Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Application Practice of UDI in Clinical Use of Medical Devices

Donglan Yu

The First Affiliated Hospital, Sun Yat-sen University

SYSU Medicine – 10 Hospitals

→ *2nd largest Healthcare System in China*

1st Affiliated Hospital
-- largest and leading

Sun Yat-sen Memorial Hospital
-- 1st western hospital

3rd Affiliated Hospital
-- Hepatology

5th Affiliated Hospital
-- Zhu Hai

6th Affiliated Hospital
-- Gastroentorology

Cancer Center
-- Top 3 cancer center

Ophthalmic Center
-- Center of Asia-Pacific Academy of Ophthalmology

Hospital of Stomatology
-- leader in oral & maxillofacial surgery

7th Affiliated Hospital
-- the youngest, Shen Zhen

8th Affiliated Hospital
-- Shen Zhen

One of the Leaders in Medicine in China

National Performance Evaluation

A++

Top 1%
1st in South China

National Key Specialties

32 (3rd in China)

1st in South China

Fudan Hospital Ranking

Ranked No. 9

Top 10 Specialties (14)

Top 1%
1st in South China

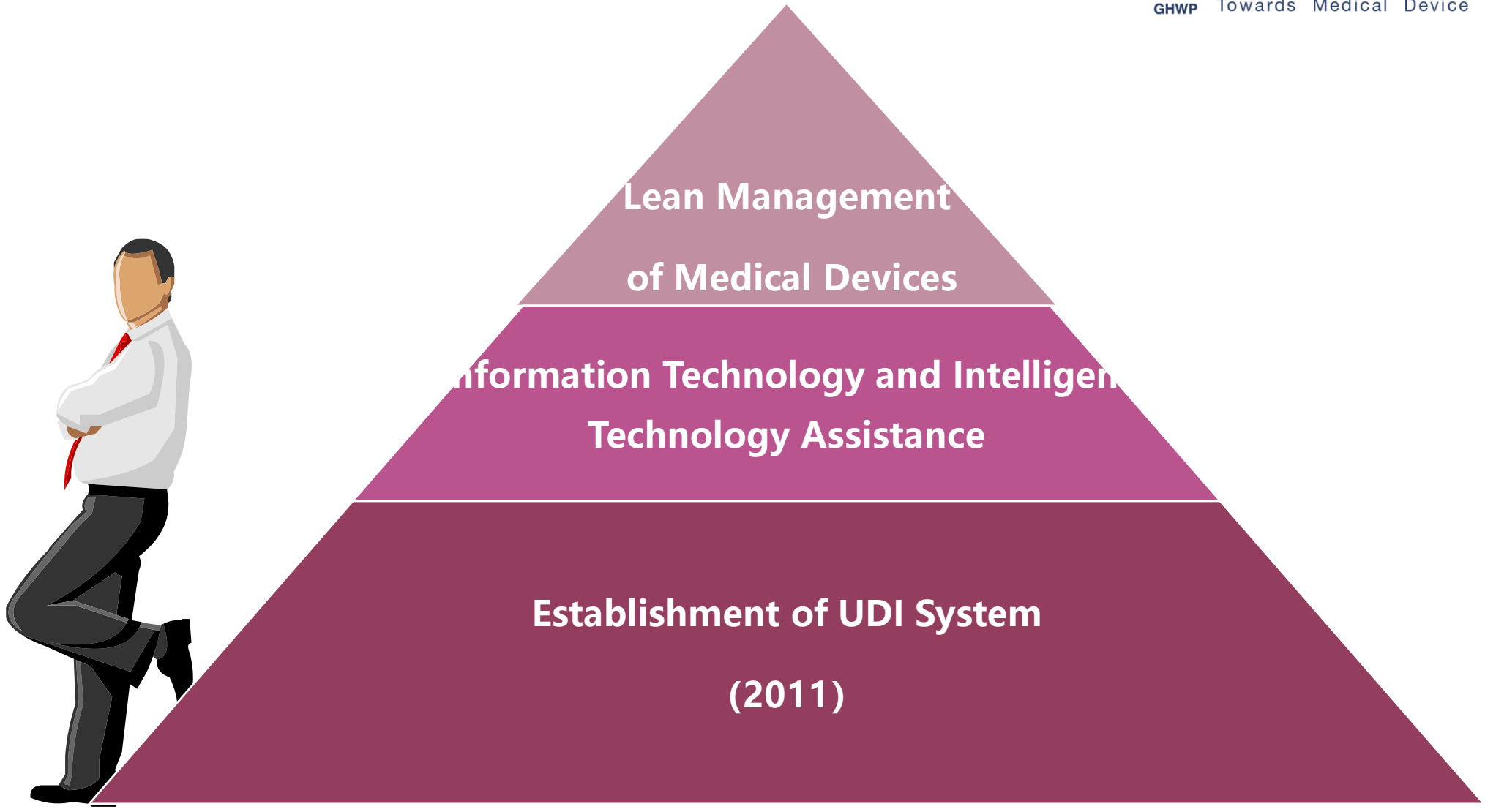
Annual OPD patients >4.5million, OR >140,000

One of the Best Hospitals in China

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Lean Management of Medical devices

