USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

PROCUREMENT AND SUPPLY MANAGEMENT

GSI STANDARDS IMPLEMENTATION

Implementation Strategies for Engaging Suppliers and Capturing GS1 Data in ARTMIS

February 9, 2017

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CONTENTS

ACRONYMS

ARTMIS	Automated Requisition Tracking Management Information System
ASN	advance ship notice
CMS	Central Medical Store
DSCA	Drug Supply Chain Security Act
EPC	electronic product code
FAQS	frequently asked questions
GDSN	Global Data Synchronization Network
GHSC-PSM	Global Health Supply Chain-Procurement and Supply Management
GLN	Global Location Number
GTIN	Global Trade Item Number
HRI	human readable interpretation
IT	information technology
LMIS	logistics management information system
SOW	Statement of Work
SME	subject matter expert
SSCC	serial shipping container code
3PL	third-party logistics
TZ E2E	Tanzania End-to-End

EXECUTIVE SUMMARY

GHSC-PSM seeks to implement GS1 Standards to enhance patient safety in client countries and also to achieve supply chain efficiencies. Many companies and trading partners have used GS1 Standards for similar reasons. The suite of GS1 Standards available covers identifying things that are important to companies (trade items, entities, locations, logistic units, etc.), the marking of those things with barcodes or radio frequency identification devices and mechanisms for sharing static, and transactional information about the things that industries make, move, and sell every day.

This document includes recommendations for how to message GHSC-PSM's desires to its suppliers; how to break down GHSC-PSM suppliers into like, manageable groups; and how to take those groups through the GS1 Standards implementation process together.

We have organized a series of projects within three industries (pharmaceuticals, medical devices, and equipment and consumer goods). Each industry is further broken down into manageable groups (top 20 by value, next 100, and remainder) that have similar experience in implementing GS1 Standards and similar capabilities.

Each project requires suppliers to implement a number of GS1 Standards within a context of five major milestones designed to provide value to GHSC-PSM or their in-county clients. The five milestones are:
1. Improved data quality
2. Improved logistics support (supplier to GHSC-PSM)
3. Improved order-to-cash operations
4. Improved patient safety
5. Enhanced supply chain security

Each milestone represents the implementation of certain GS1 Standards, and each set of standards forms a foundation for the next milestone.

Each milestone within an industry represents a project that requires a team of GHSC-PSM-led resources who provide project oversight, project management, facilitation of supplier implementation update calls, and information technology (IT) to support GHSC-PSM's capabilities in also using GS1 Standards.

Each supplier's progress will be tracked using supplier implementation scorecards. As progress is made, it is recommended that GHSC-PSM develop in-house expertise in GS1 Standards and develop a guideline that can be used by suppliers and GHSC-PSM (reference in contracts) to continue implementations and educate new staff members.

Implementing any one GS1 Standard within a single supply chain typically amounts to a multiyear effort. Successful implementation of the suite of GS1 Standards across three supply chains will depend on GHSC-PSM's adequate funding and resources to bring the Automated Requisition Tracking Management Information System (ARTMIS) into compliance and roll out the suggested implementation plan with suppliers. A resource estimate has been developed based on similar supplier implementation experience. A core team of between five and six persons will be

needed with additional staff of up to four subject matter experts at various points in the project and subprojects.

INTRODUCTION

The GS1 Standards Implementation Project developed strategic recommendations for implementing and supporting GS1 Standards across USAID's global health supply chain. Primary objectives included ensuring that ARTMIS is designed properly to capture product information according to GS1 Standards, developing a strategy for implementing GS1 Standards with the USAID supplier base, and informing country-level LMIS tools on USAID/GHSC-PSM GS1 implementation to help ensure data can continue down the chain to truly create end-to-end visibility.

Five reports were produced for this project:

- Report 1, *Technical Review of the Ability of ARTMIS to Support GS1 Standards*

- Report 2, *Assessment of the USAID Supplier Base and the Ability of ARTMIS to Support GS1-compliant and Noncompliant Suppliers*

- Report 3, *Implementation Strategies for Engaging Suppliers and Capturing GS1 Data in ARTMIS*

- Report 4, *Guidance for USAID's In-country LMIS Projects*

- Report 5, *Summary of Key Findings and Additional Recommendations*

This document is Report 3, *Implementation Strategies for Engaging Suppliers and Capturing GS1 Data in ARTMIS.*

IMPLEMENTATION STRATEGY

STRATEGIC MESSAGING

To ensure supplier cooperation, it is important to stress the mission of GHSC-PSM and USAID, provide a reminder of the patients being served, and emphasize GHSC-PSM's intent to use GS1 Standards for enhancing supply chain efficiencies. It is also important to demonstrate that GHSC-PSM and in-country programs are underway to take advantage of the changes that the suppliers are about to make to their product labeling and data-sharing processes.

The following are messaging topics that have been adapted from RC Partners clients to initiate and sustain supplier cooperation through similar GS1 Standards implementations.

    I.   Why are we doing this?
- a. Improve patient safety and patient care
    - i. Improve critical care product delivery to challenging parts of the world
    - ii. Improve the ability to manage product recalls
    - iii. Prepare the foundation for future drug authentication capability
    - iv. Prepare for future opportunities to reduce "wrong medicine" administration
- b. Promote supply chain efficiency
    - i. Lower instances of stockouts
    - ii. Lower instances of unused expired products
    - iii. Improve timing for customs clearance
    - iv. Improve receiving and distribution processes
    - v. Improve inventory visibility
- c. Improve coordination across multiple donor organizations (USAID, Global Fund, UNFPA, UNICEF, etc.)
    - i. Demand planning and forecasting
    - ii. Supply plan coordination
    - iii. Improved aggregate reporting

    II.   What quantifiable benefit do we expect to be the outcome?
- a. Lower overall supply chain costs
- b. Lower transportation costs
- c. Lower warehouse costs
- d. Faster distribution in-country
- e. Increased throughput of order-to-pay cycle (less manual interventions)
- f. Increased patient availability and access (number of patients served)
- g. Reduced product expiry and waste
- h. Lower instances of theft, diversion, and counterfeit
- i. Lower instances of mis-shipments

PHASING AND PREPAREDNESS

Phasing Recommendations

Our recommendation is to address pharmaceutical supplier medical devices and equipment suppliers and consumer goods separately. They are three entirely different supply chains with their own regulations and requirements. Within these categories, we recommend that the top

20 suppliers by spend be the first suppliers to be asked to go through the process. These suppliers most likely have gone through multiple requirement implementations like GHSC-PSM's. After the top 20, the next 100 suppliers by spend can be addressed. They will need additional implementation assistance and can benefit from questions and materials used with the first group. Within these groups, GHSC-PSM may find further breakdown helpful to complete a category such as HIV/AIDS pharmaceuticals or contraceptives.

Preparedness Recommendations
1. **Publish frequently asked questions (FAQs):** The top 20 suppliers by spend in each major product category will likely have already participated in similar projects and can provide details on what worked and why. This information along with common questions that they will ask should be documented and published for the remainder of GHSC-PSM's suppliers.

2. **Publish a guideline:** As the program matures, GHSC-PSM will increasingly be working with smaller suppliers with fewer resources. Develop a "How to Do Business With GHSC-PSM" guideline, which lays out in detail the GHSC-PSM requirements and keeps in step with similar guidelines developed by various countries and purchasers. The guideline should explain all requirements in detail and identify where the supplier can get help with any topic in the guideline. Topics covered in the guideline should include (but not be limited to):

    I.   Overview of GHSC-PSM's future state
    II.   Overview of GS1 Standards used by GHSC-PSM
    III.   Benchmark scorecard
    IV.   Product identification
        a. Obtaining a GS1 company prefix
        b. Using GS1 application identifiers (serial number, expiration date, lot number, etc.)
    V.   Data capture
        a. Barcode types
        b. Explicit barcode examples
        c. Labeling standards
        d. Labeling guidance for logistics units
    VI.   Data sharing
        a. Using Global Data Synchronization Network (GDSN) for trade item master data synchronization
        b. Using the GLN Registry to provide sold-from and ship-from data
        c. Using the GLN Registry to retrieve sold-to, ship-to, bill-to, deliver-to, and intermediate locations for track and trace purposes
    VII.   Process to verify readiness to transact at various levels
    VIII.   List of entities that can help companies implement GHSC-PSM requirements

Pharmaceuticals, medical devices, medical equipment,[1] and consumer goods have different supply chains,[2] and companies that supply these commodities are at different levels of adopting identification standards, marking, and track and trace in different regions of the world. The top 20 companies by spend in each of these supply chains should make up the bulk of purchased products and are most likely already complying with similar requirements around the world. If the "how to do Business with GHSC-PSM" guideline is completed on time, it should be the main driver for the next 100 companies by spend and the companies to follow. The guideline can be used with the 100 companies in the second group and refined or added to for the remainder of GHSC-PSM suppliers. Also, as turnover occurs in the supplier's staff and GHSC-PSM, the guideline will support consistency in operational implementation through the project's duration.

