Countries around the world continue to work together to promote the establishment of unified traceability system

全球各国继续共同努力,促进统一追溯体系建成

Yan, Liang Chairman and Senior advisor
Shanghai Pudong Medical Device Trade Association (MDTA)
CFDA SH Shanghai Institute of Food and Drug Safety (SIFDS)

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The new requirements of China 605 version of MD. regulation and supervision of medical supply chain

中国医疗器械法规和医药供应链监管新要求

Revision of China MD Regulation
State Council Order 650

New order from CFDA No. 18th enforce hospital keeping device used record

		一类	二类	三类	备注
注 册	注册申请	备案	注册证件	注册证件	
	变更注册	备案			
	延续注册	备案			
	临床试验	不要	判定	审批	
	技术检测	自行			
	产品 标签	一般			
生产	许可申请	备案	许可证件	许可证件	
	质量控制	自行体系			
经营	许可申请	放开		许可证件	
	仓储运输	没有规定			
	经营记录	没有规定			
使用	采购管理	没有规定	查许可证件	查许可证件	
	使用记录	没有规定		严格管理	

中华人民共和国中央人民政府
www.gov.cn

General Office of the State Council on Printing and Distributing the Key Tasks of Deepening the Medical and Health System Reform in 2016

国务院办公厅关于印发深化医药卫生体制改革2016年重点工作任务的通知

国办发〔2016〕26号

各省、自治区、直辖市人民政府，国务院有关部门：

《深化医药卫生体制改革2016年重点工作任务》已经国务院同意，现印发给你们，请结合实际，认真组织实施。

国务院办公厅

2016年4月21日

缩短供应链，网上公开采购，鼓励一票制的结算是国家当前医疗改革目标之一

- To push reform of medical supply chain is The policy from Central Government
- High-value consumables medical devices need to be traded on the web
- To promote the settlement between manufacturers and hospitals on one stop.

（二）全面推进公立医院药品集中采购。继续落实《国务院办公厅关于完善公立医院药品集中采购工作的指导意见》（国办发〔2015〕7号），实行分类采购，每种药品采购的剂型原则上不超过3种，每种剂型对应的规格原则上不超过2种。推广地方经验做法，鼓励和引导省际跨区域联合采购，综合医改试点省份内可鼓励一定区域间的带量联合采购。优化药品购销秩序，压缩流通环节，综合医改试点省份要在全省范围内推行“两票制”（生产企业到流通企业开一次发票，流通企业到医疗机构开一次发票），积极鼓励公立医院综合改革试点城市推行“两票制”，鼓励医院与药品生产企业直接结算药品货款、药品生产企业与配送企业结算配送费用，压缩中间环节，降低虚高价格。总结评估国家药品价格谈判试点工作，逐步增加谈判药品品种数量，合理降低专利药品和独家生产药品价格。总结地方经验，推进完善政策措施，进一步推进高值医用耗材集中采购、网上公开交易等。综合医改试点省份要选择地区开展高值医用耗材集中采购，率先取得突破。进一步完善国家药品供应保障综合管理信息平台和省级药品集中采购平台规范化建设，完善药品采购数据共享机制。（卫生计生委、食品药品监管总局、发展改革委、工业和信息化部、商务部、人力资源社会保障部、综合医改试点省份人民政府负责）

CFDA encourage manufactory to adopt

UDI in MD and DRUG traceability system

An unified traceability model in world market

that seems establishment

(US + EU + CN)

国家药监总局明确鼓励医疗器械生产商

采用UDI唯一标识，器械全球统一追溯体系基本形成

国家食品药品监督管理总局 CFDA
China Food and Drug Administration

总局关于推动食品药品生产经营者完善追溯体系的意见

食药监科〔2016〕122号

2016年09月27日 发布

The Guideline Document of CFDA for

Promoting the Food and Drug Manufacturers and Distributors Improving the Traceability System

CFDA Document (FDSS) 2016 No.122 on Sept. 27th 2016

Item 3: for Drug and Medical Device

① All drug and device manufacturers, distributors have the main responsibility for Recall and Traceability.

② Encourage them to adopt Device UDI and Drug UDI.

③ All Implantable devices need to trace at LOT or S/N level

④ Hospital should according to the CFDA Rules of keeping the USING RECORD.

