for all implants especially the following high-risk medical devices down to patient level—		

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	27	1	i	Supply Chain	mechanical heart valves;	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	27	1	ii	Supply Chain	implantable pacemakers, their electrodes and leads;	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	27	1	iii	Supply Chain	implantable defibrillators, their electrodes and leads;	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	27	1	iv	Supply Chain	implantable ventricular support systems; and	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	27	1	v	Supply Chain	implantable drug infusion systems.	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	27	2			If tracking is not possible for any individual medical devices (e.g. the tracking does not have the patient's consent), the tracking system is still required as follows—		
5	27	2	i	Supply Chain	to track the medical devices down to the healthcare facility level; or	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	27	2	ii	Supply Chain	to keep track of the following— - the date of the medical device was put into service or implanted into a patient, and - the date the device permanently retired from use or for an implanted medical device, the date it was explanted.	Inventory record	Refer Part 5, Sec 21 1 (iii)
5	27	3		RA	The establishment shall submit surveillance reports to the Authority at least once a year for all the above stated medical devices.	Inventory record	Refer Part 5, Sec 21 1 (iii)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	28				Specific requirements for active medical devices		
5	28	1		Engineering	The establishment shall establish and maintain documented procedures and work instructions for performing installation, testing and commissioning and maintenance activities in accordance with Malaysian Standard MS 2058:2009 - Code of Practice for Good Engineering Maintenance of Active Medical Devices and any other requirements as specified by the Authority.	Installation, Testing & Commissioning SOP	More guideline from MDA
5	28	2			The establishment shall—		
5	28	2	i	Engineering	establish and maintain documented procedures, work instructions and reference materials, tools and test equipment and reference measurement procedures, for performing servicing activities including calibration, repair, maintenance and verifying that they meet the regulatory requirements and applicable standards;	Calibration & Preventive Maintenance SOP	More guideline from MDA Maintain relevant records
5	28	2	ii	Engineering	establish documented requirements which contain acceptance criteria for installation, testing and commissioning of the medical device;	Checklist for installation, testing and commissioning	Checklist should include criteria for passing installation, testing and commissioning.
5	28	2	iii	Engineering	establish installation qualification and maintain adequate installation and inspection instructions for medical devices requiring specified installation requirements, and where appropriate, test procedures;	-ditto-	-ditto-
5	28	2	iv	Engineering	ensure proper installation, testing and commissioning;	-ditto-	-ditto-

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	28	2	v	Maintenance	ensure equipment used for testing, maintenance and conservation of medical devices are calibrated or verified at specific intervals;	-ditto-	Refer Part 2, Sec 6 2 (ii), including to ensure equipment used for this purpose is calibrated
5	28	2	vi	Maintenance	ensure the calibration and maintenance of test equipment conforms to the applicable standards; and	-ditto-	Refer Part 2, Sec 6 2 (ii), including to ensure equipment used for this purpose is conforms to standard
5	28	2	vii	Engineering	maintain testing and commissioning, installation, calibration and maintenance service records.	Records Control	
5	28	3			The establishment shall, as appropriate—		
5	28	3	i	Engineering & HR	establish an appropriate technical support which include maintenance service, training, calibration, management of spare parts, workshop setup and management;	Installation, Testing & Commissioning , Calibration & Preventive Maintenance SOP TNI & TNA, Training records,	
5	28	3	ii	Engineering	establish maintenance management mechanism to support the customers;	Calibration & Preventive Maintenance SOP	
5	28	3	iii	Engineering	ensure the technical and maintenance support services for active medical devices conform to the applicable regulatory requirements.	Installation, Testing & Commissioning , Calibration & Preventive Maintenance SOP	

