GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD)

Appendix 4 Schedule 3 Medical Device Regulation 2012

Seminar

Updates on Medical Device Regulations

Penang, 28 May 2014

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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GDPMD

- Medical device supply-chain
- Risks in supply-chain
- Activities & parties involved in supply-chain
- What is GDPMD & Why need GDPMD?
- Misconceptions on GDPMD

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...FROM SOURCING.... THRU' TO DISPOSAL

Importation

Office

Product sourcing

Post-market surveillance & vigilance

Installation

Transportation

Sales, marketing

Tracking

Maintenance

Warehousing

Stock handling

Testing & commissioning

Delivery

Disposal

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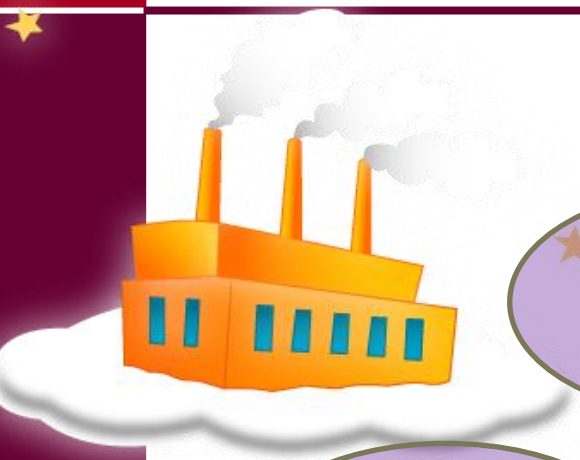
SAFETY & RISK ASSESSMENT

- Approach in medical device safety: risk assessment
  - Estimation of the potential of a device becoming a hazard that could result in safety problems and harm
- Risk is a measure of combination of
  - The hazards (potential for an adverse event)
  - The likelihood of occurrence of the hazards
  - The severity or overall impact
- Risk assessment involves
  - Risk analysis to identify possible hazards
  - Risk evaluation to estimate the risk of each hazard

ANALYZE, EVALUATE & MANAGE RISKS IN SUPPLY-CHAIN



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RISKS IN MEDICAL DEVICE SUPPLY-CHAIN

- A series of activities in medical device supply chain
- The level of risks associated with these activities may be of similar degree as those in the manufacturing environment
- Lack of control over these activities may affect safety and performance of the medical devices
- Risk-based monitoring process is essential to ensure that safety and performance of medical device are protected and preserved throughout the supply chain

RISK MANAGEMENT

- The regulatory framework is about **effective implementation of risk management process** and other regulatory requirements by the manufacturer
- No absolute risk-free
  - The risks of driving fast to reach a destination early
  - The risks of heart disease in eating too much good food
  - The risks of working in risky environment for a living
- **Balance the risks with the benefits**

