



Good Distribution Practice of Medical Devices

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Good Distribution Practice of Medical Devices

WHO → [selected] Economic Operators in the MD Supply Chain.

Manufacturer (Mfr)	Importer	Authorized Representative	Distributor
<ul style="list-style-type: none">• Design & Manufacture.• Prepare Technical File.• Labeling.• Post Market Surveillance.• Corrective Actions.	<ul style="list-style-type: none">• Brings in MD into territory• Acts on behalf of the AR.	<ul style="list-style-type: none">• Acts on behalf of <u>Foreign</u> Mfr.• MD Product Registration.• Communication with RA.	<ul style="list-style-type: none">• Storing, transporting, and delivering MD to end-users.• Appointed by the AR.

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[other selected] Economic Operators in the MD Supply Chain.

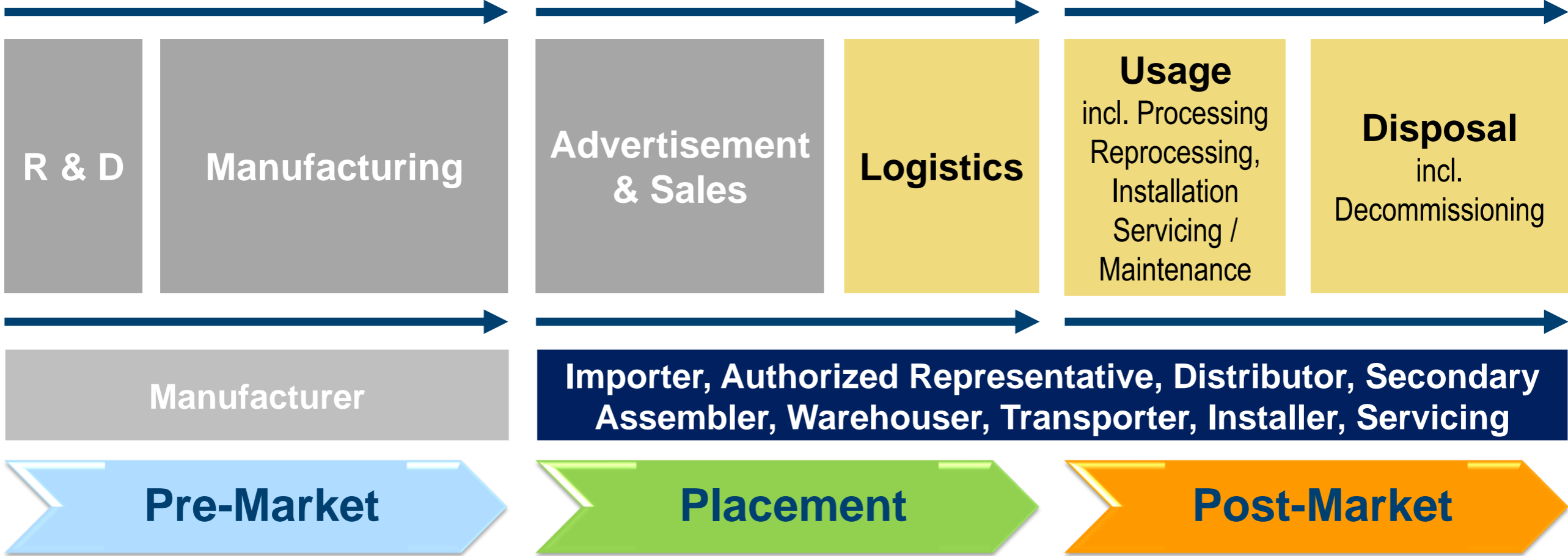


Manufacturer	Importer	Authorized Representative	Distributor	Secondary Assemblers	Transport Service Providers	MD Installation Providers	MD Servicing Providers
X	''''''''	''''''''	''''''''	Transferring an intact primary packaged MD into another container/ Package.	Warehousing, and Logistics.	Installation, Testing & Commissioning <i>(including the required facilities).</i>	Maintenance and Calibration <i>(including the required facilities).</i>

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WHO → [selected] Economic Operators in the MD Supply Chain.

