

Why Your Data Needs to be in the GDSN

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Presenters



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Agenda



(Quick) UDI Compliance Update

GDSN Overview

UK NHS eProcurement Overview

GDSN Buyer Data Requests

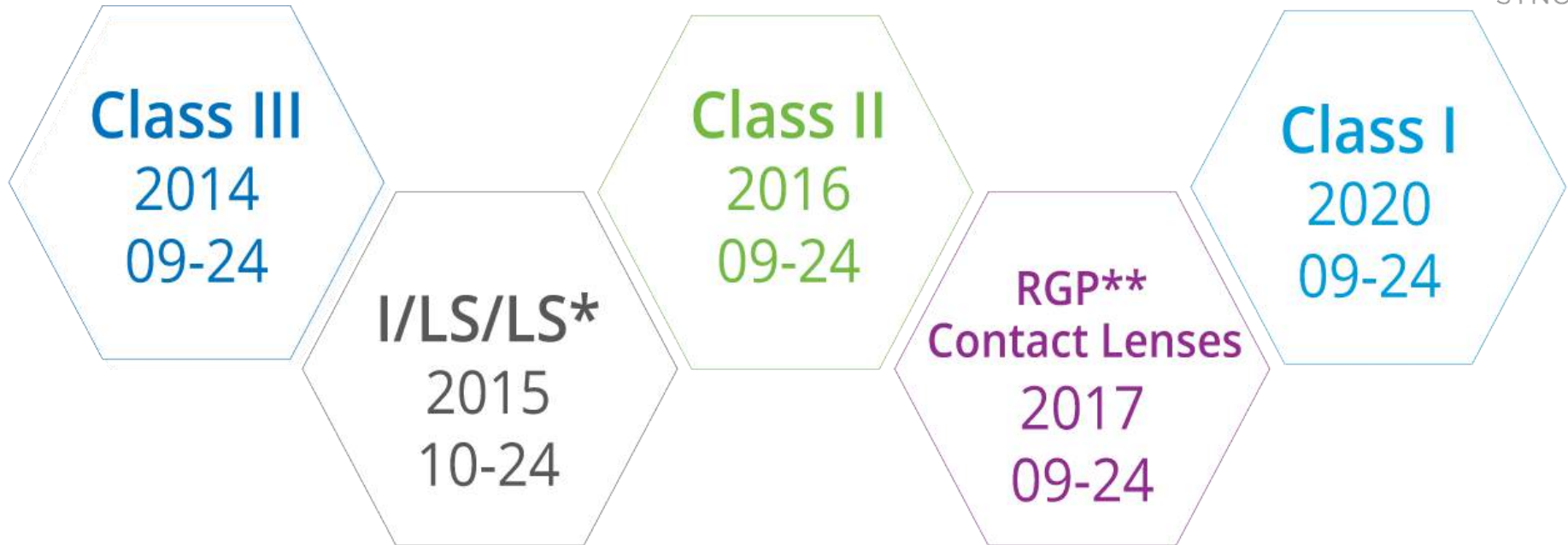
How Reed Tech & 1WorldSync Can Help

Q&A

UDI Compliance Update

UDI Compliance Update

- March 2017 FDA GUDID SPL Specification Update
- FDA ESG GUDID Submission Acknowledgement Update
- Soft Contact Lens Labeler Extension (does not apply to Rigid Gas Permeable lenses)
- **Class I Extension to September 24, 2020**



* Implantable, Life-Supporting, and Life-Sustaining Devices
* **Rigid, Gas Permeable**

GDSN Overview

What is the GDSN?



- Formed nearly 15 years ago as a Supply Chain initiative
- \$50 billion lost annually due to bad data related issues
- Today supports nearly 5000 item data attributes for...
 - Consumer Packaged Goods
 - Foodservice
 - Healthcare
- Solving for initiatives like...
 - FDA UDI
 - NHS
- Aligns critical transparency and regulatory information
- 1WorldSync offers global expertise and support

GDSN – Business Benefits



- Allows the end customer to access trusted and real time product information
- Complies more effectively with nutrition and healthcare standards and regulations
- Eliminates manual processes and reduce errors
- Cuts down on data management time errors and reduces distribution costs
- Brings new products to market quickly and simply

Global Data Synchronization Network (GDSN)



How the GDSN Works

The GDSN allows trading partners to synchronize standard product and location information with each other in five steps:

- 1 LOAD DATA**
The data owner registers product and company information.
- 2 REGISTER DATA**
A small subset of this data is sent to the GS1 Global Registry.
- 3 REQUEST SUBSCRIPTION**
The data recipient, through its own data pool, subscribes to receive a seller's information.
- 4 PUBLISH DATA**
The source data pool publishes the requested information to the recipient's data pool.
- 5 CONFIRM & INFORM**
The data recipient sends a confirmation to the data owner via each company's data pool, which informs the supplier of the action taken by the retailer using the information.

