Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

The Role of UDI in Product Life Cycle Management

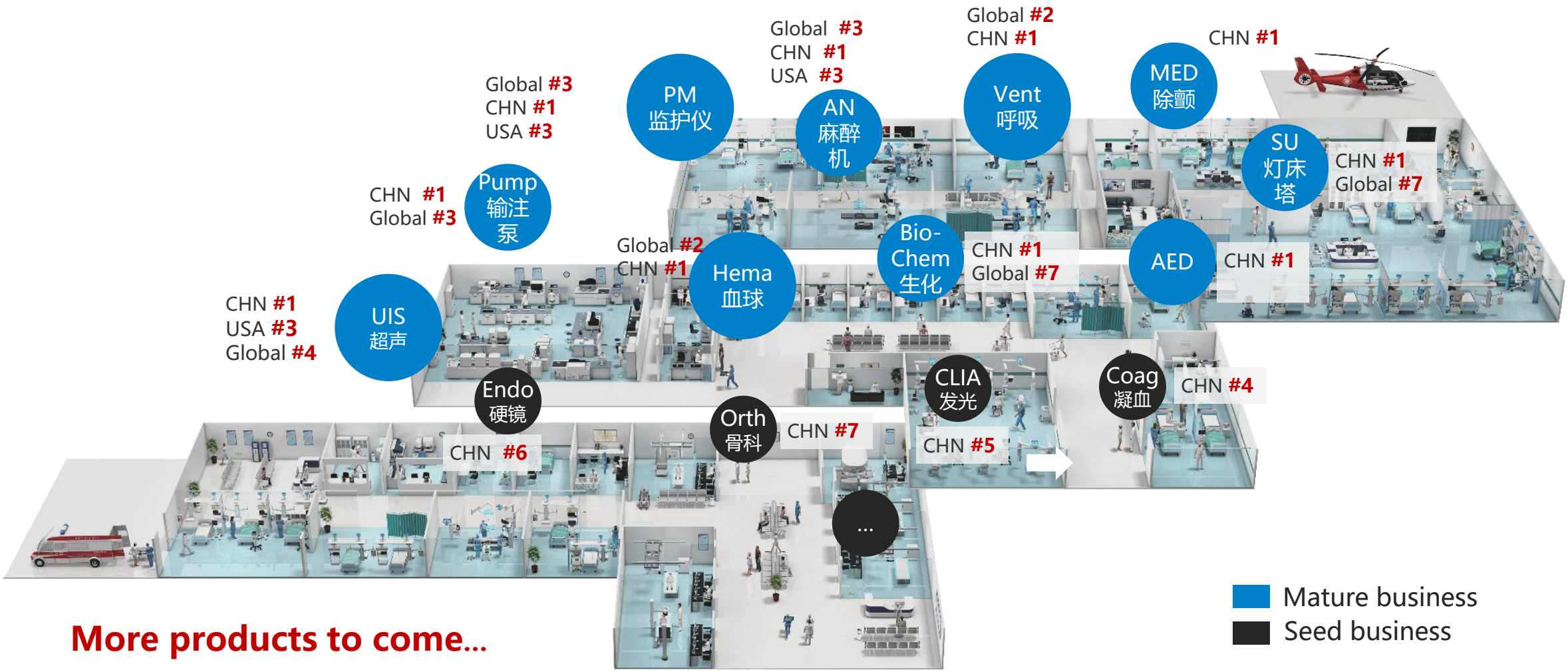
mindray 迈瑞

Xinbing Wang

Content

Mindray at a Glance

Wide-ranging, Competent Products and Solutions



More products to come...

UDI for Diverse Product in Mindray

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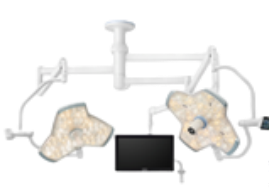
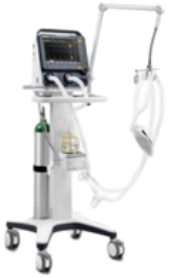
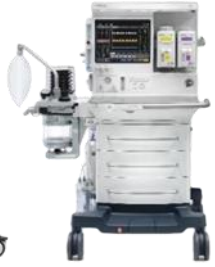
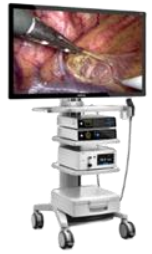
Single Device







