UDI: Past, Present, and Future
Perspective from Industry

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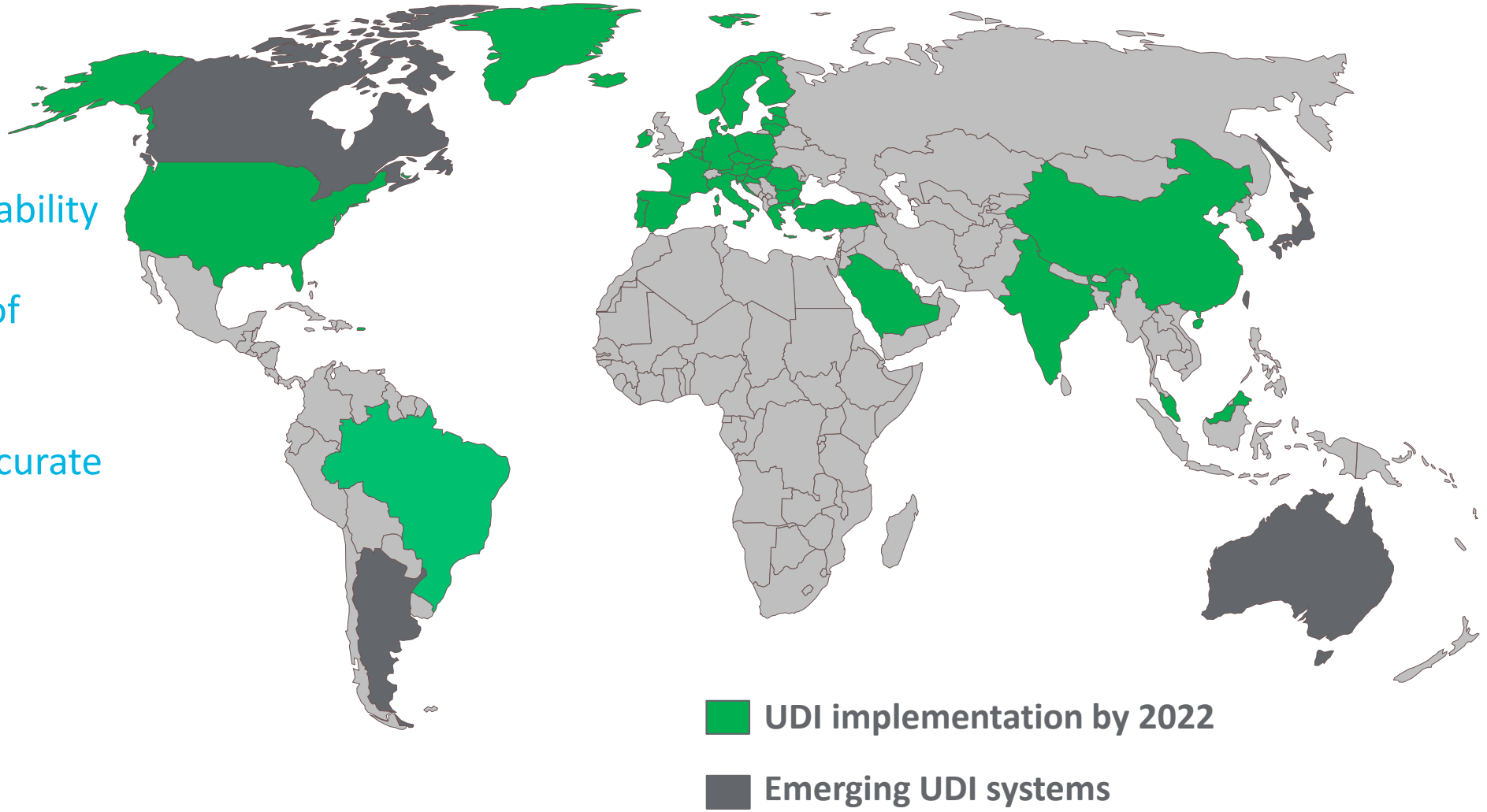
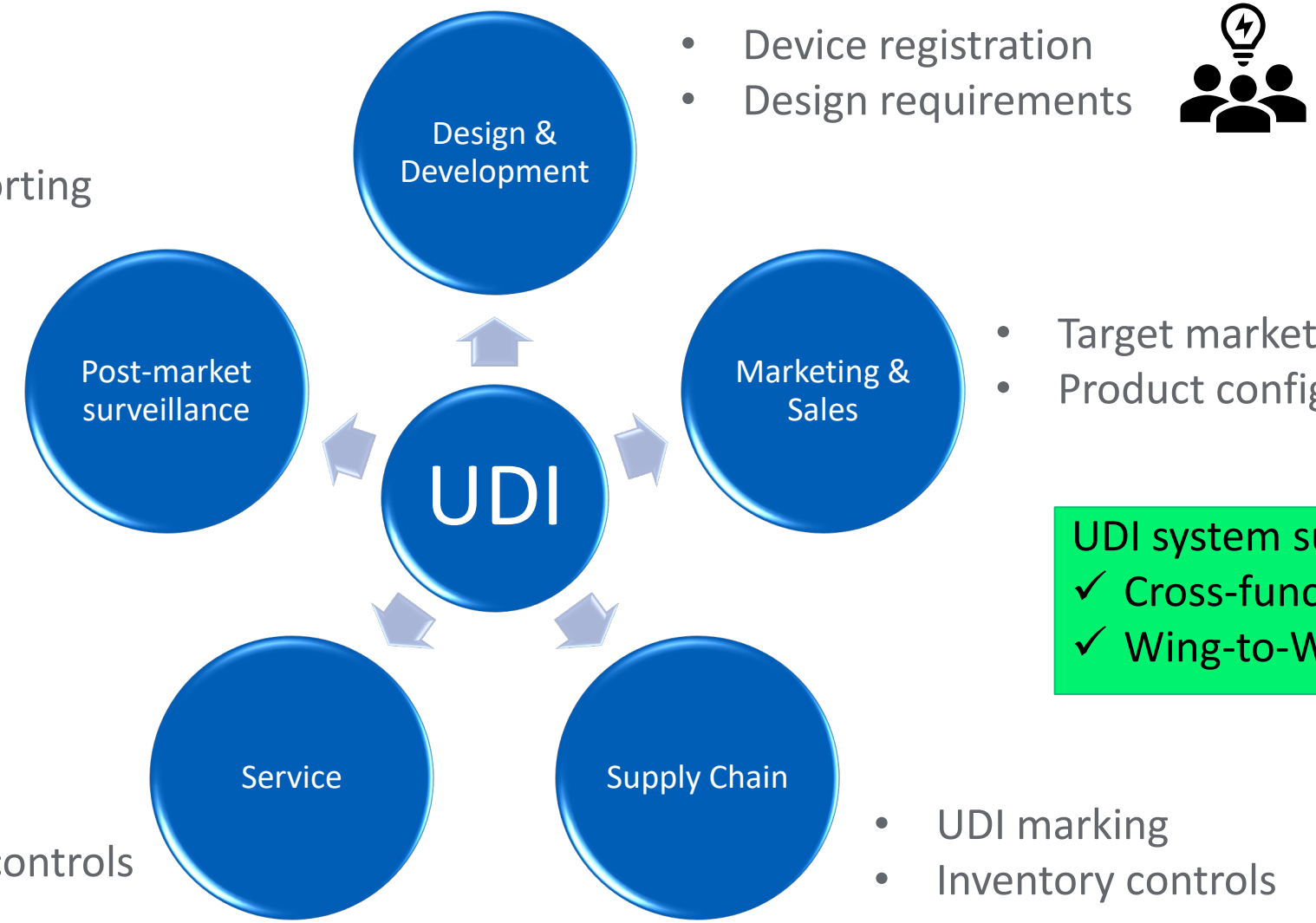
The global UDI landscape is changing…

