



AIDC Data & Serialisation

Orlando, Florida

June 6, 2007

Tom Heist, GS1 GO

The global language of business

www.gs1.org

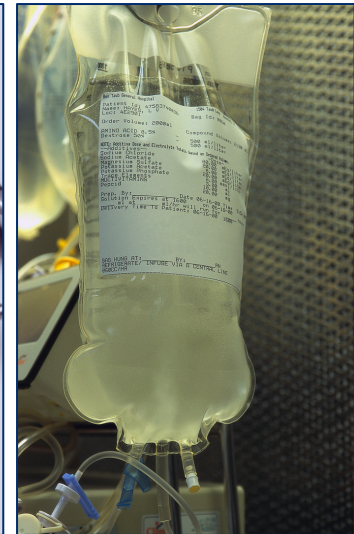
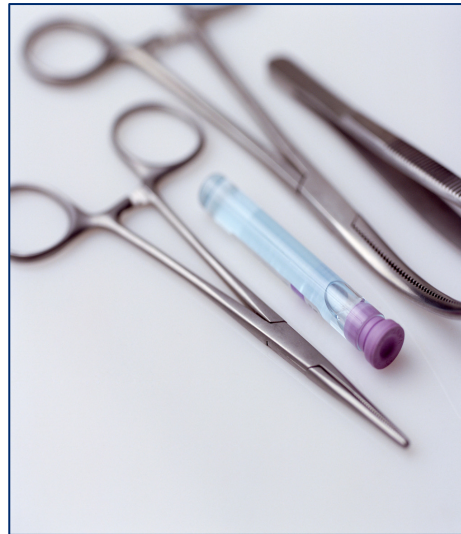
Introduction

- Overview – Work Group Relationships
- Auto-ID Data Work Group
- Serialisation Work Group

Work Group Relationships



We intend to create a healthcare application standard that meets our users' requirements.