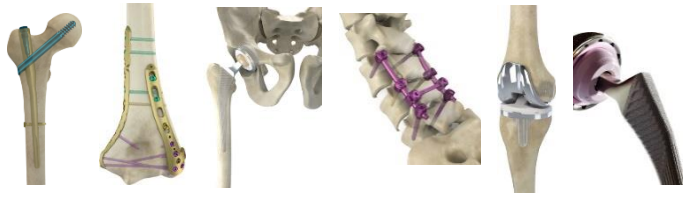


Configurable Device

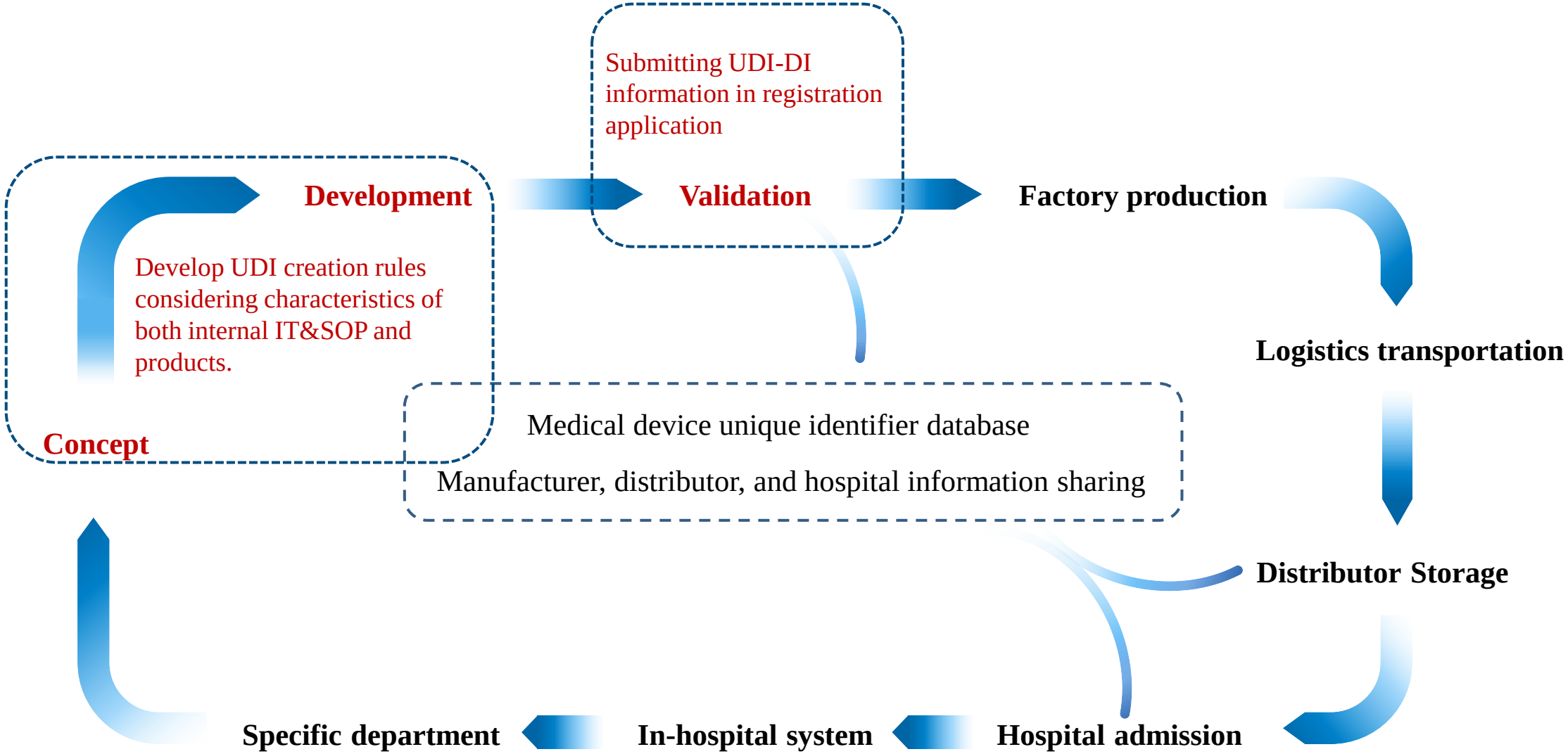
Software Device

IVD Kits

Implantable Device



Application of UDI in Product Life Cycle



Product Basic Information for UDI

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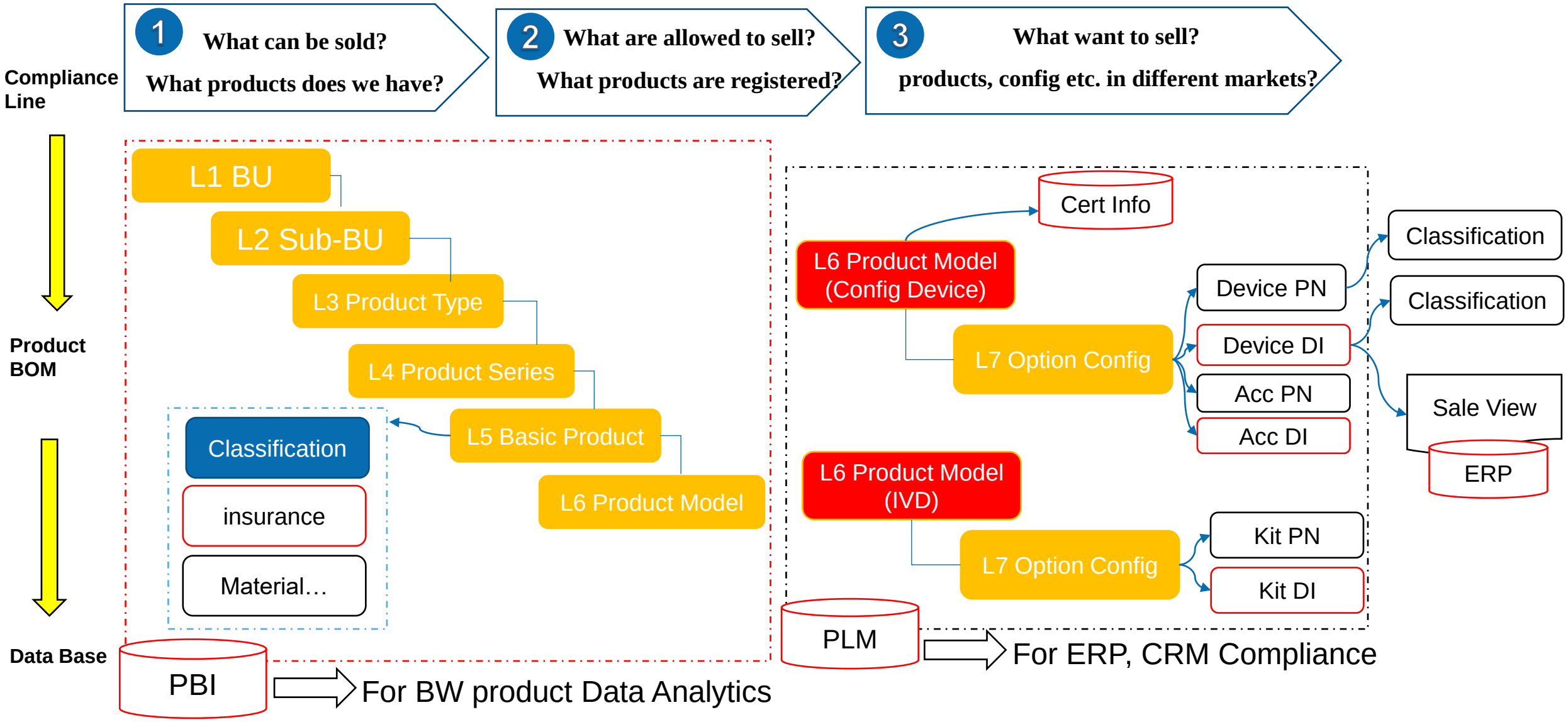

