



HLS BAG Serialization Task Force

Final Update and Proposal

21 September 2006



Discussion Points

- Original Serialization Task Force Goal
- Current State of Serialization Discussion
- Business Drivers and Requirements
- Architecture Review Committee Proposed Solutions
- Next Steps



Original Goal

Take lead in ensuring development of a viable mechanism for mass-serialization of pharmaceuticals at various packaging levels, including item level.



Current State of the Union

Q4 05

Jan 06 – Aug 06

Now

Oct 06 – Q? 2007

Flexible Pharma
Proposal

DEA NDC Guidance Letter

HLS Requirements
Definition

Aug 21 -
ARC/HLS
F2F mtg

Proposal Review
(including HUG)

TDS

Ratified New
Schema

HLS Industry
Adoption

Framework
Guidelines
& Business
Processes



Business Drivers

- Core Requirements
 - Supply Chain Partner Requirements (Mfg to Patient)
 - Throughput, Cost Efficiency
 - Patient Requirements
 - Safety, Privacy
 - Product Security Requirements
 - Non-authorized access to sensitive data
 - Global Requirements
 - National code support, Enterprise management of schemas across Rx and FMCG
- Technical/Other Constraints
 - Encryption
 - Serialized schema size
 - Data Transmission and Interpretation Speed
 - Minimal disruption as possible to legacy barcode
- Item vs Case
 - Meeting the above requirements can be different at each level (e.g. patient requirements less of an issue at case for Rx products)



Requirements

- **Uniqueness**
 - ID refers to no more than one object
 - Must be unique forever
- **Large Enough**
 - Capacity to handle future volumes of item level product
 - Backward compatible
- **Extensible**
 - Allow for future extensions that may be required (country specific)
 - Support non-sequential numbering
- **Neutral**
 - Supported by multiple issuing authority
 - Not tied to any one organization
- **Persistence**
 - Unique forever



Requirements

- **Secure**
 - Should be able to leverage EPCglobal security standards as they become available
 - Manageable across multiple trading partners in the supply chain
- **Private**
 - Ability to manage disclosure of the item to prevent viewing by unauthorized parties
- **Global**
 - Identifier is recognized worldwide but does not identify point of origin/production
- **Granularity**
 - Ability to filter on various logistical levels (e.g. pallet/case/item)
- **Administration**
 - Global / Enterprise assignment of numbers
 - Ability to support multiple manufacturing sites/lines



Requirements

- **Legacy Support**
 - Should be compatible with existing identifiers
 - Possible shift from tag to application for support of NDC and other information
- **Resolution**
 - Must be able to be able to be translated to a network address
- **Interoperability**
 - Must be interoperable with bar codes and other RFID tags



Proposed Serialization Alternatives

Coding Scheme	Description	Level
#1 [Name TBD]	<ul style="list-style-type: none"> -DEA requirement that may not be fully addressed by existing GS1 standards Entirely new schema for GS1 (similar to SSCC and GIAI tag formats) -96-bit encoding -Manager Code -No Product Code -Larger capacity serial number than SSCC -Could be fully ser. w/ Manager Code of Issuing Auth. -Could apply to controlled substances 	<ul style="list-style-type: none"> -Item -Case -Pallet (option)
#2 SGTIN96	<ul style="list-style-type: none"> -Serialized Global Trade Identification Number -Existing and in use schema for GS1 -Contains Manager Code -Contains Product Code 	<ul style="list-style-type: none"> -Item -Case -Pallet
#3-N National Code Support •when companies are ready to apply RFID tags and ship to these countries	<ul style="list-style-type: none"> -For non-GS1 code requirements - Structure follows national code's own structure; e.g. Bolini, Vignette, etc. -May or may not include Product Code -If GSIN/SGTIN is not sufficient -Goal is to have as few of these as possible 	<ul style="list-style-type: none"> -Item -Case -Pallet
#4 SSCC96	<ul style="list-style-type: none"> -Standard Serialized container Code -Used when SSCC already used to identify pallets 	<ul style="list-style-type: none"> -Pallet



Working Proposal from ARC – Serialization Framework

- Highlights.
 - Utilizes existing GS1 schemas and new headers/schema for corner cases as needed
 - instead of using sub-headers to categorize types of use cases (e.g. product code/no product code on EPC),
 - Corner cases would be non-standard national codes needs, e.g. Italy
 - May require the creation of 1 new schema for “no product code on EPC” use case.
 - expanded schema (similar to SSCC) that will handle the volume requirements.
 - Leverages existing SGITN96 and SSCC96 schemas.
 - TDS standards around logistical unit filters will need to be “genericized” from current Consumer Goods label perspective.
 - GS1 actioned to drive international regulatory bodies to leverage existing GS1 schemas as much as possible.
 - Pharma Guidelines to be developed on when to use each type of schema, though goal is defacto industry standard of one in future.



Next Steps

- October 06:
 - HLS representatives work with FDA and other government organizations on Serialization recommendations
 - **Joint HLS/HUG review Serialization - today**
 - HLS Industry Adoption Group to develop draft proposal of guidelines around Serialization implementation
 - Analysis of requirements by GS1/EPCglobal Task Force to make recommended solution for Identifiers to be used for Serialized Item/case level identification without Product code.
- November 06
 - Review results of analysis with GS1 Healthcare membership (HLS and HUG)
 - GS1/EPCglobal begin work on development of solution for Serialization at Item/Case level without Product code
 - Workplan for Solution published to GS1 Healthcare membership



Questions?