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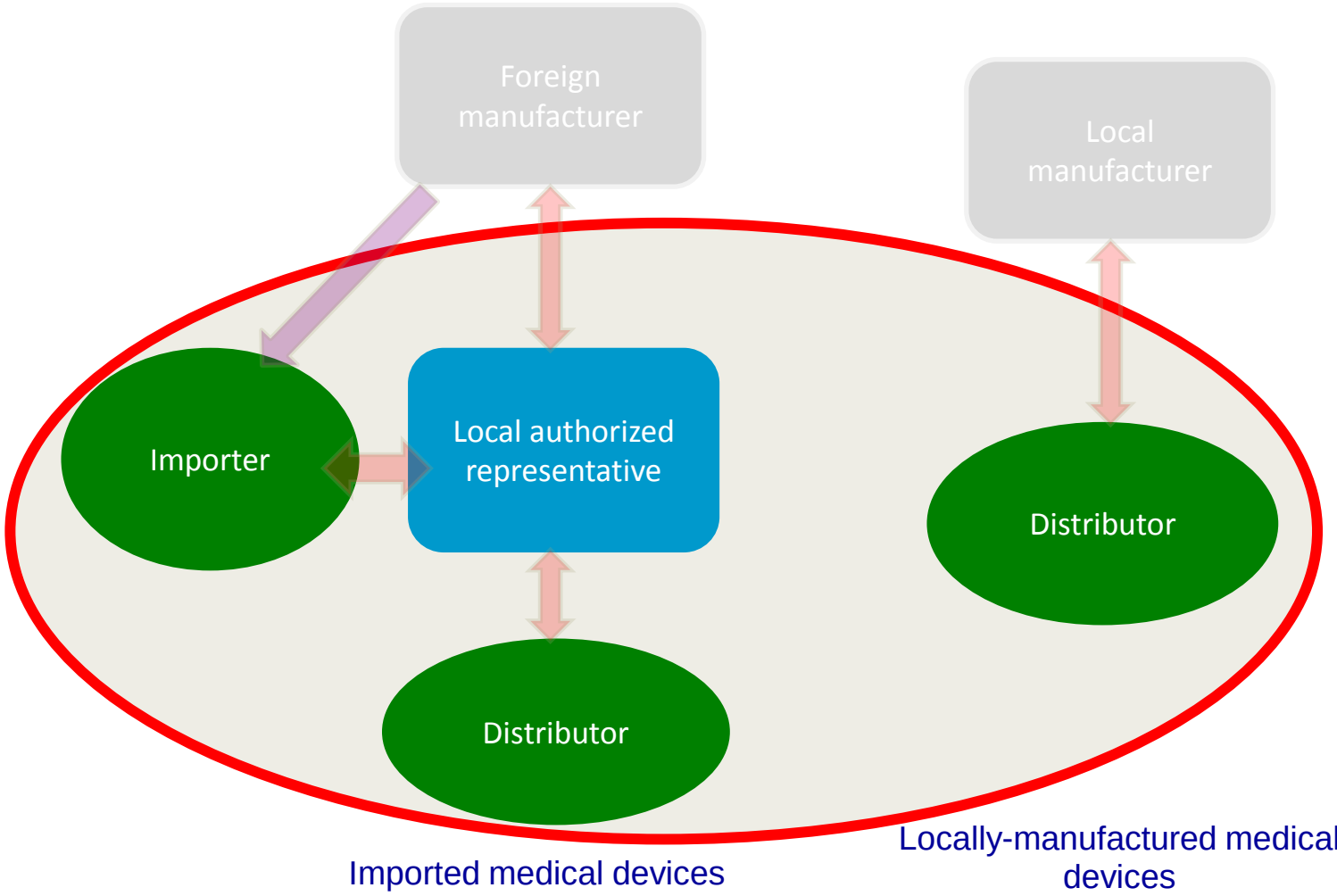
PARTIES INVOLVED