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	29				Outsourced activities. The establishment shall—		
5	29		i	Sourcing	ensure control over outsourced process within the scope of the GDPMD;	Handling of Outsourced Activities	To specify the procedure in managing and controlling outsourcing activities, including the identification of auditing needs and periodic vendor quality and satisfaction check.
5	29		ii	Sourcing	establish requirements to ensure that the outsourced activities conform to specified requirements;	Qualifying specification for outsourced activities	Refer Part 2, Sec 5 (ix)
5	29		iii	Sourcing	ensure the type and extent of control applied to the supplier are dependent on the impact on meeting the requirements of GDPMD;	Handling of Outsourced Activities	Refer Part 5, Sec 29 (i)
5	29		iv	Sourcing	ensure, for outsourced activities, the supplier of outsourced activities is audited as part of the establishment's system unless the supplier is already certified to GDPMD covering the scope of the outsourced activities; and	Qualifying specification for outsourced activities	Refer Part 2, Sec 5 (ix)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	29		v		develop written agreements with outsourced party to ensure that appropriate measures are taken to safeguard the safety and performance of the medical devices, including maintaining appropriate documentation and records, and such agreements should be in accordance with regulatory requirements and any relevant statutory requirements. *Note: Establishment shall ensure control over outsourced processes does not absolve the establishment of the responsibility of conformity to GDPMD, statutory and regulatory requirements.*	Vendor's agreement	Qualifying specification may be reference in the agreement
5	30				Counterfeit adulterate, unwholesome and tampered medical services. The establishment shall, upon finding in this distribution network any counterfeit, adulterate, and tampered medical devices—		
5	30		i	QA	physically segregated from other medical devices to avoid any confusion;	Handling of Nonconforming Material	Refer Part 4, Sec 16 (v), including proper segregation, labeling and informing authority
5	30		ii	QA	clearly label any counterfeit, adulterate, and tampered medical devices found in the distribution network as “Not for Sale” or other similar phrases/words; and	Handling of Nonconforming Material	-ditto-
5	30		iii	QA	inform the Authority and manufacturer immediately.	Handling of Nonconforming Material	-ditto-

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	31				Secondary assembly including repackaging . General requirements:		
5	31	1			The establishment shall plan and carry out secondary assembly of medical devices under controlled conditions and shall include, as applicable—		
5	31	1	i	RA	the availability of information that describes the characteristics of the medical devices;	Product Master List	Refer Part 2, Sec 6 1 (iii)
5	31	1	ii	Production	the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary;	Secondary Assembling SOP	Specify procedure in generating and printing of critical info (lot#, expiry date). A copy of SOP and WI is to be furnished to principal
5	31	1	ii	Production	the use of suitable equipment;	Work instruction for each re-packed products	
5	31	1	iii	Production	the availability and use of monitoring and measuring devices;	Equipment Master List	With indication of suitability of equipment
5	31	1	iv	Production	-ditto-	Equipment Master List	With indication of monitoring and measuring devices

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	31	1	v	QA	the implementation of monitoring and measurement activities;	In-Process Quality Control	A copy of IPQC SOP is to be furnished to principal
5	31	1	vi	QA	the implementation of release of medical devices, their delivery and post-delivery activities; and	Final Product Release	A copy of FPQC SOP is to be furnished to principal
5	31	1	vii	Production	the implementation of defined operations and packaging of medical devices.	Work instruction for each re-packed products	Refer Part 5 Sec 31, (1) (ii)
5	31	2			The establishment shall—		
5	31	2	i	Production	establish and maintain a record for each batch of medical devices that provides traceability and identifies the amount assembled and the amount approved for distribution; and	Batch record	Batch record (or commonly known as device history record - DHR) is to be maintained and archived, aligned with record retention time, this should be available for each batch of production / assembling and reflecting the real time of production, activities taken place and PIC
5	31	2	ii	Production	ensure the batch record shall be verified and approved by qualified personnel.	Batch record	Batch record format should have verification and approving particulars

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	32				Assembly documents. The establishment shall ensure—		
5	32		i	Production	batch assembly record is kept for each batch or part batch assembled which carries the batch number and the quantity of bulk medical devices to be packed;	Batch record	Refer Part 5 Sec 31, (2) (i)
5	32		ii	Production	the assembly shall be made or completed at time each action is taken to trace all significant activities concerning the assembly of medical device; and	Batch record	Refer Part 5 Sec 31, (1) (ii)
5	32		iii	Production	the records are retained for a period of time— - as specified in the regulatory requirements; or - at least equivalent to the lifetime of the medical device as defined by the product owner of the medical device; or - no less than two years from the date that the medical device is shipped from the establishment, whichever is longest.	Records Control	Refer Part 2 Sec 7, (5) (iii)
5	33				Materials control. The establishment shall ensure—		
5	33		i	QA	for each delivery, the incoming medical devices are checked for integrity of package and seal, for correspondence between delivery note and the supplier's labels, and for compliance with quality specification;	Incoming inspection	Refer Part 5 Sec 20, (i), including check for seal integrity, correspondence between delivered items and supplier's note

