HUG/HLS Serialisation
Work Team Feedback Session

Berlin 1 February 2007
Stephen Hess, Merck

The global language of business

A Combined effort of GS1 HUG and HLS
Global focus
All Healthcare products

Please Welcome our New work team co – lead

Massimiliano Molinari J & J

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We are looking for diverse participants that:

1) Represent the different roles in the supply chain, such as:
   - ✓ Manufacturers
   - ✓ Wholesalers
   - ✓ Retailers
   - ✓ GPOs
   - ✓ Hospitals
   - ✓ GS1 Member Organizations

2) Represent small, medium and/or large enterprises

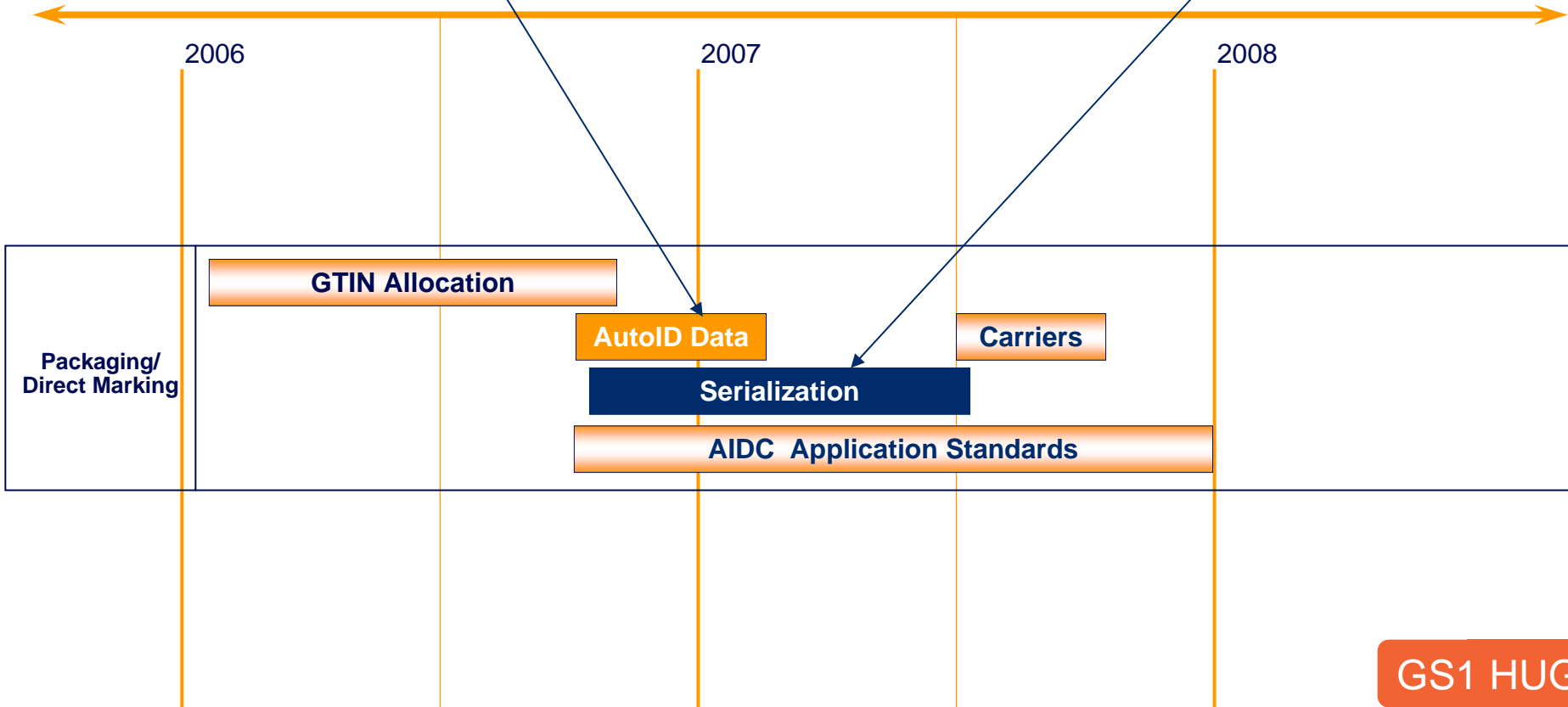3) Work locally and think globally

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- Abbott
- AdvaMed
- Aesculap
- Amgen
- Astra Zeneca
- Baxter
- Boston Scientific
- B.Braun
- Cardinal Health
- Cook
- FDA
- GSK

