



**Global Harmonization Working Party**

GHWP Towards Medical Device Harmonization

# Case Sharing of QMS Implementation in China

Mindray QMS Introduction



Mindray at a glance

# Strong business performance with increasing global presence and impact



Serving <b>190+</b> countries and regions	Over <b>18,000</b> employees from 30 countries	<b>Over 50</b> international subsidiaries around the world
<b>\$4.82 B</b> revenue in 2023	<b>4,400+</b> R&D engineers worldwide	<b>12</b> R&D centers across the globe

**Europe** | **660+** teaching hospitals in Europe

**US** | **Top 20** hospitals in the U.S.

**9** of top 10 cardiac hospital in the U.S.

**China** | **99%** of Tier 1 hospitals in China

# China Regulations and Mindray QMS

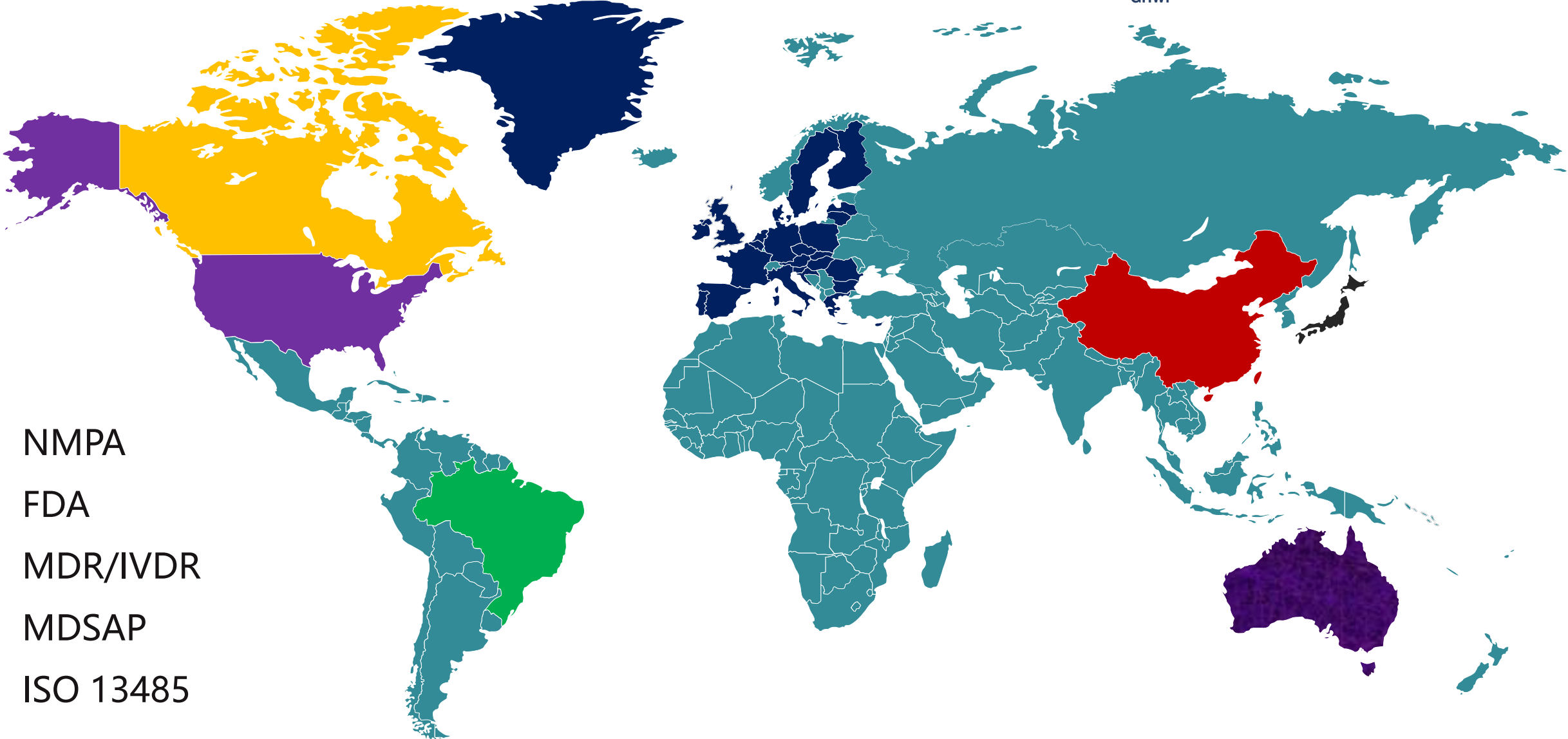


# Global Quality and Compliance Strategy



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NMPA

FDA

MDR/IVDR

MDSAP

ISO 13485

28<sup>th</sup> GHWP Annual Meeting and 28<sup>th</sup> GHWP TC Meeting, 9<sup>th</sup> - 12<sup>th</sup> Dec 2024  
Kuala Lumpur, Malaysia

# Customer-oriented & Globally compliant QMS

## Customer-oriented Quality Management System

ISO 13485  
Certification

ISO 9001  
Certification

QC 080000  
Certification

AEO  
Certification

### Integrated Quality Management System



Requirements  
Management

V&V  
Requirements  
Implementation

Integrated  
Supply Chain  
management

Service full-  
scene  
system

Post-Market  
Surveillance  
Management



Customer  
Needs



Customer  
satisfaction

Compliance



Manufacturing License, GMP Certification, MDD Certification, MDR Certification, IVDD Certification, IVDR Certification

# QMS based on business chain collaboration



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Comprehensive quality control ensures product consistency from material to product delivery