ALTERNATIVES FOR MASTER AND TRANSACTIONAL DATA CAPTURE

Using GDSN Is a Best Practice

The GDSN and its associated group of data pools provide automated synchronization of a manufacturer's trade item master data. That is, every change to this data is automatically communicated to subscribing companies and applied locally to their master data, which may reside in more than one application.

Currently, the pharmaceutical, medical device, and equipment and consumer goods product categories experience different levels of GDSN use. This difference will change as more purchasers of goods continue to require GDSN use.

> **Recommendation:** GHSC-PSM should use GDSN as the primary source of trade item information and require suppliers to provide their trade item data through GDSN. A single source of the truth is important to establish quality and dependable data. Implementation should be a high priority for GHSC-PSM. Many trade items are already in GDSN that will be useful, and the support of GDSN by GHSC-PSM will strengthen suppliers' reasons to publish trade item data through GDSN.

> **Recommendation:** Due to certain country regulations, GHSC-PSM should develop an archiving strategy for data supplied from GDSN. GDSN carries only "current state" data (and some future state data for new product introductions). For example, the U.S. requires that certain data (including some trade item master data) be kept for six years.

All other means of acquiring trade item master data are categorized as master data alignment. Full sets of data are made available either to "swap out" the current set used or determine which attributes have been updated. Small manufacturers may be equipped only to provide trade item master data through other data formats such as Excel spreadsheets, CSV, etc. These forms will require manual processing and are more likely to be out of sync over time.

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[1] GHSC-PSM may be able to address devices and equipment together, as there are items that may be categorized in different categories by countries.

[2] There are exceptions, such as kits, which may include pharmaceuticals and medical devices, as well as convenience kits, which are assembled post-sale for specific hospitals.

Entity/Location Master Data and the Global Location Number (GLN) Registry
Acquiring accurate supplier sold-from, ship-from, and return-to master data as well as providing each supplier accurate sold-to, ship-to, and bill-to becomes a risk to accurate order-to-cash transactions as well as accurate shipments, possibly leading to stockouts within the GHSC-PSM supply chain and in recipient countries. Using GLNs and adhering to GS1 Standards for changes to entity/location data (GLN allocation rules) will allow GHSC-PSM to establish quality metrics on entity and location data, thereby reducing shipments to wrong addresses, receiving product from improper regions, etc. The use of a service such as GS1 US Data Hub provides suppliers with a one-stop place to go for updates, further reducing the risk of shipping errors.

> **Recommendation:** The GS1 US Data Hub can be used by GHSC-PSM, suppliers, and recipients to share entity and location data with all stakeholders simultaneously. Much like GDSN, this service allows companies to establish, maintain and share accurate entity and location data in a single step, ensuring changes are accurately and safely communicated to stakeholders who need the information. This also allows trading partners to reduce the amount of redundant data being shared daily in order-to-cash transactions.

Transaction Data
ARTMIS currently has specifications on the data it requires from suppliers and the format of electronic data interchange (EDI) transactions. As the use of the Global Trade Item Number (GTIN) and GLN becomes more institutionalized, those specifications need to be updated to reflect GHSC-PSM's requirements on product identification and data exchange using GS1 Standards and communicated to suppliers.

RISKS, IMPLEMENTATION OBSTACLES, AND MITIGATION STRATEGIES

GHSC-PSM Readiness
Currently, ARTMIS is unable to capture and operationalize the use of GLNs to identify internal and external entities and locations (supplier identification, ship-from, ship-to, bill-to, ship-to, deliver-to). Also, ARTMIS is unable to capture and operationalize serial shipping container codes (SSCCs) and serial numbers and can capture but not operationalize GTINs in order-to-cash transactions.

> **Mitigation:** As these capabilities are planned for and implemented, the dates within this document and subsequent supplier roadmaps will need to be examined and adjusted. For example, requesting a supplier to provide an advance ship notice (ASN) using GTINs to identify trade items and GLNs to identify ship-to and bill-to addresses will need to align with the capability of ARTMIS to generate a purchase order using GTINs and GLNs.

Ability to Read Supplier-provided Barcodes
Depending on each supplier's printing choices (ink, laser etching, type and color of labels, etc.) as well as handling throughout the supply chain, barcodes may be difficult or impossible to read. Suppliers will, most often, be using high-end barcode readers under optimum environments, whereas warehouses and health-care facilities may be using economy readers in harsh environments.

> **Mitigation:** GHSC-PSM should require suppliers to verify that their barcodes can pass verification testing at a grade "C" or higher. Suppliers should submit sample labels to GHSC-PSM for testing.

Recipient-country Readiness

Beyond GHSC-PSM's own capability to use GS1 Standards in ARTMIS, one of the greatest challenges to the successful end-to-end use of GS1 Standards is that there are two separately managed parts of the supply chain involved. Each affect the timing and capability of GHSC-PSM and recipient countries to realize benefits from standardization. The first part of the supply chain extends from the manufacturer to a recipient country's Central Medical Store (CMS). The second part of the supply chain is the in-country distribution channel from the CMS through to facilities, which can include CMS, hubs, regional warehouses, sub-hubs and health-care facilities. GHSC-PSM has direct control over the first part of the supply chain, and influence over the second. Planning and timing across the supply chain can become difficult to coordinate or pilot.

> **Mitigation:** As many of the implementation requirements come from planned use within client countries; GHSC-PSM staff should continue to monitor the in-country projects to ensure that the implementation requirements asked of the suppliers remain relevant and timelines remain in alignment.

Adequate Subject Matter Experts for Support as Projects Advance

There will be many challenges along the way with such a complex set of requirements, education, and implementation schedule. This list of risks and strategies is a sample of things that could occur.

> **Mitigation:** Our recommendation is to develop internal expertise in standardized data practices and supply chain use. As a short- to medium-term recommendation, consultants with this experience should engage with a consultant who is knowledgeable in the standards and GHSC-PSM throughout the project or at least regularly to address challenges that arise from engaging simultaneously with so many suppliers from numerous industries.

Supplier Frustration

The greatest risk is overwhelming suppliers with too much change in too short a time period. Many suppliers are currently engaged in multiple serialization efforts around the world. Depending on how a supplier manufactures GHSC-PSM-purchased products (e.g., dedicated production lines, scheduled time on an existing production line, contract manufacturing), a supplier may have only a certain amount of time to schedule production downtime to make the necessary adjustments for GHSC-PSM requirements.

> **Mitigation:** Bundle requirements to lessen multiple occurrences of production downtime. For instance, as the pharmaceutical industry is already engaged in serialization efforts, companies may prefer to move from GTIN-only barcodes to GTIN, serial number, lot number, and expiration date-encoded barcodes in one step rather than adding an intermediary step of GTIN, lot number, and expiration date-encoded barcodes. Also, companies may want to first provide serialized trade items in a first phase and then aggregation (sharing which item serial numbers are in which serialized or SSCC case).

Communication: Regular calls with groups of suppliers can help to solve common problems. These calls enable suppliers to talk among themselves about how they've resolved challenges and often lead to peers helping each other offline.

Engagement With the Wrong Supplier Personnel

GHSC-PSM engages suppliers through their sales force. It is critical that suppliers provide points of contact covering a broader scope, including operations, logistics, information technology, regulatory, and others.

Mitigation: One of the first reporting requirements for suppliers should be identifying the roles of staff that the supplier has included in its project. This is especially important for the "next 100" suppliers, as they may not recognize the kind of roles they need to engage in to succeed. Understanding the types of roles that will be available on the supplier's team will let GHSC-PSM know if the supplier understands the magnitude of the requirements and is organizing for success.