3 Key elements of Traceability

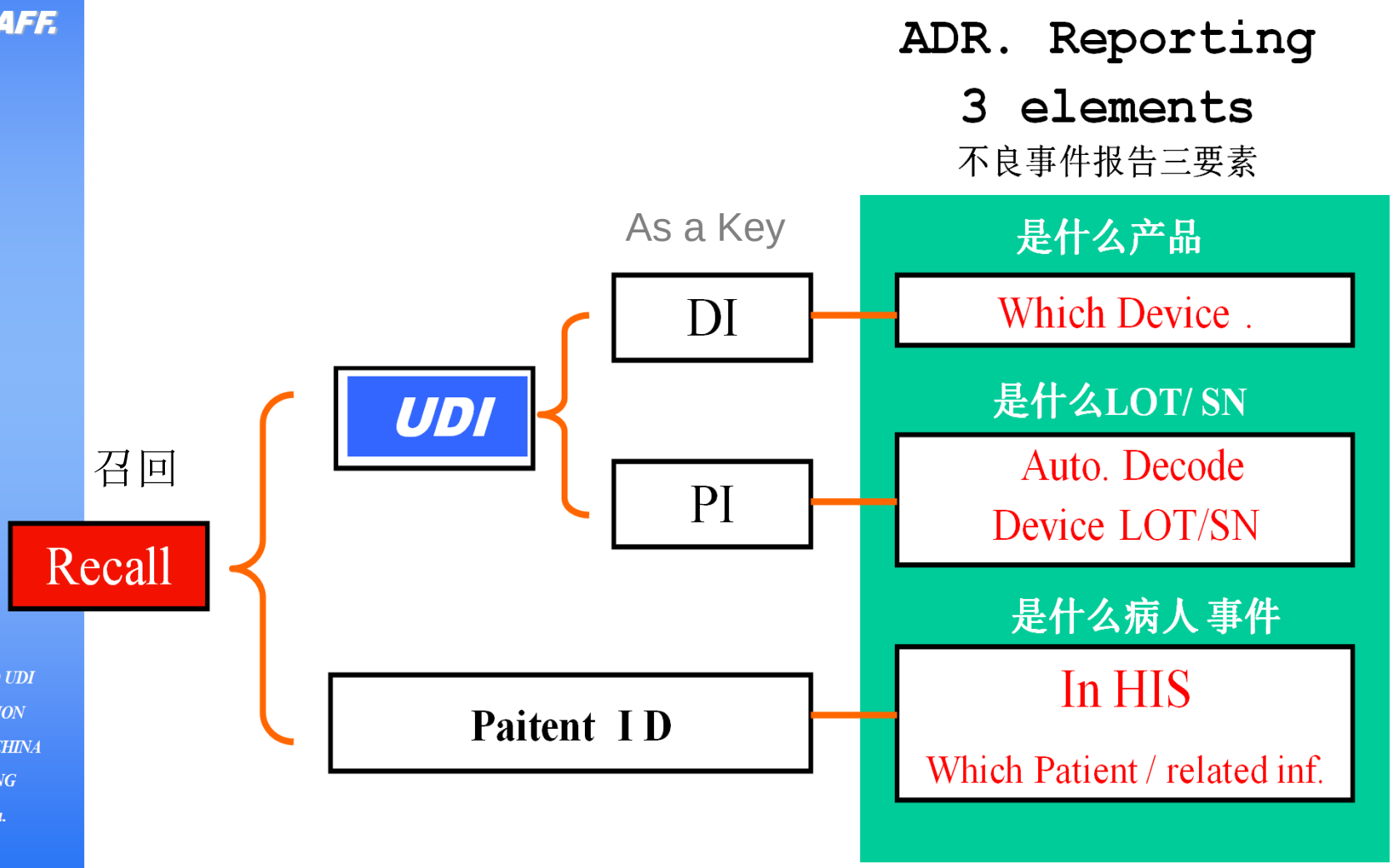
and

Minimum information of Traceability

追溯的三要素和最低追溯信息

SH-FDA
LEGAL AFF.

TRACEABILITY discussion



2009
REPORT OF MD UDI
IMPLEMENTATION
IN SHANGHAI CHINA
15th GSI MEETING
Hong Kong China.

2009-10-06

The core elements for traceability in IMDRF UDID guideline

IMDRF International Medical Device Regulators Forum

Final Document

Title: UDI Guidance
Unique Device Identification (UDI) of Medical Devices

Authoring Group: IMDRF UDI Working Group

Date: 9 December 2013

Despina Spanou, IMDRF Chair

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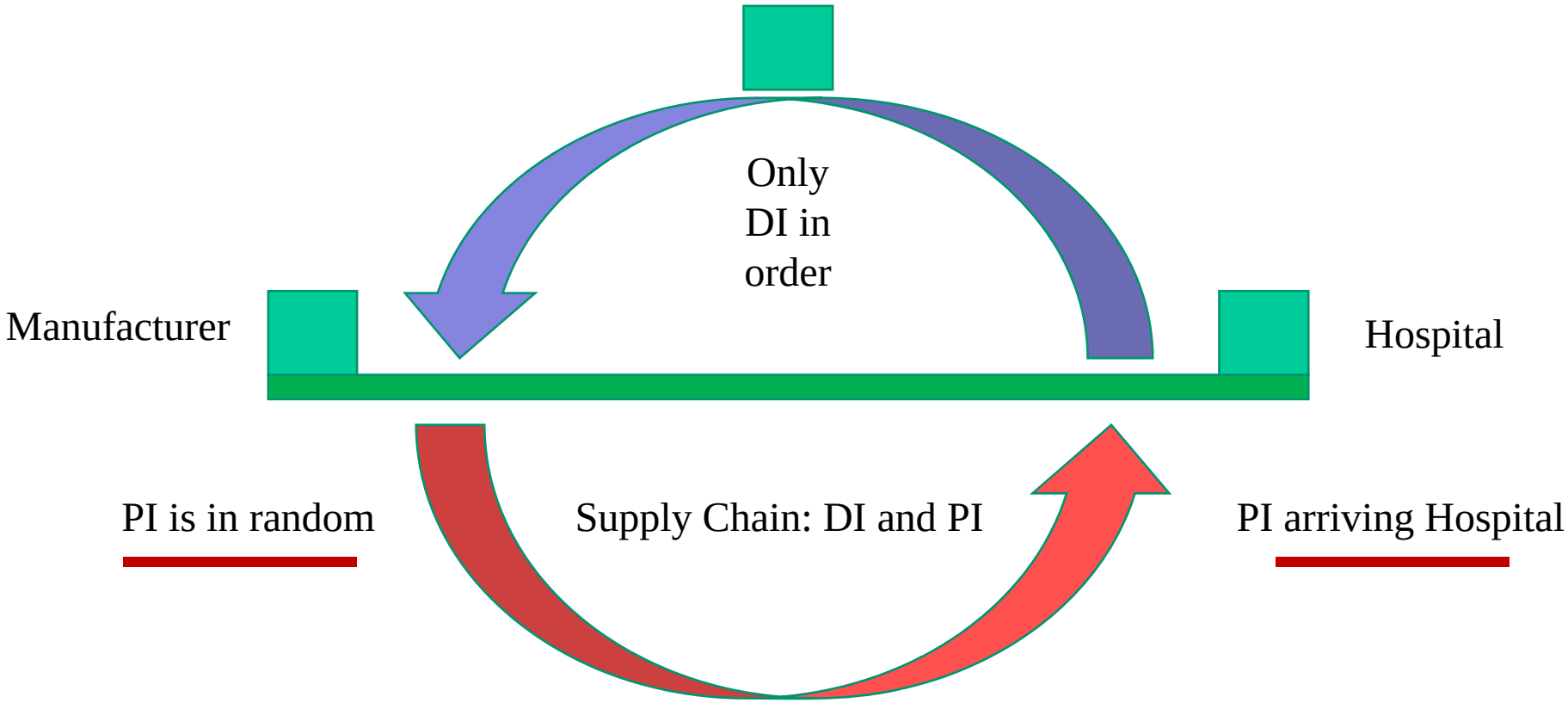
9.2 The core UDID data elements

All the core UDID data elements are mandatory, unless marked "optional". "If applicable" means the information is mandatory to be in the UDID if it is on the label.
Data elements and their definitions for the UDID are listed below:

1. For every device packaging level – the following shall be provided in a related way (for entire packaging hierarchy):
   - ✓ UDI-DI (UDI type, e.g. GS1 GTIN, HIBC-LIC, ISBT-128 PPIC),
   - ✓ Quantity per package configuration: (e.g., each, 10 each, 5 shelf packs),
   - ✓ Additional device identifier(s) (if applicable) e.g. GS1, HIBC, or ISBT-128;
2. The Unit of Use UDI-DI (see section 7.6) code;
3. Manufacturer's name (if applicable);
4. Manufacturer's address (if applicable);
5. Manufacturer's customer service contact information (country/region specific, could be multiple);(If applicable)
6. Authorized Representative's name (regional representatives responsible for the medical device) (country/region specific, could be multiple) (if required by the local/regional regulatory authority) (see GHTF/SG1/N55:2009);
7. Authorized Representative's contact information (country specific, could be multiple);
8. Global Medical Device Nomenclature (GMDN) preferred code/term (valid at the time of the UDI submission);
9. Brand Name (if applicable);
10. SaMD version;
11. Device model or version; (see section 10.6)
12. Reference and/or catalogue number (if applicable);
13. How the device is controlled: serial, lot/batch number, and/or expiration date (or manufacturing date) or software version or software released date or ISBT-128 – check boxes (if applicable);
14. Clinical Size (including Volume, Length, Gauge, Diameter) (if applicable) (e.g. 8F catheter);
15. Additional product Description (optional) – Additional clinically relevant information, e.g. radio-opaque;
16. Storage conditions, as labeled or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight;
17. Handling conditions (if different than storage conditions), on the label or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight;
18. Labeled as single use? (Yes/No);
19. Packaged sterile? (Yes/No);
20. Need for sterilization before use? (Yes/No) – *if yes, then the method of sterilization should be indicated*;
21. Restricted number of reuses (if applicable);
22. License and/or marketing authorization or registration number (if required by the relevant regulatory authority)
23. URL for additional information, e.g. electronic IFU (optional);
24. Critical warnings or contraindications (as labeled) – if a particular regulation requires that the label of the device contains a critical warning or contraindication associated with the use of the device
    a. [e.g.: Labeled as containing latex? (Yes/No),
    b. Labeled as containing DEHP? (Yes/No)
    c. Labeled as MRI compatible? (Yes/No).]
25. Date of discontinuance (referring to devices no longer placed on the market).

Pedigree of Products in Supply Chain is important than going to cloud

Checking and tracing PI at the end-user */ END to END*



The traceability situation of medical device by adopted UDI Global Format

History can be traced back to the 2006 Shanghai pilot program

中国医疗器械采用全球唯一标识UDI的追溯情况

上海从2006年开始启动UDI追溯植入物计划

Tracking & Tracing

in Healthcare Supply Chain

“追溯”：已经形成标准解释

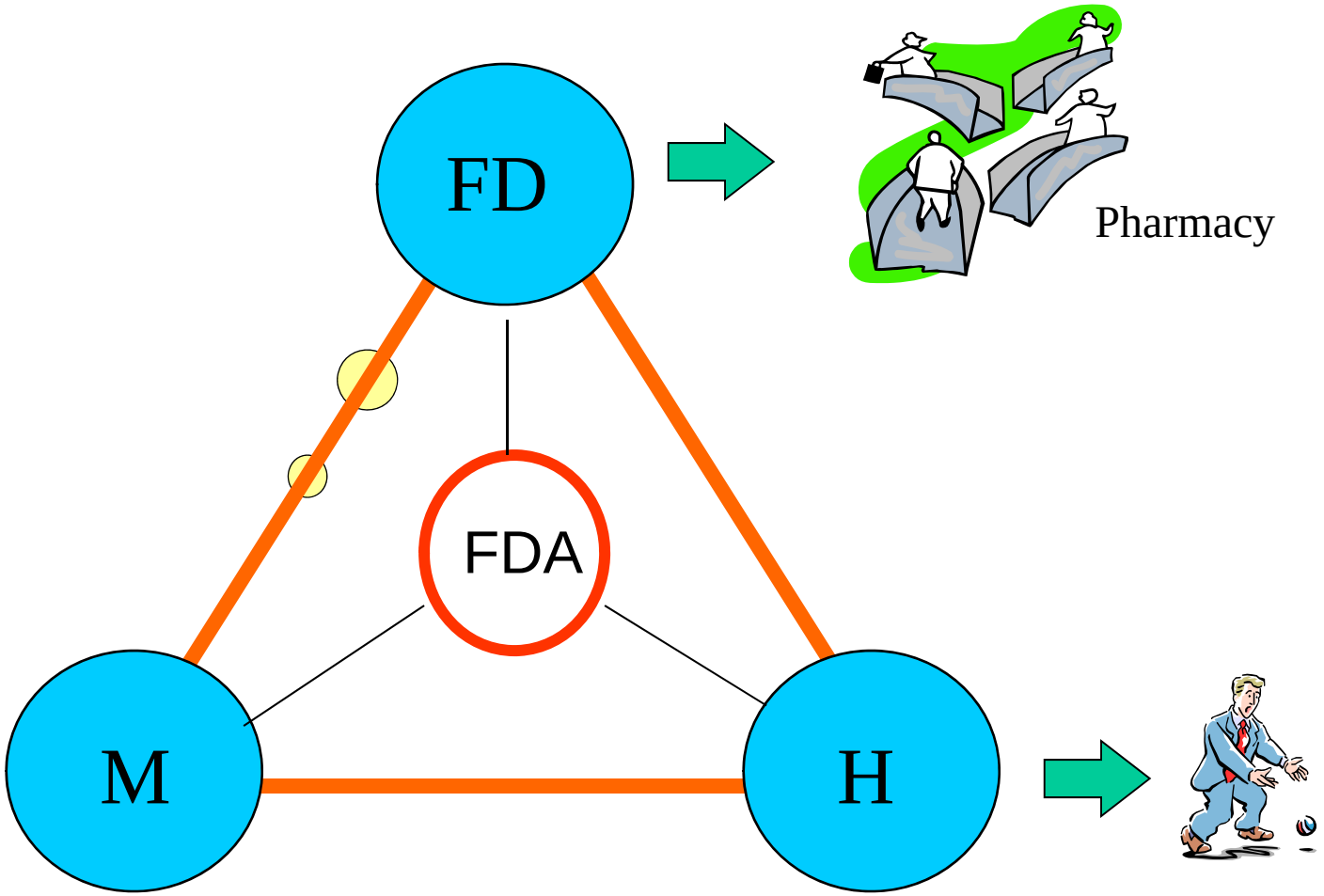
注册信息与患者安全需求

通过标签*UDI*信息联系起来

UDI and distributing model

How to Track device in the post-market

医疗器械
唯一标识
UDI＋P:ID



Shanghai Food and Drug Administration

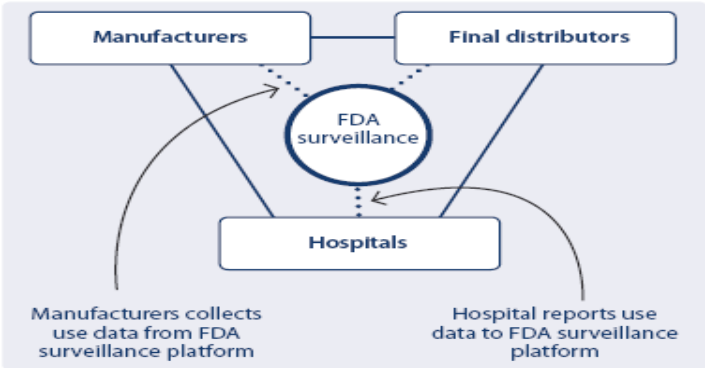
Implementation of a post-market traceability program for implantable medical devices adopting unique device identification