- HDMA
- Johnson & Johnson
- McKesson
- Medtronic
- Merck Germany
- Novartis
- Pfizer
- Purdue
- Roche
- Sanofi-Aventis
- St. Jude
- Tyco Healthcare
- Wyeth

- **GS1 MO**
- Australia
- Austria
- Canada
- China
- France
- Hungary
- Italy
- India
- Ireland
- Japan
- New Zealand
- Spain
- Switzerland
- UK
- USA

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"AIDC Application Standards"

AutoID Data Work Team
Serialization Work Team

2006

2007

2008

**Packaging/
Direct Marking**

GTIN Allocation

AutoID Data

Carriers

Serialization

AIDC Application Standards

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Serialization

	2006			2007					
	Nov	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**	
Review Mission & Vision	▬								
Establish Team	▬								
Approve Objective & Scope	▬								
Approve Business Requirements		▬▬▬▬▬▬							
Approve Data Requirements					▬▬▬▬▬▬▬▬▬▬				
Submit Change Request									▬

Berlin   tbd

key

- - - physical meetings

▬▬▬ task scheduled

▬▬▬ task complete

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What's the interest in serialization?
To determine the global healthcare industry's size and structural requirements for specific data elements *(e.g., lot numbers, serial numbers)* to support patient safety and product authentication for healthcare products as defined by GS1 HUG below:

- Vaccines
- Biologics
- Therapeutic nutritional products
- Pharmaceutical
- Medical Devices (e.g., Instruments, Implants)

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The Serialization WT will review and document business and regulatory requirements for serialization by:

- Size (capacity needed)
  - All Healthcare
  - By product (GS1 HUG)
  - By product (GTIN)
  - By lot
  - By serial number
- Meaningful numbers versus randomization & affect on capacity
- Decentralization/centralization of allocation & affect on capacity
- Structure
  - Numeric length
  - Alpha-numeric length

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Manufacture   Distribution   Care Facility

