



The Global Language of Business

Pharmaceutical Serialisation and Traceability

Panel Discussion

Wednesday 11th April 2018 - 14:15 – 15:30

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**



Mark, Aggregate, Track, Report for International eXchanges



Servier-GS1 Bogota meeting

Agenda



4

1. Introduction
2. Key figures
3. MATRIX scope
4. REX Servier



The diagram illustrates the timeline of DSCSA implementation from 2016 to 2022. It features a central horizontal timeline with boxes for each year. Above the timeline, key regulatory milestones are marked with arrows pointing to specific years. Below the timeline, specific regulatory actions for the USA and Russia are noted with arrows pointing to their respective years.

- 2016:** Europe 9 Feb 2016 Delegated Acts Safety Features Adopted! (indicated by an upward arrow from the 2016 box to the text).
- 2017:** USA New 2017 DSCSA - Serialised product identity (indicated by a downward arrow from the 2017 box to the text).
- 2018:** Russia Q3 2018 Serialisation requirement for a selection of products (indicated by a downward arrow from the 2018 box to the text).
- 2019:** Europe Feb 2019 Implementation FMD Safety Features (Delay until 2025 for Italy, Belgium, Greece) (indicated by an upward arrow from the 2019 box to the text).
- 2020:** Note: Greece and Belgium announced extension to be EU FMD-compliant from 2021 (indicated by a downward arrow from the 2020 box to the text).
- 2021:** (No specific event noted).
- 2022:** (No specific event noted).

Additional context from the slide:

- Timeline:** 2016, 2017, 2018, 2019, 2020, 2021, 2022
- Key Milestones:**
 - 2016: Europe 9 Feb 2016 Delegated Acts Safety Features Adopted!
 - 2017: USA New 2017 DSCSA - Serialised product identity
 - 2018: Russia Q3 2018 Serialisation requirement for a selection of products
 - 2019: Europe Feb 2019 Implementation FMD Safety Features (Delay until 2025 for Italy, Belgium, Greece)
 - 2020: Note: Greece and Belgium announced extension to be EU FMD-compliant from 2021
- Timeline Label:** DSCSA extension



Key Figures _ Serviers Landscape (Serialization)