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

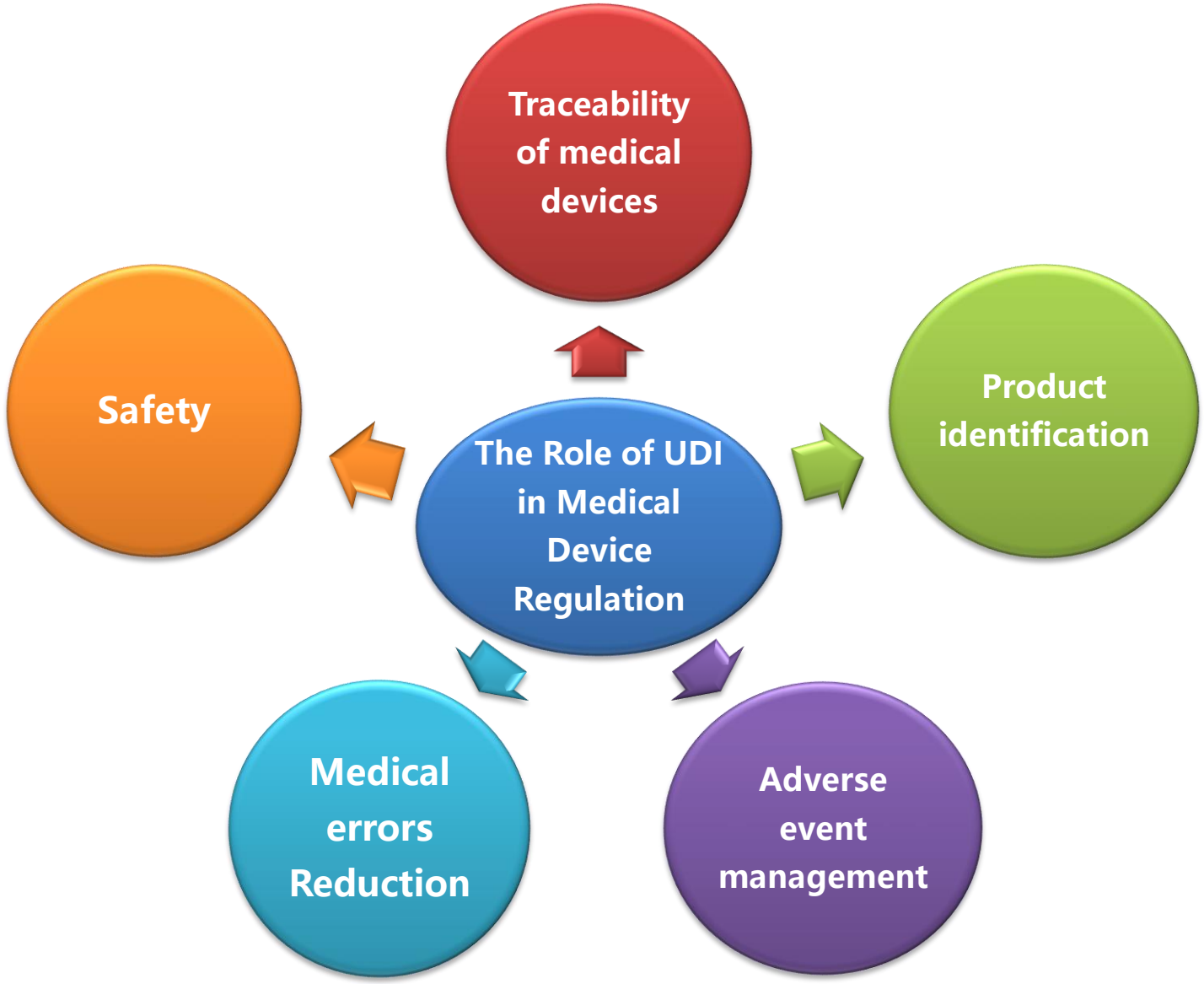


One of the First Pilot Users of UDI System in the Country (2019)