WHAT → Requirements to preserve MD quality, safety & performance throughout the MD Supply Chain.

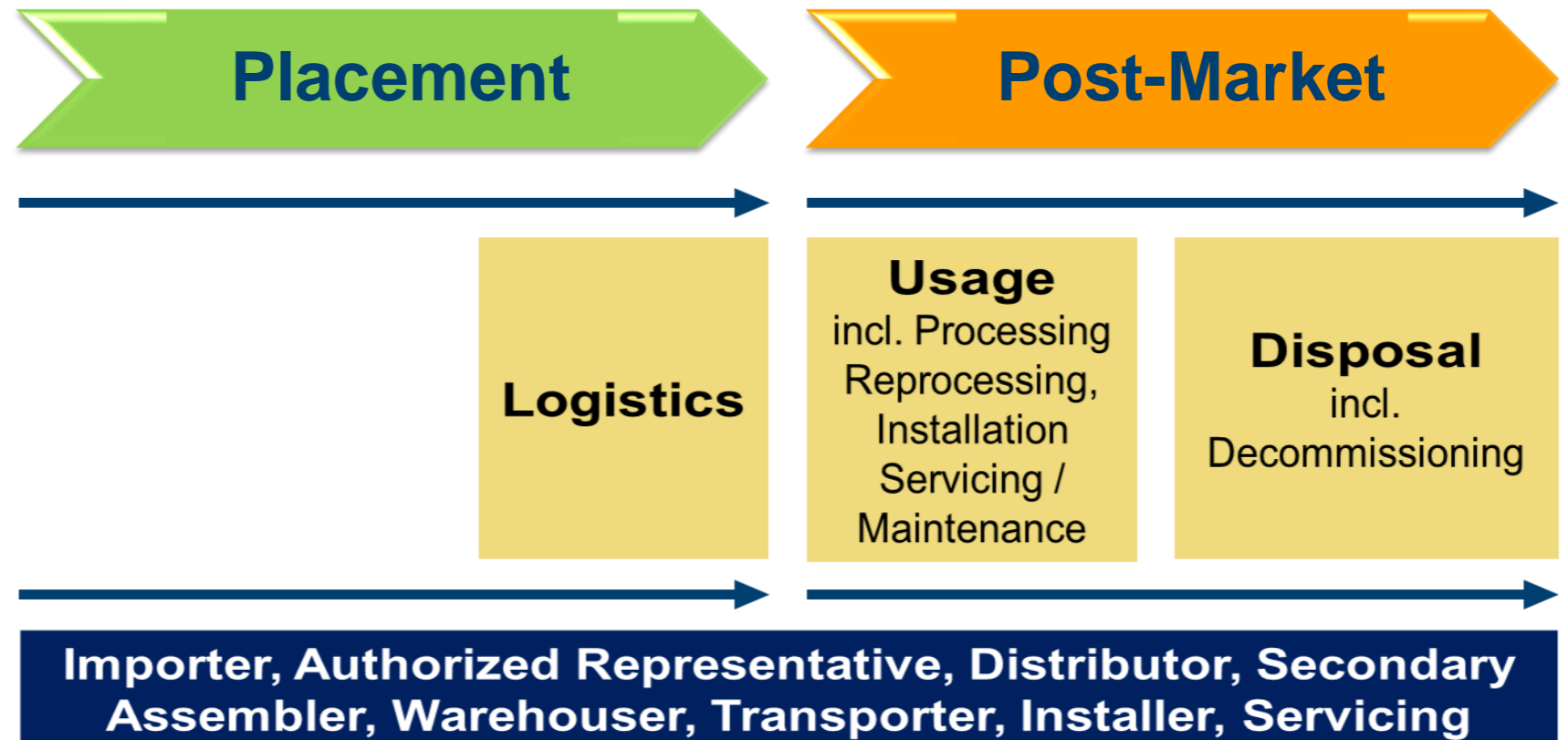


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WHO → [selected] Economic Operators in the MD Supply Chain.

