ASK THE EXPERTS

Reed Tech & 1WorldSync

The Role of Medical Device UDI & GDSN in Regulatory Compliance Strategy

Co-Hosts

Scott Brown is the Sr. Director of Global Data Strategy with 1WorldSync. He has wide-ranging experience in data governance, community and program management, and industry/supply chain data strategies.

Gary Saner is a Sr. Regulatory Principal at Reed Tech. He is a subject matter expert on medical device Unique Device Identification and other structured content reporting to regulatory agencies and commercial organizations.

Agenda

- Learn how 1WorldSync and Reed Tech work together to develop winning product data management strategies
- Get an update on Health Authorities around the globe and UDI timelines
- Who is asking for data in Global Data Synchronization Network (GDSN) and why they need it
- What are the best practices for creating, collecting, cleansing and compliance of product data

1WorldSync simplifies the creation and distribution of impactful content that's accurate, consistent and relevant everywhere commerce happens.

1WorldSync By the Numbers

17K+

Customers

35K+

Brands

2K+

Retailers & Distributors

26M+

GTINs

85%

Of Leading Brands & Retailers

65%

Of Global Registered Product Data

Solution for Product Content Orchestration

Product Master Data that Powers Item Setup

Supply chain and logistics data that enables omnichannel commerce

Supply Chain & Logistics

Needed to manage the product lifecycle, design, manufacturing, sales & distribution, etc.
In practice, sourced from the supplier but sometimes incomplete, inaccurate or non-existent.

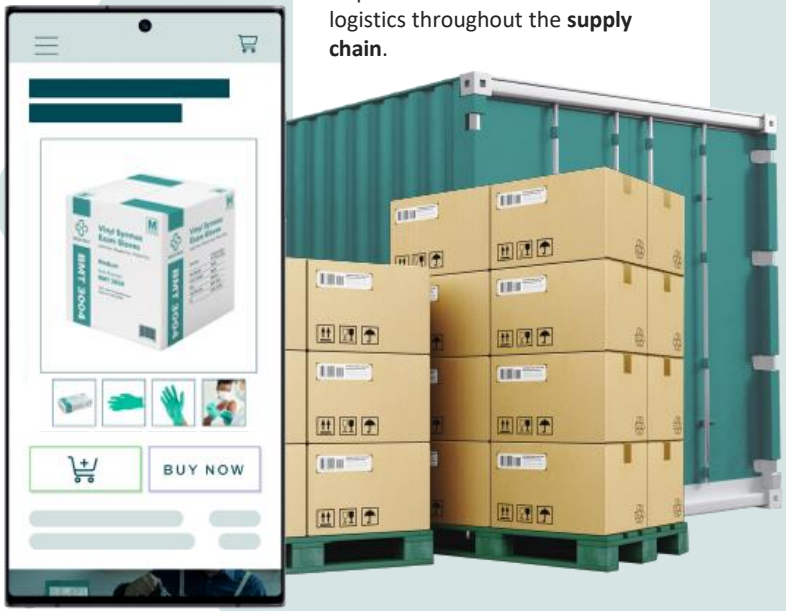
User-Facing Content

User facing, descriptive information and content is required to set an item up.

1WorldSync delivers programs and solutions to help suppliers comply with retailer and distributor requirements.

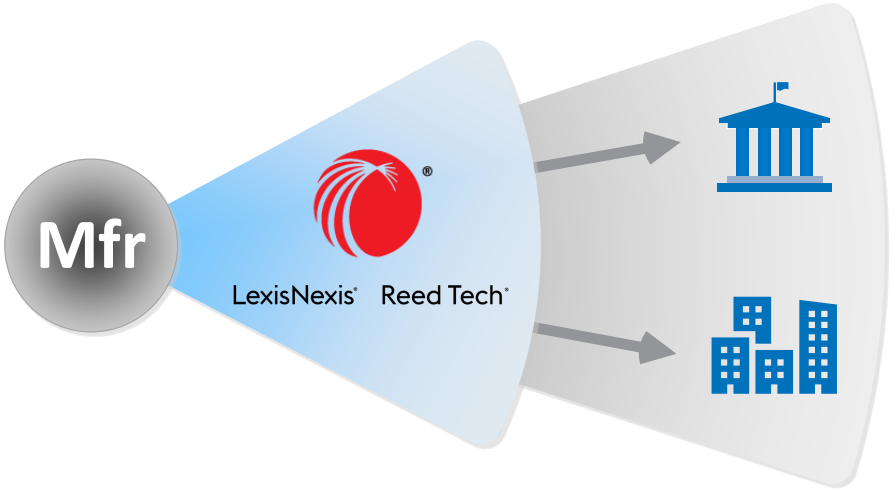
Packaging Hierarchy

Complete packaging hierarchy data required in order to account for the logistics throughout the **supply chain**.



About Reed Tech

Reed Tech's product and service **data management solutions** and **consulting support** help **medical device, pharmaceutical, and cosmetic** manufacturers comply with Health Authority regulatory and trading partner commercial requirements.