Communication: Early on, communicate to the suppliers (especially the smaller organizations) the roles in their organization they will draw on throughout the project.

Lack of Clarity and Specificity About Requirements

GHSC-PSM needs to specify the implementation requirement of each standard that is being used. GHSC-PSM is asking its suppliers to implement change on many levels (identifiers, labeling, barcoding, order-to-pay transactions, serialization, track and trace). Standards are a big help, but they do lend themselves to interpretation. Even specific "industry" guidelines often have some choices documented. As a result, this initiative requires a significant effort from GHSC-PSM to specify how these standards will manifest themselves in various data, labeling. and documentation requirements. In our experience, trading partners asserting requirements (hospital groups, group purchasing organizations, wholesalers, etc.) have created detailed guidance that shows explicit examples of what they will accept and what they will not accept in response to their requirements.

Mitigation: Plan to create a GHSC-PSM-specific guidance (referred to in this document as "Doing Business With GHSC-PSM"). Use input from the first group (first 20 companies) to develop the guideline as they move through implementation. This might start just as a published FAQ list; however, our recommendation I is to create a specific GHSC-PSM implementation guideline for suppliers (see Preparedness Recommendations).

Communication: Communicate to the supplier community that a guidance will be available to them. Publish the FAQs above. Provide guideline sections as they become available.

SCOPE, SCALE, AND RESOURCE NEEDS

Initial thoughts are that this is a very large, multiyear effort that will need a team of resources to manage the series of projects and subprojects, documentation development, training (recommendation), supplier management, program oversight (GHSC-PSM), and IT and operations liaison. Although each team member may not be needed full time, the overall support team should consist of the following roles:

Team member	Commitment	Duties
Project sponsor	Four to six hours a month for status reports and updates	Minimal, kickoff, and key milestones
GHSC-PSM liaison	Four hours a month to arrange GHSC-PSM resources	Initially weekly support; as suppliers require less interaction and help, monthly
Project manager	One full-time equivalent (FTE)	Work with facilitators to manage subprojects/work with facilitators
Pharmaceutical group facilitator	One FTE	Facilitates calls and meetings with the suppliers. Manages pharmaceutical subproject.
Medical device group facilitator	One FTE	Facilitates calls and meetings with the suppliers. Manages medical device and equipment subproject.
Consumer products facilitator	One FTE	Facilitates calls and meetings with the suppliers. Manages consumer goods subproject.
Master data manager (trade items and locations)	One FTE for data quality subprojects One-quarter FTE for other subprojects	Eight hours a week for data quality subproject As needed for other subprojects
ARTMIS design subject matter expert (SME)	One-half to one FTE	As needed throughout the project and for major milestone planning and delivery
LIMS design SME	One-half to one FTE	As needed throughout project and for major milestone planning and delivery
GS1 standards SME	One FTE initially One FTE to develop FAQs and guideline As needed on subprojects	As needed throughout the project and for major milestone planning and delivery; also needed for FAQ and guideline development
IT (as required to meet milestones)	GHSC-PSM to provide necessary IT support to make changes or workarounds to current system	Initially weekly support, monthly once project is established, more frequent for certain subprojects
Logistics SME	As needed throughout projects	Provide logistics support and estimates on value; serve as liaison with third-party logistics (3PL) providers and in-country logistics
Meeting planner	One-quarter FTE	Arrange meeting facilities for facilitators as needed

MILESTONES AND TIMELINE ALTERNATIVES AND RECOMMENDATIONS

Each of the three product categories — pharmaceuticals, medical equipment and devices, and consumer goods — requires its own subprojects to be planned and will require a similar amount of resources to accomplish its tasks. Within each of the three product category subprojects, milestones are grouped by major benefit sought and planned by three groups of suppliers (top 20 by spend, next 100 by spend, and remaining). Overall, nine groups will need to phase in implementation of GHSC-PSM requirements. An estimate of resource needs is provided in the table above.

The overall timeline can be reduced by establishing multiple support teams; however, our recommendation is that for each product category, allow the first (top 20) group to move ahead significantly so that there is ample time to document lessons learned, respond to questions, and gather and develop reference material in support of creating the "How to Do Business With GHSC-PSM" guideline to accelerate and smooth the process of subsequent groups.

IMPLEMENTATION ROADMAP AND MATERIALS

This section includes roadmaps (sets of GHSC-PSM high-level requirements, milestones, and timelines) for each major supplier group identified. Although the material is similar, there are differences to accommodate for the current state of the supply chains. Each has taken a different starting point and has focused on a different set of functionality that aligns with the milestones. Each also has challenges brought on by the nature of its products. For example:

Pharmaceuticals, biologics, and vaccines: due to product identification regulatory requirements in many developed countries as well as product sensitivities such as temperature, light, vibration, etc., companies are more advanced in logistics identification, trade item serialization, authentication, and track and trace.

Medical devices and equipment: varying levels of control; some devices are controlled only by their trade item ID. Others are controlled by a trade item ID + lot number, while others are controlled by their trade item ID + serial number. Trade items fall into different levels of control due to manufacture preference or country regulation.

Other health commodities and consumer goods: product identification and barcoding are generally widely implemented and include advanced capabilities.

Project Management Roadmap

1. **Initial supplier meeting** (supplier sales people)

   - Overview the entire program

   - Provide an understanding of the scope of activities around implementing product identification

   - Outline the team that the supplier must put together to implement through compliance

   - Ensure that suppliers understand what is being asked of them

   - Share samples of the benchmark scorecard

2. **Second supplier workshop** (top 20: operations, IT, logistics, etc.)

   - Conduct a full-day workshop with specific topic sessions (identification, marking, data sharing)

   - Provide a series of online webinars (webinars recorded and published)

   - Review details of each topic and the requirements

   - Provide documentation on how the program will proceed (roadmap, weekly calls, FAQs, development of an official guideline)

- Disseminate and review the benchmark scorecard[3]

3. **Weekly calls**

- Hold weekly calls to monitor progress and to collect/answer specific questions

4. **Testing and implementation**

- Once a manufacturer provides documentation verifying that it can comply with a requirement, schedule testing and move into production with ARTMIS staff and communicate with logistics trading partners (e.g. Kuehne + Nagel) to expect the change.

IMPLEMENTATION ROADMAP

High-Level GHSC-PSM Requirements

Note: The requirements for pharmaceuticals, medical devices/equipment, and consumer goods differ at the trade item (lowest saleable level). Pharmaceuticals are to be identified with a GTIN + serial number. Medical devices/equipment are to be identified and barcoded at the level at which they are managed by the manufacturer. Some will be identified and barcoded with a GTIN. Some will be identified and barcoded with a GTIN + lot number, while others will be identified with a GTIN and serial number and barcoded with a GTIN, serial number, lot number, and expiration date. These differences in the level of identification and barcoding are dependent on how the manufacturer currently manages its product. If a manufacturer prints the identification items on its current packaging, it is assumed that the manufacturer manages the product using those attributes and will also include them in its barcode.

Functional grouping	What?	Which standards?
Identify	Trade item — lowest saleable unit	GTIN, serial number
	Trade item — multipack	GTIN, serial number
	Trade item — case	GTIN
	Logistics item — case (when applicable)	SSCC
	Logistics item — pallet	SSCC
	Entities/locations — sold-from	GLN
	Entities/locations — ship-from	GLN
	Entities/locations — sold-to	GLN
	Entities/locations — ship-to	GLN

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[3] We have had mixed results with publishing or sharing scorecards. Initially, we thought publication would cause some competition in the group; however, many companies refused to self-report because of the publication. They felt it could be seen by analysts and reflect poorly on the company if they could not meet the exact deadlines.