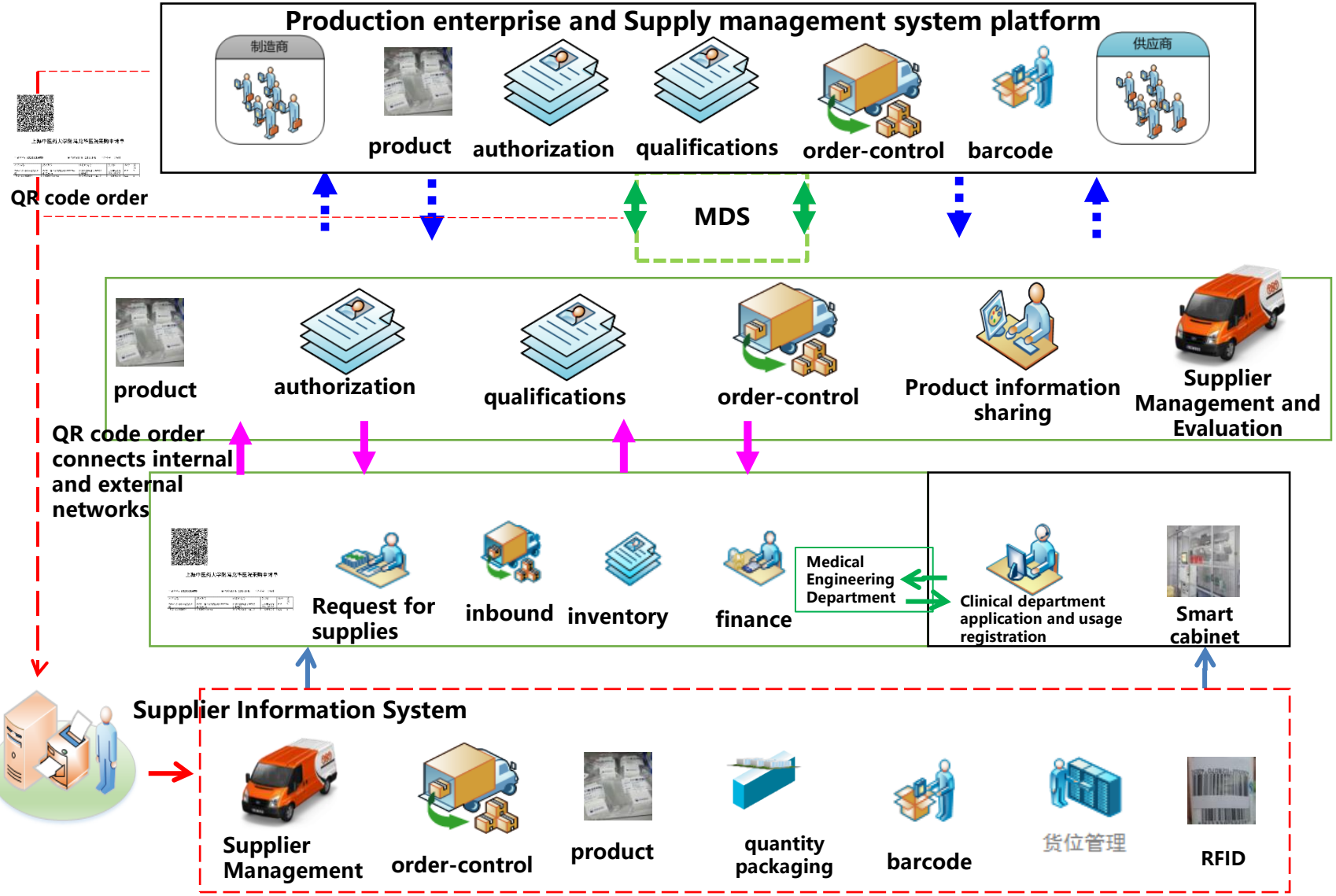
One of the First Demonstration Hospitals for the Implementation of UDI (2022)

The Role of UDI in Medical Device Regulation

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization



Intelligent life-cycle management of medical devices based on UDI



Intelligence

Precision

Traceability

Safety

Efficiency

Cost-Cutting

Intelligent life-cycle management of medical devices based on UDI

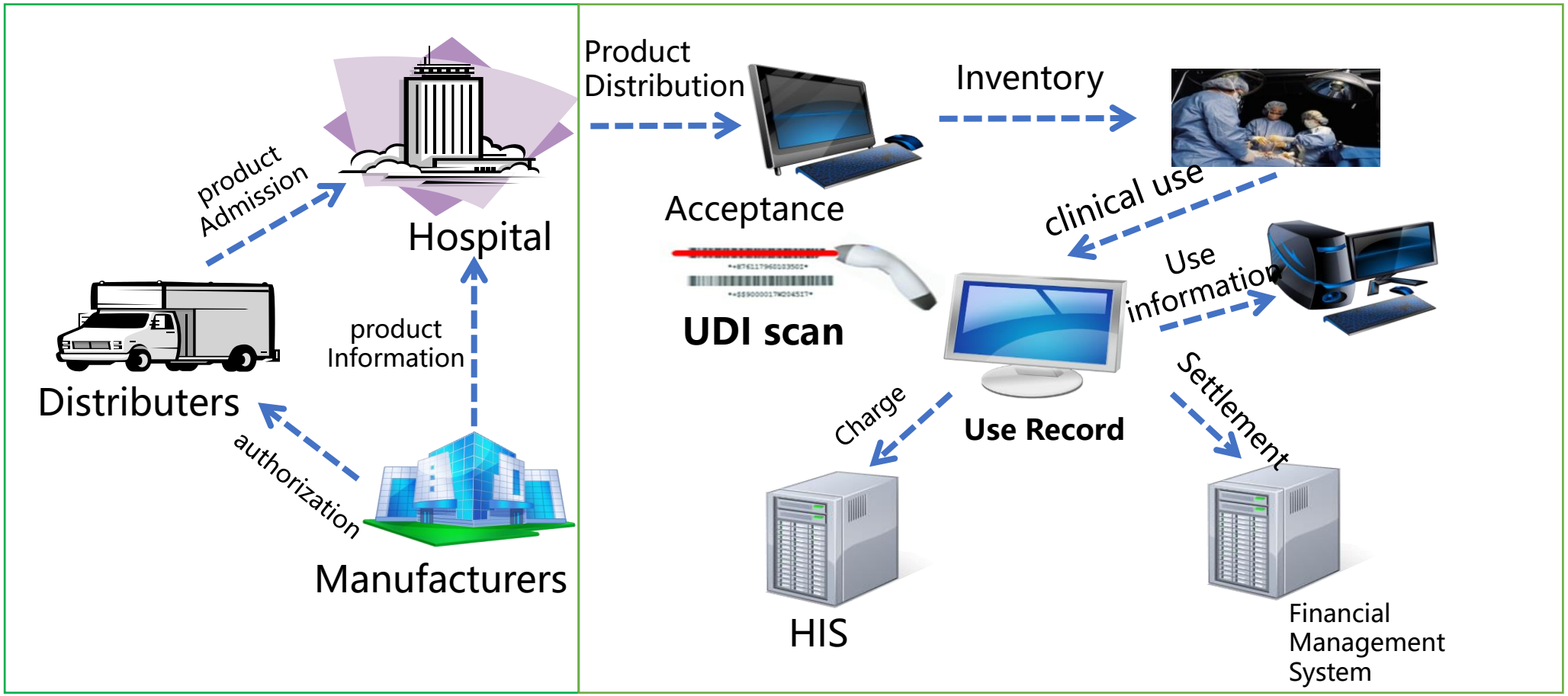
Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Intelligent life-cycle management of medical devices based on UDI