UK NHS eProcurement Overview

NHS eProcurement Initiative

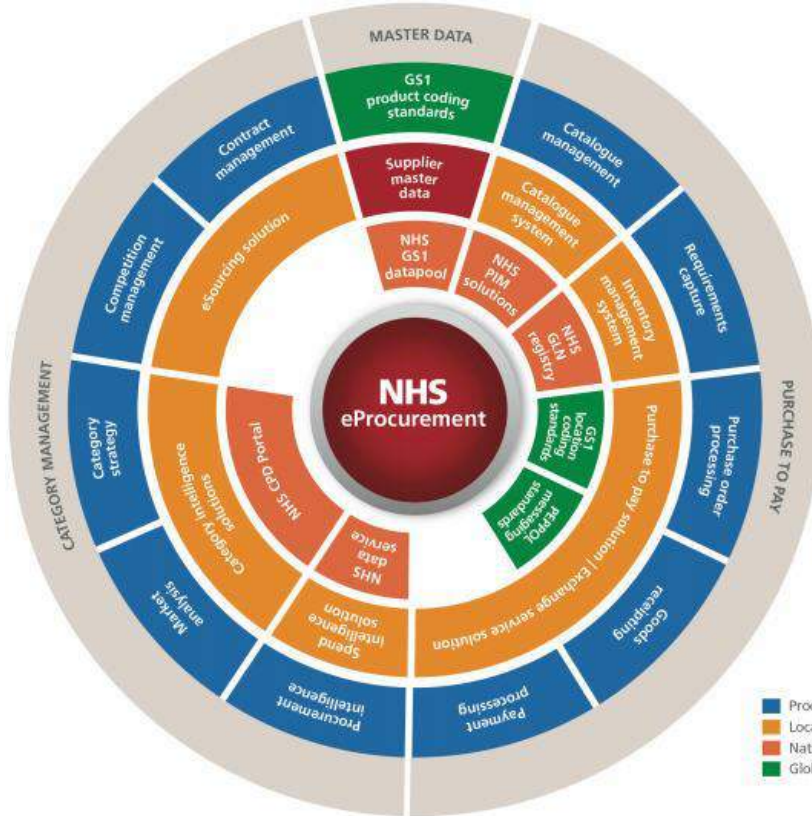


- What is it?
- Who is impacted?
- What are the GS1 adoption requirements?
- By when do I have to be compliant?

What is eProcurement?

- The goal of the National Health Service (NHS) eProcurement Strategy is to make procurement processes faster and more efficient by leveraging master data, standardization, and technology in the supply chain...
- The NHS eProcurement Strategy applies to all organizations who provide goods and services to the NHS in the United Kingdom (UK), from “purchase to pay”
- Initial implementation applies to Medical Device suppliers to the NHS

NHS eProcurement Strategy*



The eProcurement Strategy requires adoption of two key standards:

- **GS1** – Product (GTIN) and Location (GLN) Data; Data Synchronization (GDSN)
- **PEPPOL** – Purchasing and Invoicing

Who is Impacted by eProcurement?



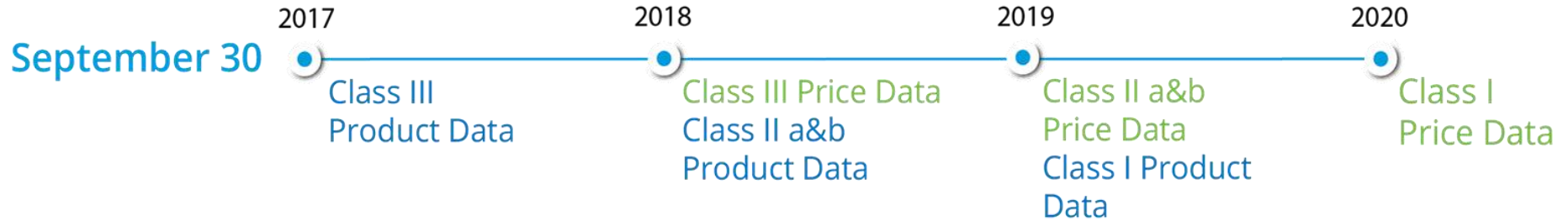
- All organizations who provide goods and services to the NHS
- NHS Supplier Adoption phased by Product/Service Type
- Initial adoption pertains to Medical Device suppliers
 - Estimate of ~25,000 Medical Device suppliers to the NHS

What must I do to comply?