	Entities/locations — bill-to	GLN
Barcoding/marking	Trade item — lowest saleable unit	GTIN + batch/lot + expiry + serial number
	Trade item — multipack	GTIN + batch/lot + expiry + serial number
	Trade item — case	GTIN + batch/lot + expiry + serial number
	Logistics item — case	SSCC
	Logistics item — pallet	SSCC
Share	Product master data *(defined by supplier)*	Shared with GHSC-PSM through GDSN
	Parties and location master data *(defined by supplier)*	Shared with GHSC-PSM through GS1 US Data Hub location
Transactions	Purchase order	GTINs and GLNs
	Order confirmation	GTINs and GLNs
	ASN	SSCCs, GTINs, and GLNs
	Packing slip	GTINs and GLNs
	Invoice	GTINs and GLNs
Track and trace	Commissioning, shipping, receiving, aggregate, disaggregate, end of trade item life events	EPCIS, Core Business Vocabulary, Tag Data Standard

Milestones and Activities

The following milestones are broken down into five capabilities that GHSC-PSM is seeking to enhance. Each supplier group (top 20, next 100, remainder) will be taken through each of the five sets of activities to accomplish those capabilities. This allows for progress to be made toward GHSC-PSM's overall vision for GS1 standard implementation while achieving "building block goals"[4] along the way.

Capability activity		Responsible
1. Improved data quality		
	1. Obtain GS1 company prefix	Supplier
	2. Assign GTINs to trade items (lowest saleable and homogeneous cases)	Supplier
	3. Provide trade item master data through GDSN	Supplier
	4. Assign GLNs to sold-from and ship-from	Supplier
	5. Accept GLNS for sold-to, ship-to, and bill-to	GHSC-PSM
	6. Use GS1 US Data Hub to exchange GLN data	Supplier/GHSC-PSM
2. Improved logistics support (supplier to GHSC-PSM)		

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[4] *See diagram in Annex 1 titled "Figure 6. GS1 Standards: hierarchy of functionality."*

	1.	Assign SSCCs to logistic items (pallets, cases)	Supplier
	2.	Provide SSCCs on ASNs (associate SSCC with trade Items)	Supplier
	3.	Provide GS1 Standard logistics label	Supplier
	4.	Receive shipments by SSCC	3PL
3. Improved order-to-cash operations			
	Use GTINs and GLNs in order-to-cash transactions		
	1.	**Orders:**	
		Provide GTINs for trade items (line items)	GHSC-PSM
		Provide GLNS for sold-from, ship-from, sold-to, ship-to, and bill-to	GHSC-PSM
		Process GLNS for sold-from, ship-from, sold-to, ship-to, and bill-to	Supplier
		Process GTINs for trade items (line items)	Supplier
	2.	**ASNs:**	
		Provide GLNS for sold-from, ship-from, sold-to, ship-to, and bill-to	Supplier
,		Provide GTINs for trade items (line items)	Supplier
		Process GLNS for sold-from, ship-from, sold-to, ship-to, and bill-to	GHSC-PSM, 3PL
		Process GTINs for trade items (line items)	GHSC-PSM, 3PL
	3.	**Invoices:**	
		Provide GLNS for sold-from, ship-from, sold-to, ship-to, and bBill-to	GHSC-PSM
		Provide GTINs for trade items (line items)	GHSC-PSM
		Process GLNS for sold-from, ship-from, sold-to, ship-to, and bill-to	Supplier
		Process GTINs for trade items (line items)	Supplier
	4.	**Packing Slips:**	
		Provide GLNS for sold-from, ship-from, sold-to, ship-to, and bill-to	Supplier
		Provide GTINs for trade items (line items)	Supplier
		Process GLNS for sold-from, Ship-from, sold-to, ship-to, and bill-to	3PL
		Process GTINs for trade items (line items)	3PL
	5.	**Participate in order-to-cash pilots**	Supplier, GHSC-PSM, 3PL
4. Improved patient safety			
	1.	**Pharmaceuticals:**	
		Phase 1 — Logistics — Enhanced Cases:	
		Mark cases with GTIN, lot number and expiration date	Supplier
		Provide sample label with appropriate GS1 DataMatrix and human readable interpretation (HRI)	Supplier
		Scan outer logistics item (case or pallet) barcode	In-country warehouses
		Phase 2 — Facilities — Enhanced Trade Items:	
		Mark trade items with GTIN, serial number, lot number, and expiration date	Supplier
		Provide sample label with appropriate GS1 DataMatrix and HRI	Supplier
		Process DataMatrix information on trade items (lot number, expiration date)	In-country facilities
5. Enhance Supply Chain Security			
	1.	**Pharmaceuticals:**	
		Phase 1 — Authentication:	

		Pre-Req: GTIN + serial number DataMatrix on trade items	Supplier
		Provide means (portal, EPCIS query) to authenticate GTIN and serial number	Supplier
		Provide means to submit GTIN and serial number for authentication	In-country clients
		Participate in authentication pilots	Suppliers, In-country clients
	Phase 2 —Track and Trace:		
		Pre-Req: GTIN + serial number DataMatrix on trade Items	Supplier
		Provide means (EPCIS events) of exchanging track and trace events (commissioning, shipping, receiving, aggregation, disaggregation)	Supplier
		Provide means (EPCIS events) of receiving and processing serialized data events (commissioning, shipping, receiving, aggregating, disaggregating)	Supplier, GhSC-PSM, In-country clients
		Participate in track and trace pilots	Supplier, GHSC-PSM, In-country clients

Timeline

As shown, many of the subprojects can be managed in parallel to realize benefits earlier. Doing so, however, will require additional support staff. There is a finite amount of parallel effort based on the availability of supplier staff, their ability to source additional project staff members, and other projects they've undertaken to comply with various government regulatory efforts.

This timeline (Figure 1) is a copy of the pharmaceutical industry timeline, as it is unknown how many subprojects GHSC-PSM can maintain at any one time. It is anticipated that the medical device timeline will be offset from the pharmaceutical timeline by at least six months to give the core group within GHSC-PSM experience in working through the similar efforts. Project plans for pharmaceuticals, medical devices, and consumer goods have been provided separately. They can be used as a starting point to develop actual project plans based on resources available.
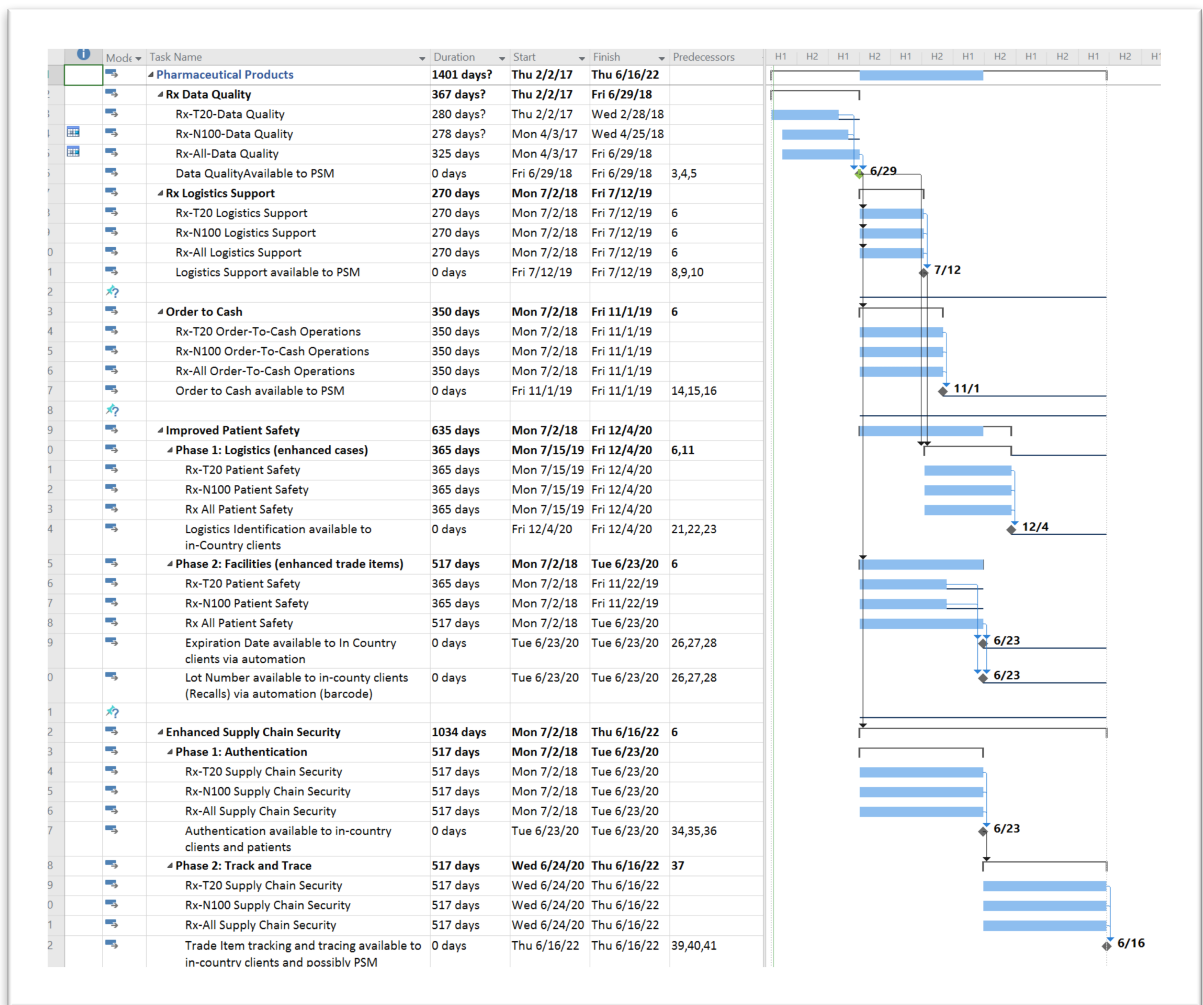
Figure 1. Pharmaceutical product timeline (top 20, next 100, remainder of companies shown)