Design, Verification and Validation of UDI

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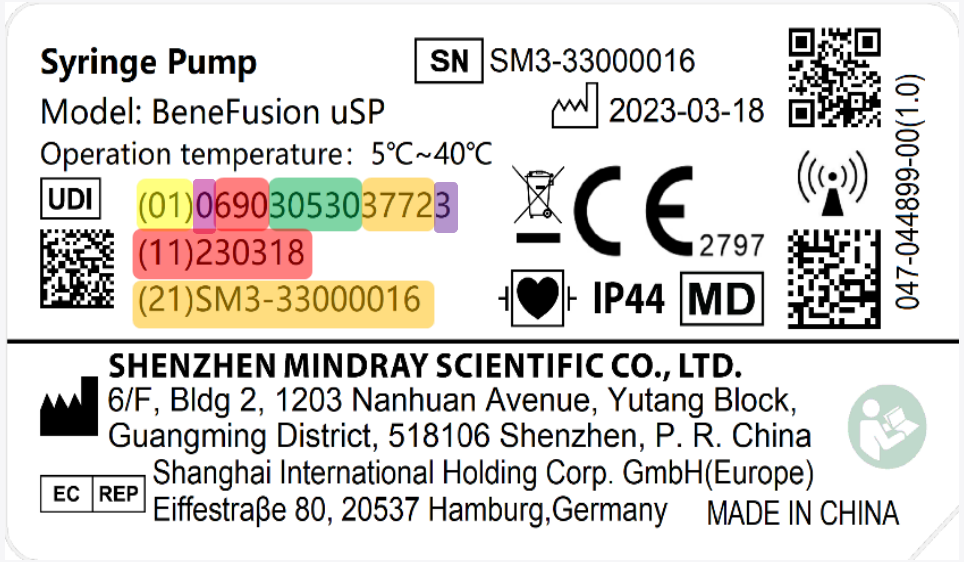
Design Input — Create DI

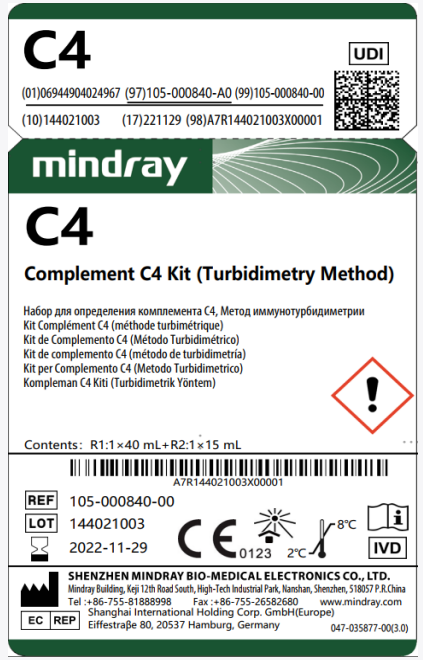
Design Transfer — Fill in the UDI data

Design Output — Material R&D Data Management
Label manual template

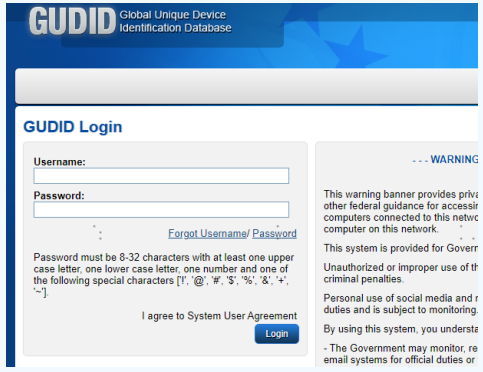
Design Validation — Evidence of UDI Compliance

