

Role of Distributor in Global Harmonization and Integrity of Medical Device Supply Chain

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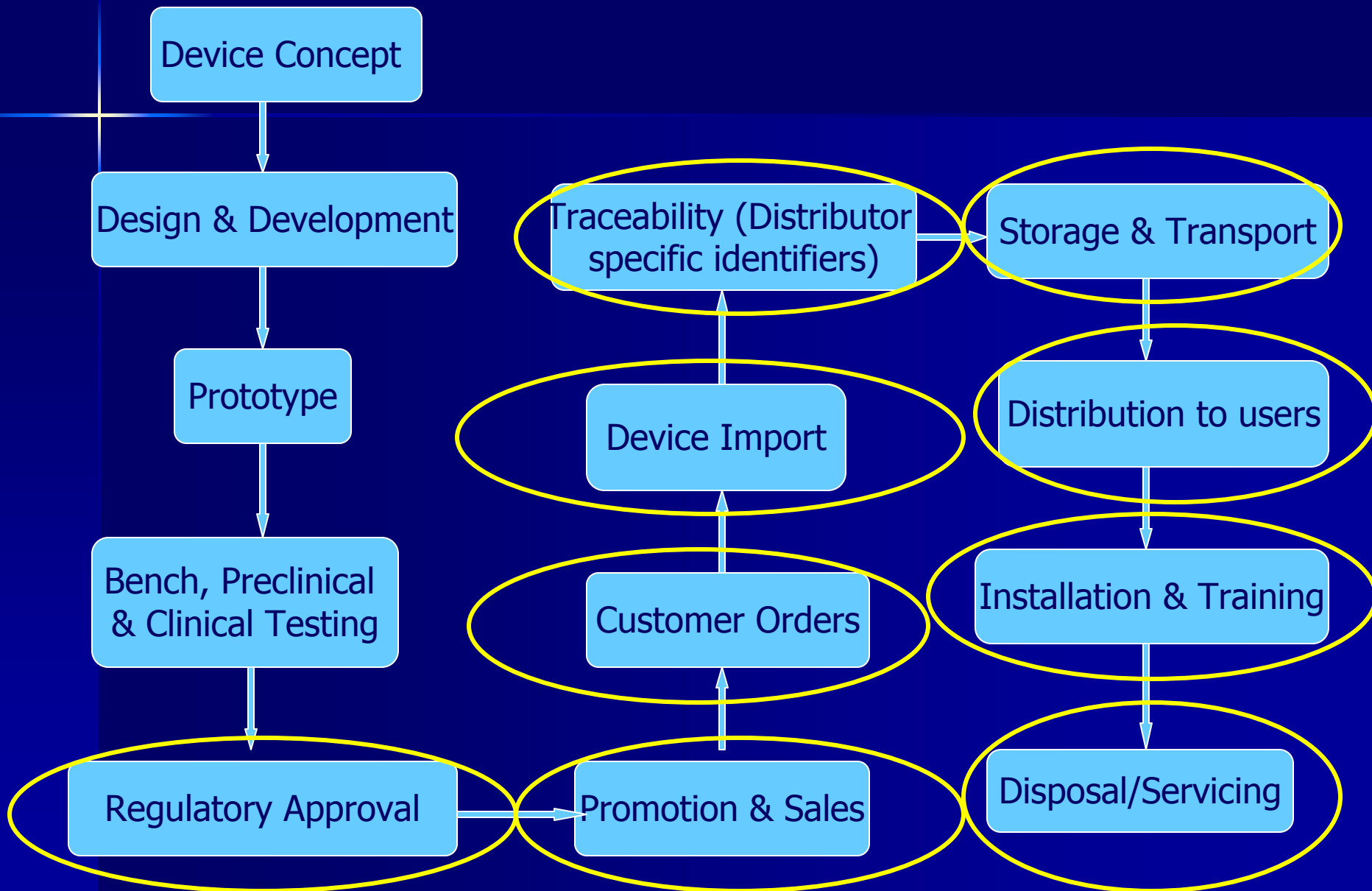
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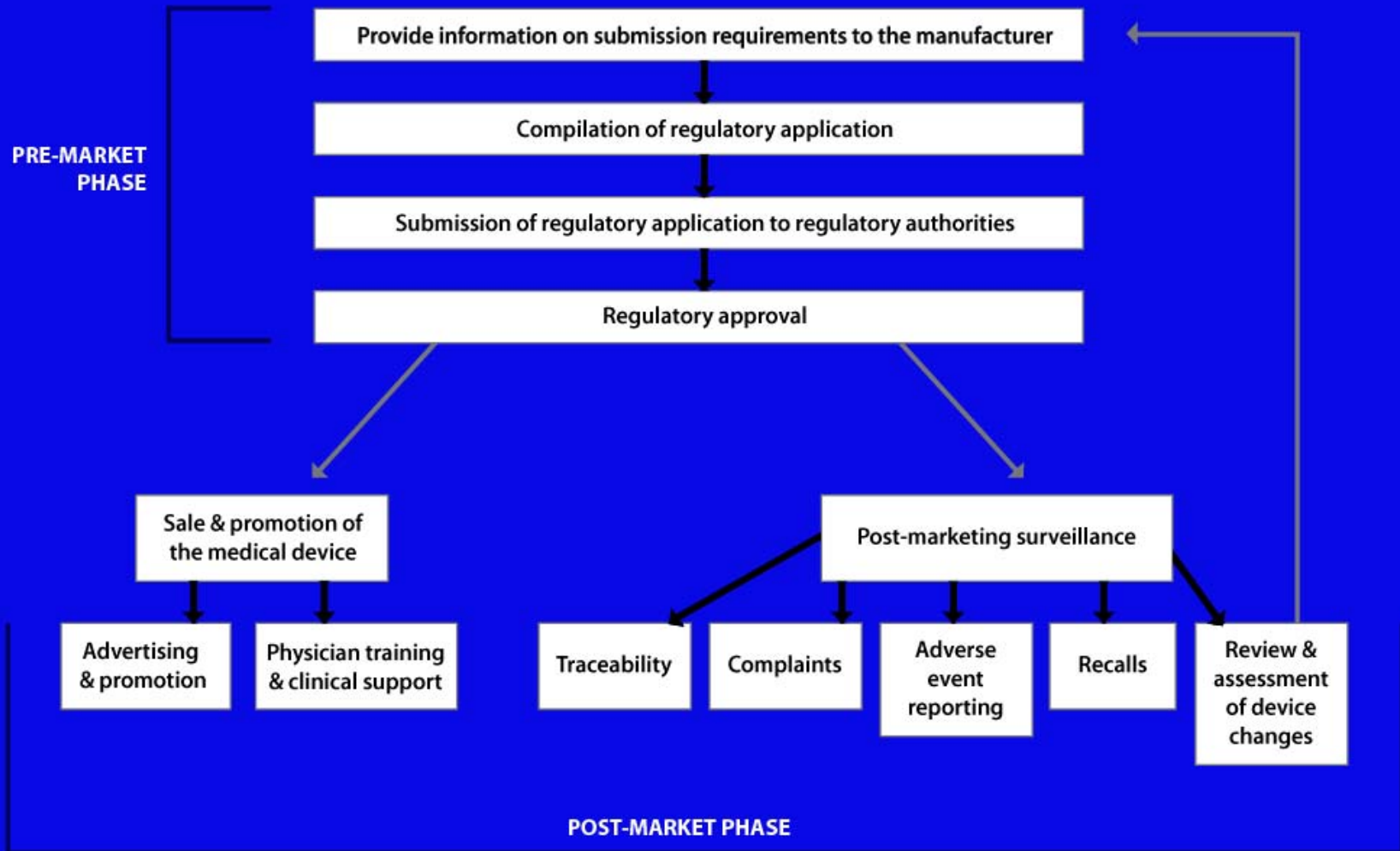
Presentation Outline