ABSTRACT

2009-2010 GS1 Reference Book

This article discusses the distribution and traceability model of Implantable Medical Devices (IMD) for post-market surveillance purposes, and the IT and automatic identification technology that has been used in the supply chain to complete post-market tracking in Shanghai. To build up this system successfully, it was necessary to establish a Unique Device Identification (UDI) for IMD's, based on GS1 Standards, to define the minimum information in the tracking process, and to establish a central data pool to support automatic reading in the hospital management system. Meanwhile it is necessary to have a Shanghai FDA monitor platform to collect the traceability information from the end user. This article also contains a real case study that took place in Shanghai.

Figure 1: IMDs sales channel and device use data reporting channel



Scan UDI after operation for every patient， keeping UDI links EHR. for AE report may occur

在病人手术后扫描产品**UDI,** 将**UDI**关联的产品信息记录到电子病历以防不良事件发生

Hospital product Database

医院产品数据库信息

HIS

医院管理信息

Lot / Batch / Series NO. In Secondary Code

产品批号 / 序列号信息

DI links

PI capture

上海市东方医院
同济大学附属东方医院

植入性医疗器械使用明细费用清单

单据编 2006104235 第 1 页，共 1 页

病人姓名	张德好		住院号	550941	手术时间	2006-10-25 12:10:15
证件类型	身份证		证件号码	342422197301132050		

手术材料明细

Ref.	商品名称	规格型号	出厂日期	有效期	Lot/SN	数量	进货价格	零售价格	最终供应商	生产商名称
7862-09	Versys金属丝锥型髋关节柄	7862-09	2006-10-24	2006-10-24	235644/362362	1	12,000.00	12,600.00	上海新高医疗	Synthes GmbH
7850-11	VerSys推荐型TM髋关节假体	7850-11	2006-10-24	2006-10-24	/234454	1	7,000.00	7,350.00	上海新高医疗	Synthes GmbH
204.070	接骨螺钉（SYNTHES）	3.5mm 皮质骨螺钉，不	2006-10-24	2006-10-24	/234454	1	2,500.00	2,625.00	上海新高医疗	Synthes GmbH
204.070	接骨螺钉（SYNTHES）	3.5mm 皮质骨螺钉，不	2006-10-24	2006-10-24	/234454	1	500.00	525.00	上海新高医疗	Synthes GmbH
204.070	接骨螺钉（SYNTHES）	3.5mm 皮质骨螺钉，不	2006-10-24	2006-10-24	/234555	1	2,500.00	2,625.00	上海新高医疗	Synthes GmbH
478.280	髓内钉系统	8.0mm非扩髓胫骨髓内	2006-10-24	2006-10-24	/513121	1	8,000.00	8,400.00	上海新高医疗	Synthes GmbH
合计金额							32,500.00	34,125.00		

