Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

GHWP Liaison Member Updates for GS1

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GS1

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Kuala Lumpur, Malaysia

GS1 is a global standards organisation

Neutral and not-for-profit

User-driven and governed

Global and local

Inclusive and collaborative

Our vision

GS1 Healthcare envisions a future in which the healthcare sector achieves **harmonised implementation** of **global standards** in **business and clinical processes** enabling **interoperability**, optimal **quality** and **efficiency** of healthcare delivery to **benefit patients.**

Patient Safety

Supply Chain
Security & efficiency

Traceability

Product Data

In healthcare GS1 standards help to improve..

supply chain efficiency **unique identification**
inventory management traceability
sustainability reliable product information
verification patient safety **reduce medical errors**
reduce waste **innovation** **medicine**
more time for patients **improve recalls**

How to implement UDI using GS1 standards?

Do not confuse

	Standardisation of the global unique identifier	Risk-based **classification** of medical devices	**Nomenclature** code
Enabled by	Organisations such as GS1	National competent authorities	Organisations such as Global Medical Device Nomenclature Agency
Example	GTIN	Class 3 medical devices under EU MDR	GMDN nomenclature EMDN (under dev.)

GS1 as UDI issuing entity

- On **7 June 2019**, GS1 was designated by the European Commission as issuing entity for Unique Device Identifiers (UDIs). Re-accredited in July 2024.

- GS1 has been accredited as a UDI issuing agency by the U.S. Food and Drug Administration since 2013

- Other regulators : e.g., Australia, Brazil, China, Saudi-Arabia, Singapore, South Korea, Turkey.

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ANNEX

List of issuing entities designated to operate a system for assignment of UDIs pursuant to Regulation (EU) 2017/745 and a system for assignment of UDIs pursuant to Regulation (EU) 2017/746

(a) GS1 AISBL

(b) Health Industry Business Communications Council (HIBCC)