ACTIVITIES & BUSINESS MODELS

Company A acts as AR, importer distributor

Office

Importation

Product sourcing

Post-market surveillance & vigilance

Installation

Sales, marketing

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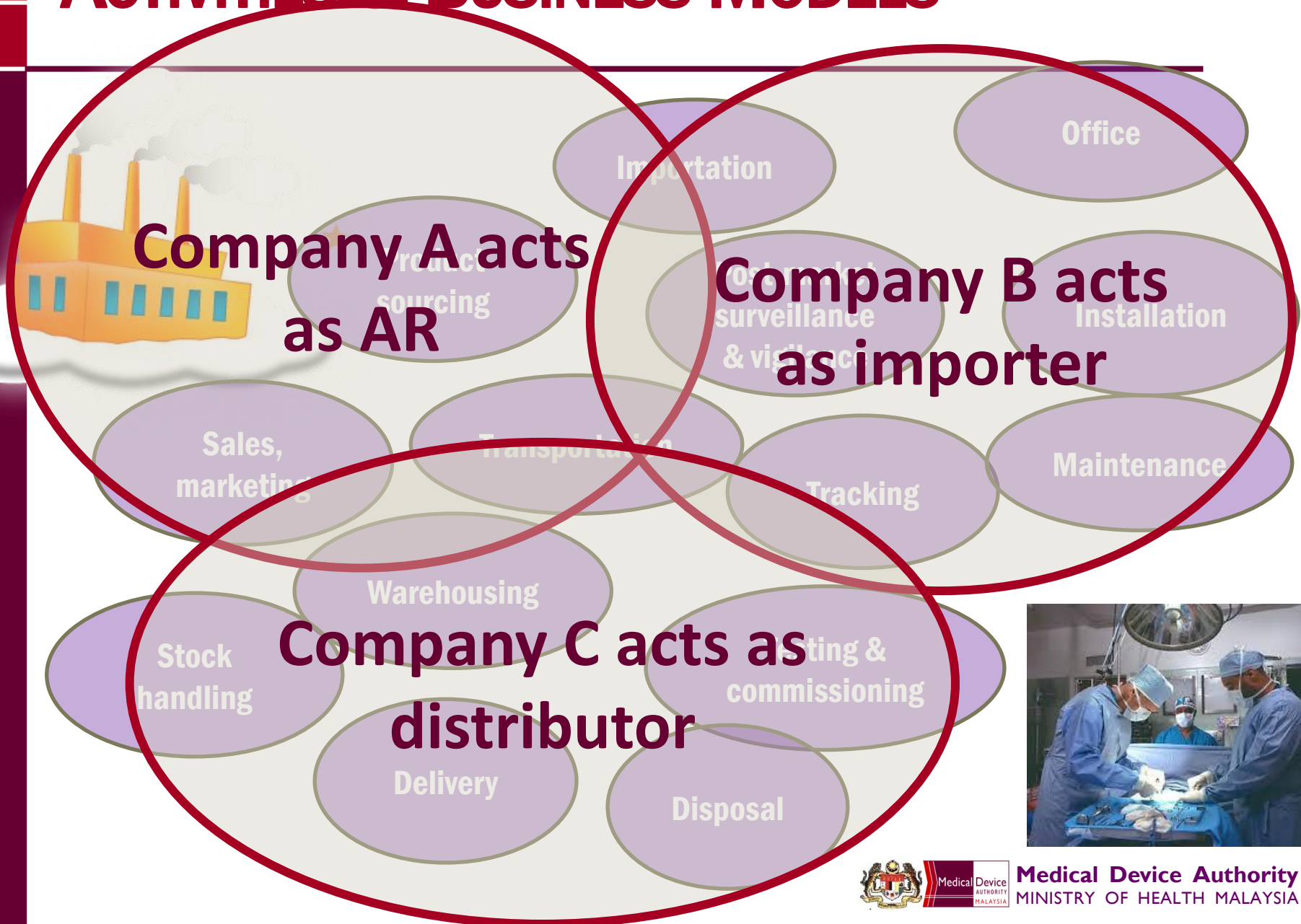
ACTIVITIES & BUSINESS MODELS