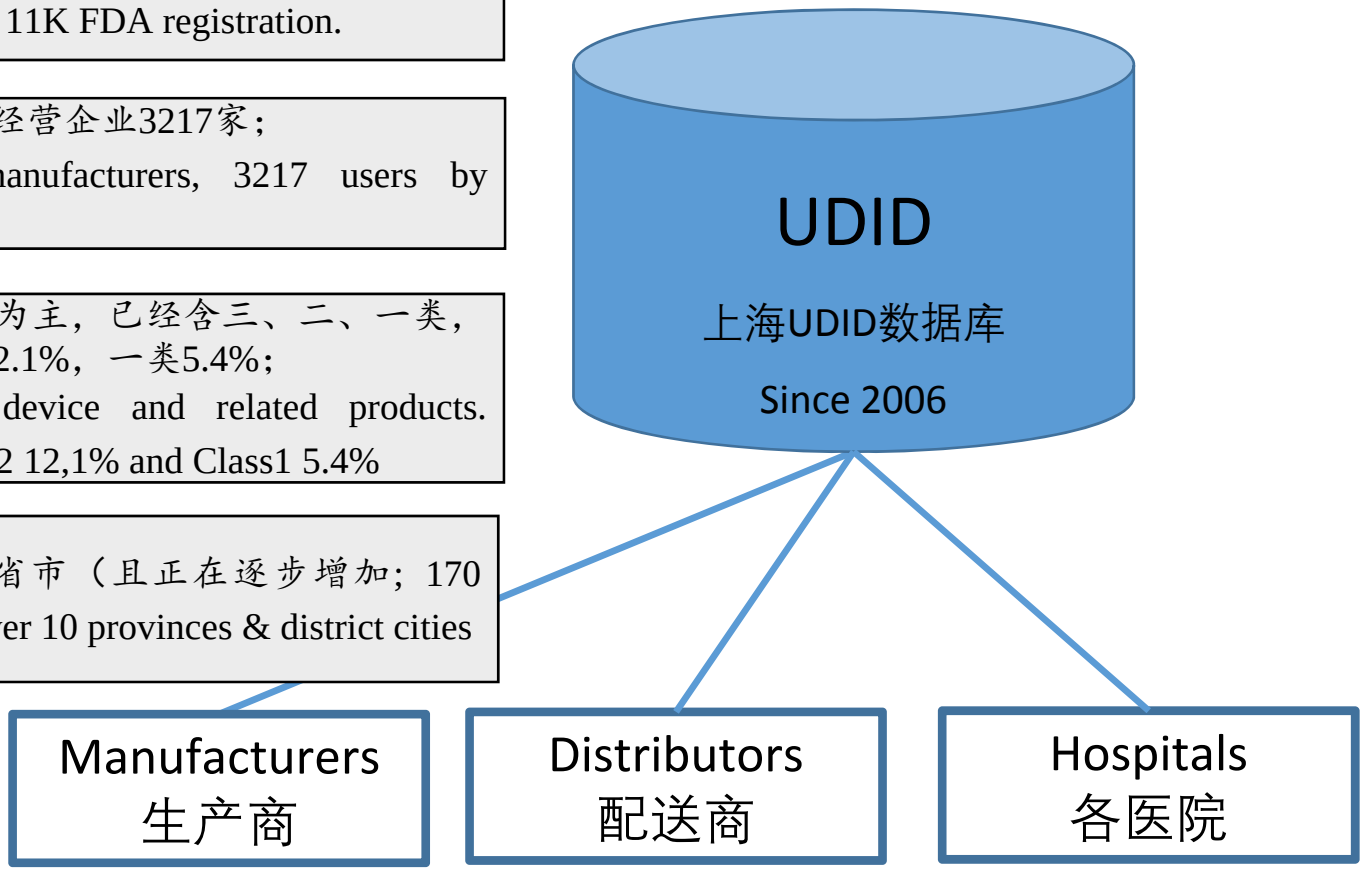
科主任签字： 手术医师签字： 科室： 操作员签名：

HIS in hospital running for traceability is supported by the Shanghai UDID for 10 years

上海的UDI数据库支持全国很多医院追溯制度运行经营有10年

Never EASY 3 C
Compliance
Correct
Clean

- 近54万种，近11,000张注册证；
  540K products, over 11K FDA registration.
- 生产企业1243家、经营企业3217家；
  1243 users by manufacturers, 3217 users by distributors
- 无源植入医疗器械为主，已经含三、二、一类，三类82.5%，二类12.1%，一类5.4%；
  Cover implement device and related products. Class3 82.5%, Class2 12,1% and Class1 5.4%
- 170家，遍及10个省市（且正在逐步增加；170 users by hospitals over 10 provinces & district cities



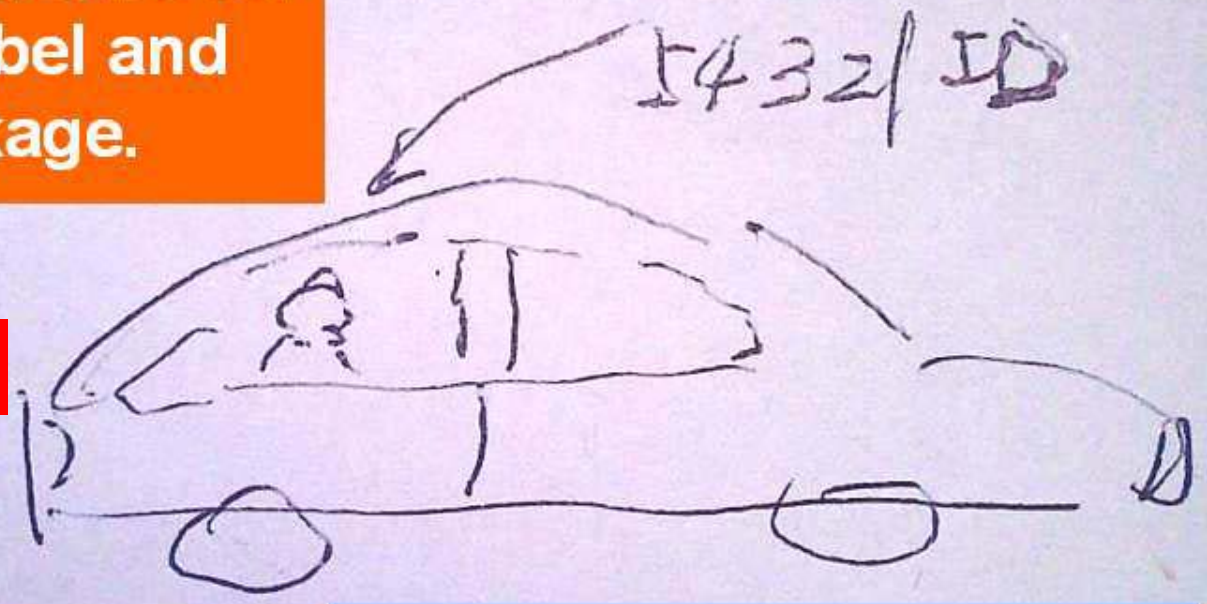
最终形成上市后监督标签编码和产品编号关联的方案

Two Code solution for supply chain

（1）Code of Article ID；（2）Code of product nomenclature

Two Code must be on the device label and primary package.