6



Million
patients
concerned
per day



Markets
with
regulations
planned



Turnover
Affected



SKU's



Internal
Packaging
Lines



Servier
Sites



External
Partners



Data
Services
Cloud

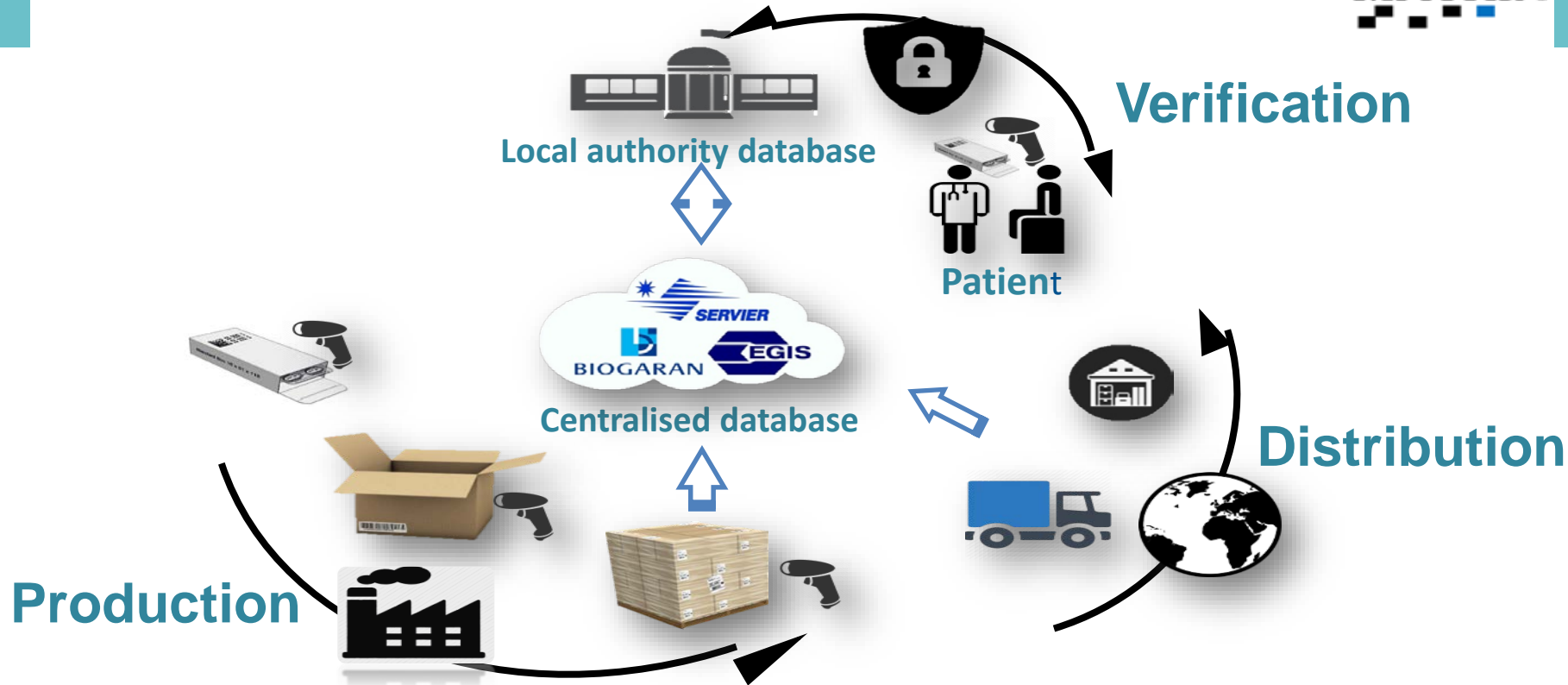


Regional
Hubs &
National