Health Authorities

Customers, Trading Partners

Reed Tech: MedTech Regulatory Compliance

Leading industry supplier of Preparation, Submission, and Lifecycle Data Management solutions for Medical Device UDI product information

Industry Experts

20 years of SPL knowledge (SPL-UDI since 2014);
up-to-date SME knowledge from guidance, pilots, and trade groups (FDA, MedTech Europe, TGA…)

Proven, Current, Compliant Systems (21 Part 11, Annex 11, Audit Trail)

750,000+ SPLs submitted to FDA GUDID; 20,000+ records to EU EUDAMED;
Direct M2M (AS2/4, APIs) connections to HAs for auto, bulk submissions

Experienced, Major Industry Provider

33% of all FDA GUDID SPL records
Support US, EU, China, Korea; Roadmap for international UDIDs

Trusted Team Partner

450+ medical device customers since inception
Small (1 record) to large (250,000 records) customers
Flexible role assignments for in-country representatives and corporate users

DEKRA DEKRA	ISO 9001 Quality ISO27001 Security
HL7 INTERNATIONAL	HL7 Member Since 2005
1 WORLD SYNC	1WorldSync Alliance
GS1 Solution Partner	GS1 Solution Partner
RAPS PREMIUM SOLUTIONS PARTNER	RAPS Solution Partner
MedTech Europe from diagnosis to cure	MedTech Europe Member
THE VISION COUNCIL	1World Sync Alliance
DTA DENTAL TRADE ALLIANCE	DTA Consultant

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Reed Tech – Key Benefits

Saves Costs

- Saves Development and Maintenance Costs
- Non-intrusive Connection to Existing Client Infrastructures

Saves Time

- Avoids Development Time; Uses Active Online System
- Fast Onboarding/Startup; Short Time to Comply

Saves Resources

- Minimizes IT and Software Development Team Effort
- Minimizes Project Mgm't and Stakeholder Support

Reliable

- Proven, Trustworthy Data Management System
- Experienced Partner

Decreases Risk

- Quickly Meets Compliance Deadline; Avoids Misbranding
- Maintains Revenue Stream
- Continues Delivery to Patients

Future Proof

- Updates per Spec Changes
- Scalable for Future Data Volume
- Future Global Channels

How 1WorldSync and Reed Tech work together

Medical Device product data management UDI + GDSN

Medical Device Lifecycle

Regulatory Registration & UDI Reporting

Product Sharing with Trading Partners via GDSN

UDI – Unique Device Identification;
GDSN – Global Data Synchronization Network

1WorldSync + Reed Tech

Long-term collaboration

- Existing M2M connection from Reed Tech to 1WS supports GDSN data flow

Renewing working relationship

- Collaborate on data management, meeting regulatory compliance and sharing product data with trading partners

PRESS RELEASE

LexisNexis® Reed Tech® and 1WorldSync enable Global Medical Device Manufacturers to Manage Regulatory UDI submissions and Product Data Syndication

Sep 30, 2024 | 8:00 AM ET

LexisNexis® Reed Tech®

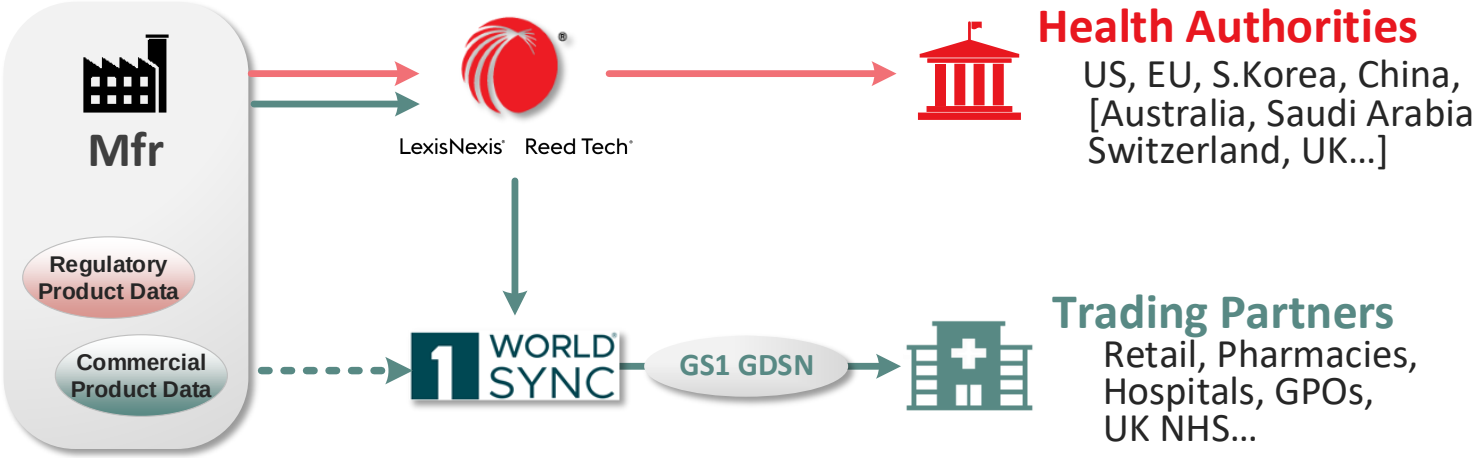
Horsham, PA, September 30, 2024, LexisNexis Reed Tech, a part of LexisNexis® Legal & Professional and global provider of regulatory data management solutions for the life sciences industry, and 1WorldSync™, the leading provider of product content orchestration solutions today announce a renewed collaboration. Pairing the Unique Device Identification (UDI) regulatory data management technology of Reed Tech SingleSource™ for Medical Devices with the Global Data Synchronization Network (GDSN) capabilities through 1WorldSync strengthens product data accuracy and accessibility throughout the healthcare chain.

Together, 1WorldSync and SingleSource™ for Medical Devices allow MedTech companies to centrally and securely manage and share product data required by global health authorities, customers and other stakeholders around the globe.

"Reed Tech is committed to continue delivering on our mission to provide MedTech companies with regulatory consulting, advanced product data management technology, and reporting services to regulatory Health Authorities and commercial trading partners," said Wendy Scott, General Manager of Reed Tech Life Sciences. "Our collaboration and automated data integration with 1WorldSync allows our clients to meet critical industry needs in publishing medical device information via the GDSN and complements our position as a market leader in global UDI data management supporting compliance requirements in US (34% of electronic GUDID records), EU, China, South Korea, and other regions."