AVAILABLE TOOLS TO COMPLETE ACTIVITIES

Verification Tools

To ensure quality of barcodes implemented by suppliers, it is recommended that GHSC-PSM require suppliers to complete third-party barcode verification and provide GHSC-PSM with the documentation of their "grade." This service is relatively inexpensive and mitigates barcode readability risks downstream in the supply chain. Often, small- to medium-size suppliers "misinterpret" the standards for building compliant, readable barcodes. Frequent errors include:

- Printing on dark backgrounds

- Not enough "quiet space" around barcodes

- Encoding the parenthesis "()" around the application identifier numbers

Several suppliers use laser etching to apply GS1 DataMatrix barcodes on packaging. Laser etching requires a black or dark background, and the laser removes the background, leaving a reverse image of the barcode (black is white and white is black). Certain barcode readers need specific software installed to be able to read this type of printed barcode.

For Track and Trace, GS1 provides an EPCIS Certification test. All EPCIS-enabled software should be GS1 certified against the current EPCIS Standard.

Supplier Resource Packet

A full guideline, "How to do Business with GHSC-PSM," should be developed as stated in "Insights and Recommendations" above. Development of a guideline with the proper amount of detail to implement could take a few months. As an example, the US guideline to comply with the Drug Supply Chain Security Act (DSCSA) took over a year and a half to develop and the latest update took two years.

Our experience with onboarding smaller suppliers is that they often don't have the resources to explore standards or make decisions based on the alternatives available within a standard. The results are that the first group (top 20), onboarding goes smoothly and the second and third groups start off smoothly but devolve into a never-ending series of questions and mistakes from the larger number of smaller suppliers. To provide support to suppliers, contract referenceable requirements and an implementation guideline should be developed that would provide knowledge and support to smaller companies, be valuable on an ongoing basis for larger companies as they experience staff turnover, and provide one voice for GHSC-PSM as they either experience staff turnover or find it necessary to establish a support or call center.

A guideline specific to GHSC-PSM's requirements would borrow heavily from that guideline and other material available, such as:

- GS1 US Guideline – Applying GS1 Standards for DSCSA and Traceability (https://www.gs1us.org/industries/healthcare/standards-in-use/dscsa/implementation-guideline)

- GS1 Standards in Action Booklet (https://www.gs1us.org/documents?Command=Core_Download&EntryId=657)

- GDSN Implementation and Package Measurement Rules (https://www.gs1us.org/education-training/resource-library#/score/DESC/0/GDSN/?Industry=Healthcare)

- Electronic Data Interchange (EDI) (https://www.gs1us.org/education-training/resource-library#/score/DESC/0/edi/?Industry=Healthcare&I-Want-To=Share-Data-Electronically)

- Healthcare Provider Quick Start Guide (https://www.gs1us.org/documents?Command=Core_Download&Entry

- GTIN Sunrise (https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=630)

- GLN Sunrise (https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=626)

- Guideline – Bar Code Symbol Placement (https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=552)

- ARTMIS Transaction Data and Formats

MONITORING AND EVALUATION AGAINST PROJECT GOALS

Recommendation: For each group (pharmaceutical top 20, pharmaceutical, next 100, etc.) that is taken through the process of implementing the GHSC-PSM requirements, the group's facilitator should initially hold weekly calls to ensure the GHSC-PSM program is clear, then move to a call every two weeks to monitor progress and answer questions. Periodically, suppliers should update their supplier readiness scorecard (see Annex 1).

PROPOSED LANGUAGE TO BE INCLUDED IN SUPPLIER CONTRACTS

I. Acquiring a GS1 company prefix
- IX. Application identifiers
- X. Barcode types
- XI. Labeling standards
- XII. Verification
- XIII. Data capture
- XIV. Timelines/phasing

Recommendation: Specific contract language is being provided separately. However, due to the quantity of changes being asked for, it is recommended that a guideline for doing business with GHSC-PSM (noted elsewhere in this document) be created. Contract language should then be created that references that "living" document and the requirements within.

OTHER SUPLEMENTAL MATERIALS DEVELOPED AS PART OF THIS DOCUMENT

Several artifacts were developed alongside this document. They have been provided separately and are listed here:
1. Pharmaceutical Project Plan (MS Project)

2. Medical Device Project Plan (MS Project)

3. Consumer Goods Project Plan (MS Project)

4. Supplier Strategy — Additional Considerations (PowerPoint presentation)– This was a presentation on considerations that other groups have taken regarding in using clear language next to the barcode in place of traditional GS1 HRI. It also provides a case for addressing case labels to support in-country clients before order-to-cash messages are addressed.

5. Supplier Strategy — Current — Future Stakeholder Requirements (Excel Workbook)

6. Statment of Work (SOW) 3 – Deliverable presentation (PowerPoint presentation)

ANNEX I

SOW 3 QUESTIONS

Should customs agents open a container with your shipment in it, SSCCs on standardized labels on pallets and cases can help the shipment clear customs by providing additional corroboration of who's shipment it is, where it is going, and what is in the shipment (through the other label information). Customs in certain countries (U.S.) use the GS1 system of standards to contact the shipper (usually the manufacturer) and automatically match information that is on the standard barcode.

This was removed from the final version. Geofencing is a method of defining a fixed area in the world. In discussions with VillageReach, we raised the possibility of using GLNs to define where facilities are in Africa, particularly in places where street addresses don't exist.

While we can't provide internal guidelines that other clients have produced, we have pulled the most relevant sections that we've seen produced by others. We can also make an introduction to them and ask if they'd share additional resources with GHSC-PSM.

REQUIREMENTS?:
Product sensitivities: (temperature, light, vibration, etc.) are often listed on labels as shipping handling or storage information.

SUPPLIER SELF-REPORTING SCORECARD

The following set of questions should be asked of each supplier at the second proposed workshop to determine the baseline capabilities of each supplier and then annually or at key milestone dates within the project. These scorecards will enable GHSC-PSM to assess when to expect a significant number of suppliers to be compliant with groupings of requirements (enough to support the project milestones and overall goals).

Scorecards can be managed for the first groups (top 20) through Excel spreadsheets and email to make it easier for suppliers to share the questions with different staff members in their companies. However, when managing the high number of scorecards that will be processed in the second (next 100) and third (rest of suppliers) groups, survey tools should be used.