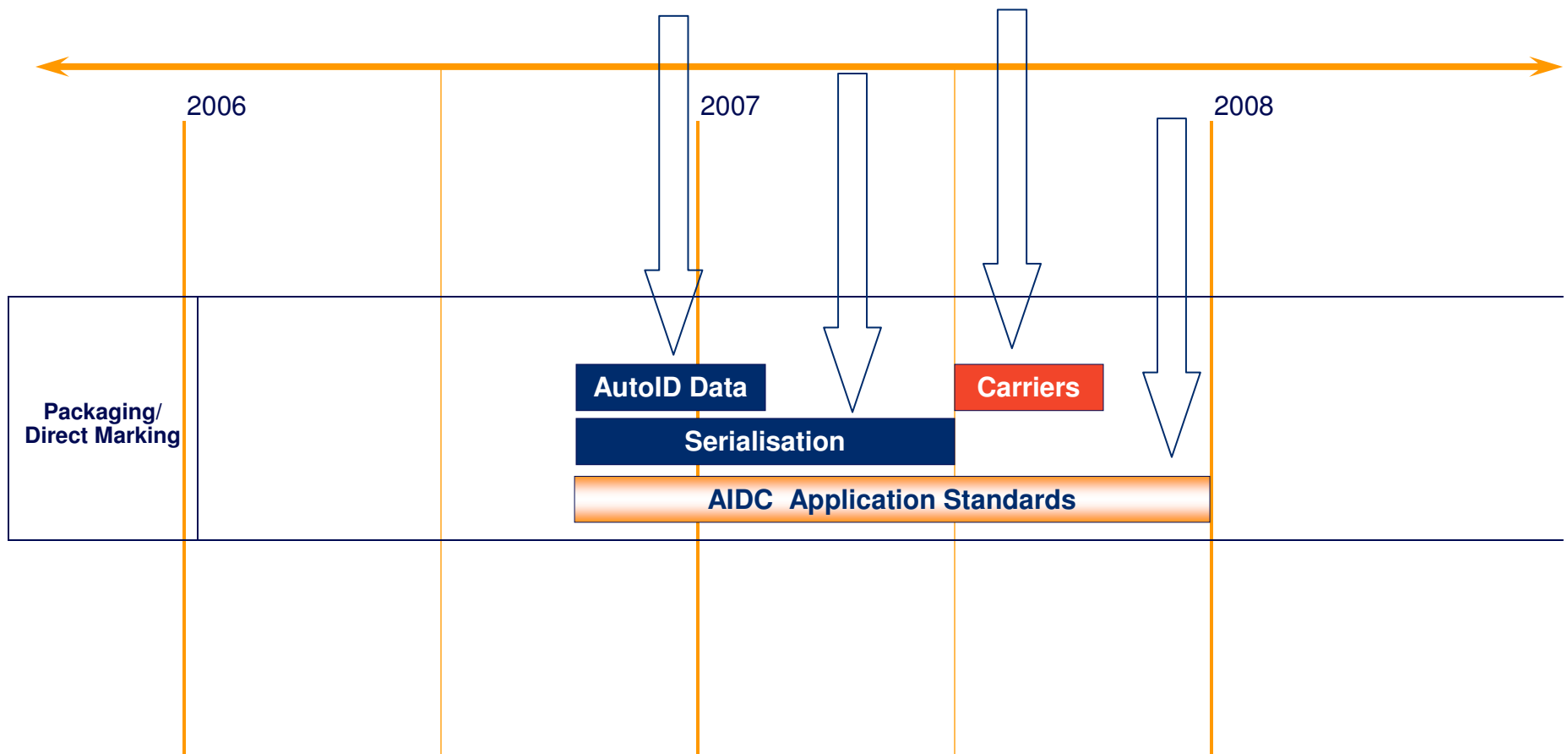


A Healthcare Standard

Must be created to meet:

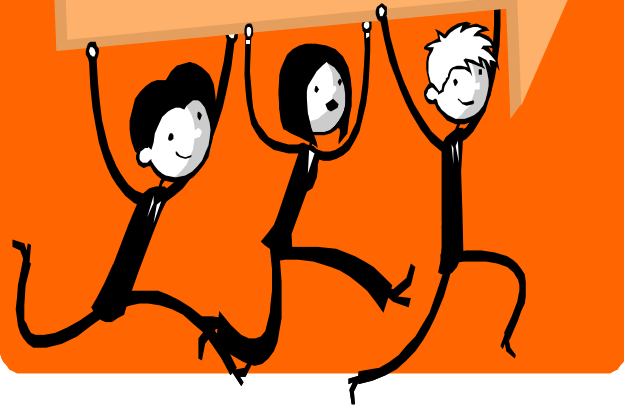
- ✓ Business Requirements
- ✓ Data Requirements
- ✓ Serialisation Requirements
- ✓ Carrier Requirements