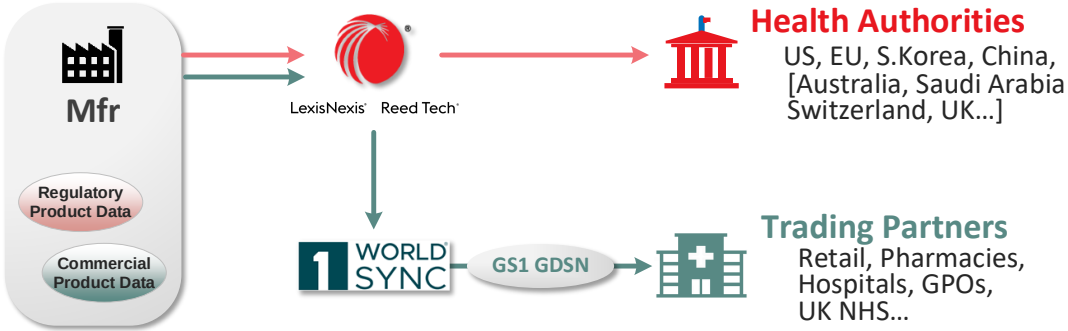
"By combining our expertise, Reed Tech and 1WorldSync are able to assist the medical device industry in providing product

1WorldSync + Reed Tech Collaboration



1WorldSync + Reed Tech Benefits

- **Global Regulatory Compliance** to Health Authority registration, listing, and UDI reporting requirements
- **Efficient, Fast Startup, Economical Master Data Hub** to downstream stakeholders
- **Precise, Timely Publication of Product Content** via GDSN framework meets customer syndication requirements
- **Peace of Mind** that all downstream customer requests are effectively fulfilled



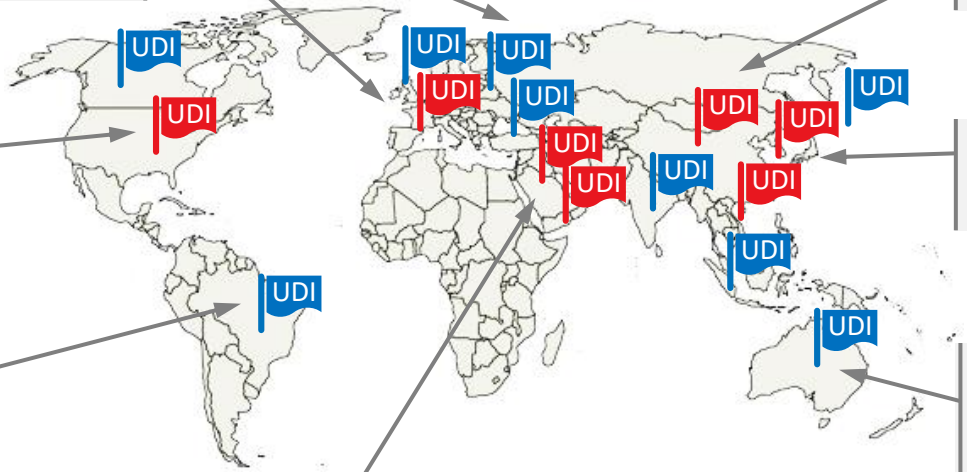
Global Health Authorities UDI update

Health Authorities Are Adopting UDI

EU
2021-Oct UDI voluntary
2026-Jan UDI req'd period start

Switzerland
2025 vol, 2026? req'd

China
2024-Jun Batch 3
(Class II List)