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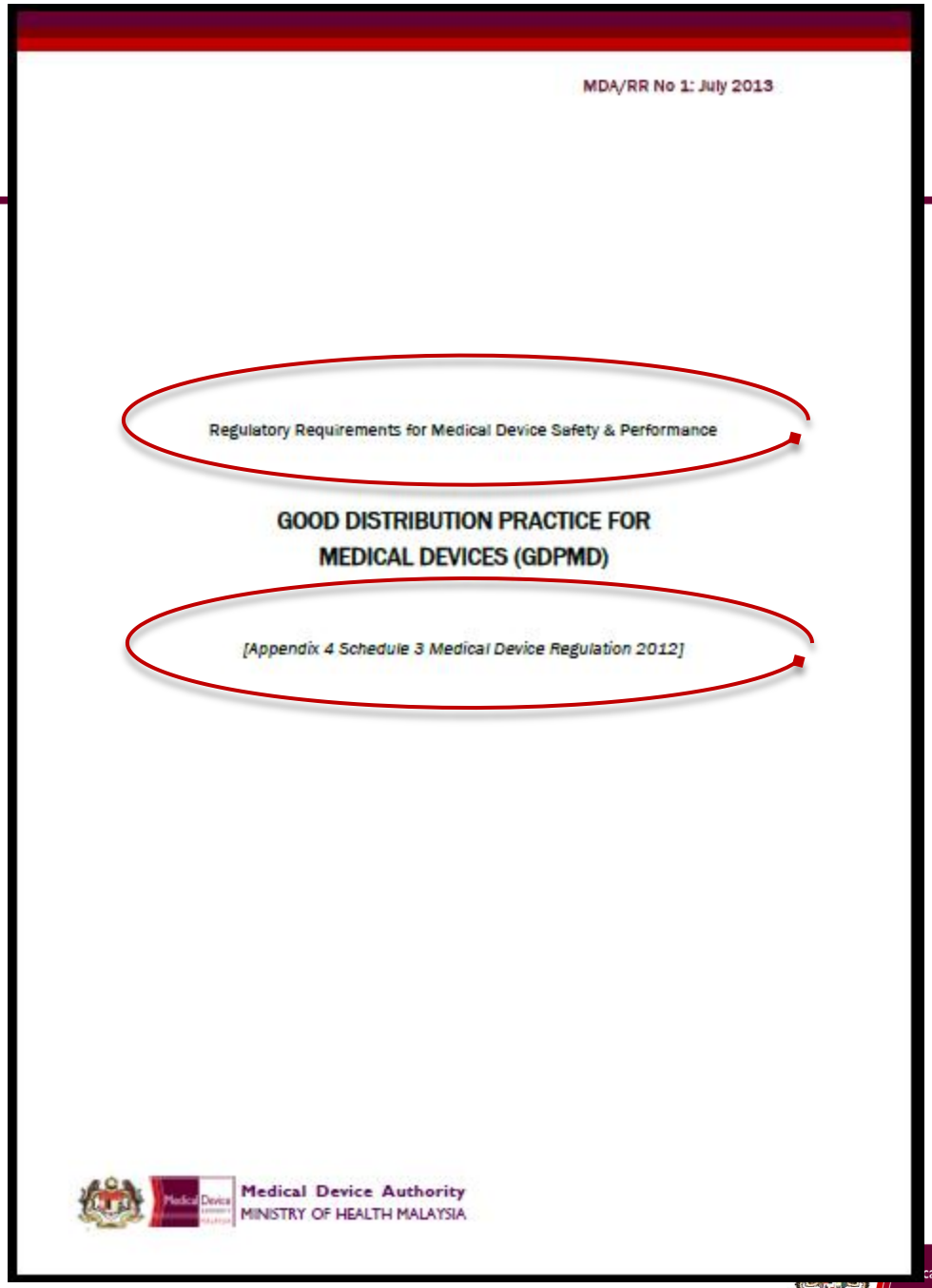

MDA/RR No 1: July 2013
Regulatory Requirements for Medical Device Safety & Performance
GOOD DISTRIBUTION PRACTICE FOR
MEDICAL DEVICES (GDPMD)
[Appendix 4 Schedule 3 Medical Device Regulation 2012]
Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

WHAT IS GDPMD?

- Made pursuant to **Appendix 4 Schedule 3 Medical Device Regulation 2012**
- Specifies **regulatory requirements** for appropriate control and management of activities in medical device supply-chain and thus comply with Act 737 and its subsidiary legislations
- Ensures medical device **safety and performance throughout the supply-chain**
- Requires establishment to **demonstrate ability** to maintain safety and performance of medical devices throughout the supply-chain

GDPMD regulatory compliance system

General

5. The establishment shall—

(i) establish, document and implement a GDPMD regulatory compliance system and maintain its compliance with the regulatory requirements;

(ii) 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;

(iii) determine the sequence and interaction of these processes;

(iv) determine criteria and methods needed to ensure that both the operation and control of these processes are effective in ensuring compliance;

(v) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

(vi) monitor, measure and analyze these processes;

(vii) implement actions necessary to achieve planned results and maintain the effectiveness of these processes to ensure compliance;

(viii) manage the processes in accordance with the regulatory requirements; and

(ix) identify and control outsourced processes in accordance with the regulatory requirements.