Change Control — ECR





FDA GUDID



EU Eudamed

NMPA UDI Database

Supply Chain with UDI

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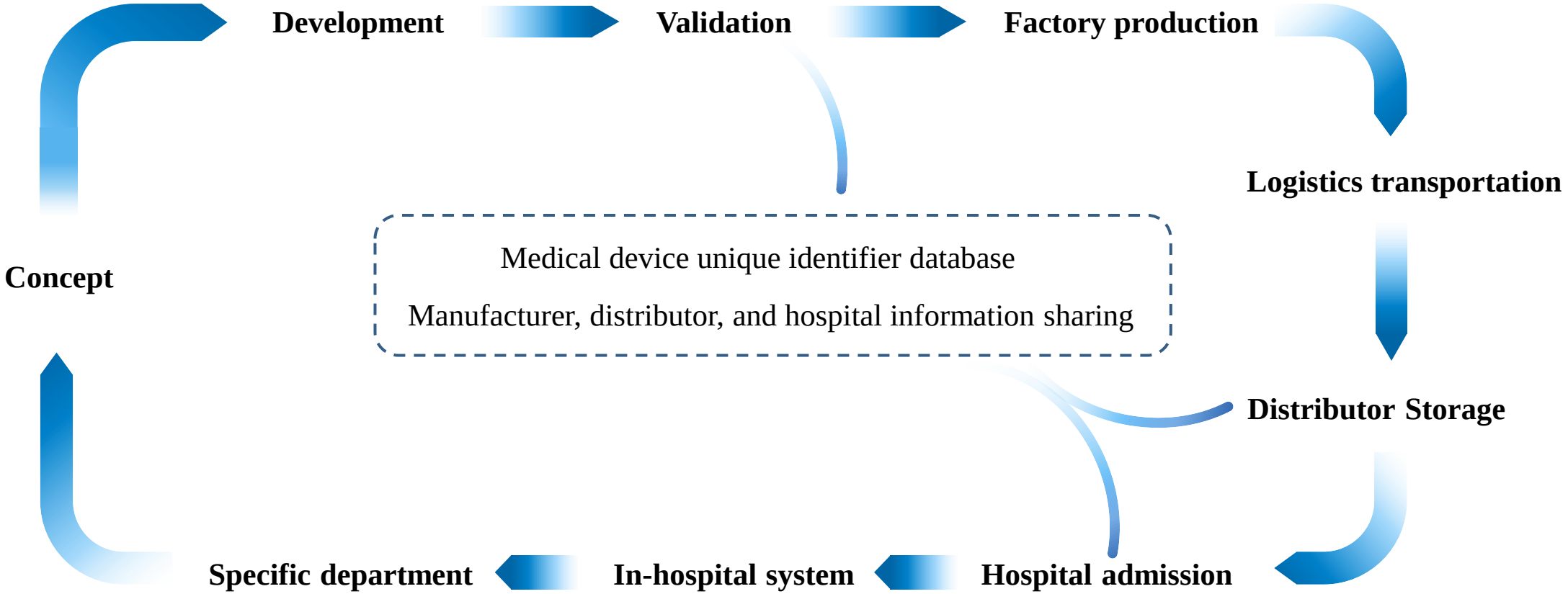
1. Manage products by the use of DI.
2. Release serial or batch number after receiving the work order, and then allocate PI according to the serial/batch number, so as to trace and manage the physical products.
3. attached an UDI label consistent with the obtained DI and PI.



Automatic Printing for Compliance

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Production auxiliary system (Receive Work Order)

Release Code

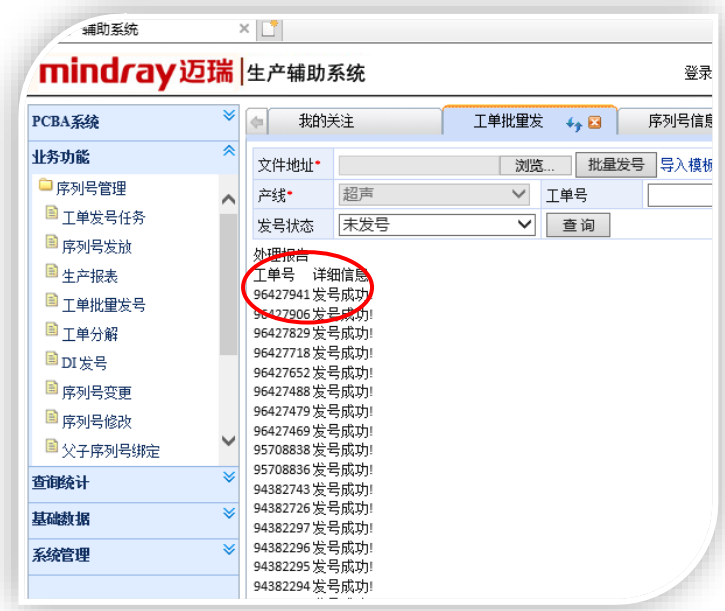
Release SN/Batch No. pursuant to work order, and then allocate PI