WHAT → Requirements to preserve MD quality, safety & performance throughout the MD Supply Chain.

WHEN → During MD Placement & Post Market stages.



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WHO

[selected] Economic Operators in the MD Supply Chain.

WHAT

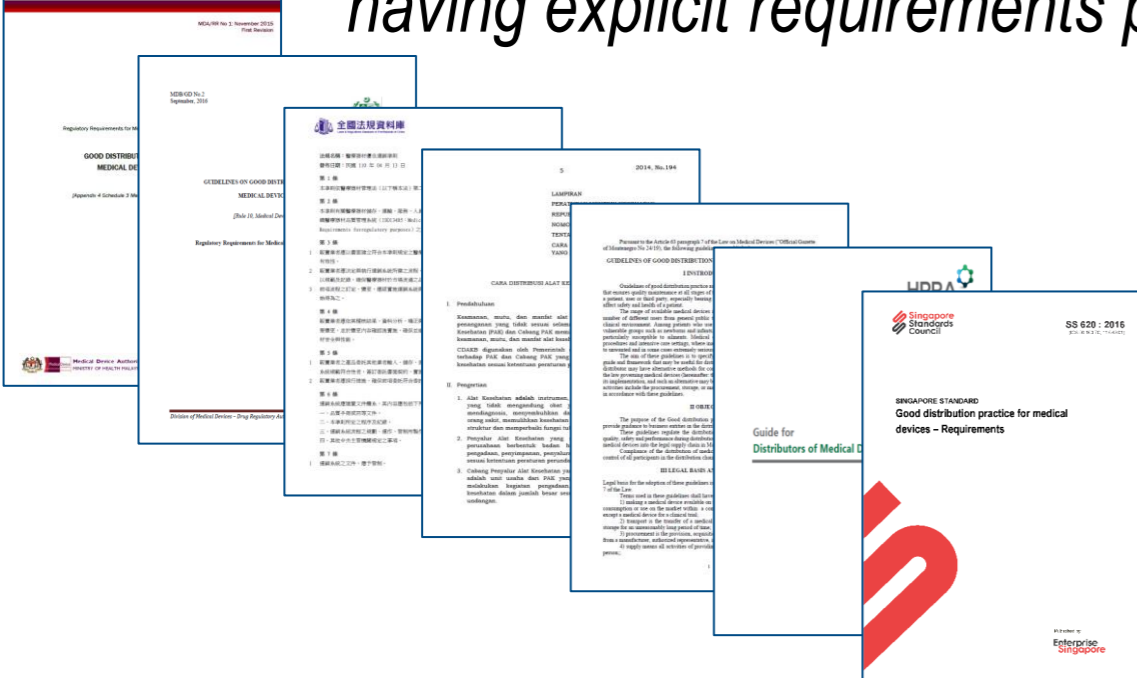
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WHEN

During MD Placement & Post Market stages.

WHERE

[general expectation of the MDR for] **Regulated Markets**, with some RA's having explicit requirements published.



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WHO

→ [selected] Economic Operators in the MD Supply Chain.

WHAT

→ Requirements to preserve MD quality, safety & performance throughout the MD Supply Chain.

WHEN

→ During MD Placement & Post Market stages.

WHERE

→ [general expectation of the MDR for] **Regulated Markets**, *with some RA's having explicit requirements published.*

WHY

→ **Ensure patient safety and protect public health interest.**

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WHY → Ensure patient safety and protect public health interest.

Contamination

Degradation

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WHY → Ensure patient safety and protect public health interest.