1.   Company name

2.   Key contact (name, email address, phone number.) for this initiative

3.   Commitment to GHSC-PSM project and requirements

4.   Estimated dates when the company will meet requirement (can demonstrate compliance)

Functional grouping	What	Standard	Estimated demonstration date
Identify	Products (lowest saleable level of packaging)	GTIN	
	Cases	GTIN or SSCC	
	Pallets	SSCC	
	Parties/locations (sold-from, ship-from, sold-to, ship-to, bill-to)	GLN	
Barcoding/marking	Products (lowest saleable level of packaging)	GTIN, batch, expiry, serial	
	Cases	GTIN, batch, expiry, serial, **or** SSCC	
	Pallets	SSCC	
Share	Product master data *(defined by supplier)*	Shared with GHSC-PSM through GDSN	
	Parties and location master data *(defined by supplier)*	Shared with GHSC-PSM through GS1 US Data Hub Location	
Transactions	Order	GTINs and GLNs	
	ASN	SSCCs, GTINs, and GLNs	
	Packing slip	GTINs and GLNs	
	Invoice	GTINs and GLNs	
Track and trace	Pallets	SSCC	
	Cases (logistic units)	SSCC	
	Cases (orderable product)	Initially: GTIN + lot number level	
		Eventually: GTIN + serial number	
	Trade items (lowest saleable level of packaging)	Initially: GTIN + lot number level	
		Eventually: GTIN + serial number	

SAMPLE PELOTON DIAGRAMS

Peloton diagrams were developed by Gillette Co. and Massachusetts Institute of Technology as a way of depicting the complex dependencies between company responsibilities, technology availability, and achievement of specific benefits. Peloton diagrams may be useful during the initial phases of the project to communicate the business benefits sought, the responsibilities of each stakeholder, and the consequences (delayed benefit, investments by other stakeholders, etc.) of delays or issues in any area that is controlled by or outside the control of the stakeholders.
As many of the benefits will be accrued by GHSC-PSM recipient countries, these diagrams may also be valuable in showing how in-country issues, e.g., delays in the ability to use barcode readers, and advancements, e.g., cellular communications making connections available ahead of schedule, might affect other stakeholders and implementation schedules.
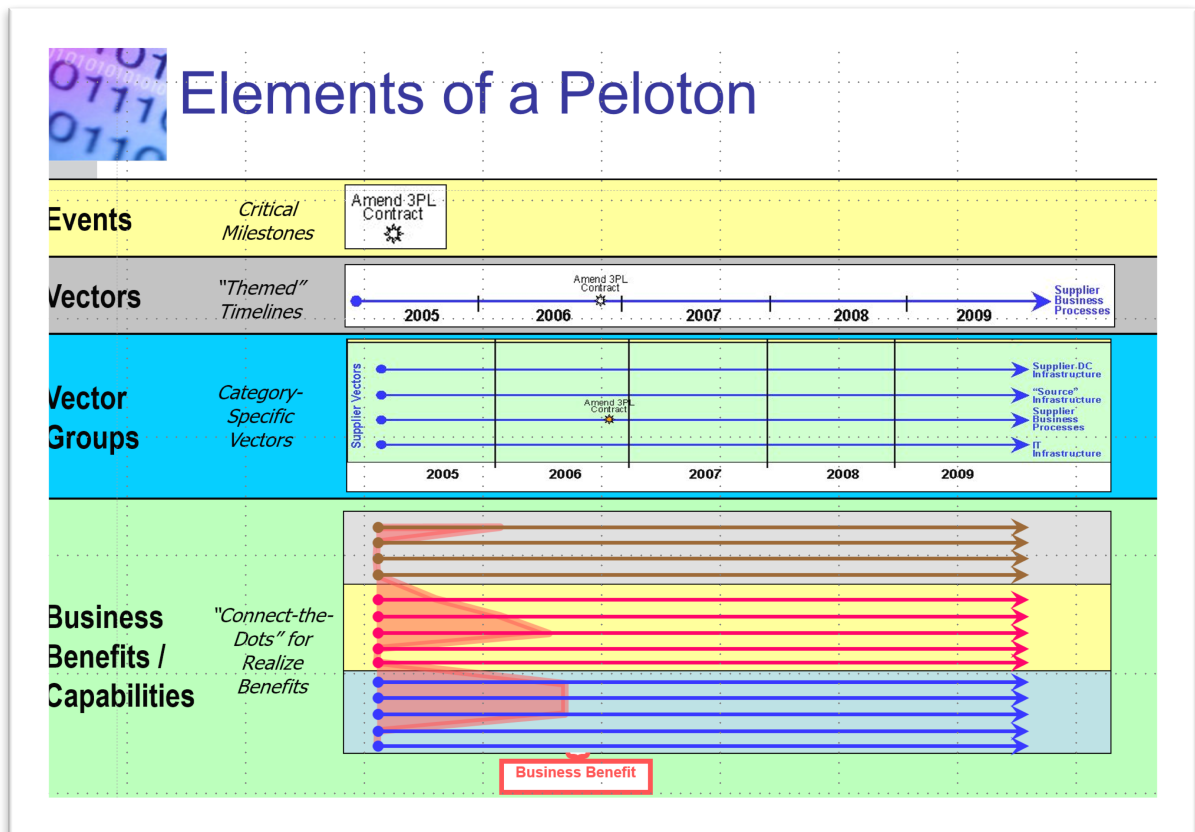
Figure 2. Elements of a Peloton
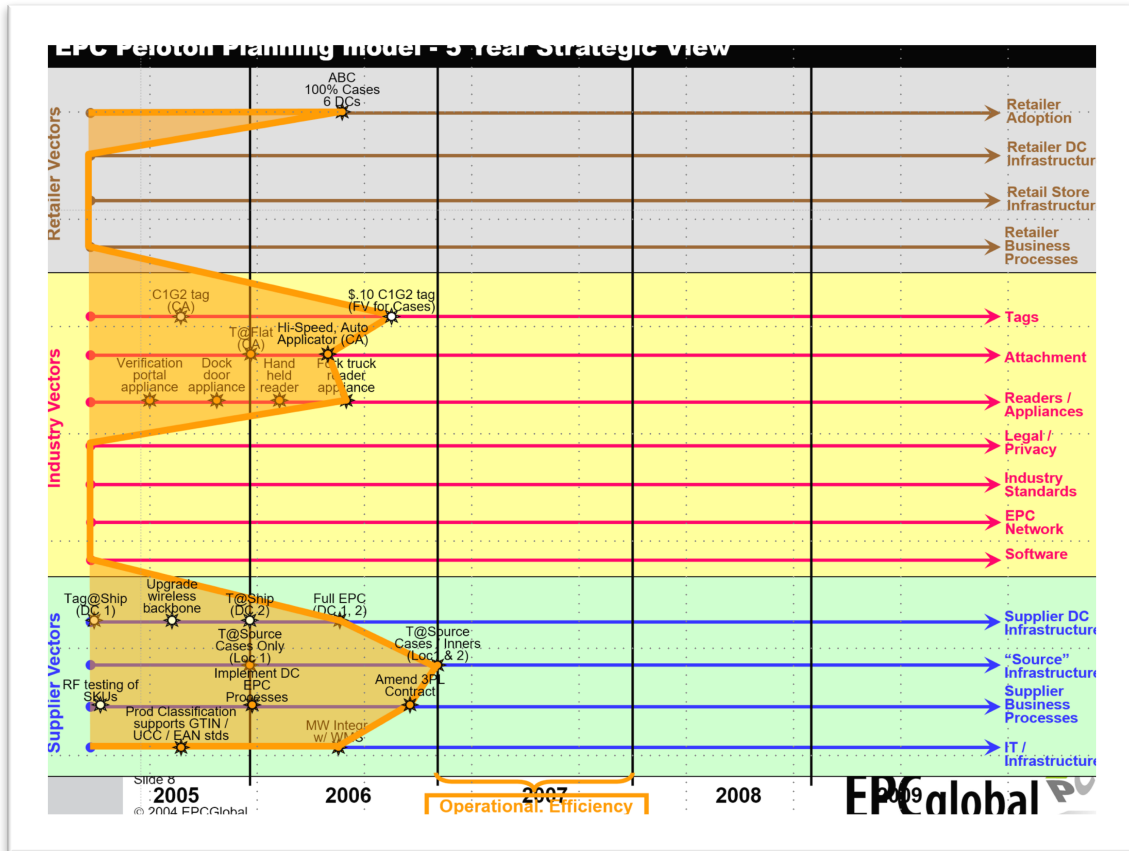
Figure 3. Peloton for operational efficiency
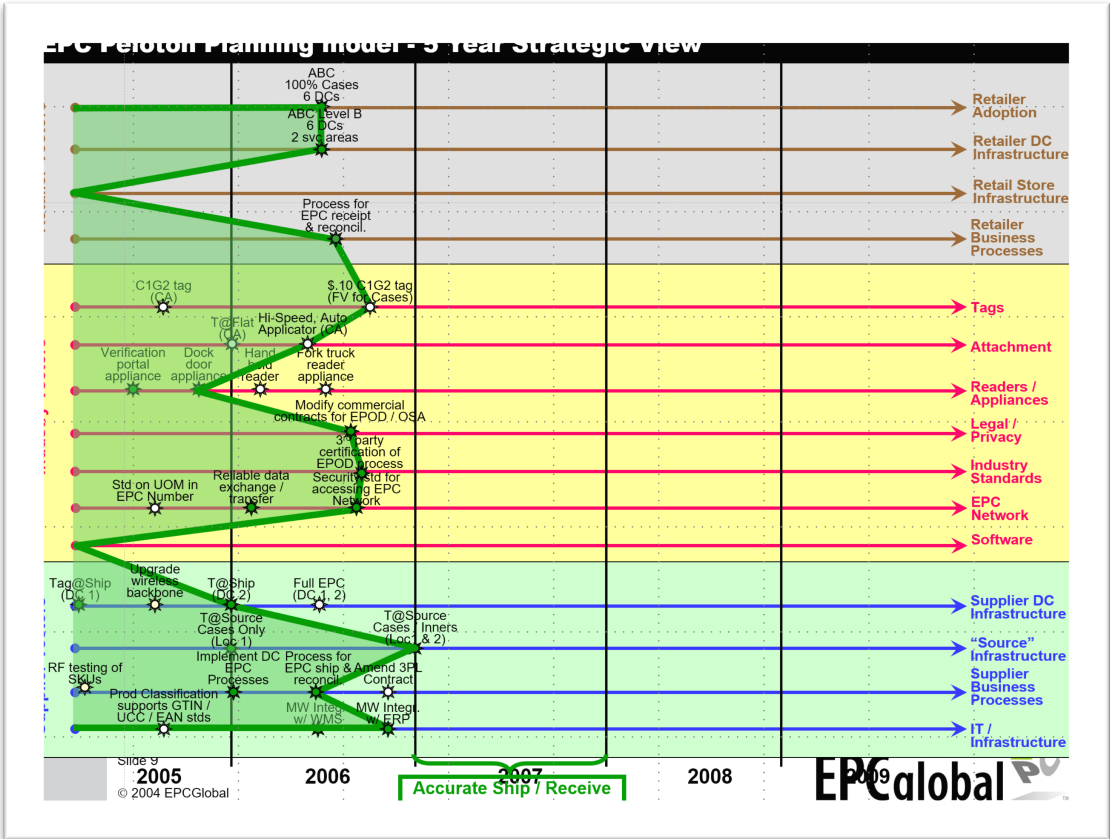
Figure 4. Peloton for accurate ship/receive