Documentation

6. (1) The establishment shall establish and maintain a Regulatory Compliance Manual which shall include the following information—

(i) establishment's profile, activities/operations, compliance to medical device regulatory requirements and obligations of the establishment, including those outsourced processes or activities/operations;

(ii) the scope of the GDPMD regulatory compliance system, including details of, and justification for any exclusion and/or non-application;

(iii) the medical devices it deals with and their status of compliance;

(iv) procedures required by GDPMD regulatory compliance system and reference to them;

(v) documents needed by the establishment to ensure the effective planning, operation and control of processes for compliance; and

(vi) records required by the GDPMD regulatory compliance system;

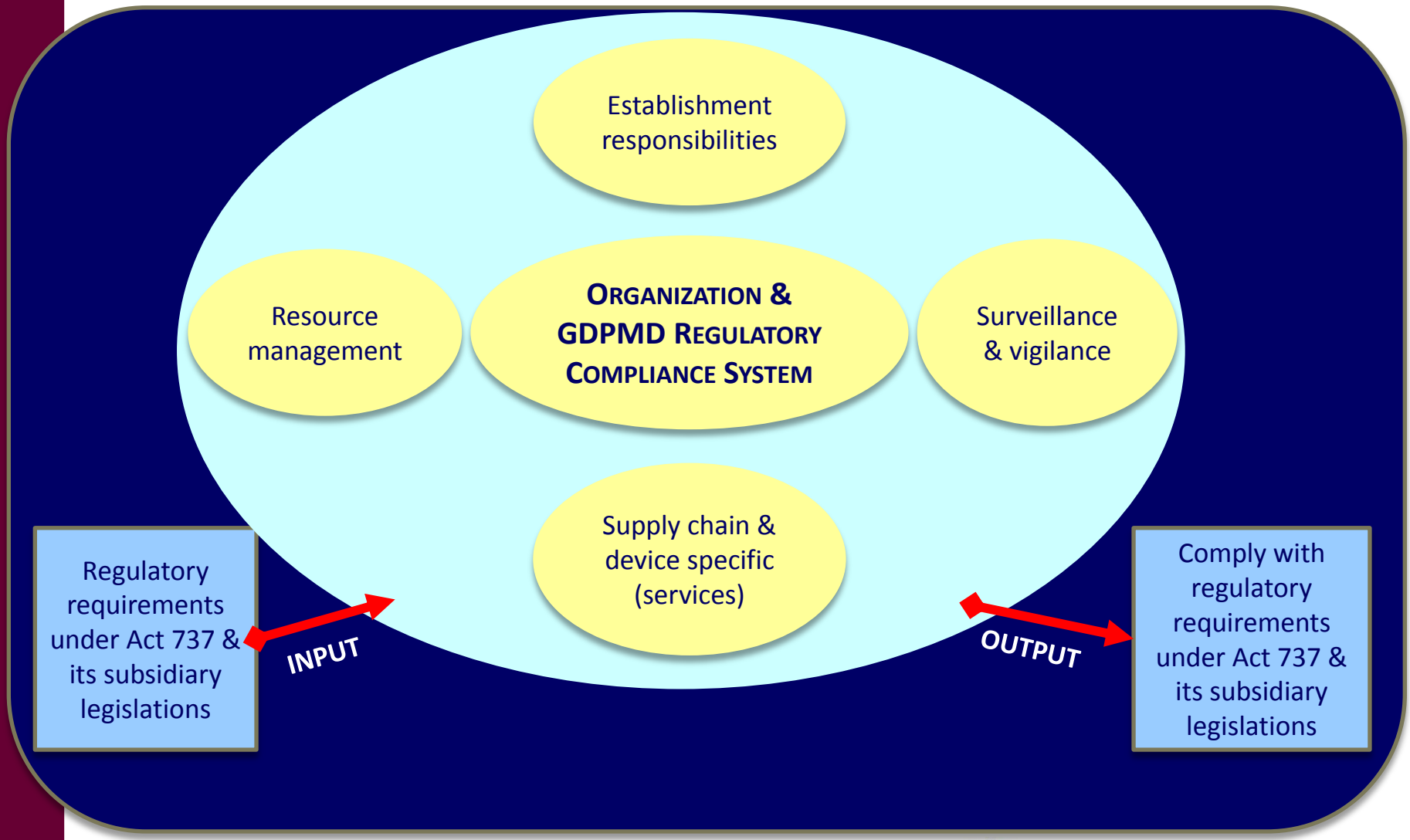
(vii) information regarding—

- the premises where activities are conducted;
- personnel conducting the activities; and
- the medical device conformity assessment and the registration holder;

WHY NEED GDPMD?