GMDN Code

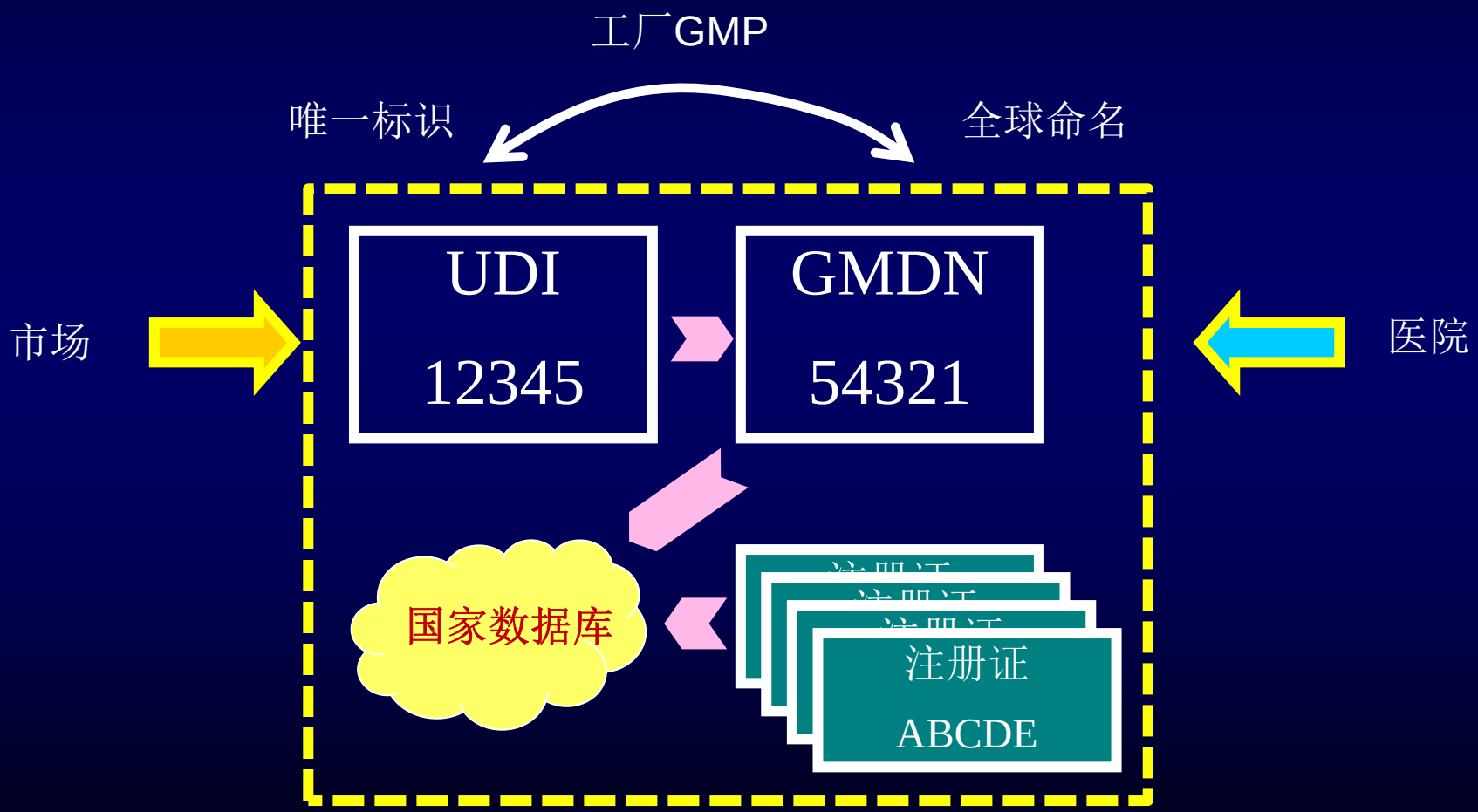


UDI Code

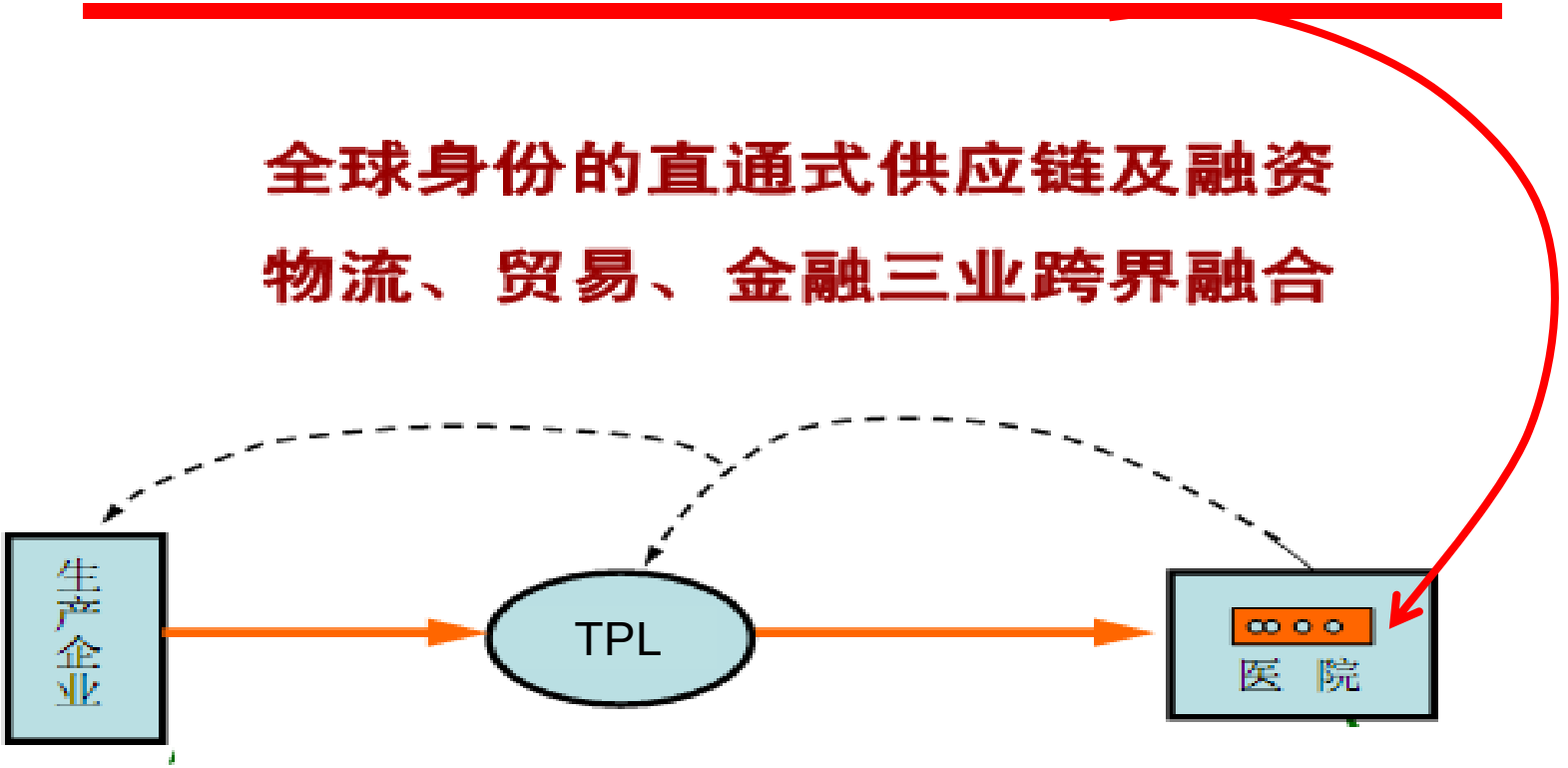
CAR ID LINK OWNER ID

用标识追溯，用命名采购

国家注册制度的发展趋势



New model of procumbent supported by one stop solution of medical supply chain

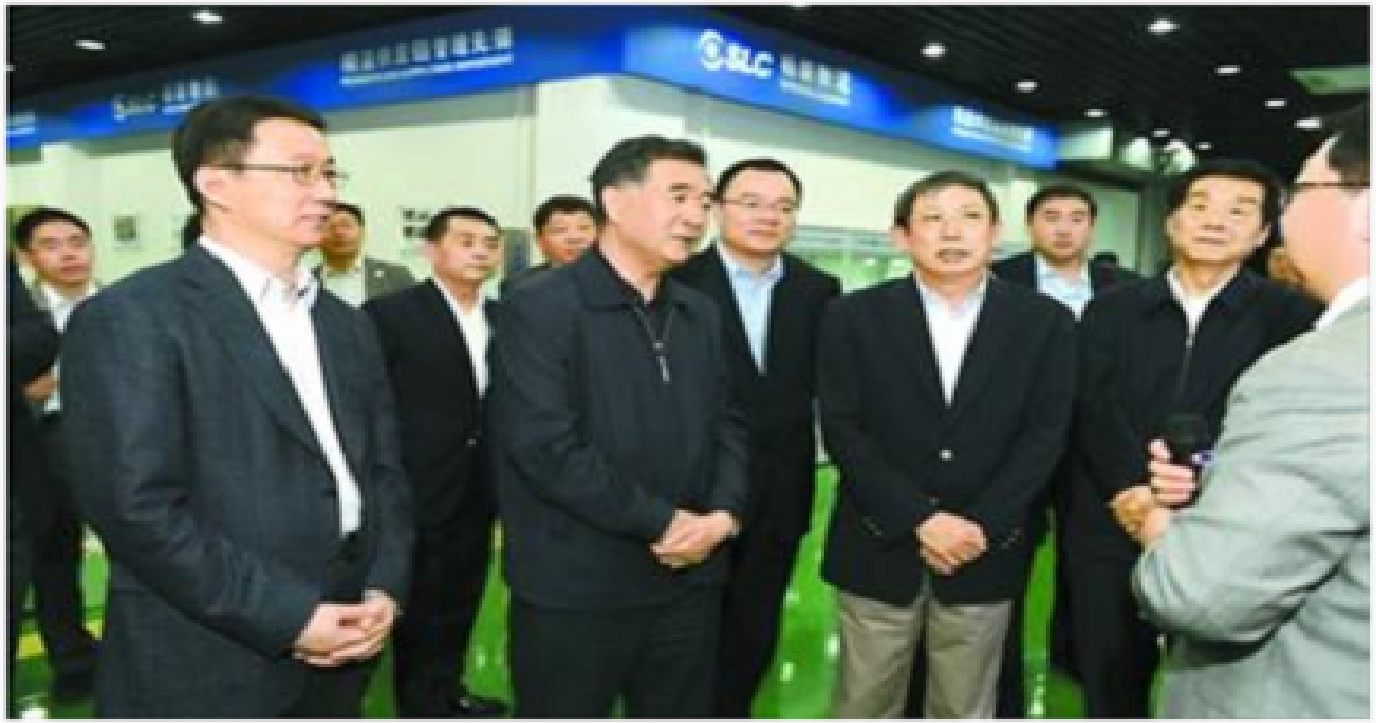


