THE ROLES & RESPONSIBILITIES IN THE SUPPLY CHAIN FOR MEDICAL DEVICES: Safety, Performance and Conformity Assessment Throughout the Total Product Life Cycle

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INTRODUCTION

- Assuring medical device safety requires oversight of the use of medical devices
- All elements of control from design through disposal are required to be put in place to ensure continued safety and performance throughout total life cycle
- Different parties are involved

TOTAL PRODUCT LIFE CYCLE

Manufacturing, import, packaging, labelling, storage, tracking, surveillance/vigilance

Advertising, distribution, transportation, storage, tracking

Installation, usage, maintenance, surveillance/vigilance, incident reporting

PRE-MARKET

PLACEMENT ON-MARKET

POST-MARKET

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ROLES & RESPONSIBILITIES OF MANUFACTURER/AUTHORIZED REPRESENTATIVE

- Ultimate regulatory responsibility
- To ensure safety and performance of medical devices are maintained throughout total life cycle of the device
- Well addressed in many GHTF documents
- Issues: Training of users and 3rd Party Service Providers

ROLES & RESPONSIBILITIES OF DISTRIBUTOR/RETAILER

- To ensure safety, quality and performance of medical devices are maintained throughout the distribution chain
- This includes storage, transportation, distribution, installation

ROLES & RESPONSIBILITIES OF DISTRIBUTOR/RETAILER

- Issues:
  - Storage, transportation & tracking of device
  - Communication channel with manufacturer/retailer/user
  - Good Distribution Practise
  - Quality of service
  - Regulatory control, standards, guidelines

ROLES & RESPONSIBILITIES OF USER

- To ensure medical devices are used in accordance to the intended use in accordance with the specifications
- To ensure continued safety and performance of medical devices from the point of installation through to disposal
- To ensure the device is decommissioned and disposed accordingly

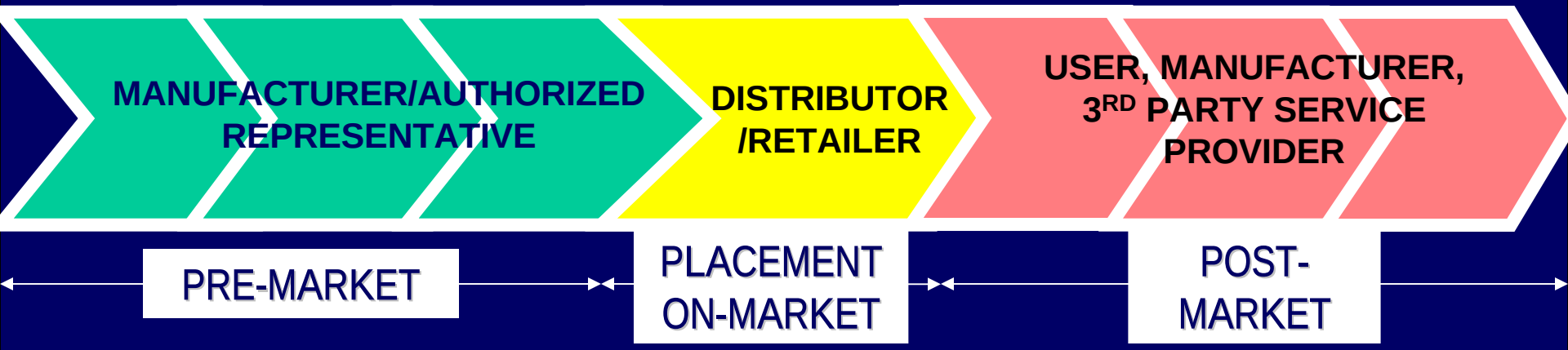
ROLES & RESPONSIBILITIES OF USER

- Issues:
  - Usage of device, no misuse
  - Installation, testing & commissioning
  - Maintenance by 3rd Party service provider
  - Safety of patients, users & public
  - Competency of user & maintenance staff
  - Performance monitoring
  - Adverse event reporting
  - Device Tracking
  - Disposal
  - Regulatory control, standards, guidelines

Manufacturing, import, packaging, labelling, storage, tracking, surveillance/vigilance

Advertising, distribution, transportation, storage, tracking

Installation, usage, maintenance, surveillance/ vigilance, disposal, incident reporting



TO ENSURE SAFETY AND PERFORMANCE OF MD THROUGHOUT TOTAL LIFE CYCLE:

Do we need to include retailer, user and 3rd party service provider and their respective activities into the scope of MD regulation??

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