US
2022-Dec final Class I

South Korea
2022-Jul final Class I

Brazil
2022-Jan UDI pkg tags
2025-Jul Class IV

Australia
2024-Q4? UDI vol
2025-Q4? Class III, IIb

Saudi Arabia
2024-Sep Class A

Active Pending

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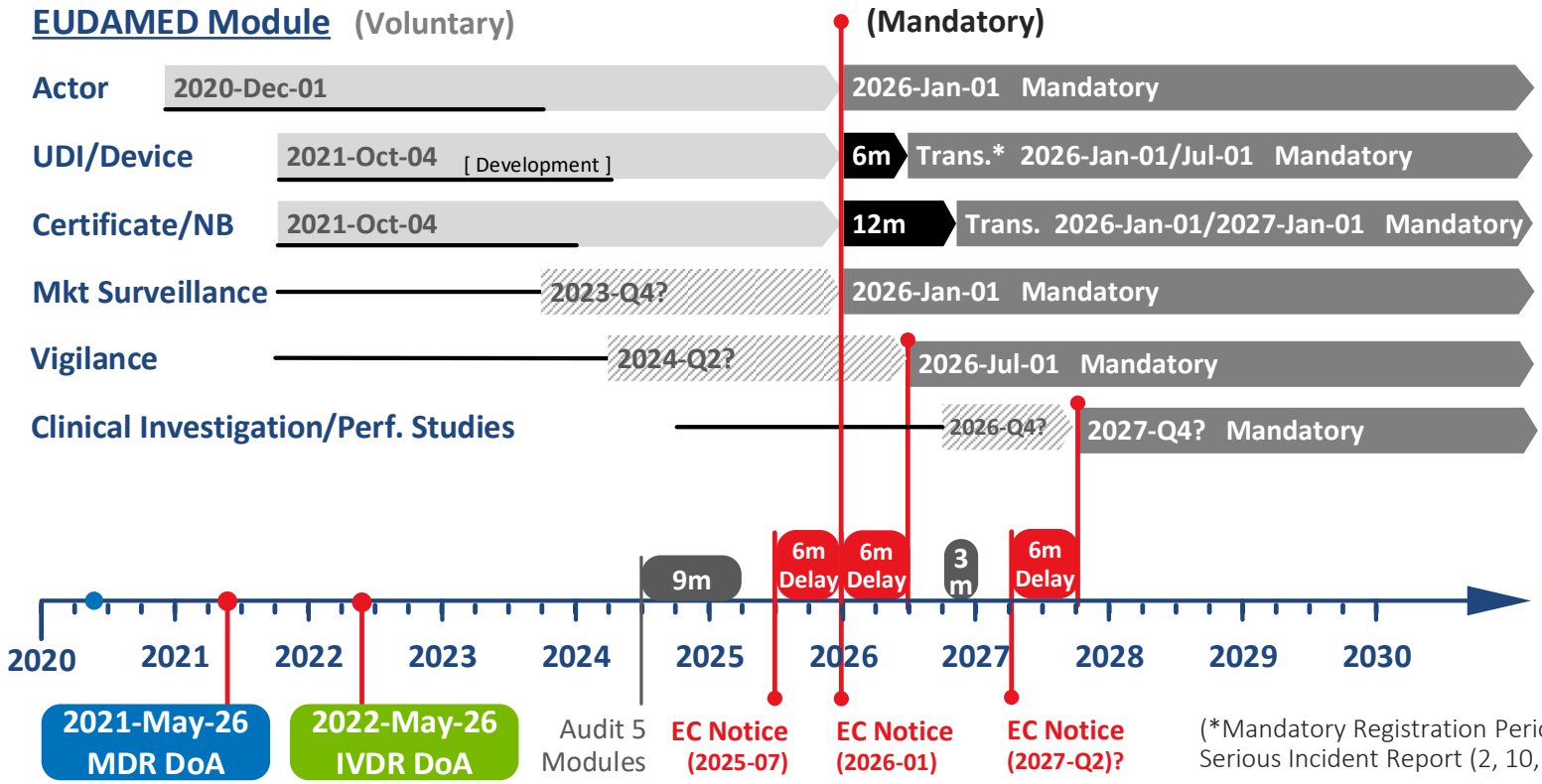
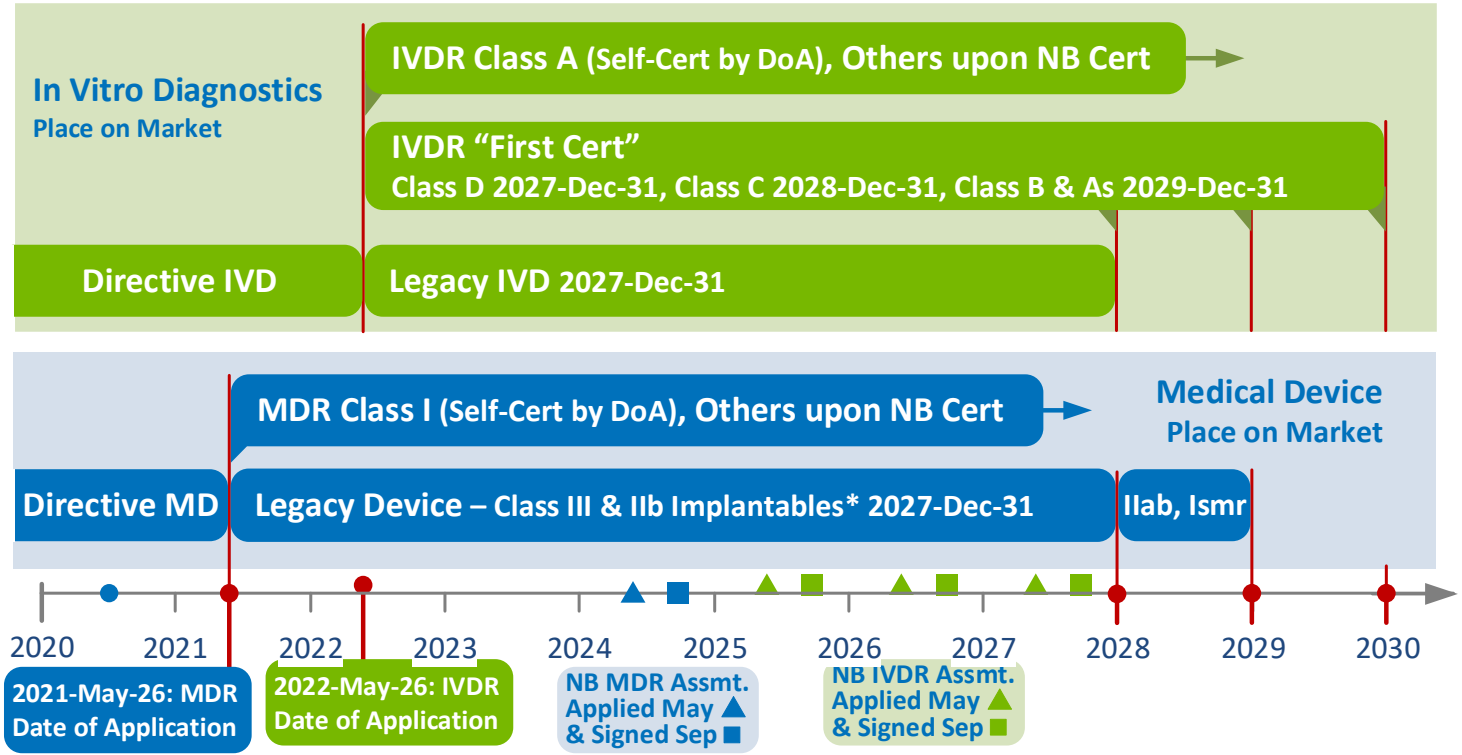
EUDAMED Timeline – 6 Modules