Data Bases

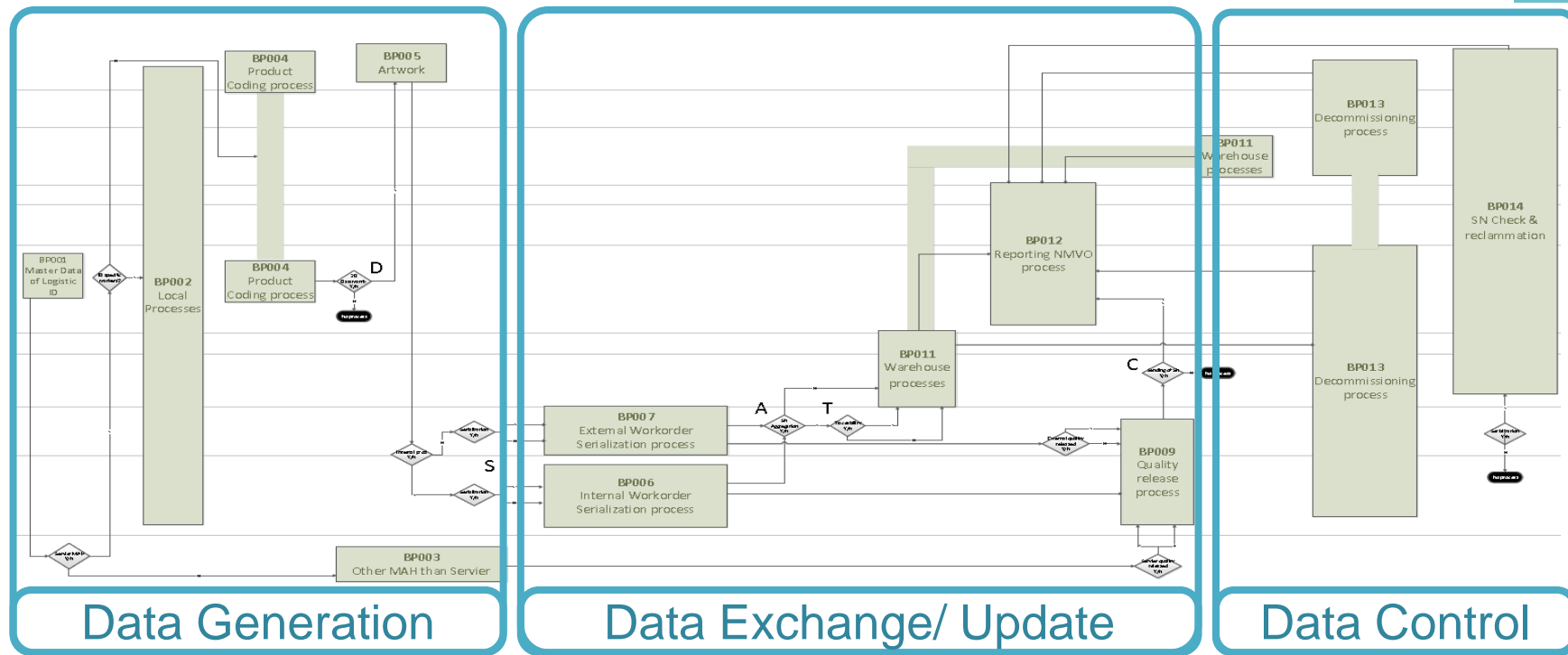
3 Business Phases



7

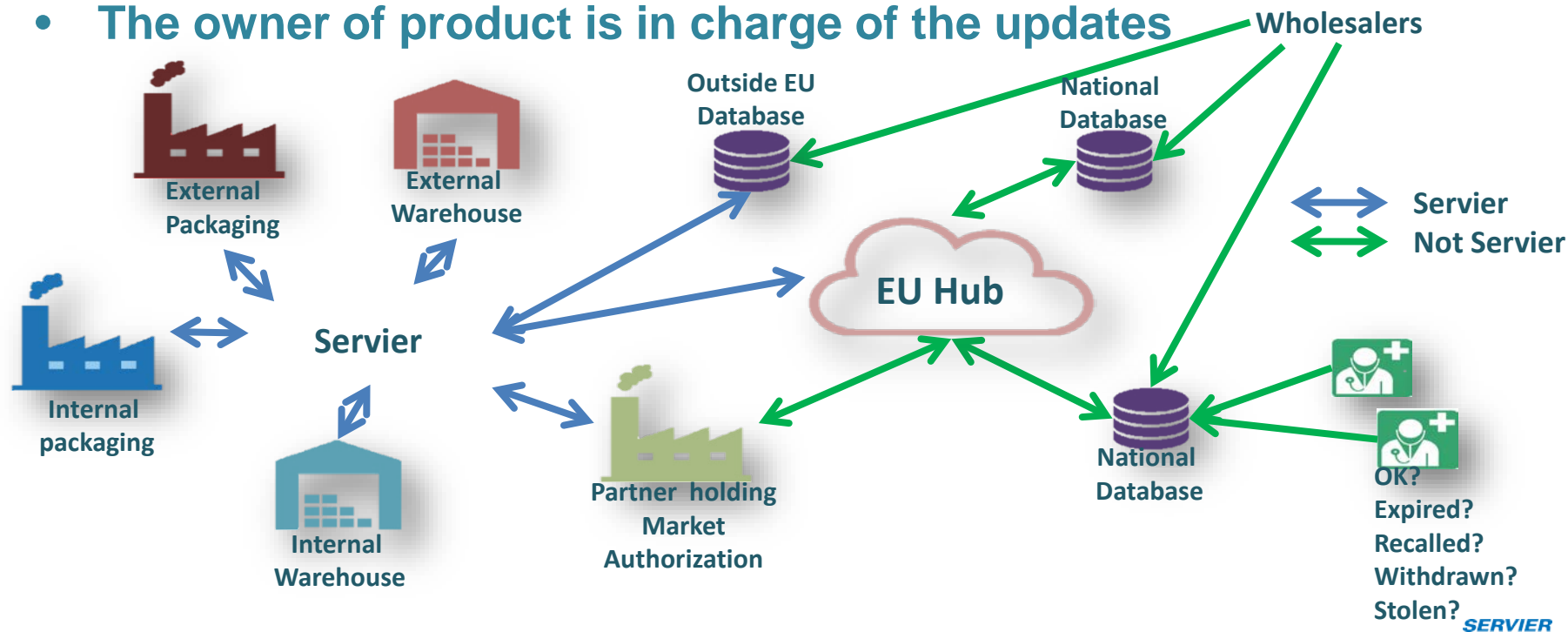