From: Finished Goods   To: End of Treatment

These are the boundaries

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Number	Role	Business Requirement (WHAT?)	Rationale (WHY?)	Mandatory/Optional	Status	Source	WT remarks
	HUG/HLS Serialisation Work Team		Updated: January 17,2007				
	Business Requirements Template		**Pharmaceuticals**				
	SCOPE: Serialisation size (capacity needed), meaningful vs. random numbers, decentralized vs. centralized; structure (numeric vs. alpha numeric) and their effects on capacity.						
	Note: **Comments provide directions for completing the template.** To see comments click View & Comments; Click View & Comments again to hide comments.						
1	Manufacturers, Wholesalers, Repackers	**Uniqueness** -- Item level identifier MUST refer to no more than one object	Federal and State regulations are suggesting serialization as the means to ensure product pedigree requirements are met.	Optional	Open	FDA - Counterfeit Drug Task Force Report -- 2006; California Board of Pharmacies Draft Regulations	
2	Manufacturers, Wholesalers, Repackers,	**Uniqueness** -- Item level identifier MUST remain unique "forever".	To ensure no possibility that two objects will ever inadvertently share the same identifier	Optional	Open	HLS Serialization Task Force	The term "forever" needs to have established & agreed to boundaries -- i.e. 20 years
3	Manufacturers, Wholesalers, Repackers	**Number Schema and Size** -- MUST have the capacity to handle current & future volumes of item level products within the Pharma Industry	To ensure no possibility that two objects will ever inadvertently share the same identifier	Optional	Open	HLS Serialization Task Force	Capacity will be dependent on the number structure and agreed to sub-category identifiers.
4	All Supply Chain Stakeholders	**Number Schema and Size** -- SHOULD be backward compatible	Inter-operability with previous versions to ensure minimal intrusiveness when migrating	Optional	Open	HLS Serialization Task Force	
5	All Supply Chain Stakeholders	**Number Schema and Size** -- MUST support alphanumeric numbering structures	Allows for flexibility in sub-components of the numbering schema which may be critical to certain industry sectors.	Optional	Open	HLS Serialization Task Force	
6	Manufacturers, Wholesalers, Repackers	**Number Schema and Size** -- MUST support enterprise assignment of numbers	Decentralized assignment of numbers is critical to the autonomous manner in which multi-national, cross industry enterprises manage and execute	Optional	Open	HLS Serialization Task Force	
7	Manufacturers, Wholesalers, Repackers	**Extensible** -- Numbering schema MUST permit for future extensions to accommodate global nuances	Requirements from regulators are evolving at differing rates, requiring a schema flexible and adaptive enough to embrace future variants	Optional	Open	HLS Serialization Task Force and GS1 Serialization Work Team	Possible use of filters.
8	Manufacturers, Wholesalers, Repackers	**Extensible** -- Numbering schema MUST support non-sequential numbering	Decentralized assignment of numbers within an enterprise necessitates the need to allow independent sites to manage the number locally	Optional	Open	HLS Serialization Task Force	
9	All Supply Chain Stakeholders	**Neutral** -- Identifier SHOULD not be tied to a particular application or interest group		Optional	Open	HLS Serialization Task Force	
10	All Supply Chain Stakeholders	**Neutral** -- Identifier SHOULD be supported by multiple issuing authorities -- i.e. EAN, GS!, country specific ...	Minimize the potential for fragmentation in standards to meet broad product and packaging types	Optional	Open	HLS Serialization Task Force	
11	Manufacturers, Wholesalers, Repackers	**Persistent** -- Identifier MUST be able to refer to the object well beyond the lifetime of the physical object		Optional	Open	HLS Serialization Task Force	Consistent with the Uniqueness requirement #2
12	All Supply Chain Stakeholders	**Secure** -- Identifier scheme SHOULD be able to contain security features if necessary (e.g. algorithmic, look-up, jammers)	DEA regulations regarding the necessity of not including the National Drug Code on the tag may be best addressed through a security solution	Optional	Open	HLS Serialization Task Force	Pros & cons of using various security solutions for "cloaking" the NDC need to be analyzed to determine cost/benefit -- other options may be available
13	All Supply Chain Stakeholders	**Secure** -- security solution SHOULD be easy to manage across supply chain partners	Concern for the cost, complexity, latency and manageability of public keys	Optional	Open	HLS Serialization Task Force	HLS interest is in taking a "Managed Risk" approach to security -- i.e. balanced with the value and susceptibility to counterfeiting of the product
14	All Supply Chain Stakeholders	**Privacy** -- MUST be able to manage the disclosure/non-disclosure of the identity of the item or custodian(s) to non-authorized parties	DEA and FDA interest in being able to authenticate the product and pedigree of a product	Optional	Open	HLS Serialization Task Force	
15	All Supply Chain Stakeholders	**Privacy** -- MAY encompass other fields beyond EPC (UID, other fields)	?? Not sure what is meant by this requirement... needs follow up	Optional	Open	HLS Serialization Task Force	
16	Manufacturers, Repackers	**Global** -- ID MUST have the same meaning and MUST NOT imply a geographic location of information about the object	A manufacturer may have dedicated facilities for producing/packaging a given product line. In these instances, know ledge of the site reveals the product, negating the anonymity desired	Optional	Open	HLS Serialization Task Force	e.g. Manager number does not indicate site of manufacture

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My role in the supply chain is…

My business requirement is… (must relate to serialization and patient safety)

The rationale for this requirement is…

This requirement is mandatory or optional

The work team evaluates and documents status open/close

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HUG/HLS Serialisation
Work Group - Questionnaire

The GS1 HUG/HLS Serialisation Work Group is distributing this questionnaire to assist in the development of business requirements with the goal of developing a global standard for the healthcare industry.

Answers to the questionnaire will help us determine the size (capacity) and structure needed to support serialization requirements.

1. I am a: _____ manufacturer   For this questionnaire our products are:
_____ distributor   _____ Vaccines
_____ wholesaler   _____ Biologics
_____ hospital   _____Therapeutic Nutritional
_____ other: _____ Pharmaceutical
                                      _____ Medical devices: *instruments/implants*

If other please describe:

2. Our largest number of healthcare products in a lot* is _____.
*for this survey lot and batch are considered identical in the external supply chain.

3. Is your lot number structure numeric or alpha numeric?
_____ numeric
_____ alpha numeric

4. Is there ever an association with lot numbers in your serialization scheme?
_____ yes
_____ no
If yes, with what frequency. _____
.

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5. When you identify serial numbers are the numbers meaningful (containing intelligence) or random?