(*Mandatory Registration Period or upon Serious Incident Report (2, 10, 15 days)

EU MDR/IVDR Timeline – Place On Market



* Except WET: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

Who is asking for data in Global Data Synchronization Network (GDSN) and why they need it

Downstream user groups

GS1 Overview

Neutral, not-for-profit, international Standards Development Organization (SDO) that develops and maintains standards for supply and demand chains across multiple sectors

Headquarters in Brussels with 114 regional Member Organizations in Europe, Middle East, Africa, Americas, and Asia Pacific, e.g., GS1 US

Industries

- Foodservice, Fresh Foods, Grocery
- Healthcare (Drug & Medical Device Manufacturers, Providers)
- Retail (Apparel, General Merchandise)
- Transport & Logistics
- Other (Aerospace, Defense, Banking, Hardline, etc.)

GS1 System of Standards

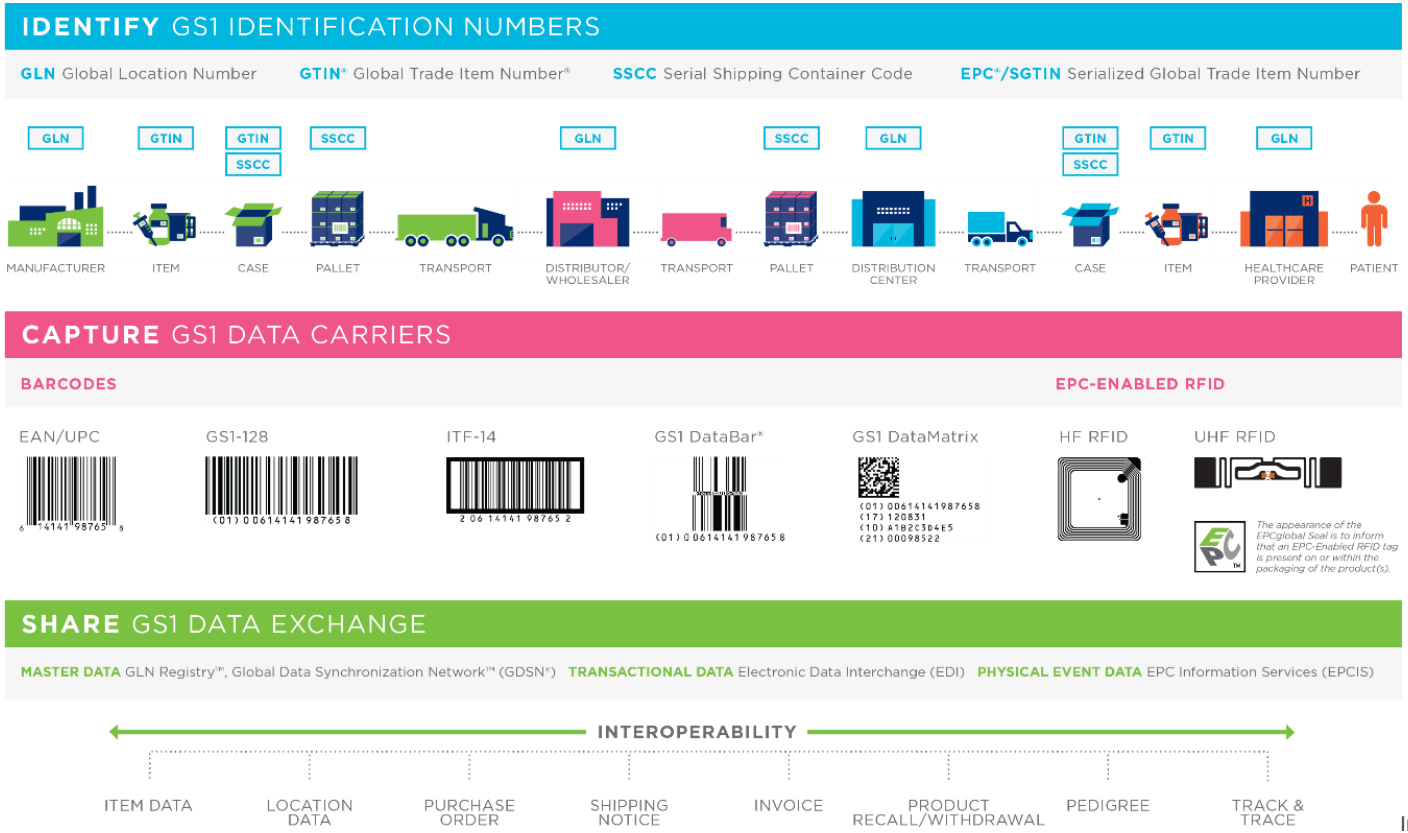


Image source: GS1

What is the GDSN?

- The world's largest product data network.
- Any company, in any market, can share high-quality product information seamlessly.
- Businesses need timely and reliable product information to ultimately benefit consumers and patients.

Image source: 1WorldSync, Inc.