Contamination

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Counterfeit

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- WHO** → [selected] Economic Operators in the MD Supply Chain.
- WHAT** → Requirements to preserve MD quality, safety & performance throughout the MD Supply Chain.
- WHEN** → During MD Placement & Post Market stages.
- WHERE** → [general expectation of the MDR for] **Regulated Markets**, *with some RA's having explicit requirements published.*
- WHY** → Ensure patient safety and protect public health interest.
- HOW** → **Structured [risk-based] QMS throughout the MD Supply Chain, which is subjected to regulatory oversight and is a requisite for certification & licensing of affected economic operators.**

Medical Device QMS w.r.t. Regulatory Phases

Medical Device Regulatory Phases



ISO 13485:2003	Yes		
ISO 13485:2016	Yes		
GDPMD	Partial		

Medical Device QMS w.r.t. Regulatory Phases

Medical Device Regulatory Phases



ISO 13485:2003	Yes	NO	
ISO 13485:2016	Yes	NO*	
GDPMD	Partial	Yes	

Medical Device QMS w.r.t. Regulatory Phases

Medical Device Regulatory Phases



ISO 13485:2003	Yes	NO	Implied
ISO 13485:2016	Yes	NO*	Yes
GDPMD	Partial	Yes	Yes

Elements of GDPMD – *non-exhaustive, subject to differences between jurisdictions*

Handling

Storage

(incl. Warehousing, Temperature & Humidity Control)

Transportation / Delivery

(incl. Warehousing, Temperature & Humidity Control)

Elements of GDPMD – *non-exhaustive, subject to differences between jurisdictions*

Secondary Assembly
(incl. Repackaging, Relabeling)

Installation

Servicing

Handling

Storage
(incl. Warehousing, Temperature & Humidity Control)

Transportation / Delivery
(incl. Warehousing, Temperature & Humidity Control)

Elements of GDPMD – *non-exhaustive, subject to differences between jurisdictions*

Though certain elements are entitled the same between ISO 13485 & GDPMD, terms & requirements are **NOT** identical.

Supplier & Outsource Management

Facilities & Equip.
(incl. Qualification & Validation)

Cleanliness & Hygiene
(incl. Pest Control)

Competency

Self Assessment
(incl. Internal Audits, Mgmt. Reviews)

Corrective Action, Preventive Action

Documentation & Records

Non-Conforming Product Control

Disposal

Authorization

Traceability

Distribution Records

Quality Management System

Risk Management

Complaints & Post Market Surveillance
(incl. FSCA // FCA & FSN)

Secondary Assembly
(incl. Repackaging, Relabeling)