**Design & Development**

R&D Quality

**Purchasing**

Purchase quality

**Production**

Production quality

**Distribution & Service**

Post-marketing quality



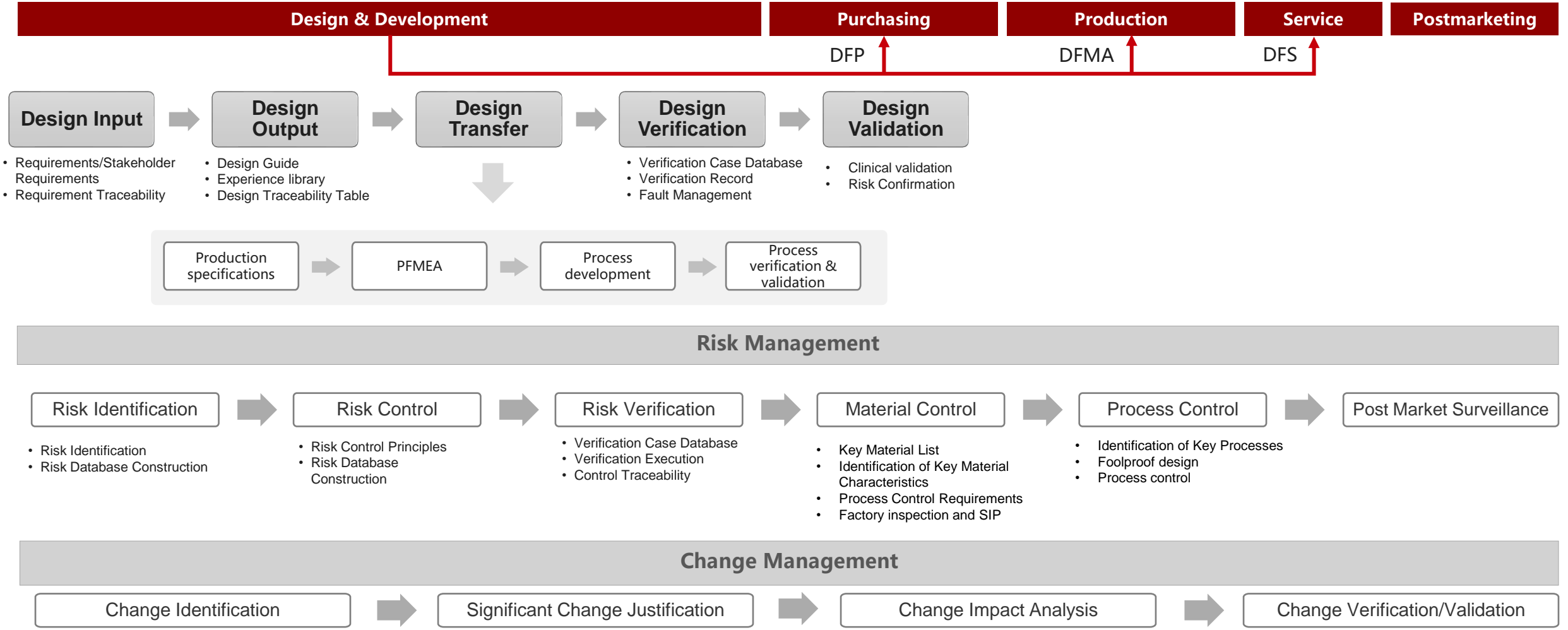
Risk Management