GS1 GDSN Adopters

Legacy Users

Foodservice, Grocery, Retail – Amazon, Walmart, Walgreens, Carrefour, Tesco, Disney, Aramark, USDA, Premier, and others

Healthcare

Medical Device & Drug Manufacturers

Regulatory Agencies

- Netherlands – Dutch National Implant Registry

GPOs – Group Purchasing Organizations

- Premier, Intalere, Vizient, Cencora (AmerisourceBergen), and others

Healthcare Providers

- NHS England – eProcurement initiative
- HTG – Healthcare Transformation Group
  (FMOL, Geisinger, Intermountain, Kaiser, Mayo, Mercy)
- USAID
- Large Hospital Networks

GDSN Statistics

Active GDSN Data Pools - 46

Total GLNs – 76,246

1WorldSync has 37,070 GLNs (49%)

Total Healthcare GLNs – 7,320
(63% are 1WS customers)

Target Market coverage for HC – 254

GDSN Total Stats	
GTINs (Registered)	43,974,096
Subscriptions	190,794,158

GDSN Healthcare Stats	
GTINs (Registered)	6,191,099
Device GTINs	5,226,288
Pharma GTINs	88,834
Other Healthcare	875,977

As of Sept 30, 2024

What are the best practices for creating, collecting, cleansing and compliance of product data

Focus on EC EUDAMED

Global Data Management – 6 Goals

1. Global Master Data Source

Trusted, uniform source of global master data with a governance policy to ensure high quality

2. Single, Central Repository

Consolidated platform for regulator and commercial trading partner data (avoid multiple silos)

3. Incremental Functionality

System expansion for future data channels; scalability for volume; flexibility for new processing reqm'ts

4. Cost-effective Solution

Save cost, time, resources w/ interfaces to existing systems; automate bulk electronic processing; preferred SaaS solution, etc.

5. Regulatory Compliance

Meet global regulators' UDI reqm'ts to maintain market access

6. Commercial Support

Meet customers' specs for product UDI information (electronic catalogs)

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Start UDI Early… Recommended Activities

UDI Foundation Activities

- ❑ Understand UDI regulations
- ❑ Identify UDI requirements/timing for your products
- ❑ Plan your UDI implementation, Train stakeholders
- ❑ Setup systems, SOPs, Data ownership, Governance, etc.
- ❑ Advise/educate internal staff, Supply chain, Customers
- ❑ Plan global UDI Data Hub approach

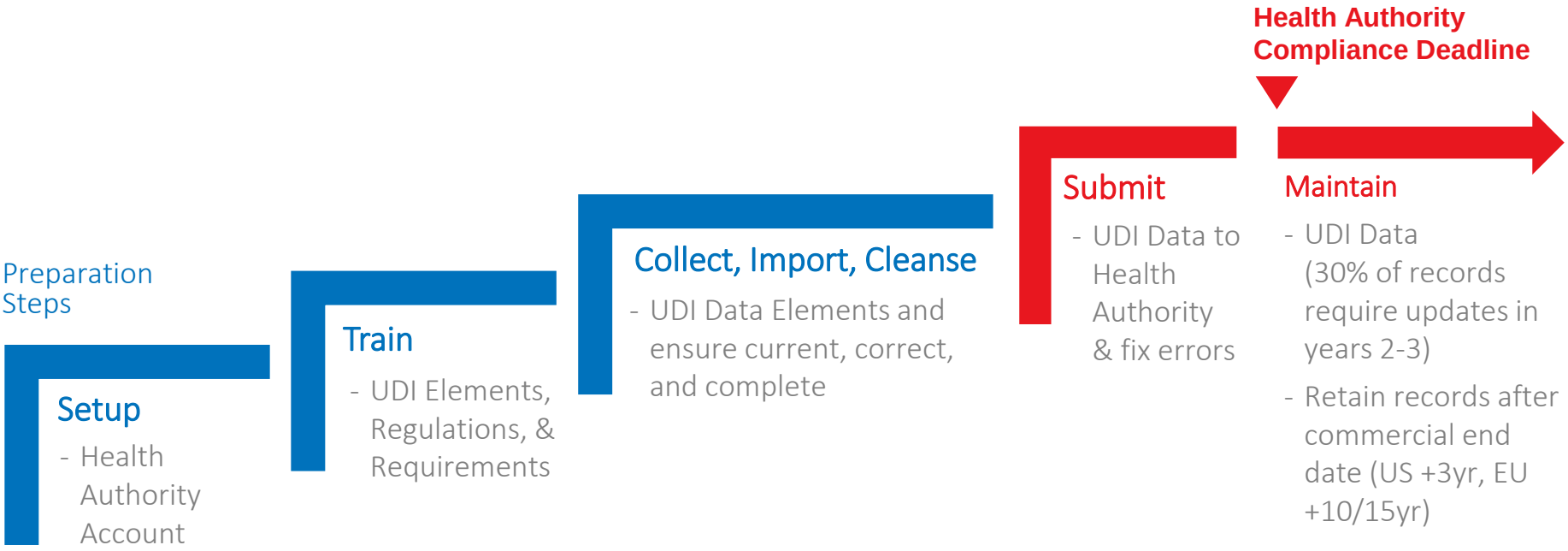
UDI Technical Activities

- ❑ Learn UDI dataset
- ❑ Locate internal data sources, Assign product and pkg device identifiers (& BUDI)
- ❑ Collect data attributes into structure, Create missing values, Enrich data from other sources
- ❑ Learn/exercise data transfer and navigation, Test & validate system
- ❑ Cleanse/validate/normalize UDI Data, Conduct pilot
- ❑ Conduct pilot with HA pre-production system, Prepare for Production Launch

Benefits:

- Avoid Rush
- Ensure Quality
- Decrease Risk
- Reserve Resources for Pending Health Authorities

Steps to Comply with UDI Deadlines



Reed Tech SingleSource ™ - EU Implementation

Ⓐ **Collect/Cleanse**: most effort, longest time; start as early as possible; comply with Basic UDI-DI creation deadline

Ⓑ **Submit to Playground**: most development done; test/validate submission pathway; check data to EUDAMED rules