- ✓ Globally harmonized approach to UDI traceability
- ✓ Worldwide exchange of medical device data
- ✓ Better, faster, more accurate post-market trending



…The medical device industry must also change

- Event reporting
- Trending



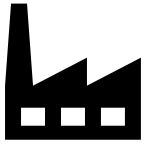
- Device registration
- Design requirements

- Target market considerations
- Product configurations

UDI system supported by:
✓ Cross-functional processes
✓ Wing-to-Wing digital infrastructure

- Install base controls
- UDI capture

- UDI marking
- Inventory controls



FDA = food & drug administration
MDR = medical device regulation
UDI = unique device identification

It is not always easy | UDI Challenges & Opportunities

An Industry View

UDI Requirements

- Consistency of UDI data elements across regulations
  - ❑ Name and definition of UDI data elements (e.g. Brand, Model)
  - ❑ Nomenclature (e.g. GMDN, EMDN, CDN)
  - ❑ Expected values and response options (e.g. sterilization mechanisms, MR safety)
- Harmonize level of data required for UDI publication
  - ❑ US FDA & EU MDR – require data associated with device models (Device Identifiers only)
  - ❑ Emerging regulations requiring Device Identifiers plus Production Identifiers

IT = information technology
UDI = unique device identification

It is not always easy | UDI Challenges & Opportunities

An Industry View

UDI Database

- Timing required to develop digital infrastructure to connect is often 1-2 years
- Development dependent on availability of technical specifications
  - ❑ Defined data field types and formats (e.g. free text, multi-select, drop down, yes/no)
  - ❑ Specified free text character lengths, allowance of special characters, lists of values, language requirements (e.g. do submissions need to be in local language or English?)
- Allowance for different connection mechanisms – machine-to machine vs. manual input, HL7 vs xml
- Defined user requirements/accounts for database accessibility – in-country only?
- Database testing opportunities and IT help desk

IMDRF = international medical device regulators forum
UDI = unique device identification

It is not always easy | UDI Challenges & Opportunities

An Industry View

Implementation Support

- Alignment with global guidance documents
  - ❑ IMDRF UDI System Application Guide
  - ❑ Use of UDI Data Elements across different IMDRF Jurisdictions
- Regional guidance documents – publicly available with translations (if possible)
- Include plan for pilots/testing (database training, connection testing opportunities, feedback sessions
- Support “help desk”

The global UDI landscape is changing…

…and we are ready to change with it

- Medical device traceability and continued surveillance is important
- Continue industry/regulator collaboration to help harmonize regulations and shape implementation strategies
- Help us drive compliance without disrupting availability of life-saving products required for global healthcare

Thank you!