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Internet data service platform (external network)

Medical devices management system (internal network)



Application Practice : Product information initialization and database construction based on UDI

Co-building Medical Devices Central Database

95437 Items

Products

1630

Manufacturers

6+661

Distributers

Admission

National UDID

Medical Devices Central Database

Classification

Medical device classification directory

Classification and codes of medical consumables for medical insurance

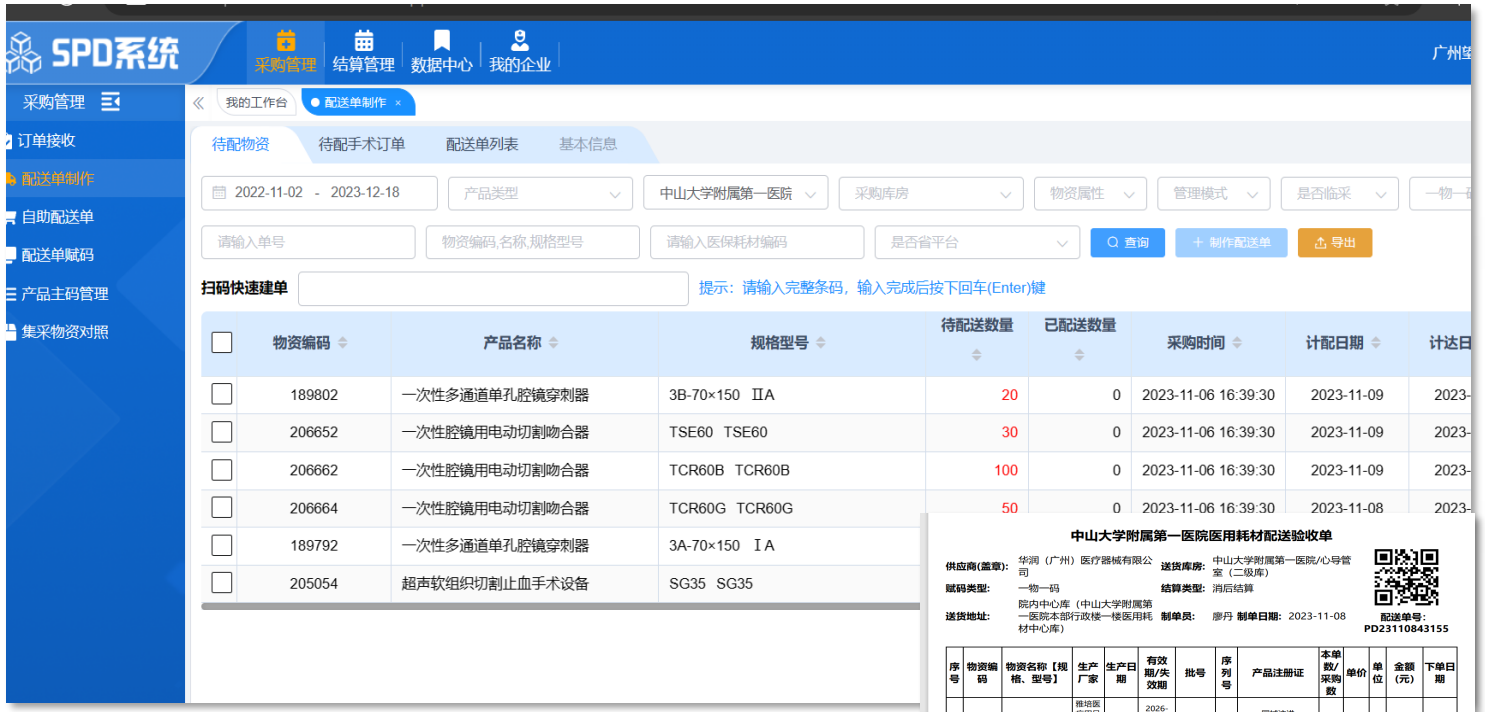
UDI Coverage Rate: 97.35%

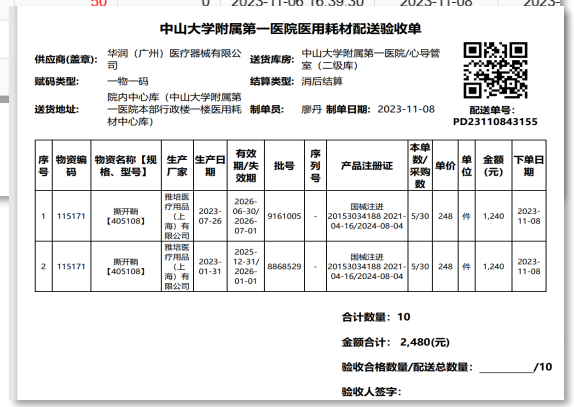
100% Mapping with Medical Insurance Codes

