Pharmaceutical Serialisation and Traceability Panelists

- **Scott Mooney (chair)**  
  Vice President Distribution Operations, **McKesson**

- **Carole Laloum**  
  Serialisation Distribution Manager Supply Chain, **Servier**

- **Stefan Artlich**  
  Director “Track&Trace”, **Bayer**

- **Senthil Rajaratnam**  
  Affiliate Serialisation Account Manager, **Eli Lilly and Company**
Servier-GS1 Bogota meeting
1. Introduction
2. Key figures
3. MATRIX scope
4. REX Servier
Changing world of ‘Serialisation’
Servier-GS meeting 11/04/2018

Key Figures _ Serviers Landscape (Serialization)

- **>60** Million patients concerned per day
- **44** Markets with regulations planned
- **60%** Turnover Affected
- **5000** SKU’s
- **50** Internal Packaging Lines
- **8** Servier Sites
- **90** External Partners
- **1** Data Services Cloud
- **>7** Regional Hubs & National Data Bases
3 Business Phases

Production

Centralised database

Local authority database

Verification

Patient

Distribution
COMEX 18/12/17

New ‘end to end’ processes

Data Generation

Data Exchange/ Update

Data Control
Complex Data exchange processes

- MAH for the first reporting
- The owner of product is in charge of the updates
Transversal Impact

MATRIX Program

Industry

Local Authorities

Supply Chain

CMOs

Regulatory Affairs

International Subsidiaries

Purchasing

Partners

IS

Internal Manufacturing Sites

Legal

Servier CDMO

Internal

Servier group

External
Many new IS interfaces to be validated & maintained
Organisational impact

**IMPACTED**
2000+ people
- Head Office (IS, WRA, Promo, Supply Chain, Industrie)
- 8 Production sites
- 44 Subsidiaries & Offices, Ext. manufacturing & distribution partners, Customers

**IMPLICATED**
40 people
- Sponsors, mentors, Business Leader, Key users, change, RH, QA, Local Reg. Affairs

**COMMITTED**
16 Core Team
- Domain Leaders, WRA, Business Experts, Project Managers
Key reminders

1. Complexity is increasing and deadlines are shortening

2. The business stakes are high

3. Company wide transverse impact

4. Internal communication, to embark key stakeholders is critical.
Thank you
Pharmaceutical Traceability

Bayer’s learnings from around the world

Bogota /// 11 April 2018 ///
Dr. Stefan Artlich
A growing and aging world population requires an adequate supply of food and improved medical care. Our research and development activities are therefore focused on improving people’s quality of life by preventing, alleviating and treating diseases. At the same time, we are making an important contribution to providing a reliable supply of high-quality food, feed and plant-based raw materials. Our understanding of the biochemical processes in living organisms helps us address these demanding challenges.

Our Purpose: “Science for a better life”
Our Business Areas

**Pharmaceuticals**
- Prescription drugs

**Consumer Health**
- Over-the-counter medicines, dietary supplements, dermatology products, foot care and sunscreen

**Crop Science**
- Innovative crop protection and seeds
- Animal Health
EU-FMD @ Bayer: Implementation Footprint

// Ensure technical readiness of 100+ parties
// Approx. 10 Bayer-owned manufacturing sites, 50+ packaging lines
// 50+ Contract Manufacturers (CMOs)
// Approx. 15 Bayer-operated warehouses
// 25+ Distribution Partners (3 PLs)
// ## Customers where Bayer acts as Contract Manufacturer (CMO)

// Establish serialization data exchange with all CMOs and Customers
// Establish exchange of regulatory and serialization data with European Hub
// Establish new / revise existing business processes for e.g. pack decommissioning, complaint handling, batch recall

// Execute change process incl. regulatory submission for approx. 4,000 products (Stock Keeping Units (SKUs))

// Be ready by February 2019
Serialization @ Bayer: Implementation Challenges

Large Variety of Packaging Dimensions

Bayer Standard

// One-flap printing
// Inline print
// 4 lines of human-readable text
// Prefixes printed inline

Variants

// Two-flap printing
  // Product code, S/N, and DMC on one flap
  // Batch and Expiry Date on other flap
// Product code printed in primary print
// Prefixes printed in primary print

In total, 10+ different printing schemes apply for Europe
Serialization @ Bayer: Implementation Challenges

Large Variety of Packaging Dimensions

Size: 30 x 22 x 92mm
1.18 x 0.87 x 3.62 inches
Weight: 5g ~ 0.011lbs
+ packaging material

Print Height DataMatrix Code
12 mm ~ 0.47 inches

Scheme: 2 flap inline printing

Size: 400 x 300 x 220mm
15.7 x 11.8 x 8.7 in
Scheme: Serialized stickers
Serialization @ Bayer: Implementation Challenges

Inline Printing at Medium-Speed and High-Speed Lines (up to 320 pcs./min.)
Serialization @ Bayer: Implementation Challenges

Maintenance of Product Codes (GTINs / NTINs)

As-Is Status

GTINs / NTINs assigned by Bayer’s country organizations / authorities / nat’l master data registrars
GTINs / NTINs (in short: GTINs) are part of artwork and printed in primary print
Correctness is checked upon approval of layout mockups

To-Be Status

Design decision: GTINs assigned centrally via automated process
GTINs are encoded in 2DMC; 2DMC and human-readable information is printed inline
Thus, existing GTINs must be entered into SAP Master Data

Challenge

How to ensure error-free entry of existing GTINs (e.g. 4.000 for EU) in SAP Product Master Data?
Who in organization is willing to do necessary 100% checking?