China Premier visit medical smart logistics in SLC PFTZ Shanghai

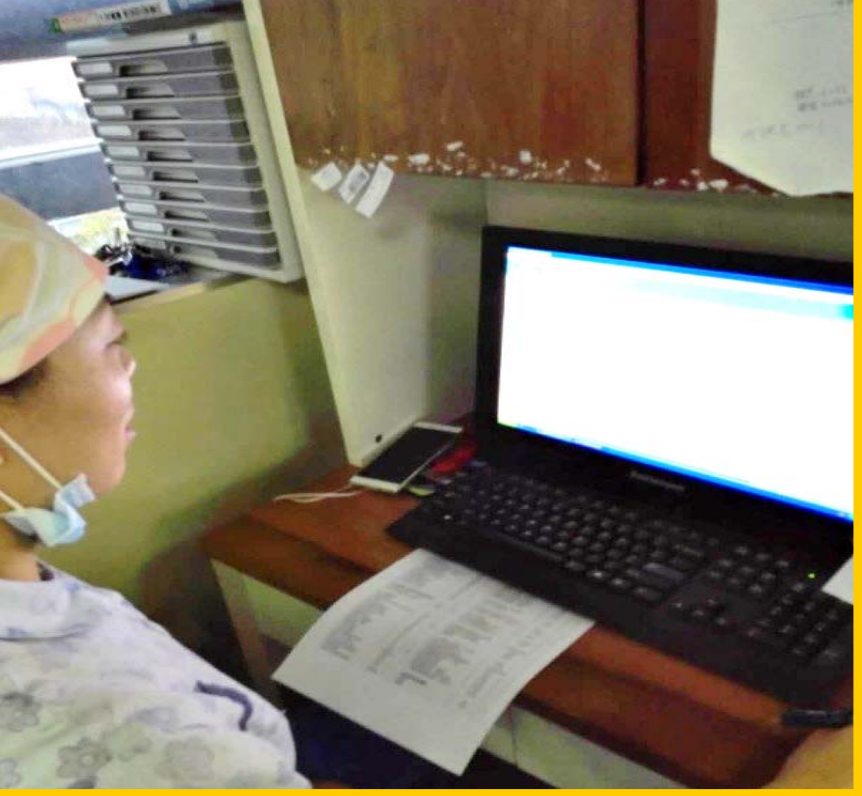
汪洋在畅联了解智能物流

2014年04月11日09:03　来源：解放日报

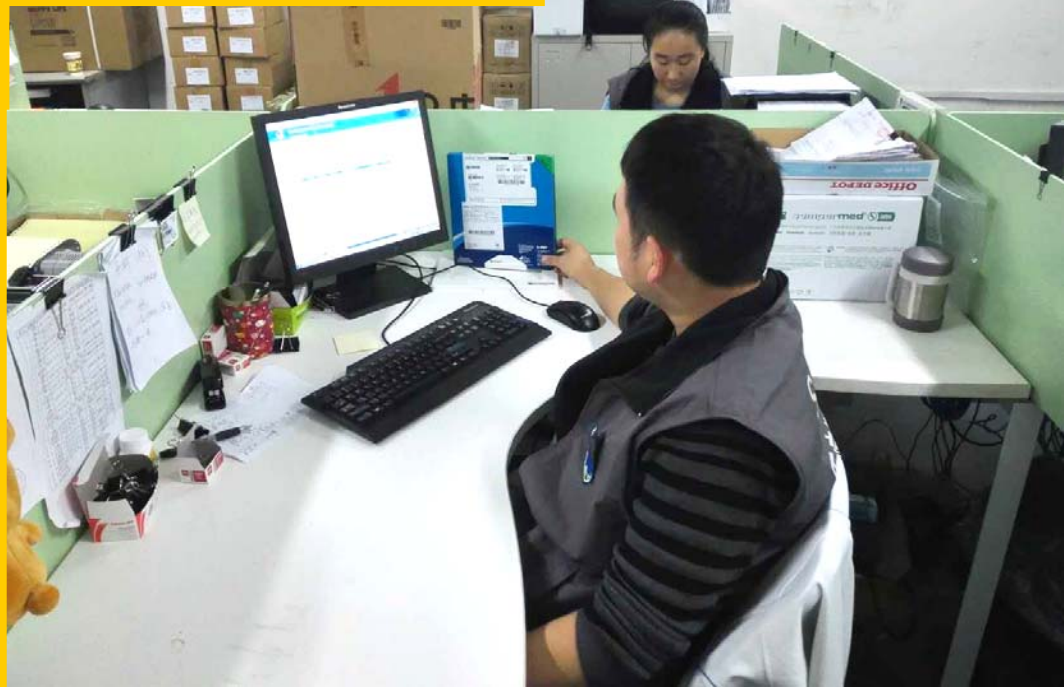
以自贸试验区为核心基地的上海畅联国际物流股份有限公司为近50家全球500强跨国公司提供中国的供应链管理服务。汪洋仔细查看该公司的总控机房，对于智能化、信息化在高端物流中的运用表示肯定。