- Role of distributor:
 - Medical Device Supply Chain
 - Harmonization
- Harmonization - Challenges

Medical Device Supply Chain



Regulatory Role of the Distributor in Medical Device Supply Chain



Medical Device Supply Chain: Regulatory Role of the Distributor

- Legal responsibility for the safety and performance of the device throughout distribution chain
- Responsible for medical device approval and continued regulatory compliance in the respective jurisdiction
- Corresponds with the regulatory authority on behalf of the manufacturer
- Provides feedback collected from the field on device performance to the manufacturer

Harmonization - Role of the Distributor

- Knowledge of regional regulatory requirements and GHTF activities
- Instrumental in deploying the harmonized approach to several manufacturers
- Assist the manufacturer to submit the regulatory application in harmonized format (STED plus regional requirements)
- Be conscious of the level of change required for the manufacturer to implement the regional and harmonization requirements into their quality system
- Maintain effective communication with the manufacturer

Harmonization - Challenges in Pre-Market Phase

- Different country specific requirements
 - Regulatory philosophy including risk based classification
 - requirement for approval from FDA/EU/country of origin
 - requirement for testing the devices (development of standards)
 - material requirements
 - labelling requirements, etc.
 - difference in submission format by the manufacturer
- Difference in timelines of implementation of harmonized requirements
 - E.g. EN 60601 standard, DEHP and BPA requirement

Harmonization - Challenges in Post-Market Phase

- Different adverse event reporting timelines & definitions of “recall” for different jurisdictions
- Lack of communication between distributor and manufacturer: prevents timely submission of adverse event reports and recall notifications

Summary & Discussion

- Role of distributor:
 - Medical Device Supply Chain
 - Harmonization
- Harmonization - Challenges