Work Teams versus Roadmap



The Deliverables

**Business & Data
Requirements**



AUTO-ID Data Team

**CARRIER
Work
Group**

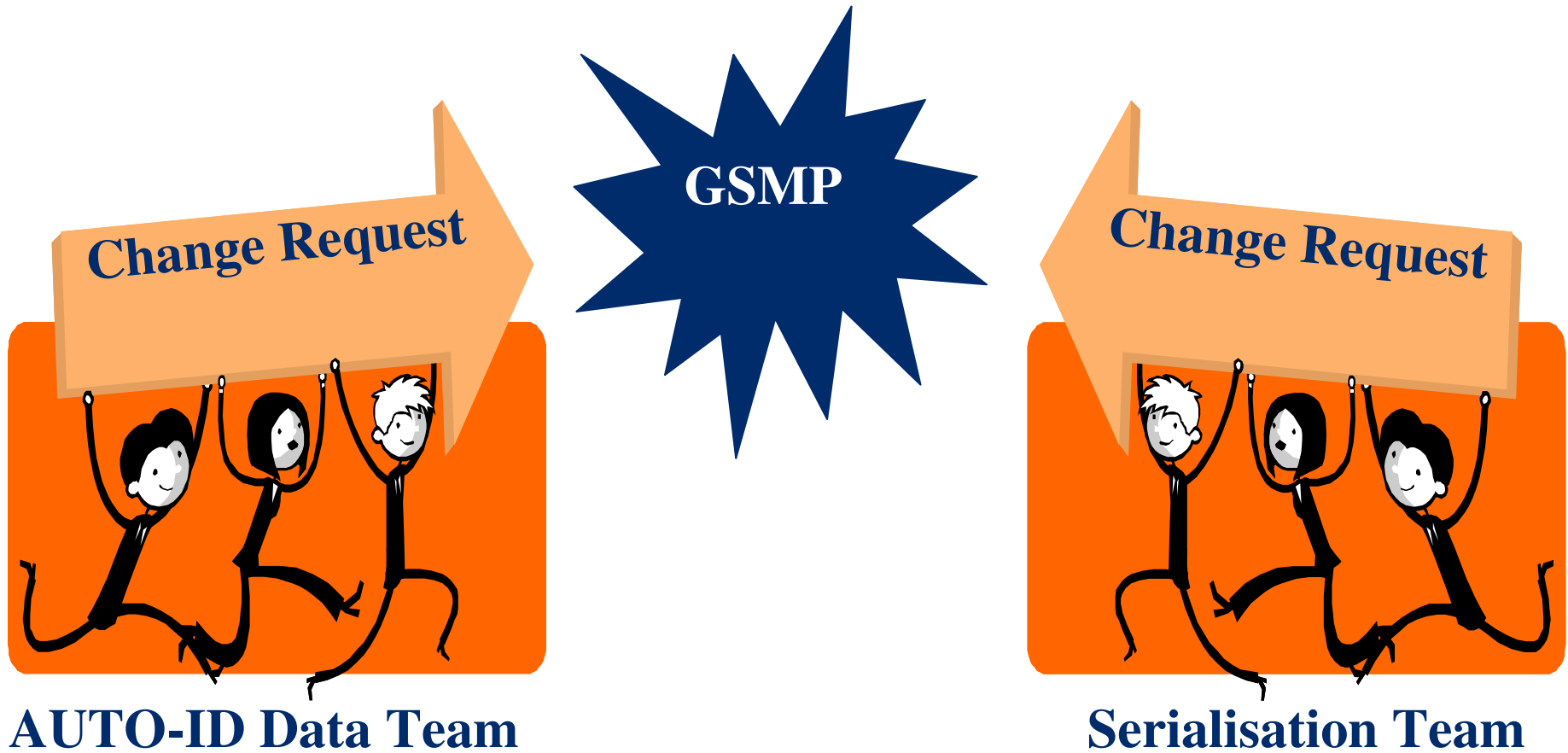


**Serial & Lot #
Size and Capacity**



Serialisation Team

The Deliverables



Auto-ID Work Group



AIDC Data Work Group's Objective

**... identify the business and data requirements
for the automatic identification of healthcare products
with the goal of improving patient safety**





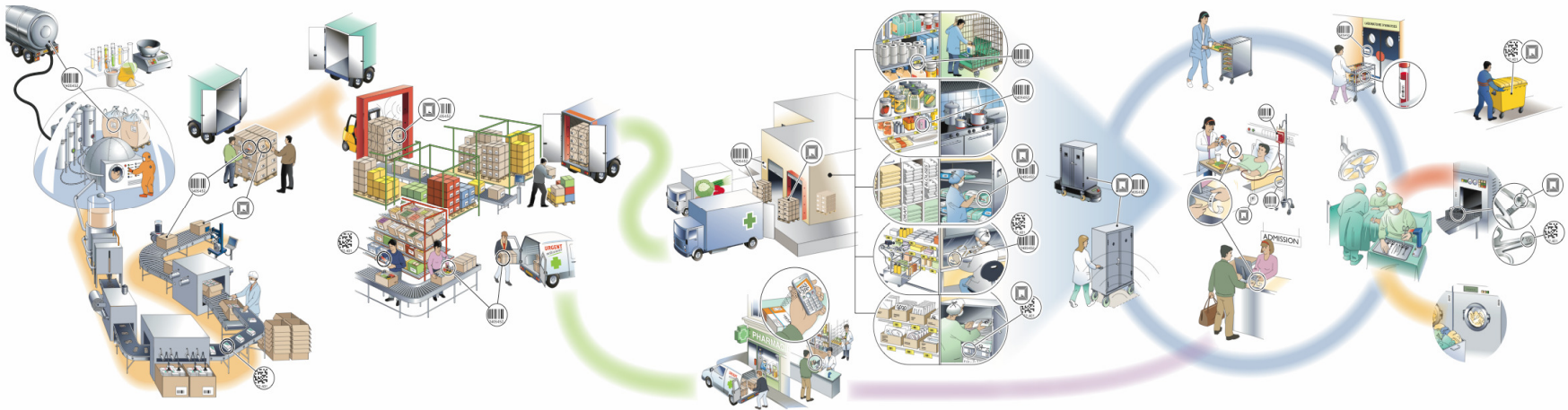
Scope Healthcare Product Areas



- Vaccines
- Biologics
- Therapeutic nutritional products
- Pharmaceutical
- Medical Devices
- Instruments
- Implants



Scope Supply Chain Boundaries



Manufacturing → Distribution → Care Facility

From: Finished Goods

To: End of Treatment

The GS1 HUG™ Auto-ID Data Work Team

A closer look



- Gathered the business requirements for data on healthcare products
- Compiled and condensed a list
- Agreed upon content

The approved business requirements have been used to establish data requirements

Business Requirements

I Manufacturer, Wholesaler, Distributor, Hospital, Retailer

NEED a statement of the requirement

BECAUSE the business rationale

Manufacturer	needs to know the expiration in time (not just YYMMDD) for products with a short life cycle	to ensure an expired product is not given to the patient.
--------------	---	---