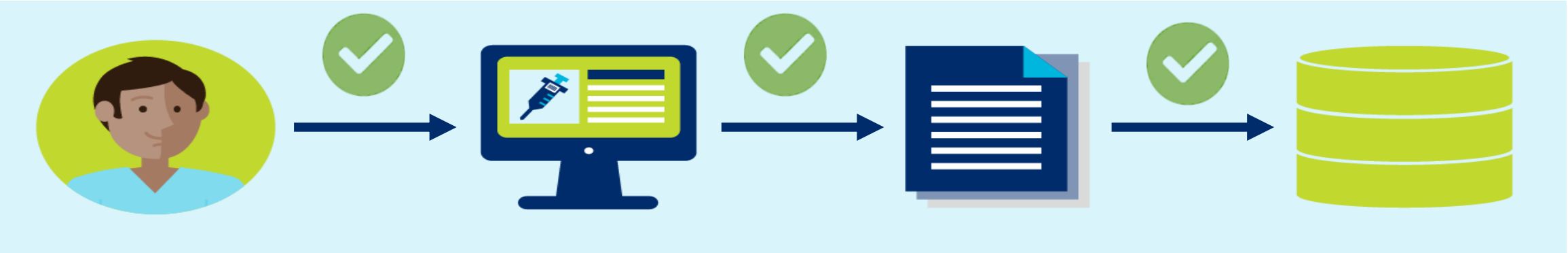
(c) ICCBBA

(d) Informationsstelle für Arzneispezialitäten — IFA GmbH

UDI and GS1

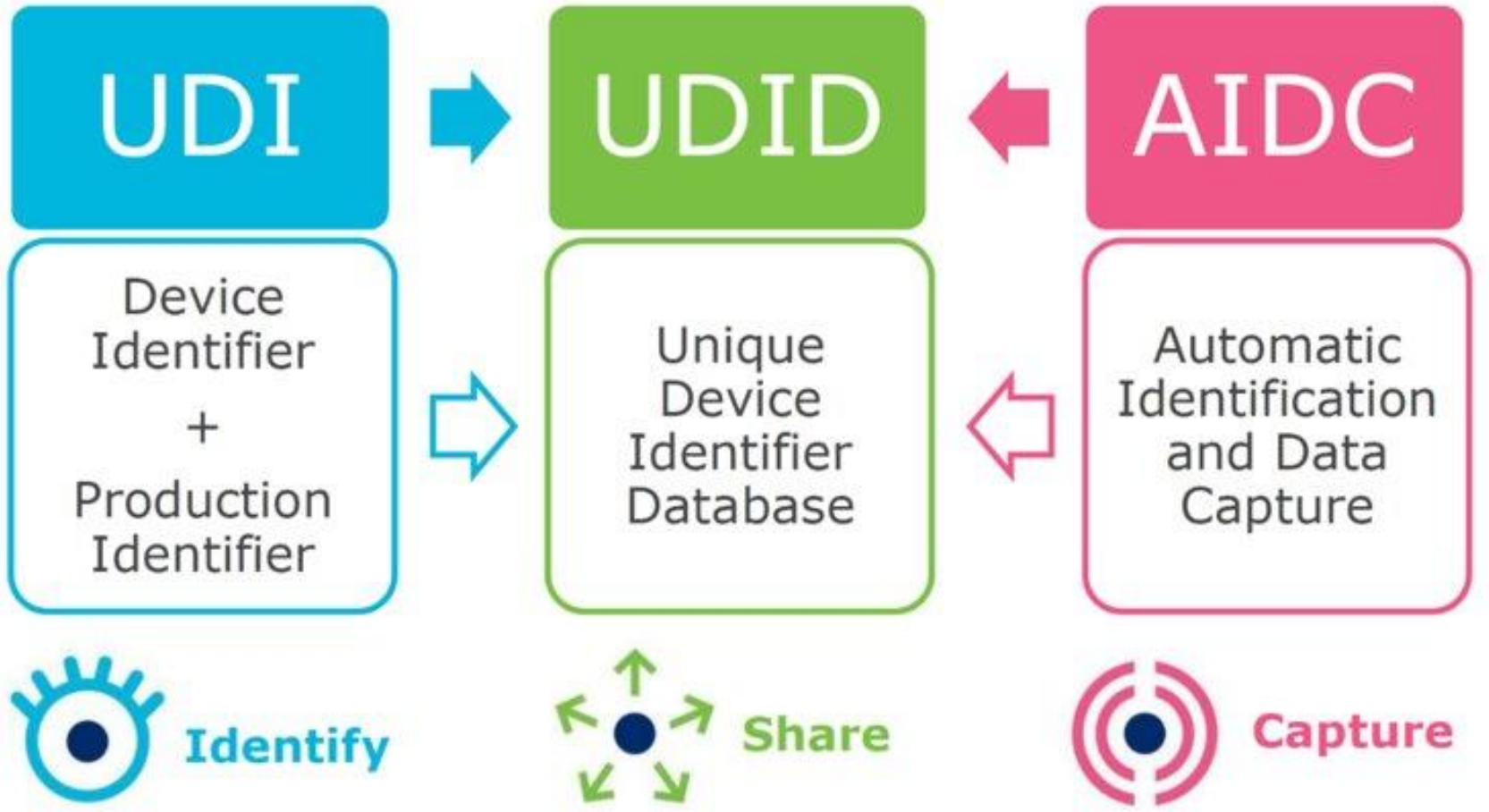
Medical devices manufacturers or authorised representatives use the GS1 keys (GMN and GTIN) to identify their devices in the UDI regulatory database

Data quality is key !



UDI and the GS1 System of Standards

In EU:
Basic UDI-DI
and
Master UDI-DI



Why UDI?

