Overview of Introduction of UDI Regulation in Japan

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Improving Traceability of Medical Device

○ by displaying a barcode on a package of medical device, product traceability system is established and utilization of barcode in logistics site and clinical environment is expected. Recently, standardized barcode display and its utilization has been promoted in Japan and internationally.

○ To improve traceability of medical devices, displaying traceability barcode became compulsory by the amendment of the Pharmaceuticals and medical devices act (PMD Act) , which will be enforced in December, 2022.

＜Display GSI barcode on package of medical device＞

GS1-128 symbol（code 128）
→ international standard which display product code and other information

(01)14912345000016(17)200831(10)AB123
Product code | Expiration date | Lot number

Main information indicated in GS1-128

(01)	Product code（GTIN/JAN）
→ specific code for manufacturer, product and package	
(11)	Date of manufacture
(17)	Expiration date
(10)	Lot number
(21)	Serial number
(30)	Quantity

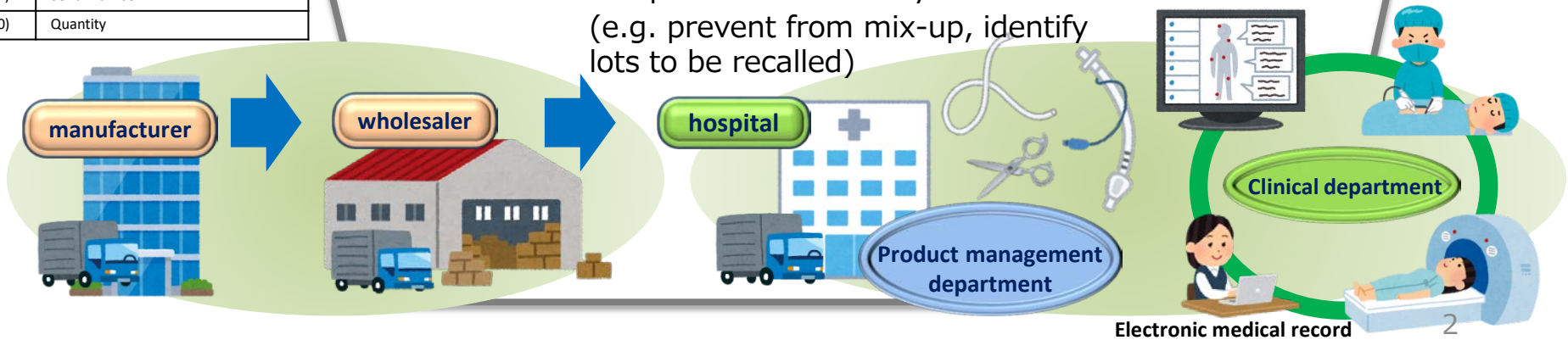
＜Register product information on database＞

Medical device database

Utilize barcode in logistics site and clinical environment

- streamline logistics management and product inventory management
- improve clinical safety

(e.g. prevent from mix-up, identify lots to be recalled)



Example of barcode display

GS1 barcode display on a label sticker
on an inner box of a medical device