Ⓒ **Submit Early to Production**: comply with recommendations for early EUDAMED Actor and UDI Reporting by EU Competent Authorities (e.g., France ANSM, Ireland HPRA), Healthcare Industry (customers), or other Health Authorities outside EU

*Setup Variables: resources, expertise, infrastructure complexities ** Data Variables: volume/location/format/quality (correct, current, complete)

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Questions & Answers

Contact the Experts

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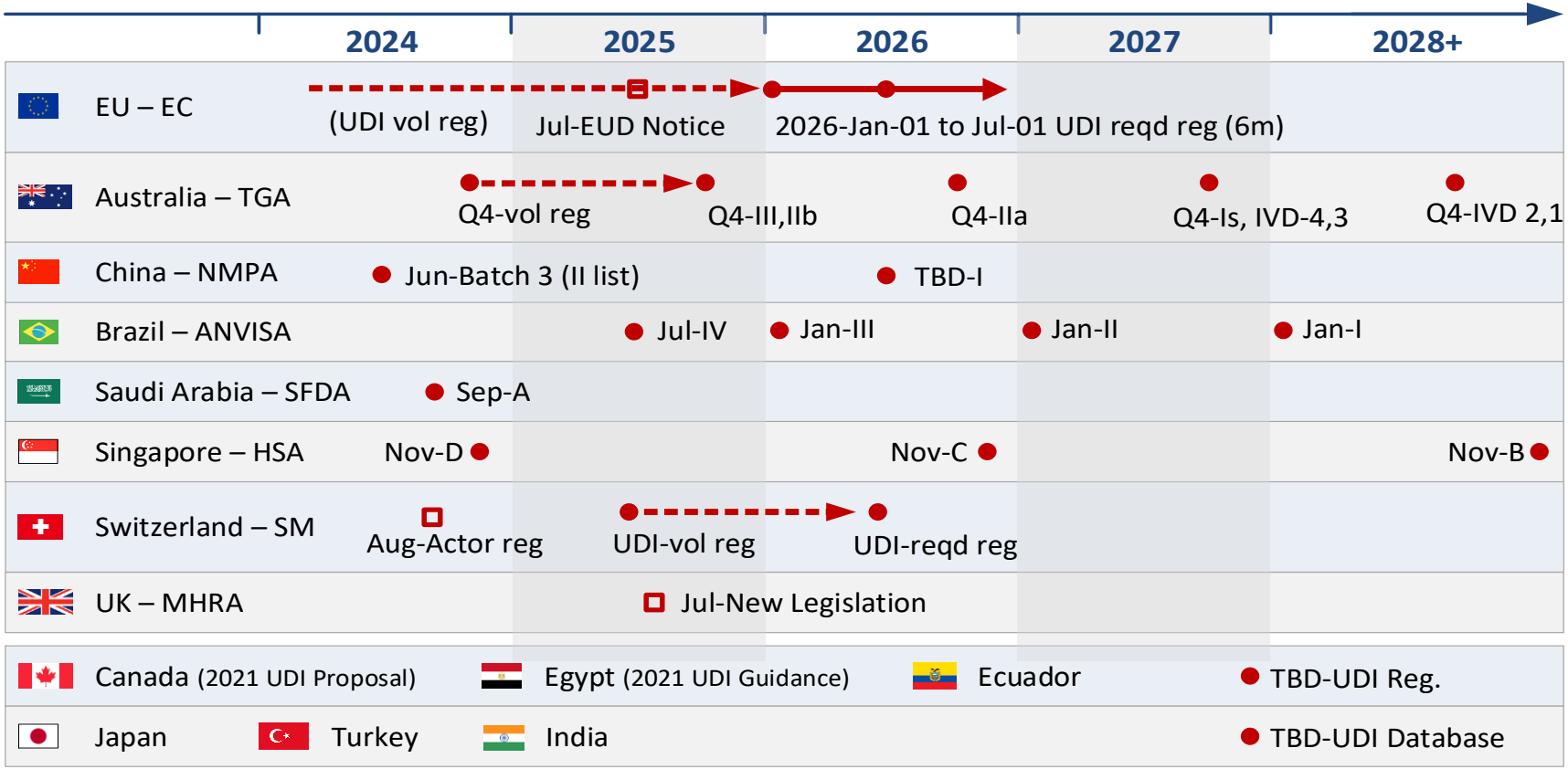
Thank you

Appendix

UDI Data Reporting Timeline – Future



● UDI Submission Deadline,
□ Milestone

Adopt the ‘Now’ Registration Strategy-Part I

1. **Meet Advanced Compliance Deadlines:** The accelerated start date of 2026-Jan-01, currently only 19 months away, and shortened mandatory submission period of 6 months, increases the need to move forward and complete EUDAMED UDI/Device preparation and registrations.

2. **Maintain Momentum:** It is more efficient and productive to continue the preparation process as that decision avoids losing team focus, avoids the cost of restarting the activity, and avoids the possible loss of trained staff during a pause in activity.

3. **Avoid Resource Overload:** Timely completion of EUDAMED preparation allows internal resources to be available and focus on complying with numerous imminent global Health Authority UDI deadlines, e.g., Australia, Switzerland…

4. **Satisfy Early EUDAMED and MDR/IVDR Adopters**: Some EU Member States already recommend use of the voluntary EUDAMED UDI/Device registration module. It is expected that many customers would favor a MDR/IVDR compliant and registered device over an outdated Directive device in making purchasing decisions.

5. **Manage Complex UDI Dataset:** The product information required to be reported to EUDAMED poses multiple challenges for manufacturers and incurs significant effort to capture/manage.