    _____ meaningful

    _____ random

6. Was number size/capacity a criterion for choosing meaningful or random numbers?

    _____ yes   _____ no

7. Is the allocation of your serial numbers centralized or decentralized?

    _____ centralized

    _____ decentralized

    _____ both

If both, please explain.

8. Was number size/capacity a criterion for choosing centralized or decentralized allocation of numbers?

    _____ yes   _____no

9. Is your serial number numeric or alpha numeric?

    _____ numeric

    _____ alpha numeric

10. Was number size/capacity a criterion for selecting numeric or alpha numeric?

    _____ yes   _____ no

11. Would there be an impact on you if you had to change your number structure?

    _____ yes   _____no

12. If your answer to 9 was yes, please explain the impact.

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- ✓ Manufacture
- ✓ Distributor
- ✓ Wholesaler
- ✓ Hospital

- ✓ Vaccines
- ✓ Biologics
- ✓ Therapeutic Nutritional
- ✓ Pharmaceutical
- ✓ Medical Devices
    - ✓ Instruments
    - ✓ Implants
- ✓ Animal Health
- ✓ Dental

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Alpha Numeric – 100%

Numeric – 0%

Meaningful – 25%

Random – 75%

Centralized – 33%

De-Centralized – 66%

Both – 100%

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Receive Q and A feedback and access

Please submit by Feb 10

Complete the business requirements case sub team

So far:

- Vaccines
- Biologicals
- Medical Devices
- Therapeutic Nutritional

Pharma – started via HLS, sub team kick off now.

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Understand and rationalize the business requirements

1st pass – Is the business requirement within scope?

    yes – move on

    no – highlight for move to parking lot

2nd pass – Is the business requirement clearly written?

    yes – move on

    no – highlight for rework

3rd pass – Is the rationale correctly stated?

    yes – move on

    no – highlight for rework

Make plan for rework of highlighted business requirements.

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Work Team Meetings

Thursday 8:30 AM NYC time

Next Call is Wednesday Feb 7 5:30 PM NYC time

1 out of 4 calls to engage our colleagues in Asia Pacific

Phone: 877-864-7187(US) +1-720-348-446(international)