Application Practice : Ordering and Delivery information sharing based on UDI

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Co-building and Sharing of Supply Chain Information





Hospital:
Send orders through the platform

Distributers:
Prepare products according to orders, Scan Original UDI Barcode to complete the compliance verification of products

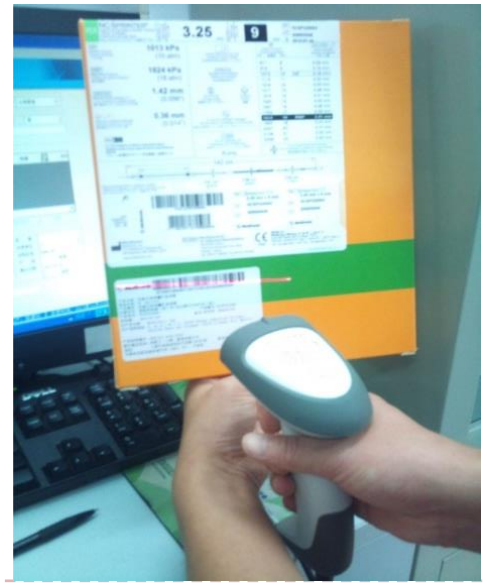
Distributers:
Generate electronic delivery documents with QR Codes

Hospital:
Scan QR Codes to get the Products information and Verification information through the platform

Hospital:
Monitor Delivery Information: Delivery Time, Quantity, Partial Deliveries, etc.

Application Practice : Acceptance Management based on UDI

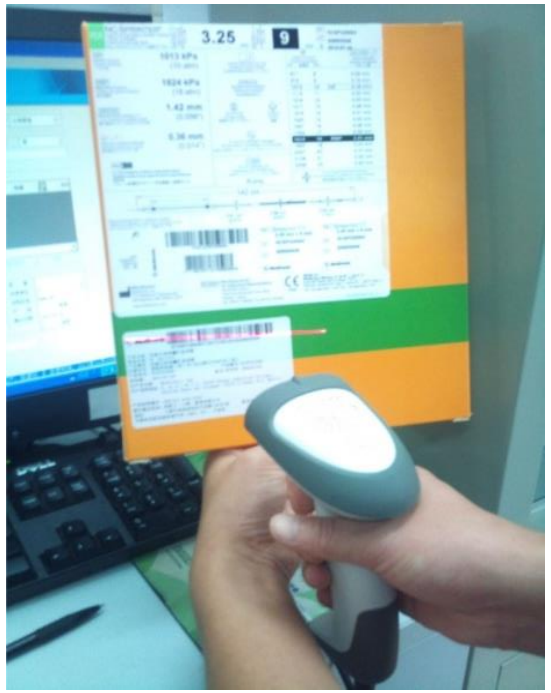
A built-in validation mechanism to automatically verify the compliance of products



- Through Device Identifier (DI), static product information from the UDI database can be obtained, including, but not limited to, required medical device details such as product name, registration certificate information, device category, specifications, manufacturer, distributer, price, etc.
- Using Production Identifier (PI), dynamic product information such as production batch number, serial number, production date, and expiration date can be parsed and obtained.
- The system incorporates a built-in validation mechanism to automatically verify whether medical devices comply with internal selection criteria, quality conditions, expiration status, etc., generating authentic, complete, and accurate records of incoming inspections.

Application Practice : Application of Lean Six Sigma in Improving the Inspection Process based on UDI

☐ Sharing of Supply Chain Information



中山大学附属第一医院医用耗材配送验收单

供应商(盖章):	华润（广州）医疗器械有限公司	**送货库房:**	中山大学附属第一医院/心导管室（二级库）
赋码类型:	一物一码	**结算类型:**	消后结算
送货地址:	院内中心库（中山大学附属第一医院本部行政楼一楼医用耗材中心库）	**制单员:** 廖丹	**制单日期:** 2023-11-08

配送单号: PD23110843155

序号	物资编码	物资名称【规格、型号】	生产厂家	生产日期	有效期/失效期	批号	序列号	产品注册证	本单数/采购数	单价	单位	金额（元）	下单日期
1	115171	撕开鞘【405108】	雅培医疗用品（上海）有限公司	2023-07-26	2026-06-30/2026-07-01	9161005	-	国械注进20153034188 2021-04-16/2024-08-04	5/30	248	件	1,240	2023-11-08
2	115171	撕开鞘【405108】	雅培医疗用品（上海）有限公司	2023-01-31	2025-12-31/2026-01-01	8868529	-	国械注进20153034188 2021-04-16/2024-08-04	5/30	248	件	1,240	2023-11-08

合计数量： 10

金额合计： 2,480(元)

验收合格数量/配送总数量： _____/10

验收人签字:

Traditional Mode—Scan UDI Barcode to complete the compliance verification of products one by one at hospital

The acceptance time of 200 products is about 45 minutes

Lean Optimization—Distributers: Scan UDI Barcode to complete the compliance verification of Products when they Prepare products, Hospital: Scan QR Codes to get the Products information and Verification information through the platform.