Change Management

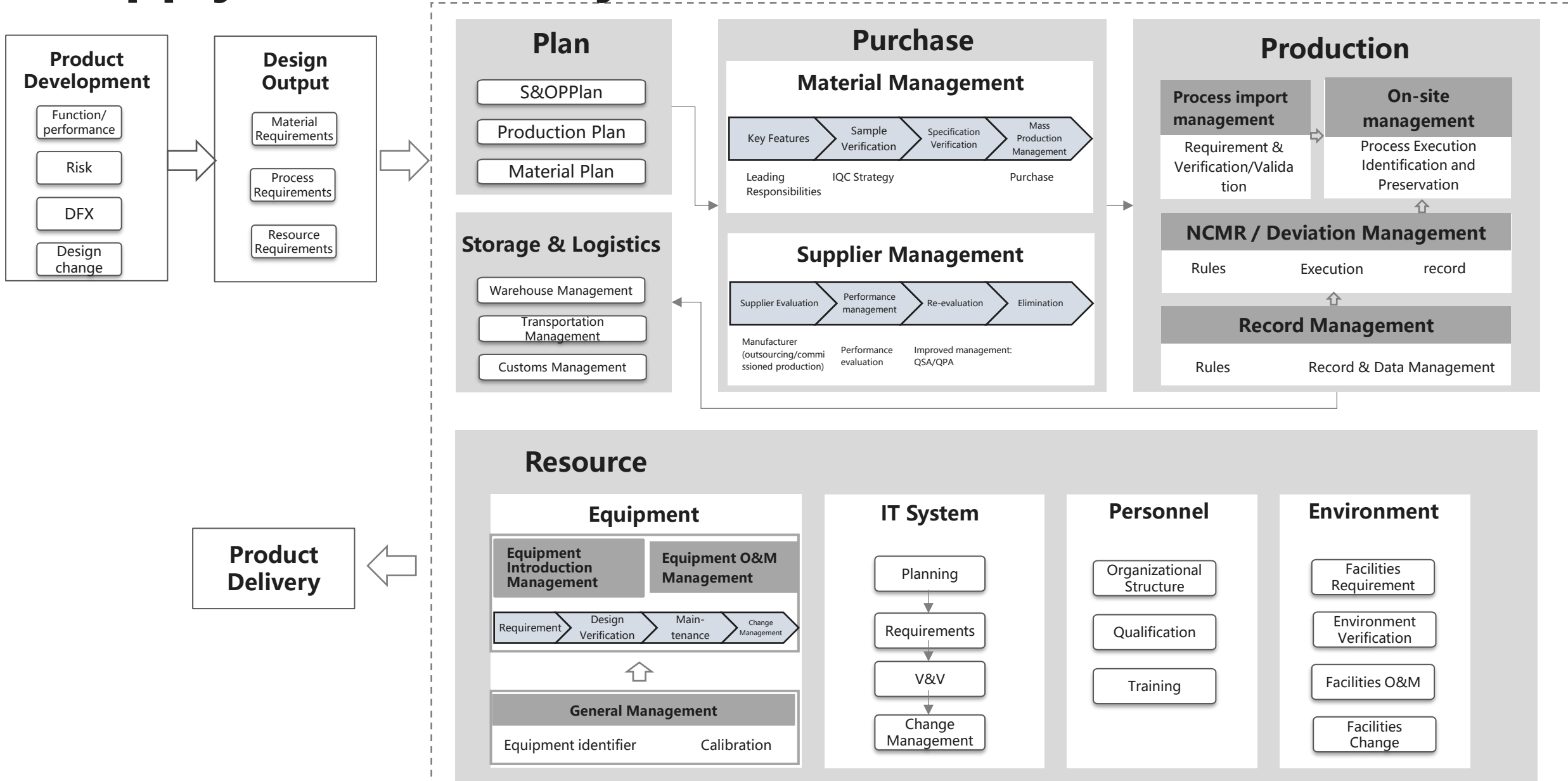
Quality Improvement

Quality System Construction

# R&D Quality



# Supply Chain Quality





# Post-market surveillance



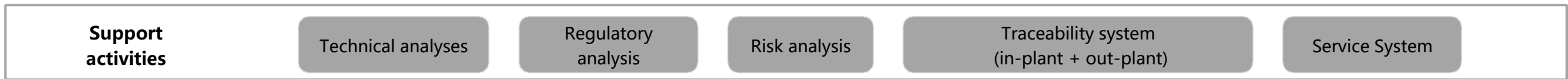