汪洋在韩正和杨雄陪同下，调研上海自贸试验区内的企业。　陈正宝　摄



DDDO in Shanghai Orient hospital (South)



The situation about the drug traceability supporting by NDC

NDC is not Global Format

中国药品采用NDC的追溯情况

China NDC not support Global ‘Unique’

Manufacturers choice GS1 for ERP reasons, but only DI no PI

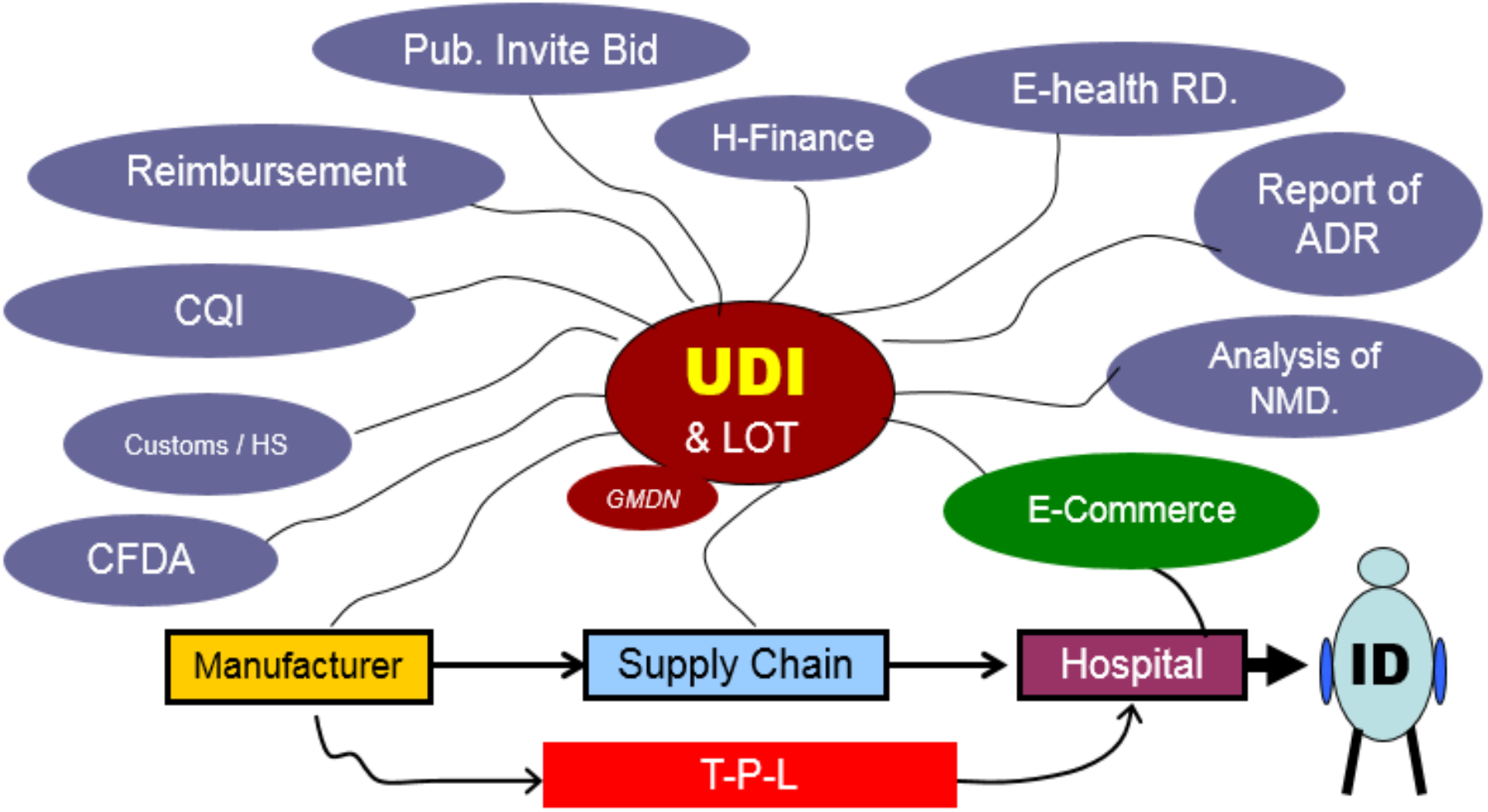
Drug distributing by a machine in China Hospital

Summary

总结

UDI links every data base in different government department

UDI in supply chain links patient' ID Which creates a recall foundation



Summary (from China 10 years story for GS1 Beijing) 2016 1027

1. **CFDA permitting manufacturers to adopt global UDI for traceability**
2. **Old NDC implementation stopped, begging to study new NDC by GS1 format.**
3. **No any change on GS1 international standard, especially in domestic market.**
4. **Capture the PI associating with Patient ID (PID) in full traceability is our final target. We can neglect the middle way of supply chain, if you no enough resource to help you control in first phase (for government point of view). End to End is correct strategy.**
5. **Implantable devices will be enforced using UDI within two years in China.**
6. **Big challenge for hospitals and manufacturers for one stop settlement and shorten supply chain connection is the current tendency of China market.**
7. **China are going to test tracing import information for patient's requiring.**
8. **UDI associating with RFID adopted by China hospital to control inventory for device and drug is not far away.**

Welcome you visit Shanghai China

Thanks

yanliang@mdta.org.cn

Yan, Liang Chairman and Senior advisor

Shanghai Pudong Medical Device Trade Association (MDTA)

CFDA SH Shanghai Institute of Food and Drug Safety (SIFDS)

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