pass code * 1527657 *

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Contact détails

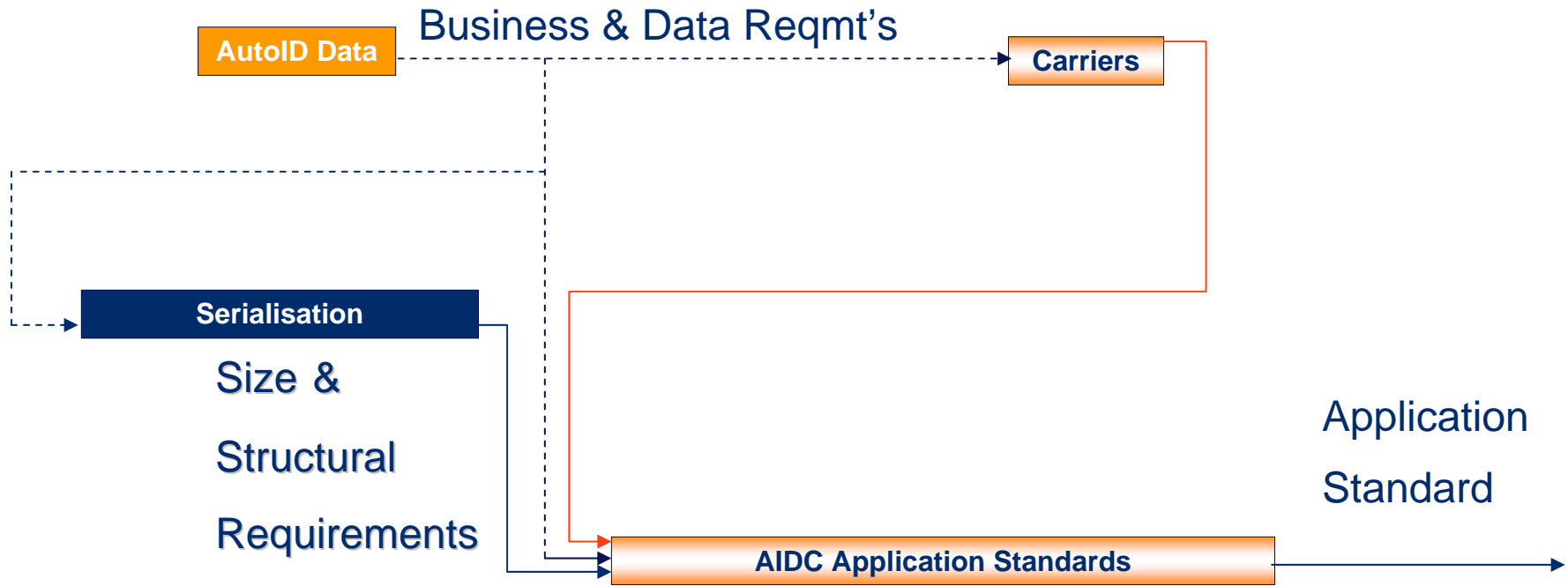Stephen Hess

Executive Director Packaging Technology

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The global language of business

Business & Data Reqmt's

AutoID Data

Carriers

Serialisation

Size & Structural Requirements

AIDC Application Standards

Application Standard

Stephen Hess

**Executive Director of
Packaging Technology**

Merck

Pierre Stoquart

**Director Packaging &
Logistics, Technical Services**

Glaxo Smith Kline

Construct packaging/direct marking AIDC application standard(s) specific to appropriate product group or sub-industry requirements, with patient safety as the highest priority and minimise the number of different healthcare application standards and associated required AIDC technologies while maintaining practicality and appropriate differentiation.

…and create a healthcare application standard to meet our business requirements …

Mass Serialization is the process of generating and applying codes to identify uniquely each individual instance of a given product entity. (For example each individual pack of a pharmaceutical product defined at SKU level). The codes may be sequential or randomized. The codes may be represented in a number of ways e.g. in human readable form (alpha-numeric) or machine readable e.g. barcode or RFID.

A serial number is a code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: Microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number.

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Draft business requirements

SCOPE: Serialisation size (capacity needed), meaningful vs random numbers, decentralized vs centralized; structure (numberic vs alpha numberic) and their effects on capacity.

Note: **Comments provide directions for completing the template.** To see comments click View & Comments; Click View & Comments again to hide comments.

Number	Role	Business Requirement (WHAT?)	Rationale (WHY?)	Mandatory/Optional	Status	Source	WT remarks
1	Spainish Government	A unique serial number shall be applied to every unit of sale	New Regulation	Mandatory	open	GS1 spain	Currently no one is complying
2	Italian Government	A unique serial number shall be applied to every unit of sale	Bollini Law	Mandatory	open	GS1 Italy	Most comply but question effectiveness
3	State Of California	A unique serial number shall be applied to every unit of sale	2009 law to go into effect unless further "stay"	Mandatory	open	State Of California	Could be deferred an additional 2 years
4	Manufactureres	A unique serial number shall be applied to every unit of sale	The serial number could be authenticated at the point of dispensing	optional	open	Merck/Baxeter	
5	Manufactureres	A unique serial number shall be applied to every unit of sale	A serial number could be used to support supply chain visibility and invntory control	optional	open	Baxter	
6	Manufactureres	A small unique serial number	A small A/N code should be easier to print, verifya nd authenticate	optional	open	Baxter	
7	Manufactureres	A serial number should not include country specific logic	GTIN should be more appropriatte and efficitn to manage	optional	open	merck and baxter	
8	Payors	A unique serial number shall be applied to every unit of sale	Payors will use the serial number to assure that they only pay for authenticat products	optional	open	Merck	
9	Immunization records	A unique serial number shall be applied to every unit of sale	A serial number could be useful to support the immunization recordkeeping required for vaccines	optional	open	PHAC	
10	Manufactureres	A unique serial number shall be applied to every unit of sale	a unique serial number could be useful to support product traceability	optional	opne	merck	
11	Manufactureres	A uniique serial number to survive cold chain.	Many vaccines requie cold chain	mandatory	open	merck	

Identify the role that needs the business requirement. Exampes: Manufacturer, Distributor, Wholesaler, Hospital

A business requirement should identify a single specific need. The business requirement must be within the scope of our work (serial numbers and patient safety). The words SHALL or MUST are used for mandatory requirement. The words SHULD or MAY indicate an optional requirement.

The rational explains why the business requirement is needed and/or how the business requirement is to be applied.

A business rule will be given an open status until approved by concensus within the Work Team. Once approved a closed status is assigned. When closed the business requirement is no longer open for discussion or change.

This column should be used to identify the source of the requirement. (The person and/or company providing the requirement)

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