Installation

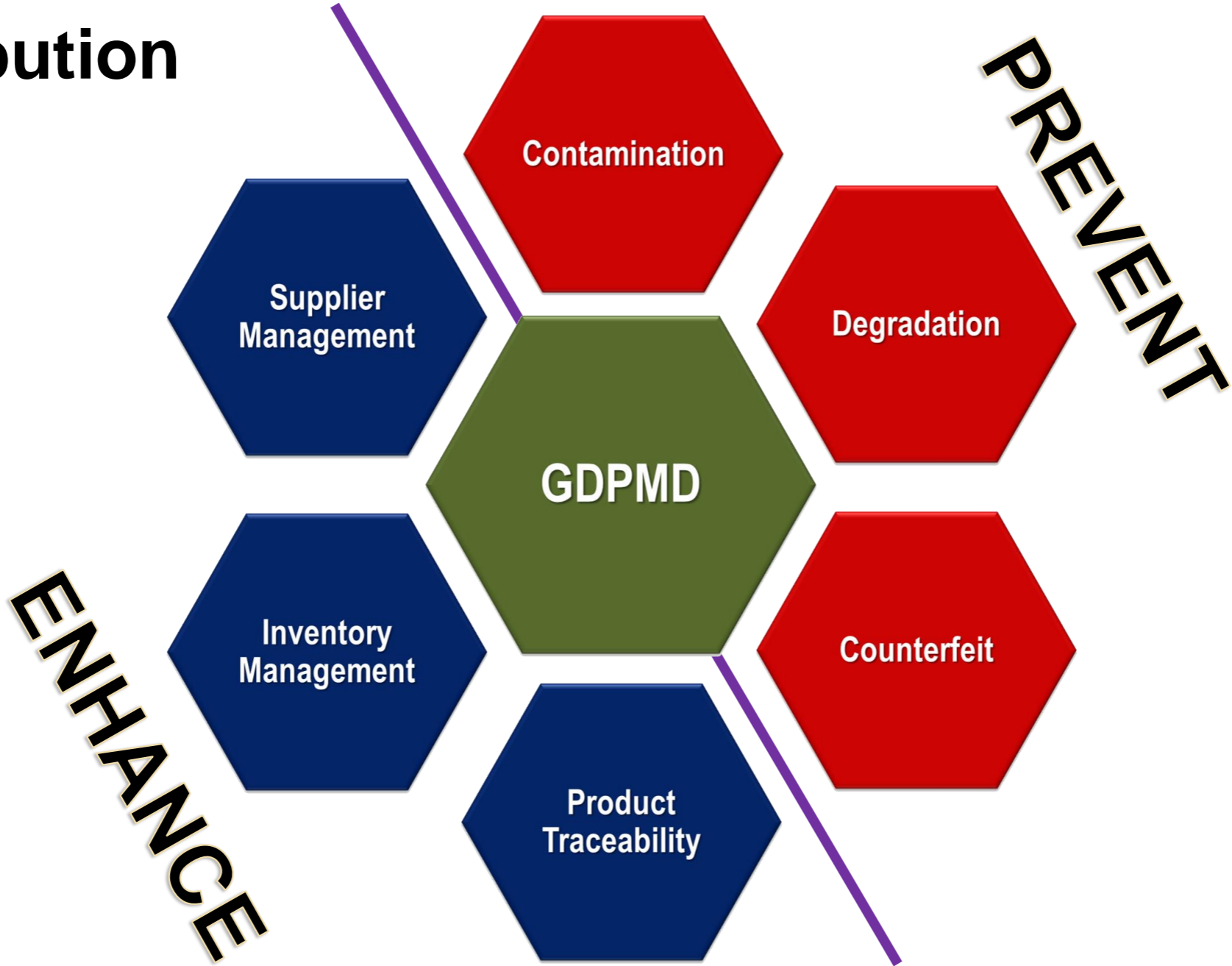
Servicing

Handling

Storage
(incl. Warehousing, Temperature & Humidity Control)

Transportation / Delivery
(incl. Warehousing, Temperature & Humidity Control)

Assurance of MD Quality, Safety, & Performance during MD Distribution



Quality Management Systems

ISO 13485:2016

- For Manufacturer (& related Service Providers)
- 8 Clauses
- Quality Manual
- Circa 20++ / 30++ SOPs dependent on Regulations + Manufacturers Product, Processes & Scope
- Records required
- *CSDT // *TF / DHF, DMR



MDA/RR No.1:Nov 2015

- For Authorized Representative, Importer, Distributor, Secondary Assembler, Warehouse, Transporter, Installer, Servicing
- 45 Clauses forming 6 Parts
- Regulatory Compliance Manual
- Circa 20++ SOPs dependent on Establishments Product, Processes & Scope
- Records required
- *CSDT

Rationale for GDPMD

- Whilst ISO 13485 : 2016 attempts to cover the entire product lifecycle, it does **not** adequately address handling, storage, and transportation activities during MD distribution.
- Such absence of control can lead to compromised quality, safety, and performance of MD, ultimately putting patients at risk and have a negative impact public health interest.
- Additionally, a RA defined GDPMD system plays a crucial role in ensuring compliance of affected economic operators to regulatory requirements. This compliance is essential in reducing the risk of non-compliance and associated penalties.