Label printing

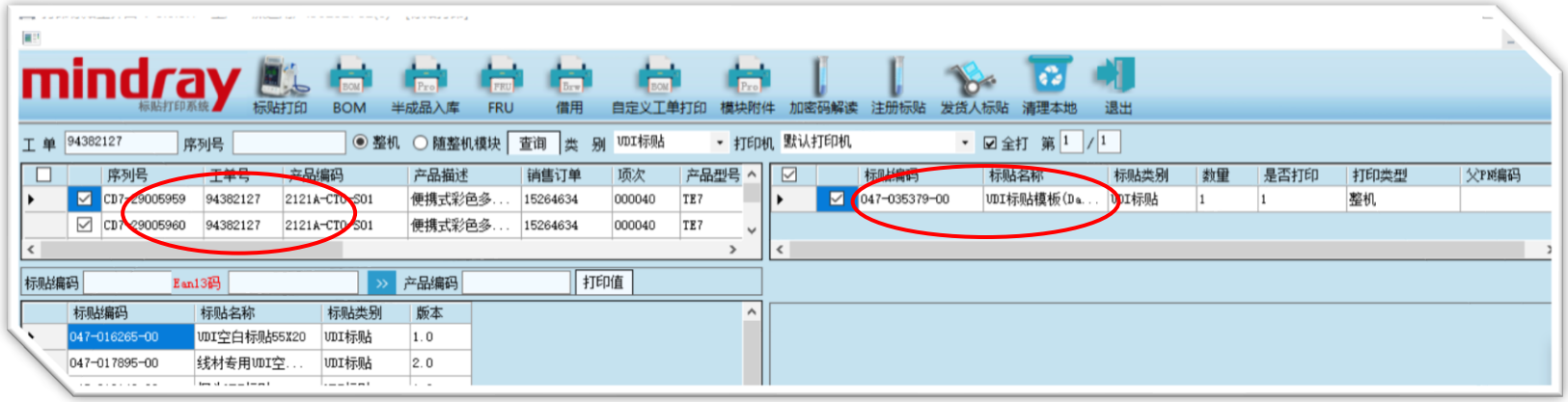
Template selection and printing

Warehousing

Scanning and warehousing



The automatic printing system assure labels, certificates of conformity, and GSP accompanying bills for compliance.



Single Data Entry, Multiple Uses

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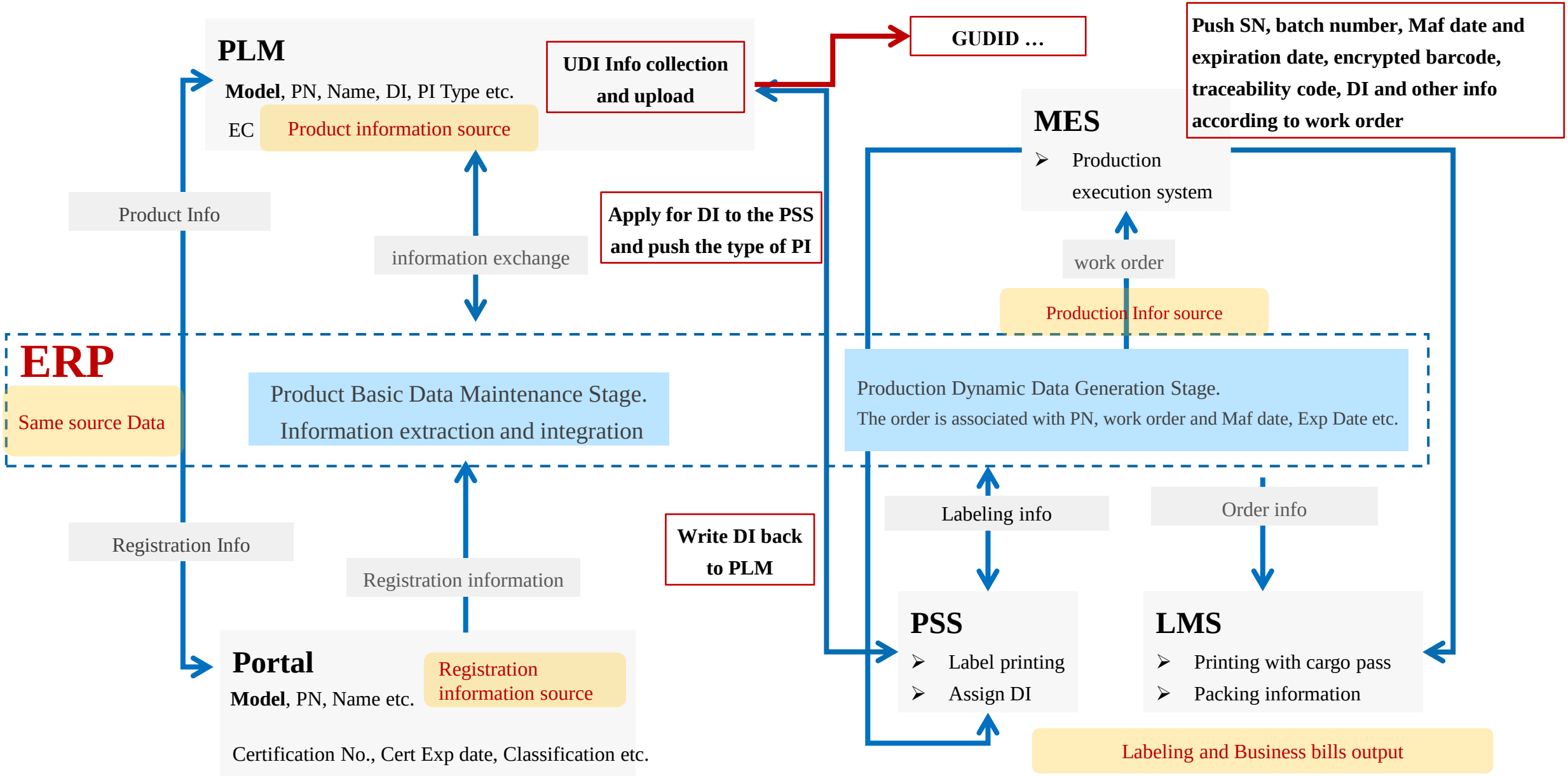
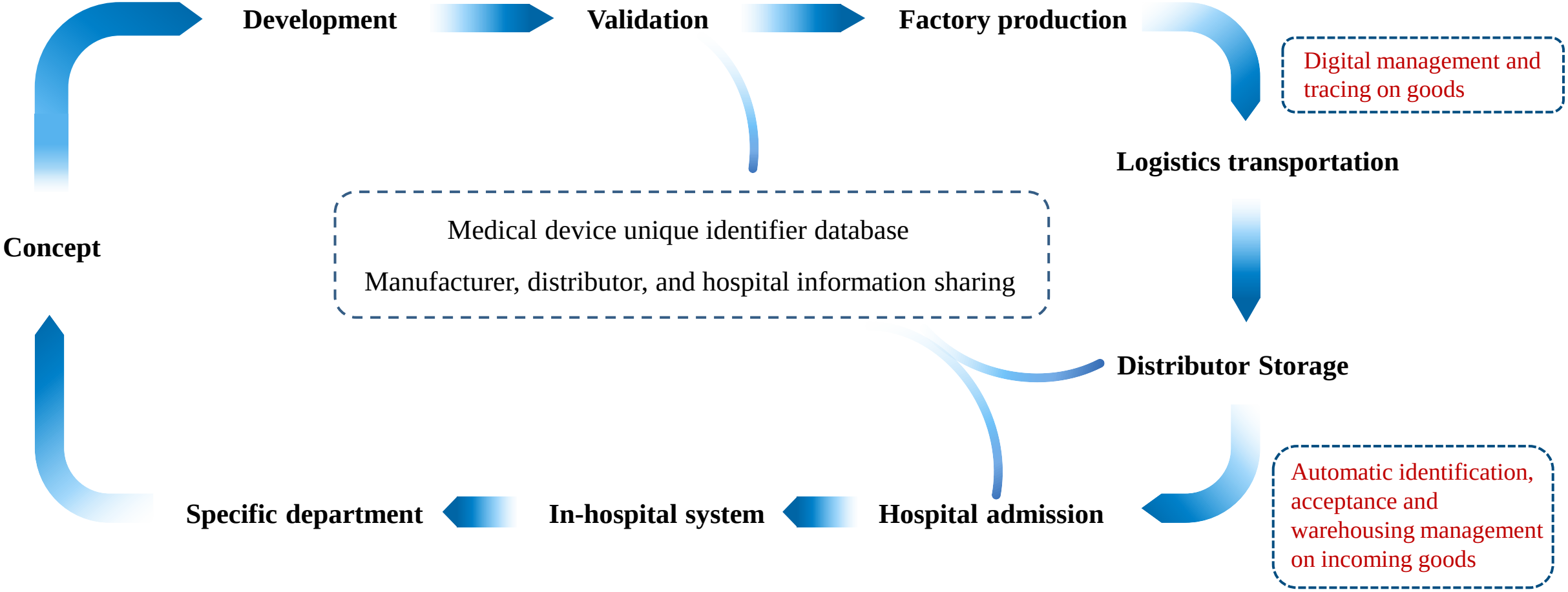