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	33		ii	QA	medical devices with breached primary package are not used for secondary assembly;	Incoming inspection	Refer Part 5 Sec 20, (i), including decision on non conforming incoming materials, e.g.: breached of primary packaging
5	33		iii	QA	medical devices in the storage area are appropriately labeled;	Warehouse & Shipping	To address storage of devices pre and post assembling, inclduing labeling of it for status clarification
5	33		iv	QA	appropriate procedures or measures are taken to assure the identity of the contents of each packing of the medical devices;	In-Process Identification	To address the identity of each devices during assembling process
5	33		v	QA	bulk containers from which quantities of the medical devices have been drawn are clearly identified;	In-Process Identification	Refer Part 5, Sec 33, (iv)
5	33		vi	Supply Chain	medical devices requiring special storage conditions are placed in areas which are designed and equipped to provide the desired conditions;	Special storage master list	Same as Part 5, Sec 21, (4)
5	33		vii	QA	the storage and conditions are continuously monitored and recorded;	Environmental Control and Practices	Same as Part 4, Sec 15, 1 (i)
5	33		viii	Supply Chain	the actual storage temperature are expressed quantitatively;	Storage Condition Monitoring	Same as Part 4, Sec 16, (iii)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	33		ix	Supply Chain	the purchase, handling and control of all packaging materials are accorded attention similar to that given to starting materials;	Raw Material Handling	To specify purchase, handling and control of packaging materials
5	33		x	Supply Chain	packaging materials are issued for use only by authorized personnel in accordance with the documented procedure;	Raw Material Handling	To specify authority and procedure in packaging material issuance
5	33		xi	Production	when setting up a program for the packaging operations, particular attention is given to minimize the risk of cross-contamination, mix-ups or substitutions; and	Line Clearance	To avoid cross contamination
5	33		xii	Production	different medical devices shall not be packaged in close proximity unless there is physical segregation.	Line Clearance & segregation	To ensure no devices are packed in close proximity
5	34				Labeling The establishment shall ensure the repackaged medical devices bear all original labeling (including instruction for use, label and any other information sheet or leaflet, etc) and all labeling information, except for quantity and the distributor identity.	Labeling WI for each product	To address the procedure in labeling product and specify what is to be included (can be presented in artwork)
5	35				Good assembly practices. The establishment shall ensure—		
5	35		i	QA	all medical devices and materials used for assembly are checked before use by a designated person for quantity, identity and conformity with the packaging instructions;	In-Process Quality Control Criteria of IPQC for each product	Refer Part 5, Sec 31, (1) (v)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	35		ii	Production	line clearance are performed prior to commencement of the assembly operation;	Line Clearance	Refer Part 5, Sec 33, (xi)
5	35		iii	QA	the correct performance of any printing operation which is carried out separately or in the course of packaging are checked and recorded.	Incoming inspection In-Process Quality Control	Refer Part 5, Sec 33, (ii) Refer Part 5, Sec 31, (1) (v)
5	35		iv	QA	printing by hand is re-checked at regular intervals;	In-Process Quality Control Criteria of IPQC for each product	Refer Part 5, Sec 31, (1) (v)
5	35		v	Production	assembly equipment/apparatus are cleaned according to detailed and written procedures and stored only in a clean and dry condition;	Cleaning	To specify cleaning steps and schedule for equipment and facility
5	35		vi	Production	assembly equipment/apparatus do not present any hazard to the medical devices;	EHS	To identify potential hazard from equipment and facility to products (devices)
5	35		vii	Production	the parts of assembly equipment/apparatus that come into contact with the medical devices do not affect the quality of the medical devices and present any hazard; and	EHS	Refer Part 5, Sec 35, (vi)
5	35		viii	Production	control equipment shall be calibrated and checked at defined intervals and adequate records of the calibration shall be maintained.	Calibration	To specify the calibration requirement and schedule