Key GS1 Milestones for Class III Products:

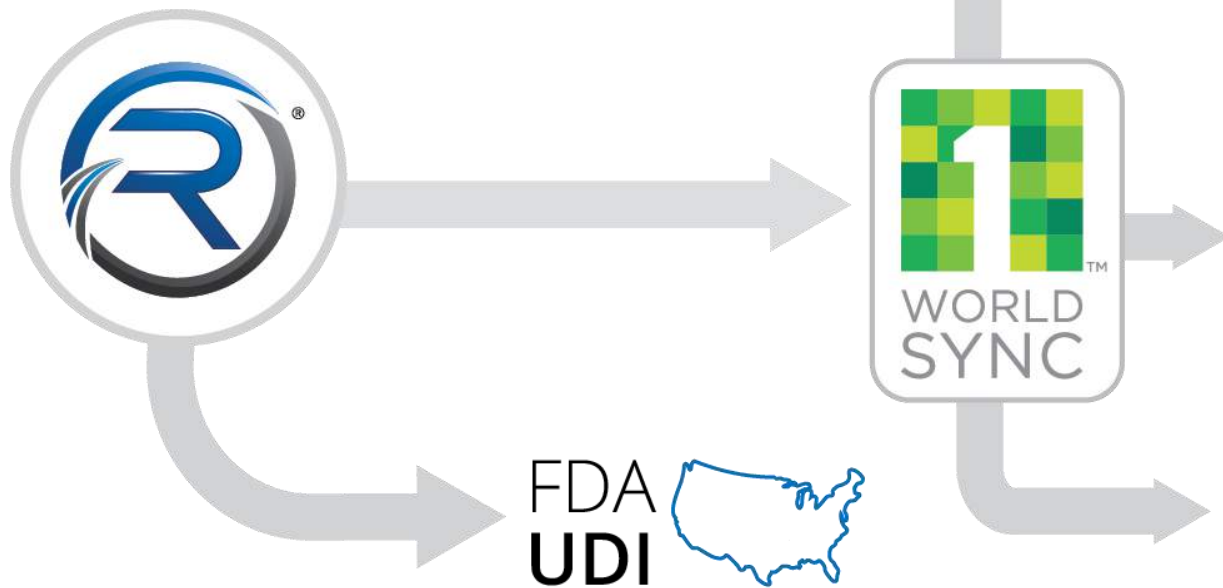
- Join GS1
- Upload GLNs to GLN Registry
- Allocate GTINs at all packaging levels including unit of use
- Update packaging label to carry GS1 GTIN barcode, GS1 GTIN and production identifier barcodes
- Join GDSN certified data pool
- Publish product and pricing data to GDSN data pool, according to NHS GDSN timeline

UK NHS eProcurement GDSN Adoption Timeline



How Reed Tech and 1WorldSync Can Help

How Reed Tech & 1WS can help



UK NHS
eProcurement



GPOs



Hospital
Network

How Reed Tech & 1WS can help



- Reed Tech service and product expansion to support GDSN data management:
 - Supporting US Buyer Trading Partners and the NHS in the UK
- Certified connection from Reed Tech solution to 1WS data pool
- Initial service launch July 2017; SaaS option available Q4 2017

How the solution works



- Initial setup with 1WS data pool services (if not already a subscriber)
- Gather product data pertinent to your GDSN use cases (US buyers and/or NHS eProcurement)
- Send product data to Reed Tech for:
 - GDSN Trade Item “Add” or “Modification”
 - GDSN Trade Item Linking
 - GDSN Trade Item Trading Partner Publication
- Leverage Reed Tech and 1WS Subject Matter Experts (SMEs)
- Option to switch to SaaS model in Q4 2017

