Serialization – The Tracking and Tracing of Pharmaceuticals from a Solution Perspective

Leiden, 11. October 2011
Serialization traces the complete lifecycle of a pharmaceutical

Definition Serialization

- Serialization stands for the registration and labeling of pharmaceuticals with a distinctive number
- It enables the complete documentation of the product throughout its complete product lifecycle
- The traceability of the product improves anti-counterfeiting and reduces the danger of economic losses for the producer
- Serialization is induced by country legislation and therefore made mandatory for all pharmaceutical producers and distributors
- Traceability is achieved by the generation of distinctive serial numbers, each of them applied to a particular product package using e.g. data matrix codes or RFID
- The information stored on the package include e.g. batch number, expiry date, serial number and GTIN
Serialization is becoming a mandatory requirement for pharmaceuticals around the world

### Global Serialization Requirements

- **Turkey** is mandating serialization and reporting by December 2011
- **China, Belgium and Italy** are mandating a serial number at each saleable pack today. **France** mandate: December 2010
- **EFPIA** is running a unique coding solution for Europe to perform product authentication at the point of dispensing
- **Spain** issued a Royal Decree mid 2008 and is preparing for showcasing RFID and 2D Data matrix via parallel pilots
- **Serbia** to implement ext. control labels in 2011
- **The European parliament** approved a bill against the counterfeiting of prescribed pharmaceuticals on 16.02.11 which leaves the member states with a period of 24 months for the integration in their legislation
- **Brazil** intends to make serialization mandatory in 2011/12
- **India** will require the serialization of pharmaceuticals of exporting producers within 2011. Producers for the domestic market to follow.
- **California:** The Ridley-Thomas Senate Bill 1307 requires Pharma manufacturers item-level serialized electronic pedigrees by January 1, 2015. Wholesalers and retailers to receive and send item-level serialized electronic pedigrees by **July 1, 2016**
Serialization is to cover the complete supply chain.
Serialization incurs organizational and strategic changes in packaging for manufacturers.

Challenges for pharmaceutical manufacturers:

- Different existing and unpredictable future legal requirements
- Multiple products and manifold serialization requirements
- Manage a heterogeneous solution landscape
- Realization of additional benefits from serialization
- Master changes in organization and packaging
- Serialization
A serialization solution in manufacturing extends from the device to the ERP level.
An integration of product data and business data is crucial for serialization.
Only the close coordination between all levels allows for a seamless serialization

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
<th>Functions</th>
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| 4     | Enterprise Layer | • Production/Packaging Order Generation  
• Enterprise-level Serial Number Repository  
• Central Number Range Mgmt.  
• Rule Setting  
• Analytics and Archiving  
• Security |
| 3     | Auto ID Connector | • ERP Interface  
• Production Order Mgmt.  
• User Mgmt.  
• Web Interface  
• Reporting and monitoring  
• Packaging Recipe Handling  
• Serial Number Handling  
• Export Data  
• Aggregation Management  
• Line Controlling Interface |
| 2     | Line Controller | • Serialization of Pharmaceuticals  
• Data Generation for Packaging Hierarchies  
• Controlling of Level 1 Devices  
• Failure Handling  
• Serial Number Buffering |
| 1     | Devices | • Printing  
• Code Reading and Verification |

Item Level  
Bundle Level  
Case Level  
Pallet Level
## Benefits of Serialization

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<th>Benefit</th>
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<tbody>
<tr>
<td>Improved product safety, mitigating the risk of counterfeiting and safeguarding</td>
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<tr>
<td>Consumers' health and well-being</td>
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<tr>
<td>Streamlined, traceable production and distribution processes enabling cost reductions and minimizing frictional losses</td>
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<tr>
<td>Protection of your brands, your customers and your revenue</td>
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<tr>
<td>Increase in supply chain efficiency and value generation allowing for added business agility and profitability</td>
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Serialization will become more harmonized and integrated along the distribution chain.

### Trends in Serialization Solutions

- **Serialization Templates to provide for harmonized serialization solutions**
- **Downstream integration will grow as legislation will “pick up”**
- **Solution flexibility with regard to legal requirements will prevail**
- **Development of additional functionalities for serialization solutions to increase customer benefit**
Thank You

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