The acceptance time of 200 products is less than 10 minutes

Application of Lean Six Sigma in Improving the Inspection Process of Consumables—Winner of the Second Prize in the Modern Hospital Lean Management Practical Case Study Awards

Application Practice : Utilization Management (Core of Quality Control and Management)

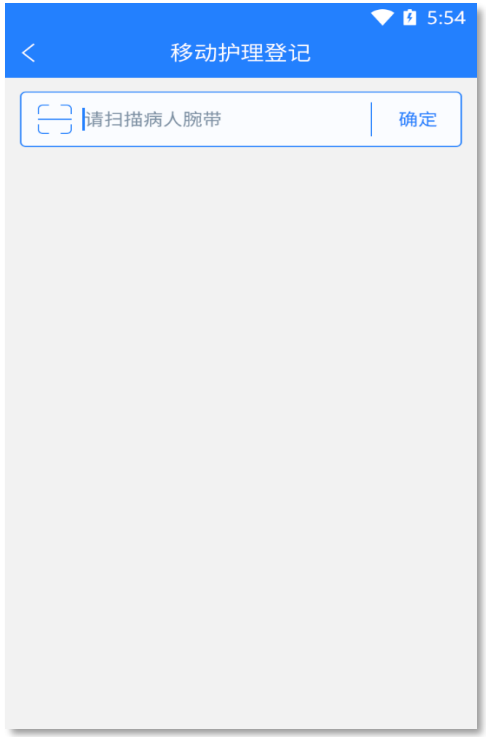
- Scan Original UDI Barcode to Verify the Validity of Products again, record product information and create electronic use records (OR)

Application Practice : Utilization Management (Core of Quality Control and Management)

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Trace Clinical use behavior

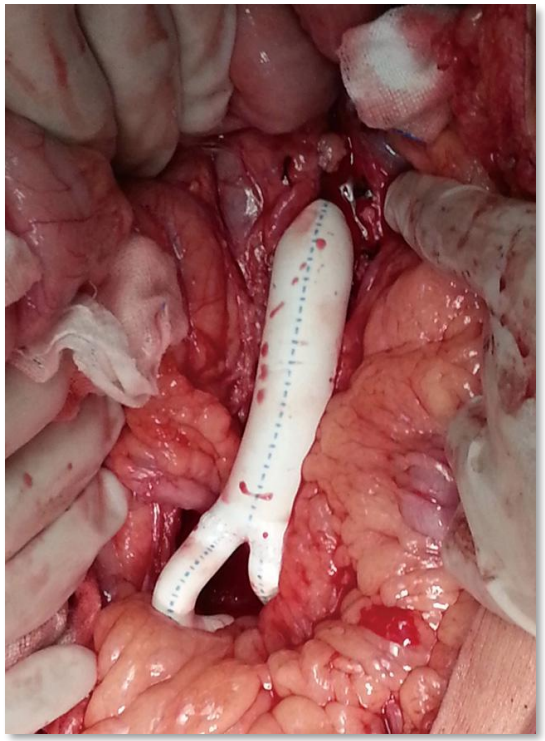
Based on the UDI code, through the SPD system and mobile nursing linkage (Inpatient Wards)



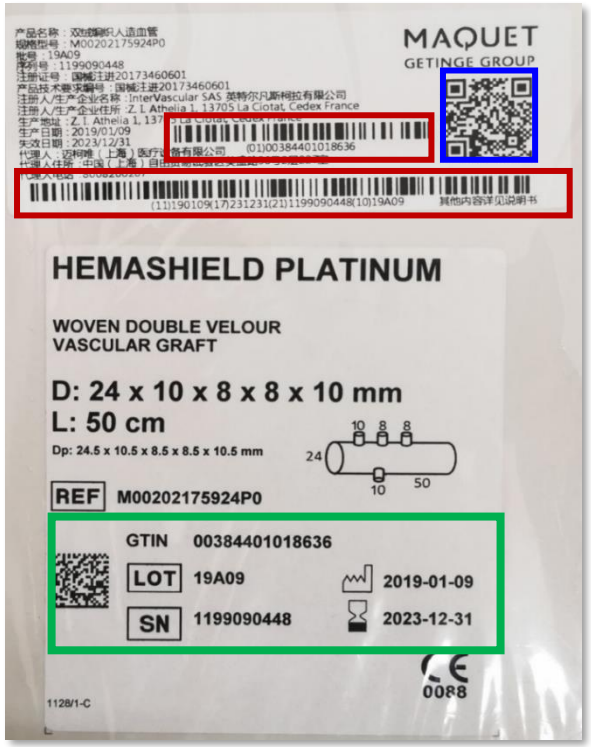
Scan patient wristband → **Scanning UDI Barcode** → **Clinical use records of medical consumables**

Mobile Care Billing

Application Practice : Utilization Management (Medical insurance and Settlement)



medical devices



UDI

Medical insurance code

Establish the relationship between medical devices and information (records) with AIDC model