New 'end to end' processes



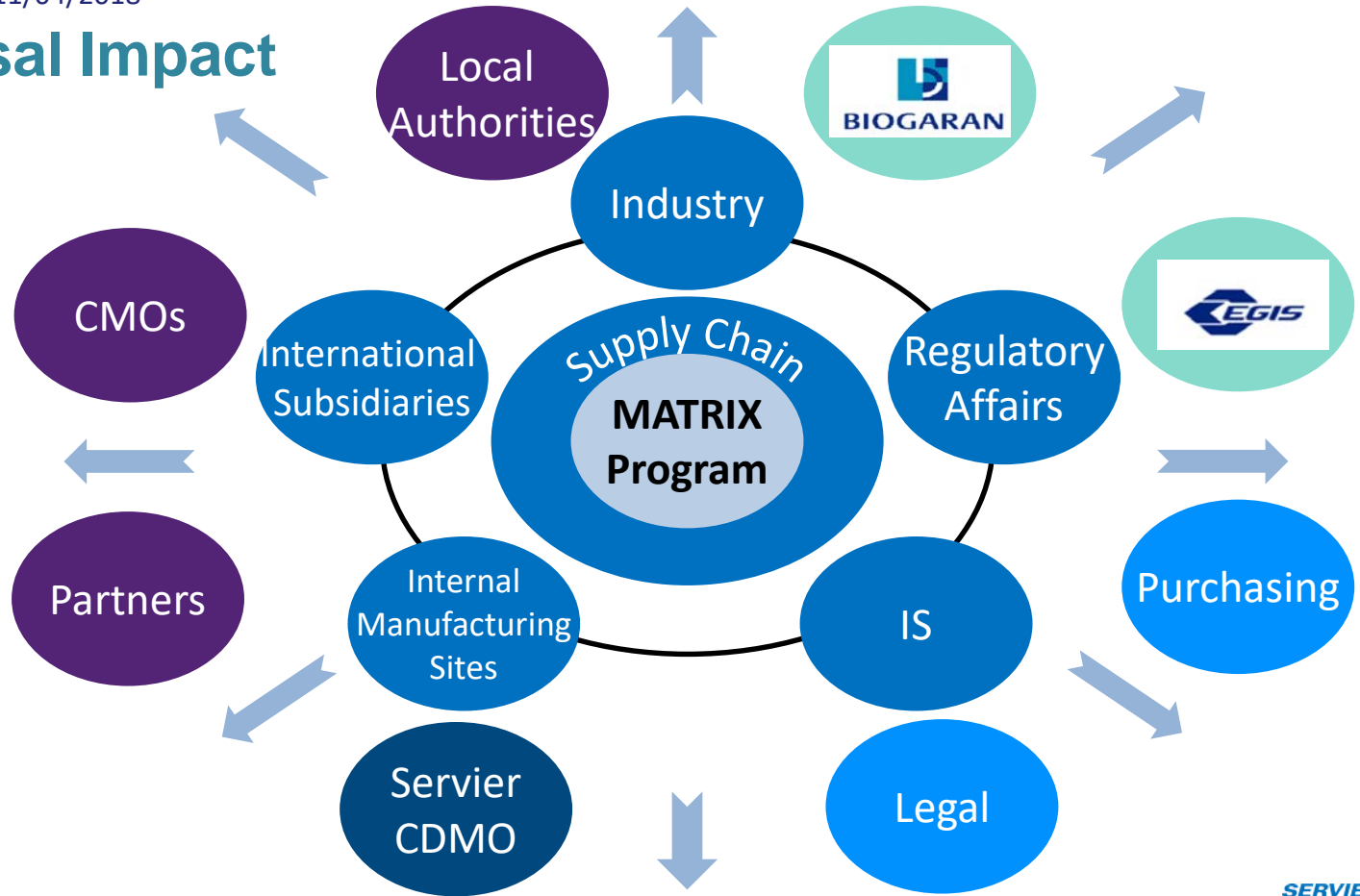
Complex Data exchange processes

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