Collection

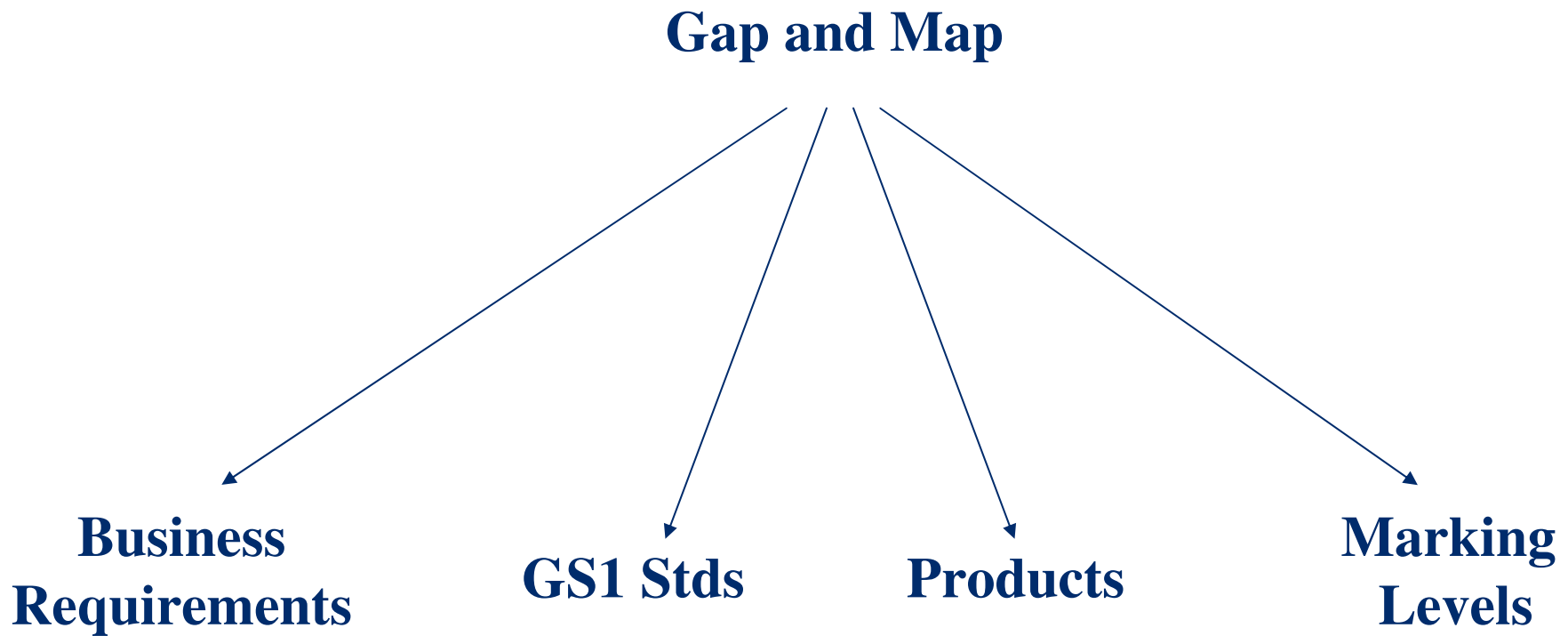
Over 166 business requirements collected from

- Hospital Survey
- Sub – Teams (by product type)
 - Manufacturers
 - Distributors
 - Wholesalers
 - Retailers
 - Hospitals
- Local/Regional HUGs
- Healthcare Organisations
- Regulatory Agencies

Analysis & Disposition

- Combined (similar)
- Split (smaller, clearer)
- Scope (in or out of scope)
- Approved
- Parking Lot
- Deleted

YIELD = 60 Final Approved Business Requirements



Gap Analysis

Manufacturer	needs to know the expiration in time (not just YYMMDD) for products with a short life cycle	to ensure an expired product is not given to the patient.
---------------------	--	--

✓GTIN

✓GLN

✓GSRN

✓SSCC

✓Serial #

✓Lot #

✓Expiration Date

✓OTHER = time

Mapping Example

Product

Product Class					
Marking Level	Direct Part Mark	Unit of Use	Carton	Case / Shipper	Pallet
Business Requirement Numbers	#1	#1			
Data Reqmts for Manufacturer	AI(01) GTIN	AI(01) GTIN			
for Repacker					
for Wholesaler					
for Retailer					
for Hospital					