GS1 HEALTHCARE STANDARDS HOUSE

The following diagram is helpful in understanding how certain GS1 Standards are meant to be built upon to achieve additional benefit. This diagram complements Figure 6, Hierarchy of functionality.
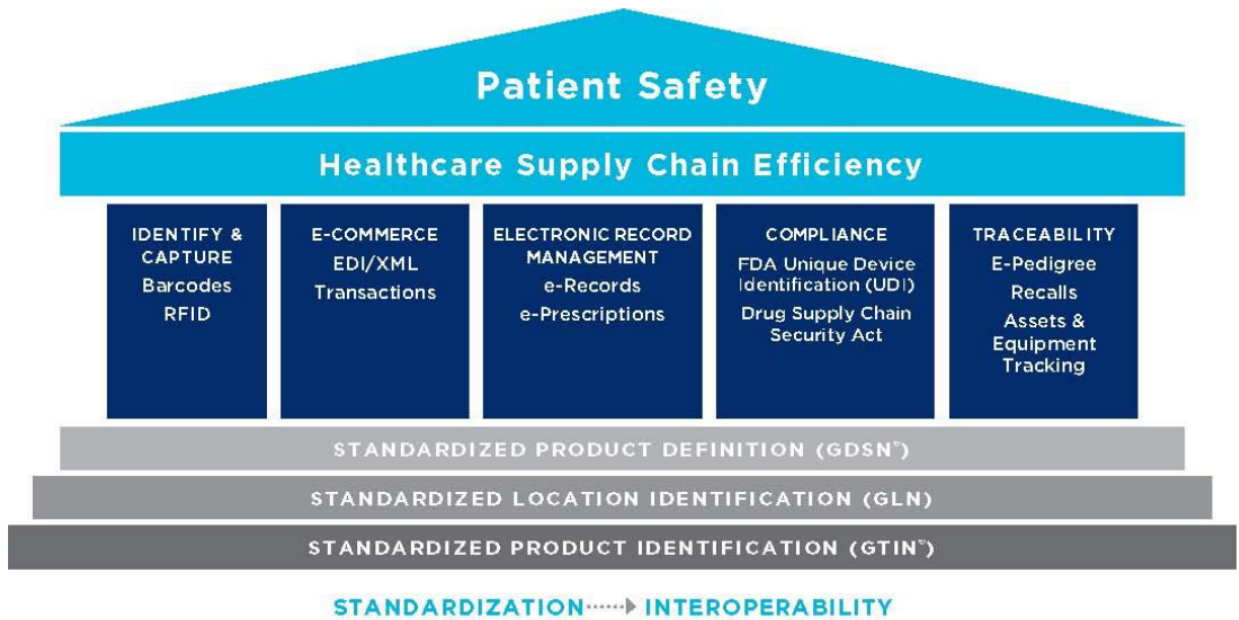
TRACK AND TRACE

The following diagrams are helpful in understanding track and trace issues and how the suite of GS1 Standards are helpful in building track and trace functionality between trading partners and within a company itself. Track and trace is an advanced concept that requires trading partner, solution partner, and intracompany cooperation to establish and maintain. Most warehouse and enterprise resource planning systems are unable to manage serialized products for the purposes of track and trace. Most companies implementing track and trace functionality currently use separate solutions to manage and share track and trace data. The pharmaceutical industry in the U.S. currently uses extended ASNs to share item- and lot-level information, with plans to use GS1 EPCIS enabled solutions to track individual serialized items.

Improving Aid Effectiveness

Driving efficiencies and improved information to Patient Care and Supply Chain Processes

- Patient Safety -----------------------> Patient Care

- Manual Processes ------------------> Automated Processes

- Information -------------------------> Information Availability

- Linking information & Physical Objects (via barcodes and omni-channel capable devices for healthcare providers and patients)