- To achieve the goal to protect public health and safety by ensuring safety & performance of medical devices
- To provide a clear legal framework regarding the obligations of those involved in the supply-chain
- To make those in the supply-chain responsible and accountable for the medical devices they are dealing with

GDPMD Model: A Regulatory Compliance System



HOW COMPLEX/SIMPLE GDPMD IS?

- **Not a "one-size-fits-all"**
- Depends on:
  - the **size and structure** of establishment
  - the **scope of activities** undertaken
  - the **processes** employed
  - the **type of medical devices** being dealt with
- **No uniformity** in the structure of quality systems or documentation
- To be **certified by CAB**

CONFORMANCE & COMPLIANCE

- GDPMD **certification** is about–
  - **inspection and assessment of evidence of all applicable (non-exempted) clauses against GDPMD document** (MDA/RR No 1: July 2013 - Regulatory Requirements for Medical Device Safety & Performance Good Distribution Practice for Medical Devices) and Act 737 and its subsidiary legislations
  - **conformance to all applicable (non-exempted) clauses in GDPMD document** (MDA/RR No 1: July 2013 - GDPMD
  - **compliance with Act 737 and its subsidiary legislations**

PART 2: ORGANIZATION AND GDPMD REGULATORY COMPLIANCE SYSTEM

Documentation

- Establish, maintain a Regulatory Compliance Manual (RCM)–
  - profile, activities, compliance to requirements, obligations;
  - scope, justification of exclusion;
  - medical devices dealt with and status;
  - procedures;
  - documents to ensure effective planning, operation, control of processes;
  - records;
  - information on premises, personnel, medical device conformity assessment and registration holder;
  - how relevant/applicable requirements are addressed
- Establish, maintain a file defining product specifications and installation qualifications (if applicable); complete distribution process.

PART 6: SURVEILLANCE AND VIGILANCE

Internal audits

- Establish procedure, defining the responsibilities and requirements for planning and conducting audits and reporting of the results and maintenance of the audit records;
- Plan audit program;
- Define the audit criteria, scope, frequency and methods;
- Donduct internal audits at planned intervals;
- Maintain records of the audits and their results;
- take actions to eliminate detected nonconformities and their causes.

Corrective action

- Eliminate the cause of nonconformities;
- Establish procedure defining requirements to review nonconformities; determine causes of nonconformities; evaluate the need for action to avoid recurrence; determine and implement the action needed, record the results of investigation and of action taken; and review corrective action taken and its compliance.

PART 5: SUPPLY CHAIN AND DEVICE SPECIFIC

Specific requirements for active medical devices

- Establish installation qualification and maintain adequate installation and inspection instructions for medical devices requiring specified installation requirements, and where appropriate, test procedures;
- Ensure proper installation, testing and commissioning;
- Ensure equipment used for testing, maintenance and conservation of medical devices are calibrated or verified at specific intervals;
- Ensure the calibration and maintenance of test equipment conforms to the applicable standards; and
- Maintain testing and commissioning, installation, calibration and maintenance service records.
- As appropriate, establish an appropriate technical support which include maintenance service, training, calibration, management of spare parts, workshop setup and management;
- As appropriate, establish maintenance management mechanism to support the customers;
- As appropriate, ensure the technical and maintenance support services for active medical devices conform to the applicable regulatory requirements.