Two codes mapping

Procurement-Use-Settlement Consistency Association

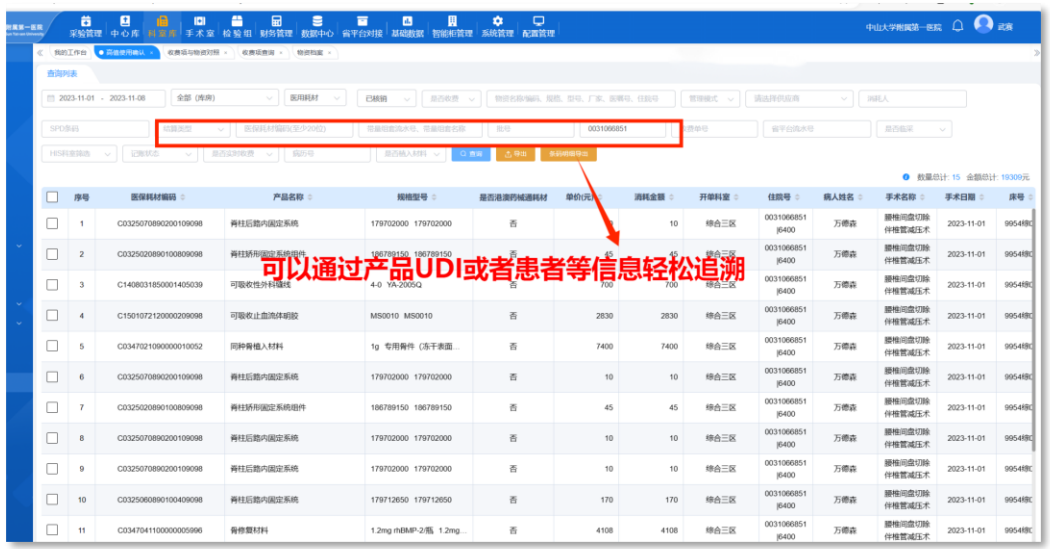
Application Practice : Quality and Clinical use monitoring

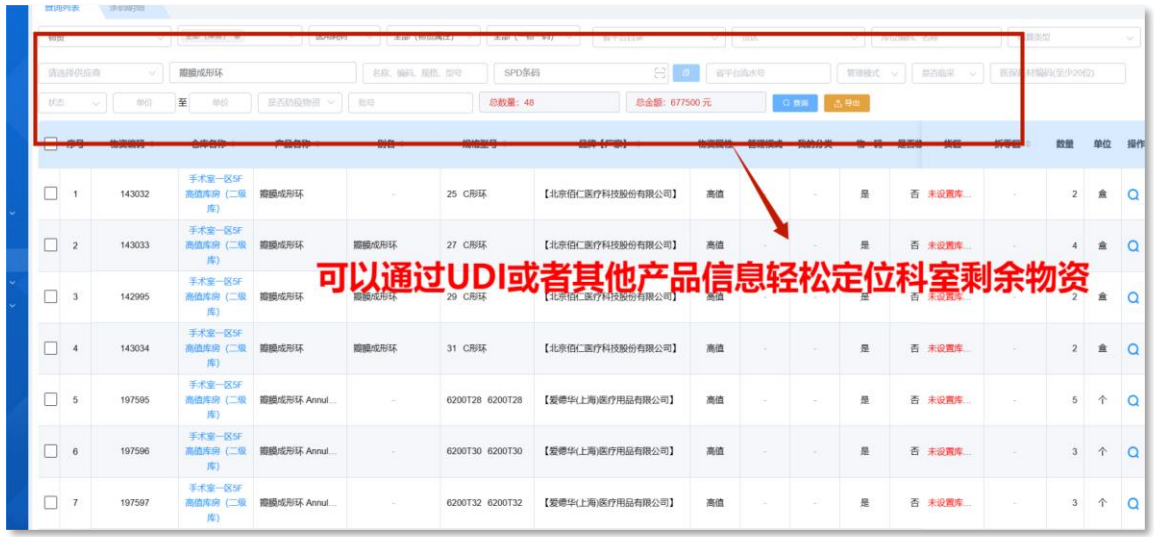
Quality monitoring: Adverse events and Recalls

Quickly locate the safe use and inventory situation, including the use of patients, the number of use cases, inventory quantities, manufacturers, etc.

Authentic, accurate, comprehensive, precise and loop-locked use data of medical devices to help monitor and analyze the consumption of medical devices for better Management and Cost control

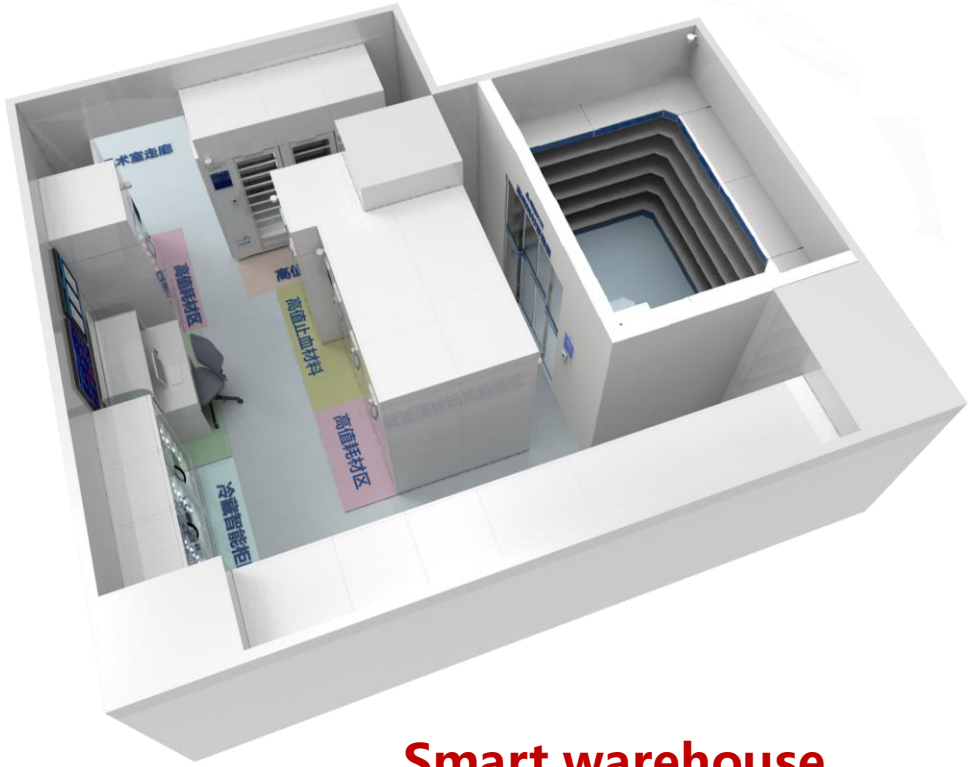
Clinical Use monitoring: Clinical use management