- Making the Internet of Things available

Figure 5. Why track and trace?
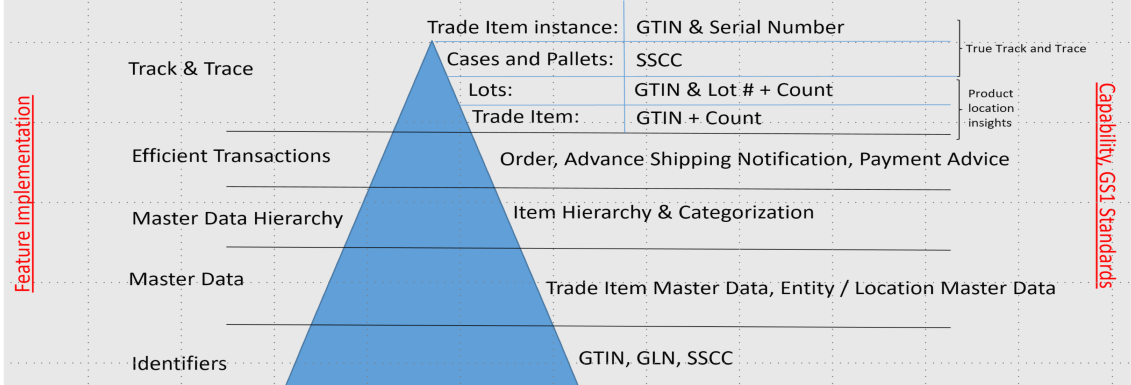
Figure 6. GS1 Standards: Hierarchy of functionality
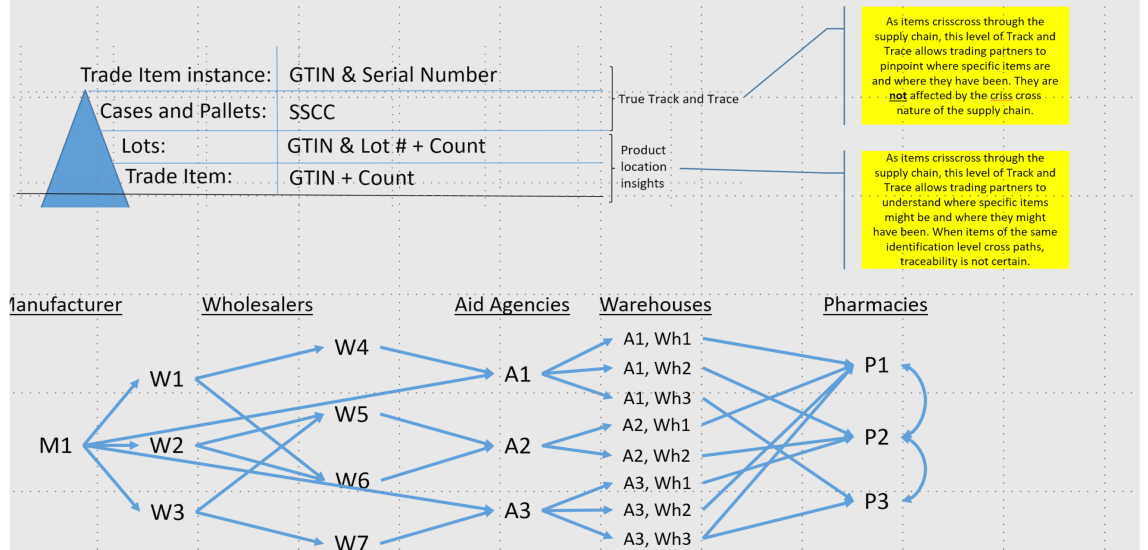
Figure 7. Understanding the value of levels of track and trace
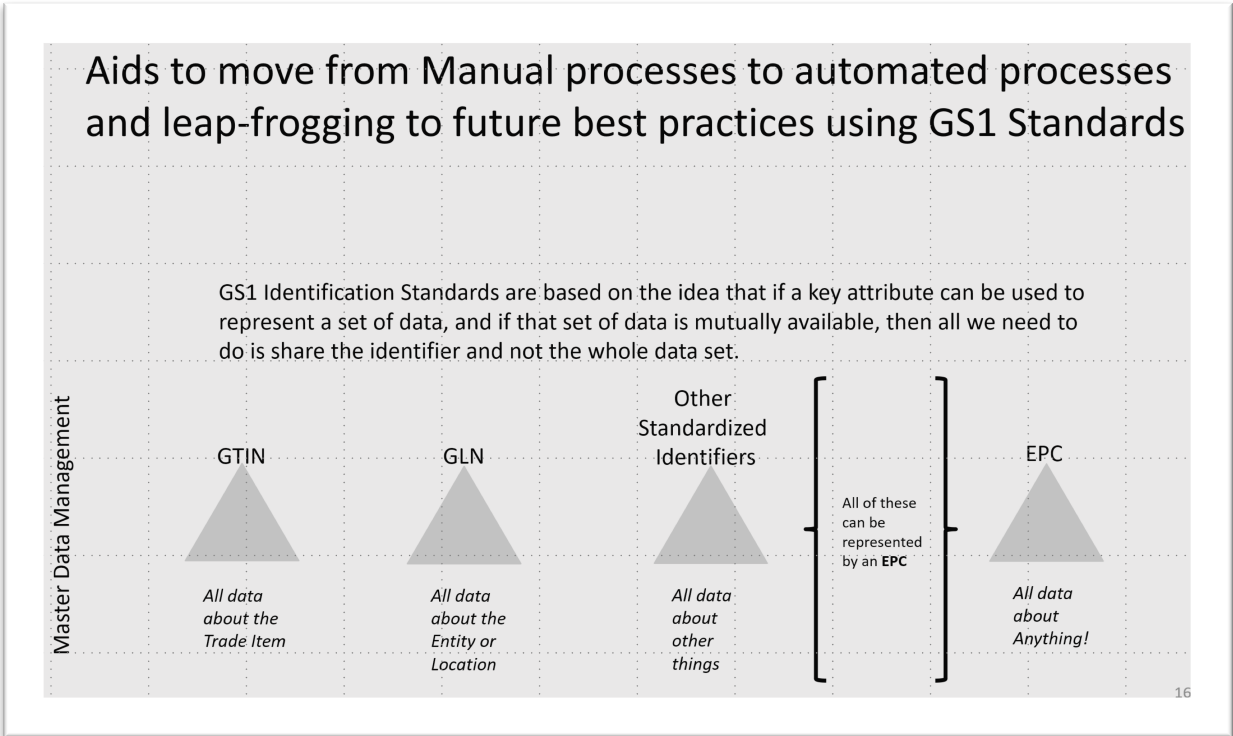
Figure 8. Understanding the use of the electronic product code (EPC) in event-based architectures
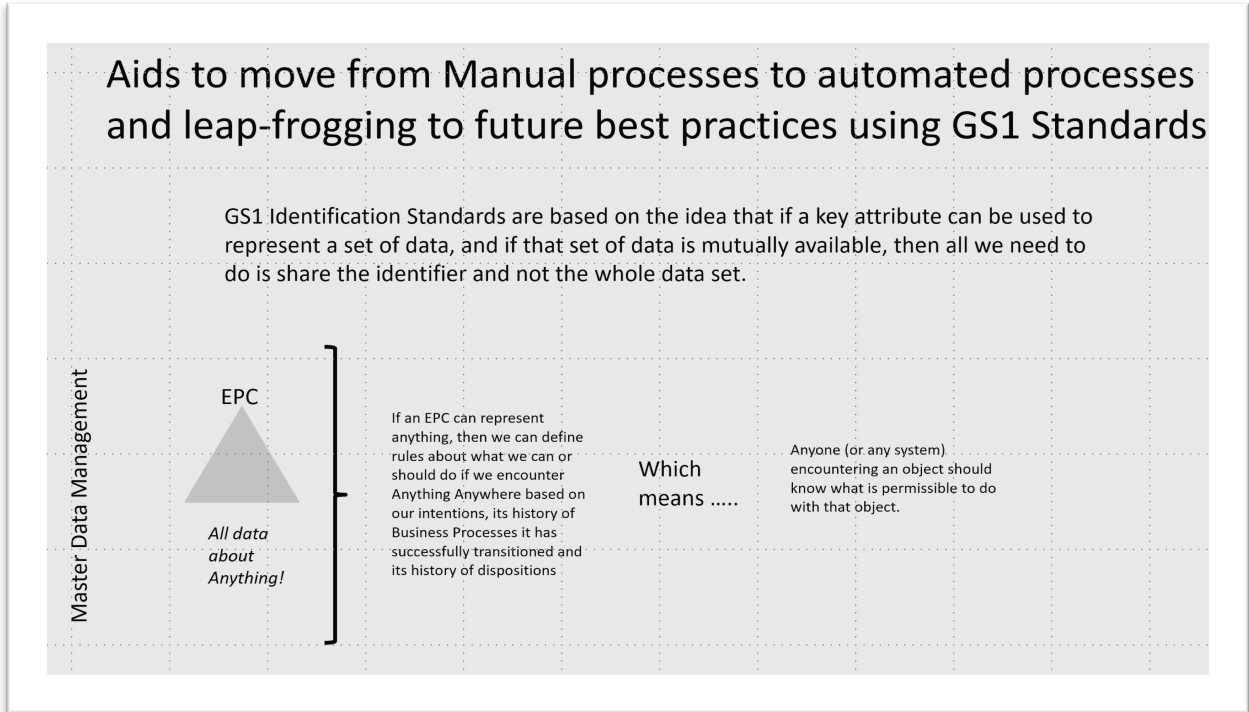
Figure 9. Understanding the use of the EPC in event-based architectures

EPC and the URI format

Example – Converting a GTIN-14 + serial number into EPC URI Format:

GTIN-14   **2 030001 123498 7**

Serial Number   **123456789012**

Corresponding Barcode Human Readable Text   **(01) 2 030001 123498 7 (21)123456789012**

Corresponding SGTIN-EPC URI   **urn:epc:id:sgtin: 030001 . 2 123498 . 123456789012**

ⓘ *The spaces in the examples above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.*

Figure 10. Understanding the EPC

Figure 11. Core business vocabulary used with EPCIS

Figure 12. Event-based systems

Figure 13. Event-based systems

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