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
5	36				Quality Control. The establishment shall ensure—		
5	36		i	QA	finished medical device assessment shall embrace all relevant factors, including assembly conditions, a review of packaging documentation, compliance with finished medical device specification and visual examination of the final finished pack; and	Final Product Release Criteria of FPQC for each product	Refer Part 5 Sec 31, (1) (vi)
5	36		ii	QA	the process of secondary assembly shall not compromise the conformity of the medical device to essential principles of safety and performance, as stipulated in Act 737 and its subsidiary legislations.	Final Product Release	Refer Part 5 Sec 31, (1) (vi)
6					Surveillance and Vigilance		
6	37				The establishment shall establish and implement a documented procedure for monitoring safety and performance of medical devices imported, exported and placed in the market.		
6	38				Medical device complaints		
6	38	1			The establishment shall ensure—		
6	38	1	i	QA	establish and implement a documented procedure for handling complaints regarding medical devices;	Complaint Handling	Same as Part 5, Sec 19 (ii)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
6	38	1	ii	QA	all complaints and other information concerning potentially defective and counterfeit medical devices shall be reviewed including the description of the action to be taken and reporting to all relevant parties, where appropriate;	Complaint Handling Form	To specify information to be recorded, action and reporting of defective and counterfeit devices
6	38	1	iii	QA	any complaint concerning a defective medical device shall be recorded and thoroughly investigated to identify the origin or the reason for the complaint;	Complaint Handling	Same as Part 5, Sec 19 (ii), including investigation for both quality and clinical complaint.
6	38	1	iv	QA	maintain records of the complaint, investigation and any subsequent actions taken; and	Record Control	Maintain record
6	38	1	v	QA	where necessary, appropriate follow-up action should be taken after investigation and evaluation of the complaint.	Complaint Handling	Same as Part 5, Sec 19 (ii), including follow-up action
6	38	2		QA	The establishment should put in place a system by which the complaints, the response received from the medical device manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties.	Customer Feedback System	A system regardless of manual or electronic.
6	39				Distribution records. The establishment shall ensure—		
6	39		i	Supply Chain	document all activities relating to the distribution of medical devices including all applicable receipts, storage, delivery and disposal; and	Inventory Record	Refer Part 5, Sec 21 (1) (iii)

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
6	39		ii	Supply Chain	the records shall contain at least the following— - the name, address, e-mail and telephone number of the manufacturer, authorized representative, importer, exporter, distributor and customer of the device where appropriate; and - the name of the device, its class and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family.	Inventory Record	Refer Part 5, Sec 21 (1) (iii)
6	40				Field corrective action (FCA) and field safety notice (FSN) . The establishment shall ensure—		
6	40		i	RA and Supply Chain	establish documented procedures for handling of FCA and field safety notice (FSN);	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii)
6	40		ii	RA and Supply Chain	define the responsibilities for planning, conducting and reporting of corrective actions in the documented procedure;	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii), including defining responsibility, planning, executing and reporting (RACI matrix)
6	40		iii	RA and Supply Chain	establish in writing a recall or withdrawal procedure in consultation with manufacturer;	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii), including consultation with manufacturer

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
6	40		iv	RA and Supply Chain	inform the Authority prior to execution of FCA and FSN;	Field Safety Corrective Action	Pending FSCA guidance from MDA , if any (how to inform MDA prior to execution)
6	40		v	RA and Supply Chain	inform all customers to whom the medical device was distributed with the appropriate degree of urgency;	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii), including notice to affected customers, aligned with degree of urgency (pending MDA guidance, if any)
6	40		vi	RA and Supply Chain	inform overseas counterparts on the FCA and FSN if the medical devices are exported;	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii), including notice to overseas if relevant, aligned with degree of urgency (pending MDA guidance, if any)
6	40		vii	RA and Supply Chain	request that the affected medical devices be removed immediately from usable stock and stored separately in a secure area until they are disposed of in accordance with manufacturers' instructions; and	Field Safety Corrective Action Handling of Nonconforming Material	Refer Part 5, Sec 19, (ii), including handling of in-house stock
6	40		viii	RA and Supply Chain	maintain records of all actions taken in connection with the FCA and FSN and their approval by the manufacturer and the Authority.	Field Safety Corrective Action	Maintain record

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
6	41				Recall . The establishment shall ensure—		
6	41		I	RA and Supply Chain	establish a documented procedure to effectively and promptly recall medical device known or suspected to be defective or counterfeit;	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii) Efficiency of recall is important.
6	41		ii	RA and Supply Chain	ensure that the system comply with the regulatory requirements;	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii) Pending guideline from MDA (if any)
6	41		iii	RA and Supply Chain	the manufacturer and/or authorized representative shall be informed in the event of a recall;	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii) Communication channel is to be specified
6	41		iv	RA and Supply Chain	where a recall is instituted by an entity other than the manufacturer and/or authorized representative, consultation with the manufacturer and/or authorized representative should, where possible, take place before the recall is instituted;	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii), including consultation with manufacturer
6	41		v	RA and Supply Chain	recall information shall be reported to the Authority; and	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii), including reporting to MDA
6	41		vi	RA and Supply Chain	the progress of a recall process should be recorded and a final report issued, which includes a reconciliation between delivered and recovered quantities of products.	Field Safety Corrective Action	Refer Part 5, Sec 19, (ii), including handling of in-house stock

