Serialisation

Initial discussion: How to address some current and potential U.S. regulations at the state and federal level about controlled substances and electronic pedigree.

Evolved to defining a way to serialise pharmaceuticals at pallet, case and packaging and item level.

Focus then moved to global work, covering all healthcare themes.
Introduction – Work Teams versus Roadmap

“AIDC Application Standards”

AutoID Data Work Team
Serialisation Work Team

Packaging/Direct Marking

GTIN Allocation
AutoID Data
Serialisation
AIDC Application Standards
Carriers

2006
2007
2008
Serialisation Work Team

Work Team Leaders

Stephen Hess
Executive Director of Packaging Technology
Merck

Pierre Stoquart
Director Packaging & Logistics, Technical Services
Glaxo Smith Kline
Serialisation Work Team
Members

- 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
- And GS1 Organizations from:

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

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<th>Task</th>
<th>2006</th>
<th>2007</th>
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<td>Review Mission &amp; Vision</td>
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<td>Establish Team</td>
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<td>Approve Objective &amp; Scope</td>
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<td>Approve Business Requirements</td>
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<td>Approve Data Requirements</td>
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<td>Submit Change Request</td>
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**Key**
- Physical meetings
- Task scheduled
- Task complete

- **Berlin**
- **tbd**
Objective
Auto-ID Application Standards Team’s Objective

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 alphanumeronic, 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.
What's the interest in serialisation?
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)
The Serialisation WT will review and document business and regulatory requirements for serialisation 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
Scope
Supply Chain Boundaries

Manufacture  Distribution  Care Facility

From: Finished Goods  To: End of Treatment

These are the boundaries
Contact details

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The global language of business
www.gs1.org
AIDC Data & Serialisation Work Teams
Deliverables

AutoID Data → Business & Data Reqmt’s → Carriers

Serialisation
Size & Structural Requirements

AIDC Application Standards

Application Standard