GAP ANALYSIS IS COMPLETE

MAPPING IS UNDERWAY

DRAFT REPORT PREPARED

NEED ONLY

- Final Data Analysis Charts
- Team Review and Approval

THEN.... Develop A Plan For Parking Lot Issues

Serialisation Work Group



Serialisation Work Groups Objectives



**To determine the size and structural requirements
for lot numbers and serial numbers to support
patient safety and product authentication
for healthcare products**



Healthcare

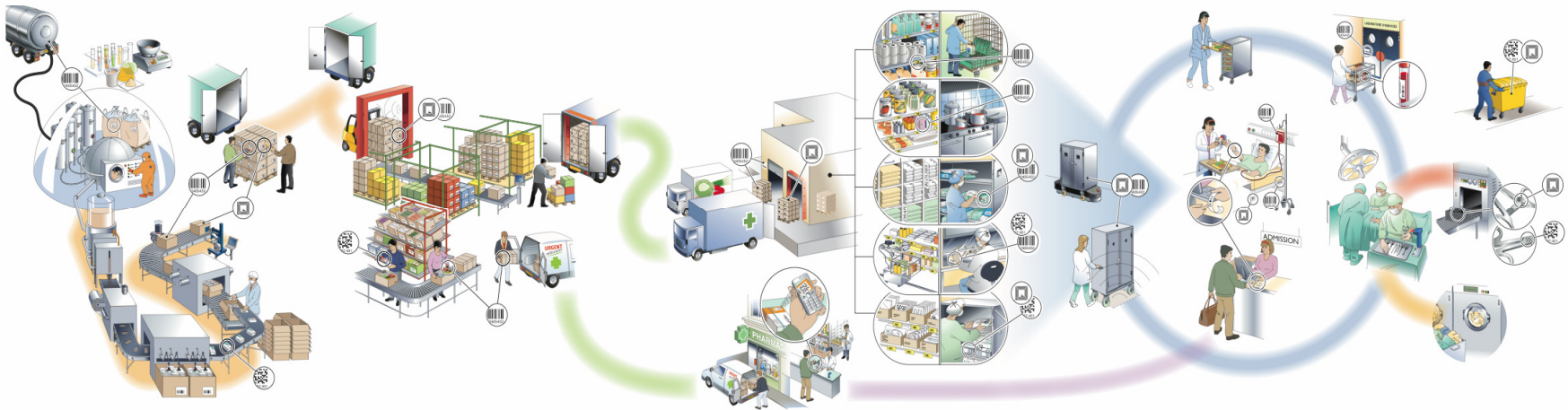
SCOPE HEALTHCARE PRODUCT AREA



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



Scope Supply Chain Boundaries



Manufacturing → Distribution → Care Facility

From: Finished Goods

To: End of Treatment



Healthcare

SCOPE



The Serialisation WG will review and document business and regulatory requirements for serialisation by:

- Meaningful numbers versus randomization & capacity affect
- Decentralization/centralization of allocation & affect on capacity
- Structure
 - Numeric length
 - Alpha-numeric length



Scope Review



The Serialisation WT will review and document business and regulatory requirements *for serialisation by Size (capacity needed).*

Number	Product	Company	Industry
Serial #	all	one	any
Serial#	all	one	healthcare
Serial#	largest	one	healthcare
Lot #	largest	one	healthcare

DATA COLLECTION

Number Structure and Capacity Data Collected



- ✓ By Company
- ✓ By Product Types
- ✓ By Number (Lot number & Serial number)
- ✓ By Number Selection (Intelligent number or Random number)
- ✓ By Number Assignment (Centralized or Decentralized)
- ✓ By Number Structure (Numeric or Alpha-numeric)



Over 39 Responses

Representing:

- ✓ **All product types**
- ✓ **Manufacturers**
- ✓ **Distributors**
- ✓ **Hospitals**
- ✓ **North America**
- ✓ **Europe**
- ✓ **Australia**
- ✓ **New Zealand**



Largest Numbers Collected

Number of serial numbers needed if 1 is assigned to every product “instance” produced for:

	any channel	healthcare	highest volume
vaccines	2 Billion	2 Billion	2 Billion
biologics	5 Billion	3 Billion	400 Million
therapeutic nutritional	2 Billion	2 Billion	1 Billion
pharmaceuticals	4 Billion	50 Billion	50 Billion
medical devices	2 Billion	50 Billion	50 Billion
instruments	10 Million	10 Million	20 Thousand
implants	10 Million	10 Million	20 Thousand

STATUS

Data Collection Is Closed

Data Study Started

- Serialisation Factors

Conclusions To Be Reported

Thank You