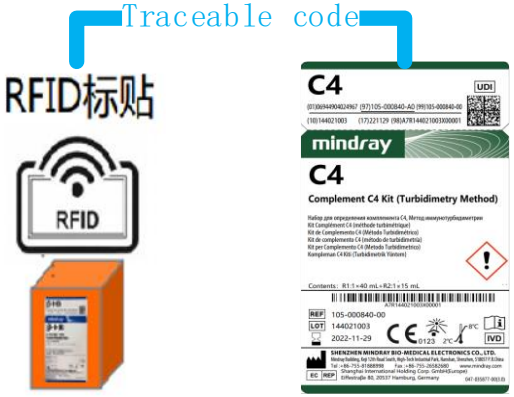
Smart Distribution



Smart Distribution

Mindray Production

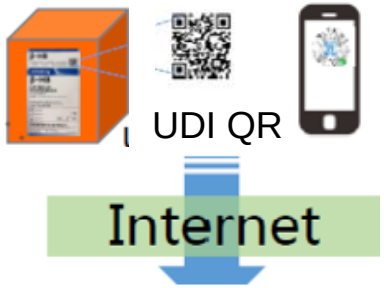
- **UDI QR code is pasted on the package**
  - ✓ **Product identification code**
  - ✓ **Batch No.**
  - ✓ **Production date and expiration date**
  - ✓ **PN code**
  - ✓ **DI**
  - ✓ **Traceable bar code**
- **Write the traceable bar code into the RFID label**



Mindray Delivery

- **Mindray ERP System Delivery**
- **The Mindray DMS system synchronously generates the documents to be warehoused.**