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
6	42				Mandatory problem reporting		
6	42	1			The establishment shall establish documented procedure for incident/problem reporting to comply with the regulatory requirements, which include—		
6	42	1	i	QA	the identification of the nature of the incident/problem;	Complaint Handling	Refer Part 5, Sec 19 (ii), recording the nature in a complaint handling form
6	42	1	ii		the investigation;	Complaint Handling	Refer Part 5, Sec 19 (ii), Investigation should be recorded too
6	42	1	iii		the evaluation and analysis; and	Complaint Handling	Refer Part 5, Sec 19 (ii), evaluation & analysis should be recorded too
6	42	1	iv		the action to be taken.	Complaint Handling	Refer Part 5, Sec 19 (ii), Action should be recorded and follow up for closure
6	42	2			Each incident report shall lead to a final report where corrective actions are applicable.	Complaint Handling Corrective Action	Refer Part 5, Sec 19 (ii), CA required or not is to be specified in complaint closure

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
6	43				Internal audits. The establishment shall ensure—		
6	43		i	QA	establish a documented procedure, defining the responsibilities and requirements for planning and conducting audits and reporting of the results and maintenance of the audit records;	Internal Audit	Refer Part 2, Sec 5 (iv), define responsibility, requirement, reporting and maintenance of records
6	43		ii	QA	plan an audit program, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits;	Internal Audit	Refer Part 2, Sec 5 (iv), define audit program, some dept can be omitted with good audit trail.
6	43		iii	QA	define the audit criteria, scope, frequency and methods;	Internal Audit	Refer Part 2, Sec 5 (iv), criteria may include “no conflict of interest between auditor and auditee.
6	43		iv	QA	conduct internal audits at planned intervals to monitor the implementation of and compliance with the requirements of GDPMD;	Internal Audit	
6	43		v	QA	records of the audits and their results shall be maintained; and	Internal Audit	Maintain record
6	43		vi	QA	take actions to eliminate detected nonconformities and their causes without undue delay.	Internal Audit	Maintain record and must be able to show actions have been taken on NCR resulted from internal audit, also to be analyzed in Mgmt Review

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
6	44				Corrective action. The establishment shall ensure—		
6	44		i	QA	take action to eliminate the cause of nonconformities in order to comply with GDPMD and regulatory requirements under Act 737; and	Corrective Action	Refer Part 6, Sec 42 2
6	44		ii	QA	a documented procedure shall be established to define requirements for: - reviewing nonconformities (including customer complaints); - determining the causes of nonconformities; - evaluating the need for action to ensure that nonconformities do not recur; - determining and implementing action needed, including, if appropriate, updating documentation, - recording of the results of any investigation and of action taken; and - reviewing the corrective action taken and its compliance with GDPMD and regulatory requirements.	Corrective Action	Refer Part 6, Sec 42 2

How?

Part	Sec	Sub-sec 1	Sub-sec 2	Lead Dept	GDPMD	SOP / WI / Std / Other Doc.	Remarks
6	45				Preventive action. The establishment shall ensure—		
6	45		iii	QA	determine proactive action to eliminate the causes of potential nonconformities in order to comply with GDPMD and regulatory requirements and preventive actions shall be appropriate to the effects of the potential problems; and	Preventive Action	Refer Part 6, Sec 42 2
6	45		iv	QA	establish a documented procedure to define requirements for— - determining potential nonconformities and their causes; - evaluating the need for action to prevent occurrence of nonconformities; - determining and implementing action needed; - recording of the results of any investigations and of action taken; and - reviewing preventive action taken and its effectiveness.	Preventive Action	Refer Part 6, Sec 42 2

What If....

1. Under staff → transfer worker from other operation and handle medical devices?
2. Expired products → email to principal and obtained agreement via email → dispose off into dustbin?
3. Air conditioner set at 20oC and leave it to run 24 hours, assuming it is working all the time, no workers complaint of hot temperature, hence no recording is required?
4. Incoming product with shortage of 2 units → goods received and placed in the right/normal location, enter into inventory system later (after feedback from principal)?
5. Sent wrong product to customer, returned and placed back into normal location directly?
6. No complaint received from customer, no non conformance from GDPMD audit, operation running well, hence can omit internal audit and management review meeting?

In a nutshell…..

GDPMD enables you to…..

1. Ensure quality, safety & performance is maintained
2. Know the inventory and details at anytime
3. Know the vendors and customers and details at any time
4. Have traceability for recall effectiveness and efficiency
5. Effective and efficient complaint and recall handling
6. Post-market (service and maintenance) compliance
7. Managing change
8. Managing non conformance
9. Have competent resources

THANK YOU