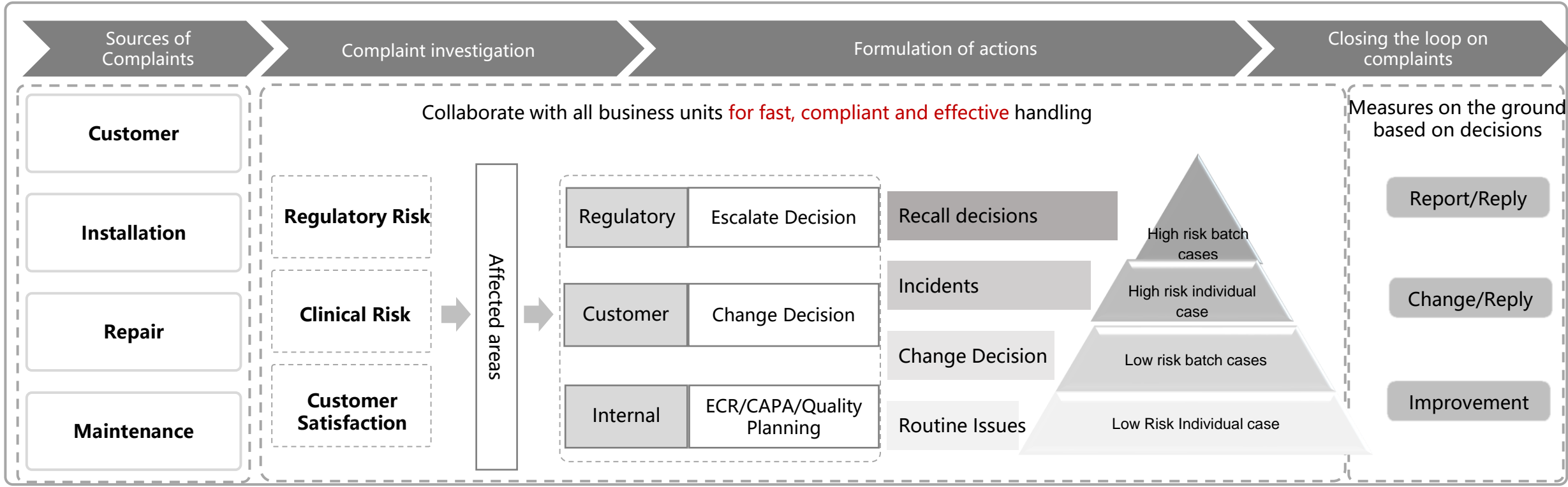
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Post-launch monitoring activities focus on the complaint handling activities





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# THANK YOU