    1. The UDI dataset includes 111 attributes per device, roughly twice the U.S. FDA count
    2. The registration has multiple Device Types, e.g., Legacy Devices, Medical Devices, In Vitro Diagnostics, Systems/Procedures Packs, each with custom business rules
    3. The dataset is organized in a two-tier structure: Basic UDI-DI (group) and UDI-DI (device)
    4. The dataset has unique EU identifiers: SRN (Single Registration Number for an organization), EMDN (European Medical Device Nomenclature for device type), etc.

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Adopt the ‘Now’ Registration Strategy-Part II

1. **Process High Volume of Devices:** For those manufacturers that have a medium to high number of device records that must be collected, validated, and submitted to EUDAMED, an early start date helps ensures the workload is processed on time.

2. **Develop Complex M2M Integration:** Manufacturers implementing automated machine-to-machine data transfers, e.g., APIs, from their internal repository to a third-party data management/submitter vendor need additional time and effort to develop the data interface.

3. **Decrease Risk:** Without an early UDI/Device registration plan, there is a significant risk of failing to meet the mandatory submission period. Non- compliance may result in EC and/or EU Member State intervention with possible impacts in loss of product shipments, loss of revenue, and patient loss of necessary device products.

4. **Meet Registration Prerequisite for Vigilance Reporting:** Early UDI/Device registration enables Serious Incident Reports to be submitted quickly within the 2-, 10-, and 15-day requirements.

5. **Meet Compliance Retention Requirements:** Early UDI/Device registration facilitates device record maintenance and retention requirements for 10 years (and 15 years for implants) after the product is no longer placed on the market.

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Reed Tech Connections to Industry

Industry Standards, Health Authorities, and Assoc.

- Provides early information and a deeper understanding of regulatory requirements
- Learned knowledge is embedded into products and services and shared with clients
- Active in Health Authority pilots and industry work groups, e.g., SPL Process and Technical Teams (chair)

Thought Leadership

- SME shared in industry forums and on our website
- Customer exclusive webinars deliver industry and Reed Tech news and insights

Alliance Relationships

- Alliance partnerships provide customer benefits in adjacent solutions (* Trusted Consultant)

SPL – Structured Product Labeling

Reed Tech SingleSource™ Professional Services

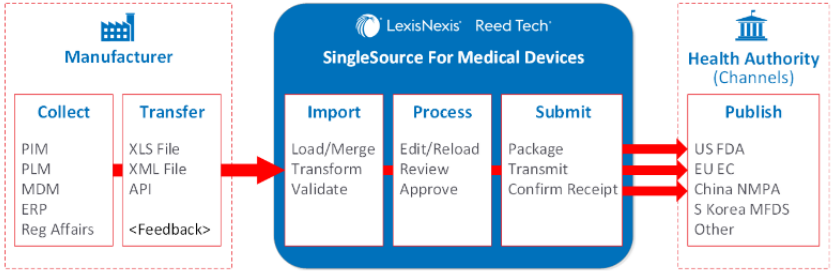
We help Life Sciences develop, implement and remediate UDI Compliance Systems

Challenges

- **Changing regulatory environments**; keeping up-do-date is important to manage risks.
  - **New regulations have nuances** and may impact your product portfolio.
- Acquisitions, mergers and partnerships within the MedTech industry have resulted in disparate, non-leveraged, non-integrated compliance systems.
- **Regulatory compliance process optimization** can serve as a business enabler and differentiator, but those opportunities are often missed.

How we can help

- **Conduct gap assessments** and develop strategies for companies to become compliant to global UDI regulations and requirements.
- **Develop strategic road maps** that address needs across UDI System Elements in Organization / Culture, Process, and Technology; create implementation of projects to enable a more holistic process.
- We provide **global UDI compliance support** for active health authorities.
- **Respond to regulatory body** or internally identified UDI system issues.



Key insight:

Most regulatory enforcement actions are due to a breakdown in the compliance systems, where the type of resources used are incorrect, or a quality culture is lacking.

MedTech Regulatory Compliance Solutions

Services Examples	Service Description
UDI Channel Launch	Expand your reach with our **UDI Channel Add-on service**, designed for seamless compliance and efficient onboarding in new regions. This service encompasses a detailed UDI attribute gap analysis, review of new channel business rules, support during health authority system integration, technical support, and regulatory compliance guidance.
Data Analytic Reports	Our **UDI Business Intelligence Service** transforms your data into actionable insights with tailored dashboards and analytic reports. Gain a comprehensive view of your UDI landscape, monitor compliance, and drive operational efficiency through data-driven decision-making.
Software Customization	**SSMD Software Customization Service**: Optimize your UDI operations with our specialized SSMD customization service. We collaborate closely with your organization to tailor our UDI software to your specific needs, ensuring a perfect fit for your processes and compliance goals.
Data Integration	Our **UDI API Integration Services** include designing, building, and implementing custom middleware tailored to address unique integration needs. We specialize in middleware development and deployment, using secure, scalable technologies, and can deploy within your IT infrastructure or cloud environment for efficient data exchange.
Data Collection / Data Migration	Enhance your UDI compliance with our **Data Management** solution, designed to thoroughly collect and migrate your data, while providing a comprehensive solution to cleanse, transform, and repurpose it to meet the unique requirements of each regulatory body—ensuring accuracy and integrity throughout your data journey.
Global Regulatory Advisory and Market Access Support	Provide **additional consulting hours** as needed for comprehensive guidance and strategic solutions to help you successfully access new markets worldwide.

Our expanded Regulatory Advisory Team can assist you with a wide variety of tasks and topics. **Click on the Inquire Now** button and fill out a few brief comments about your needs in order to facilitate an appointment. We look forward to learning more about how we can assist you.

Inquire Now

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