Reed Tech Educational Resources



ReedTech.com Knowledge Center

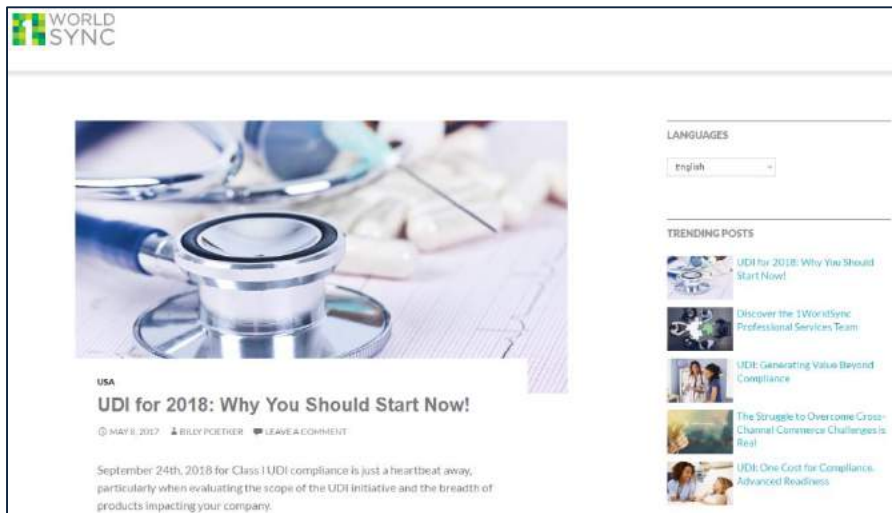


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Appendix

UDI Updates: March 2017 FDA SPL Spec

- **New Attributes**
 - Previous DI Number; Previous DI Issuing Agency
- **Updated Business Rules**
 - Previous DI Number: valid DI format; different than PDI; 0-1 occurrences; can be added/edited after Grace Period, but not deleted
 - Additional Validation of HIBCC
 - Must be 6-23 digits in length; first character alpha and last character numeric; cannot include special characters
 - Allowable SPL Version Number Updated From “999” to “99999”
- **New Controlled Terminology**
 - Store and Handling Units of Measure: Inches of Mercury; Millimeter of Mercury
 - Codification to Support Previous DI Number Attribute
- **Other Changes**
 - Catalog Number Still Optional; However, “Highly Recommended”
 - Update Secondary DI Number Post-Grace Period Editing Rules to Allow for Additions

UDI Updates: FDA ESG Acknowledgement



- ACK3 XML Now Well Formed
- Addition of New Attributes
 - Submission Environment
 - Preproduction
 - Production
 - Submission Type
 - GUDID
- Implementation Timing:
 - April 6th – Preproduction GUDID Environment
 - June 1st – Production GUDID Environment

UDI Updates: Soft Contact Lens Labeler

Extension



- FDA Letter to Soft Contact Lens Labelers on March 30th
- Update on Soft Contact Lens UDI extension set to expire on September 24, 2017
- Soft Contact Lens Labeler extension will continue until one year after FDA:
 - Develops and integrates the technical solution into the GUDID production system
 - Releases any necessary updated technical specifications
 - Notifies industry of the extension expiration date
- Product Codes with extension: LPM, NCZ, NIC, LPL, and MVN
- Additional extension **does not** apply to Rigid Gas Permeable Contact Lens Labelers
 - Must still comply with the September 24, 2017 deadline
 - Rigid Gas Permeable Contact Lens Product Codes: HQD, MUW, NUU, and MWK

1WorldSync Overview

OUR MISSION & PURPOSE

1WorldSync supports the world's largest Global Standards Compliant datapool and related advisory services



Bring Simplicity & Efficiency



Distribute & Deliver



Empower People

OUR MISSION & PURPOSE

Bring Simplicity & Efficiency

to global trading networks, through organization, standardization, integration and syndication of trusted product information and content.



INDUSTRY DATA NETWORKS



ECOMMERCE &
3RD PARTY APPS



ITEM SETUP
PROCESS



FDA



HOSPITALS
& PROVIDERS



SUPPLY CHAIN
ENABLEMENT



STORE EXECUTION



FOOD SERVICE
DISTRIBUTION



REGULATORY

OUR MISSION & PURPOSE

Distribute & Deliver

the product information and digital content that powers global commerce.



OUR MISSION & PURPOSE

Empower Healthcare

with trusted product content for
informed care decisions & everyday
well-being.



Top 1WorldSync US Healthcare Manufacturers



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