Risks: Errors only detected …

Either during production via in-process controls → termination of batch execution, disturbance in production schedule
Or in country at the Point-of-Sales when wrong product is displayed to pharmacist → market supply at risk, sales loss
Serialization @ Bayer: Implementation Challenges
Steps Towards Readiness for Requirements of Another Country

Nominate Country Project Manager

Describe Scope

// Translate country reqs. into implementation reqs., clarify missing details with Country Reg. Affairs manager
// Highlight particularities w.r.t. e.g. code content (new (AI) ?), reporting, business processes to be revised
// Determine (i) products in scope, (ii) affected own supply centres, (iii) affected Contract Manufacturers (CMOs)
// Consider upcoming manufacturing transfers, launches, and product withdrawals

Pitfalls in Implementation (Examples)

// Packaging line not ready for serialization or aggregation (in particular if OTCs are in scope) → 12-15 months
// New CMO in scope → up to 24 months
// New Application Identifier (AI) required → 6-9 months
// Usage of 2D code other than GS1 DataMatrix code → 12-18 months
// Execute change per each SKU → 9+ months
// Reporting interface to be built → 6+ months (clock starts after publication of interface specs. !)
// Requirements on 3rd Party Logistics Providers (3PLs) → 18-24 months
// Packaging transfer to new supplier including regulatory re-submission → ## months or years
Thank you!
Lilly Snapshot

- A heritage 140 years strong: founded May 10, 1876
- Headquarters located in Indianapolis, Indiana, U.S.A.
- Approximately 41,000 employees worldwide
- More than 8,000 employees engaged in research and development
- Clinical research conducted in more than 55 countries
- Research and development facilities located in six countries
- Manufacturing plants located in 13 countries
- Products marketed in 120 countries
Packaging Sites

- ALCOBENDAS
- FEGERSHEIM
- SESTO
- SUZHOU EAST LAKE
- MORUMBI
- INDIANAPOLIS
- SEISHIN

14 Contract Manufacturers impacted by serialization
55 packaging lines globally
~ 2000 SKUs Globally Impacted by Serialization
Currently, there are two types of traceability models that have been implemented in countries that have legislations in effect for product verification and traceability. Those models are:

1. **Point of Dispensing Verification**

2. **Track and Trace**
Model 1: Point of Dispensing Verification

1) MAH reports commissioned serial numbers to the EU hub
2) EU Hub Routes Data to the National Databases

Note: There is no reporting or tracing of movement throughout the supply chain in this model.
Model 2: Track and Trace with a national system

1) Manufacturer reports commissioned serial numbers to the national system
2) Each downstream supply chain entity reports their movement of serial numbers

Product Movement

Manufacturer -> Wholesaler -> Distributor -> Pharmacist

Data Movement

1) Pharmacies report serial numbers received
2) Patients may (country dependent) self-verify serial numbers
Lilly’s approach

<table>
<thead>
<tr>
<th>Single Technical Solution</th>
<th>Data Management</th>
<th>Operating in a Serialized State</th>
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</thead>
<tbody>
<tr>
<td>• Single technical solution, centrally supported, locally operated.</td>
<td>• Central serial number repository.</td>
<td>• Modify existing systems at Lilly to handle serialized products.</td>
</tr>
<tr>
<td>• Prioritized based on market deadlines.</td>
<td>• Utilize enterprise system for Lilly produced data.</td>
<td>• New lines will be built with serialization integrated.</td>
</tr>
<tr>
<td>• Aggregate at the case and pallet level, even if not required by the market.</td>
<td>• Utilize a data broker for contract manufacturer produced data (feeding into Lilly enterprise).</td>
<td>• Warehouse Management systems designed to work with serialization processes.</td>
</tr>
<tr>
<td></td>
<td>• Utilize a data broker for transmitting to downstream partners and MoH systems.</td>
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</tr>
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Best Practices

- Single global solution helped in consistency of processes and provided efficiency in managing changes for new markets and software updates.

- Built a pilot packaging line during the initial stages of the program which tremendously helped in the quick deployment at the packaging sites. New recipes/classes are built, tested and qualified on the pilot line first which minimized the line down time at the packaging sites during implementation.

- Took a broader approach and integrated serialization from level-1 through level-5 systems and made sure serialization is incorporated to all the processes starting from the packaging line all the way to the distribution warehouse in a streamlined fashion.

- Traceability is one of the few initiatives in the company that is very cross-functional, impacting multiple organizations and spanning through multiple geographies. All the departments starting from manufacturing, warehousing, distribution and affiliate supply chain had to go through an OCM (Organizational Change Management) to incorporate serialization and traceability into their business processes.
Lessons learnt

• Requirements that deviate from GS1 standards creates a huge impact to the serialization solutions and takes lot of time and effort to implement. Deviating from a harmonized approach also creates implementation challenges.
  – Here are a few examples:
    • Specific order mandated for printing human readable text
    • Specific order to encode data in the 2D barcode
    • Inclusion of new application identifiers such as AI 240, AI 27

• Early engagement in advocacy efforts, first of all within the company and also with industry and regulators could help shape up the future regulations to be harmonized and align with GS1 standards.
Questions & Answers
Networking Dinner on Wednesday, 7:00 pm

ANDRÉS D.C.
Calle 82 #12-21 Dentro del centro comercial
El Retiro, Bogotá

Meet in the main lobby for shuttle bus departure:
6:30 pm

**Bus departure:** in the main lobby at 6:30 pm
**Bus return:** beginning at 9:30 pm until 12:00 am, running on a loop
**Dress code:** business casual.

**PLEASE WEAR YOUR EVENT BADGE 😊**