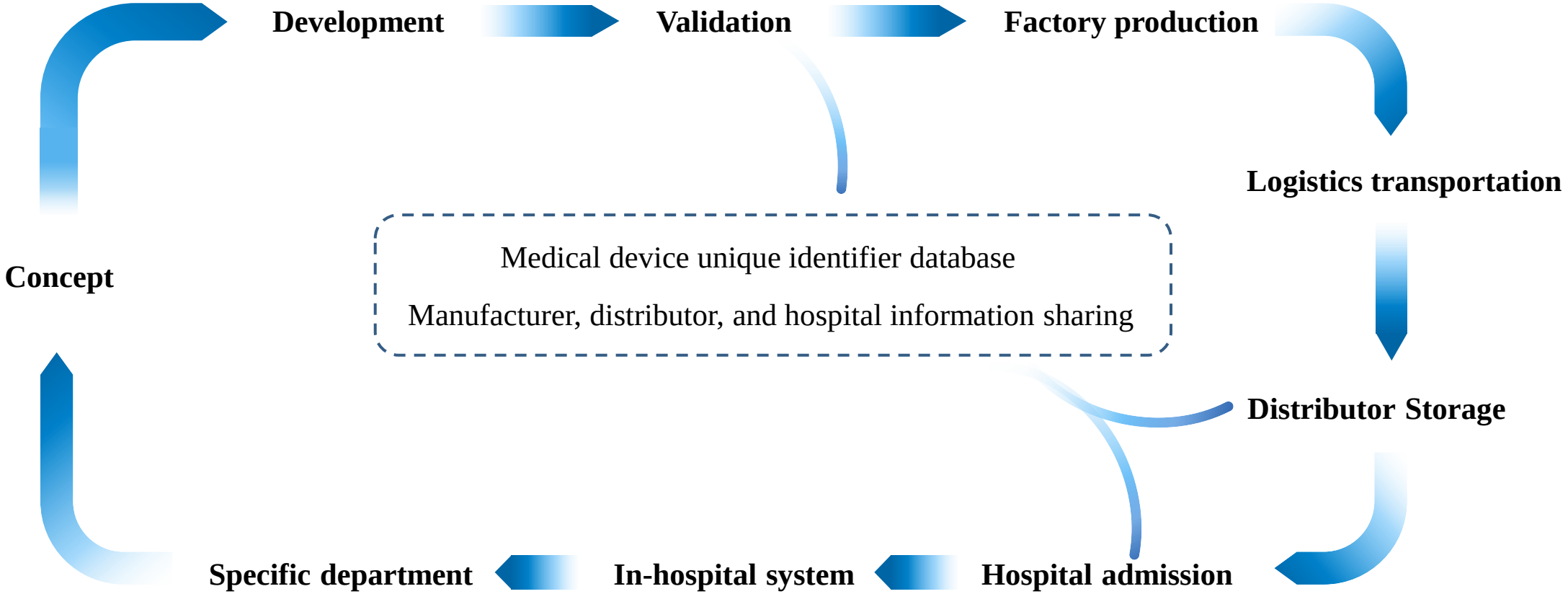
Mindray ERP Delivery note — **Internet** — **DMS Waiting List**



Distributor	DN	PN	Description	Track No.	Maf Date	Exp Date	Delivery Date
AA	81220988	105-000476-00	UA test kit	B9Q14129006X	2019-10-19	2020-10-18	2020-2-20

Relying on the cloud, we has established a collaborative platform for manufacturers, distributors and end customers, and thus leading to the development of a win-win ecosystem.