Application Practice : Applications of intelligent facilities and equipment based on UDI and RFID

☐ Intelligent inventory management of high-value medical devices



Smart warehouse

operating room area 1

Smart cabinets and Smart walls

Application Practice : Applications of intelligent facilities and equipment based on UDI and RFID

☐ Intelligent inventory management of consumables

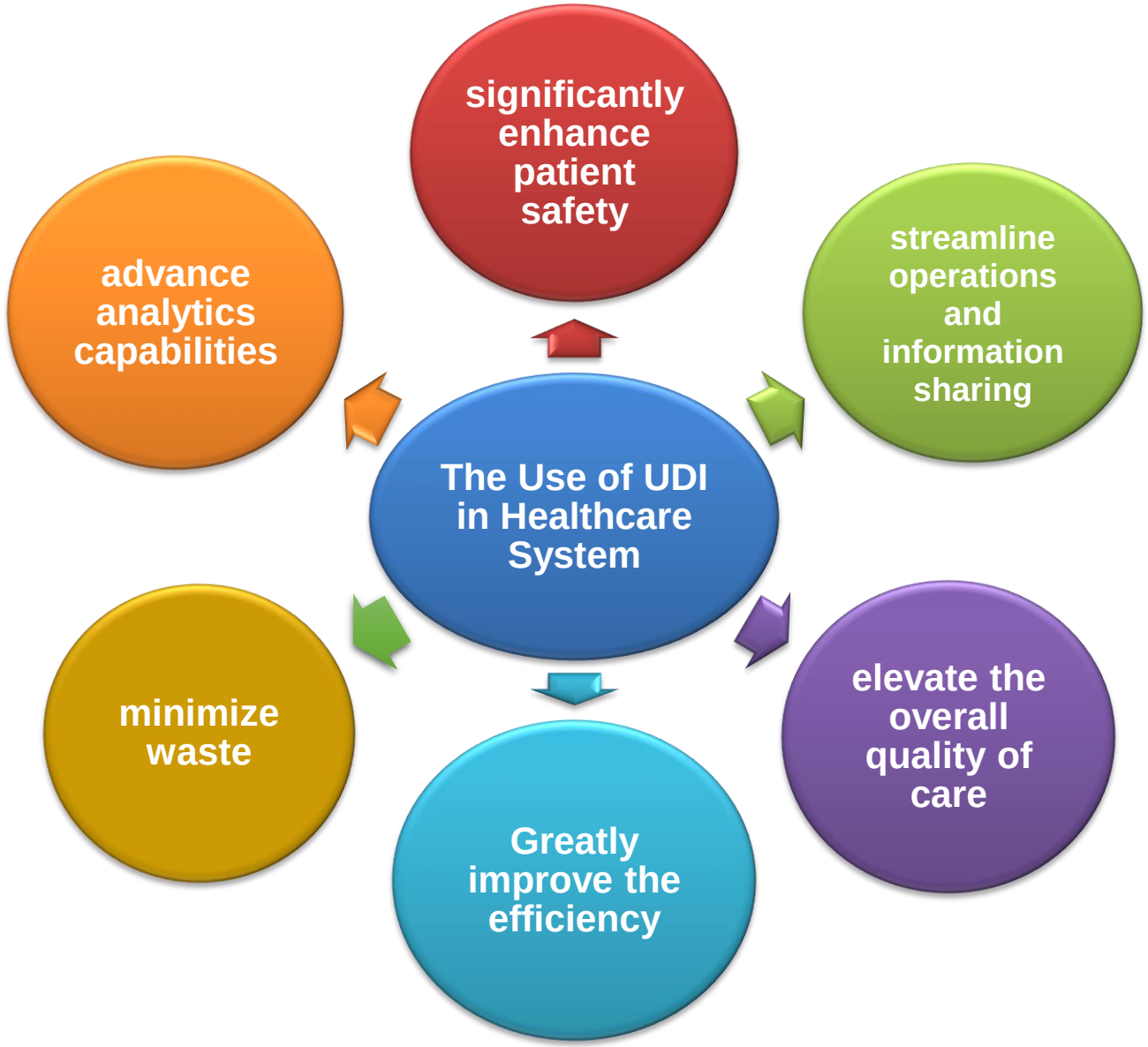
Customized smart cabinet

Suture and hemostatic material management

RFID refrigerated smart cabinet

Through customized intelligent equipment, refined management of consumables such as sutures, guidewire catheters, and hemostatic material can be achieved

The benefits from the use of UDI



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Thank you

Donglan Yu

The First Affiliated Hospital, Sun Yat-sen University