Why UDI? Patient safety and traceability

REGULATOR

- market surveillance, along across borders
- identification and documentation of devices placed on the market and used in hospitals
- customs control and fight falsified devices
- others: insurance, price control, tender requirements, inventory management

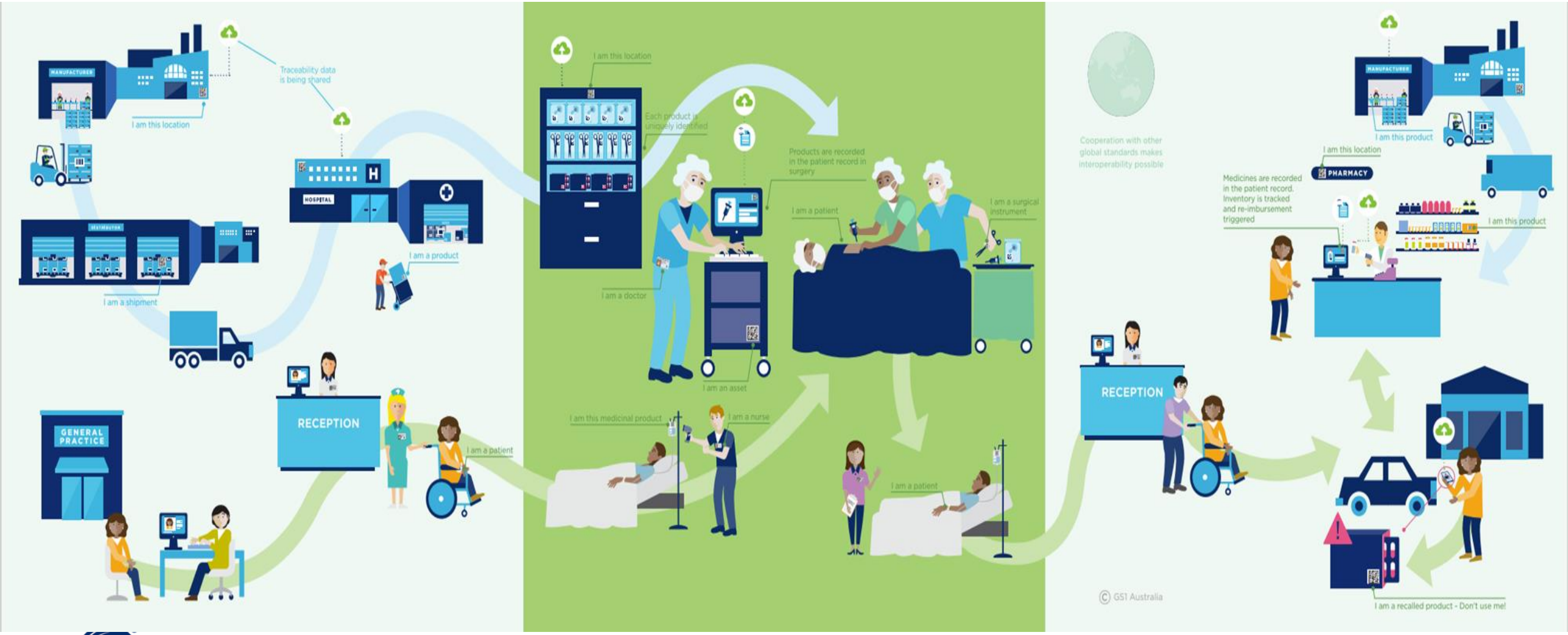
HOSPITAL / PROVIDER

- electronic health records
- purchasing, inventory, invoicing
- safety alerts and fields safety corrective actions (FSCA)
- no relabelling and less medical errors

MANUFACTURER

- compliance with regulations and tender requirements
- costs optimisation
- data synchronisation and processes efficiency

Beyond UDI Compliance



The challenge of global implementation

- Multiple UDI-DIs for the same model of device
- **Different UDI Triggers: specific WG to be launched in Q1 2025 – stay tuned!**
- Impact of multiple standards for UDIs (one per issuing agency) on cost and time to implement in healthcare
- Different positions on the UDI carrier
- Differing codes / values for data fields in the UDI databases
- Different nomenclatures
- Exceptions
- Etc

This can create regulatory and administrative burden and can undermine successful implementation from manufacturers to healthcare providers.

GS1 Resources

- GS1 UDI webpage
  - Mapping of regulation on UDI
  - UDI and GS1
  - UDI database GDSN mapping
- Public Policy and Healthcare
- Position & Discussion paper

Contact Details

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