Smart Hospital



Smart Hospital

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Contract order

Warehousing

Scanning and warehousing

Department warehousing management

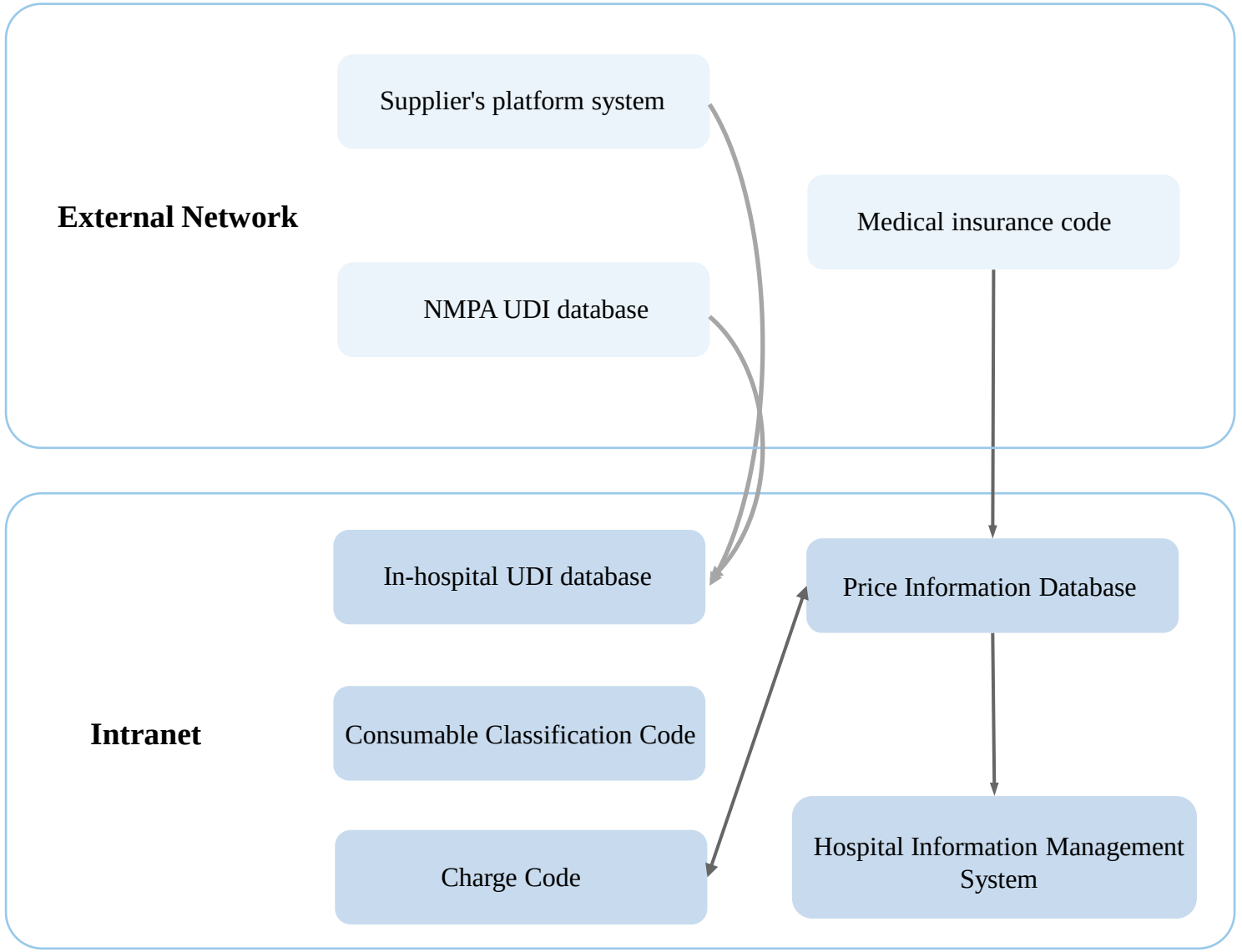
Material Classification

Department Consumption Management

Consumables unit management
General management of fixed devices
Medical insurance data connection

Inventory management

Material Return/Exchange Management
Expiration date management
Inventory Warning



How to Share Big Data?

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Set up UDI distribution rules based on IT&SOP and product characteristics.

Development

Submitting UDI-DI information in registration application

Validation

1. Use DI for product management
2. Receive the serial number or batch number of the work order. Allocate PI based on the SN or batch No., tracing and managing the physical objects.
3. Obtain the DI and PI information and attach the UDI label

Factory production

Electronic goods management and tracing

Logistics transportation

Medical device unique identifier database

Manufacturer, distributor, and hospital information sharing

Distributor Storage

Automatic incoming goods identification, acceptance, and warehousing management

Hospital admission

Automatic Product Receiving and Warehousing Validation

In-hospital system

Department allocation and automated warehouse-in/out management

Specific department

1. UDI Clinical Requirements
2. Refined management of consumables
3. Management of packaging granularity at different levels
4. Implanted product UDI information and patient medical record management
5. Tracing of post-marketing adverse events and recalls

Concept

UDI Feature in China: Two-code Mapping

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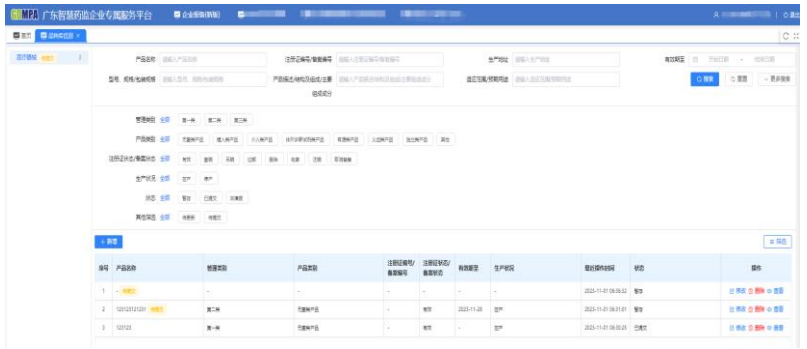
Shenzhen

Data matching and linking between medical institutes and manufacturers or distributors has been realized by using UDI to connect information along the product supply chain. The traceability of medical devices manufactured or marked in Shenzhen, from manufacturers to distributors and lastly to patients, has been dynamically presented. The flow of UDI throughout product life cycle is displayed clearly and intuitively

Guangdong Province

Fundamental databases including enterprises, product categories and personnel has been established by integrating and sorting data from Guangdong Province Medical Products Administration, leading to efficient circulation and use of data.



NMPA

Generally planned and established by NMPA, the database serves to provide data basis for medical device industry and relevant sectors based on the principle of openness and sharing.

Connect UDI and Medical insurance code (classification code) By NMPA UDI Database and National Medical Insurance system

UDI code

Global UDI Coordination

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USA

2013

UDI rule is issued by FDA.

EU

2017

Along with MDR/IVDR, the UDI implementation timeline had been confirmed.

China

2019

UDI rule is issued by NMPA.

Korea

2019

The products currently sold in Korea should meet the UDI requirements.

Saudi Arabia

2019

ClassB&C&D 2023.9.1
Class A 2024.9.1

Turkey

Implementation following EU release

Australia

Implementation following EU release

Colombia

2022

The implementation timeframe is divided into 12 months, -18 months, and -24 months from the highest risk level to the medium risk level to the low risk level.

Egypt

The GS1 international version of Egypt needs to be published.

Outlook for Future

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★Global shared UDI database

Coordinate and optimize different UDI data requirements and databases around the world to achieve compatibility of UDI data structures across countries/areas.

★UDI Identification and Carrier Requirements in Clinical Practices

For special products, like high-risk products, implanted products and software products, studies based in clinical cases shall be conducted to investigate the requirements of UDI labelling and carriers in different clinical scenarios.

Thanks !