REGULATORY REQUIREMENTS: REQUIREMENT OF CONFORMITY ASSESSMENT

- **Regulation 4 of MDR2012:**
  - Reg 4(1): All medical devices shall be subjected to conformity assessment .....3rd Schedule
  - Reg 4(2): The manufacturer shall collect all evidence of conformity, and depending on the class of ....
  - Reg 4(3): Upon completion.... CAB shall issue a report and certificate of CA...3rd Schedule

REGULATORY REQUIREMENTS: CONFORMITY ASSESSMENT PROCEDURE

- **Clause 11 of 3rd Schedule of MDR2012:** Quality management system requirement for a manufacturer, authorized representative of a foreign manufacturer, importer and distributor of medical device
  - QMS for establishment refer to **Appendix 4 of 3rd Schedule of MDR2012**

REGULATORY REQUIREMENTS: QMS

Type of establishment	QMS requirement
Manufacturer	ISO 13485
AR	**GDPMD**
Importer	**GDPMD**
Distributor	**GDPMD**

MDR2012 - Appendix 4 of 3rd Schedule

WHEN IS GDPMD REQUIRED?

Requirements for establishment licensing	Local manufacturer	Authorized Representative	Importer	Distributor
• Details of establishment	×	×	×	×
• Appropriate authorization		×	×	×
• Procedures for;				
– Distribution records	×	×	×	×
– Complaint handling	×	×	×	×
– Adverse incident reporting	×	×	×	×
– Field safety corrective action	×	×	×	×
• List of medical devices	×	×	×	×
• QMS *(ISO 13485 or equivalent)*	×			
• GDPMD		×	×	×

.....one of the requirements for application of establishment license under Act 737 for authorized representative, importer and distributor

REPORT & CERTIFICATE

- Report issued by CAB must show:
  - all applicable clauses of GDPMD had been fully audited
  - evidence had been examined and assessed
  - justifications and conclusions on compliance/non-compliance to GDPMD
- Certificate issued by CAB shall be in accordance with Annex 1 of GDPMD (MDA/RR No 1: July 2013) document

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WHAT GDPMD IS NOT?

Some Misconceptions....

- An ISO9000 QMS
  - can choose the scope to be certified
  - no need to address all relevant clauses of GDPMD
  - no need to comply with regulatory requirements, Act, regulations
  - horizontal/random sampling is okay

WHAT GDPMD IS NOT?

Some misconceptions....

- **A generic system**
  - can be issued to those who are not dealing with medical device
  - easy, simple; everyone can do and anyone can be certified
  - required for all including retailers and tender agents

WHAT GDPMD IS NOT?

Some misconceptions....

- **No legal obligation, eg section 76**
  - Certificate and report can be anything, inaccurate, misleading
  - CAB and establishment do not have to take responsibility

WHAT SHOULD BE DONE TO GET YOUR GDPMD ESTABLISHED & CERTIFIED?

- Examine & understand the regulatory requirements in Act 737 & MDR2012
- Examine & understand the scope of activities involved
- Analyze, evaluate & employ measures to control & manage risks associated with the activities & types of medical devices
- Collect & compile evidence of compliance
- Appoint appropriate CAB & discuss with CAB on the scope to be certified

CONTRACTS… AGREEMENTS…

- Should you engage with other parties in establishing your GDPMD make sure:
  - they are competent, have basic relevant qualification & experience in healthcare/ medical device, knowledgeable and understand medical device regulations
  - they sign appropriate contract/agreement

REGULATORY REQUIREMENTS: FALSE DECLARATION

Section 76 of Act 737

- Any person who makes, orally or in writing, signs or furnishes any declaration, return, certificate or other document or information required under this Act which is untrue, inaccurate or misleading in any particular commits an offence and shall, on conviction, be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.
- (2) Any person who—
- (a) without lawful authority alters, forges, mutilates or defaces any registration, licence or permit; or
- (b) knowingly makes use of any registration, licence or permit whis has been altered, forged mutilated or defaced,
- commits an offence and shall, on conviction, be liable to a fine not exceeding five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

SAVINGS AND TRANSITIONAL

Act 737 Part VI: General

- Section 80: Savings and transitional
  - 80(1): A person who has imported, exported or place in the market any medical device prior to appointed date of the Act shall apply for registration of medical device within 24 months from the appointed date
  - 80(2): A person who has imported, exported or place in the market any medical device and intend to continue shall apply for establishment licence within 12 months from the appointed date
  - 80(3): A person in 80(1) or 80(2) may continue to import, export or place in the market the medical device pending determination of application

....Thank you