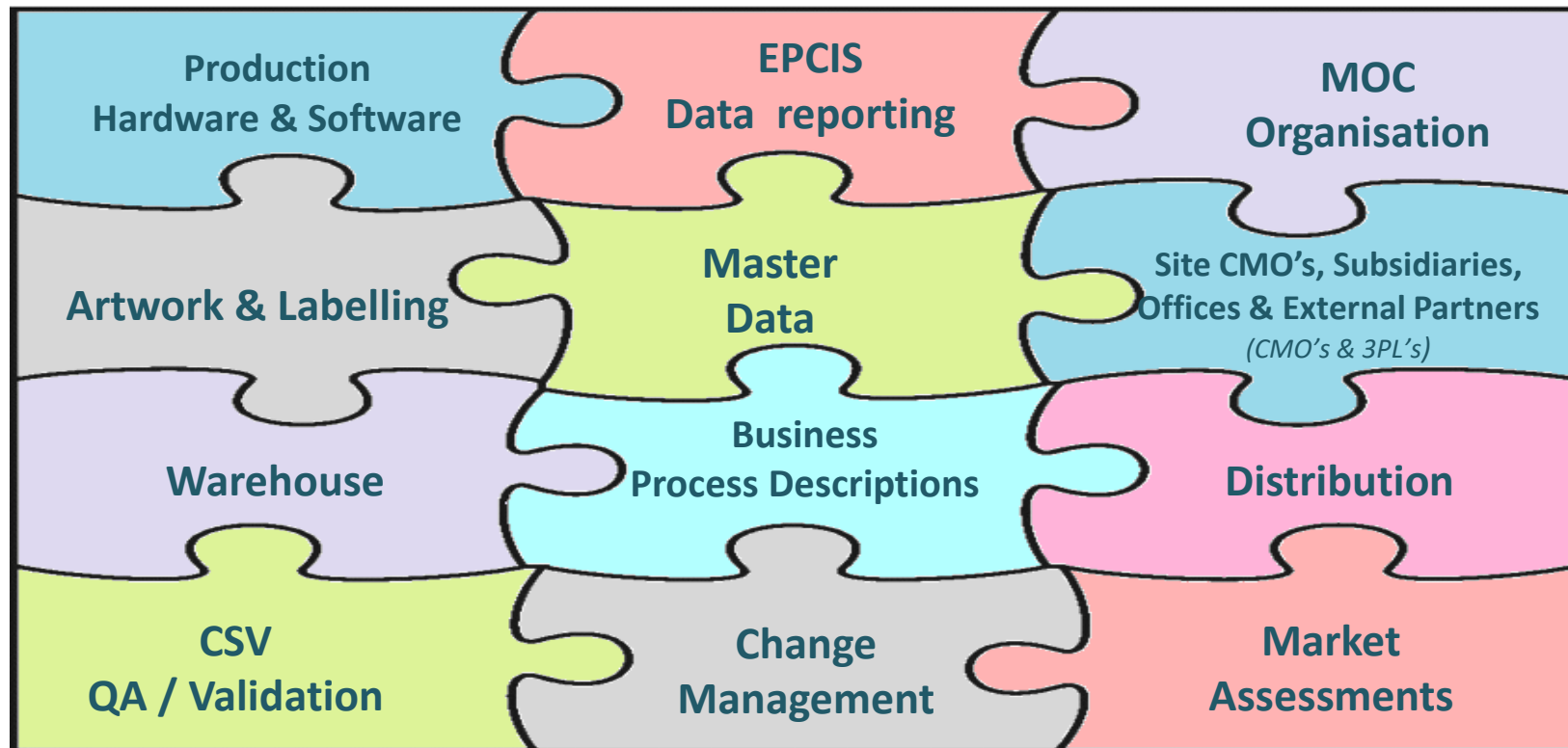
Transversal Impact

10

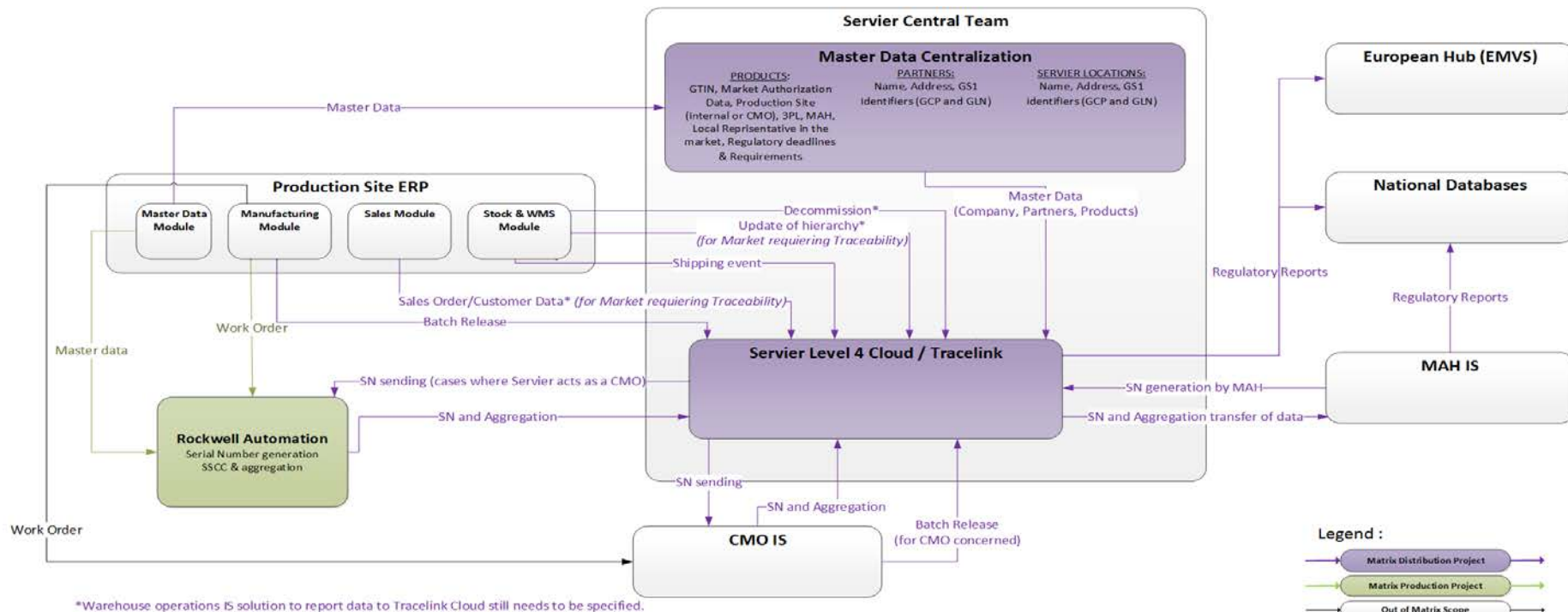


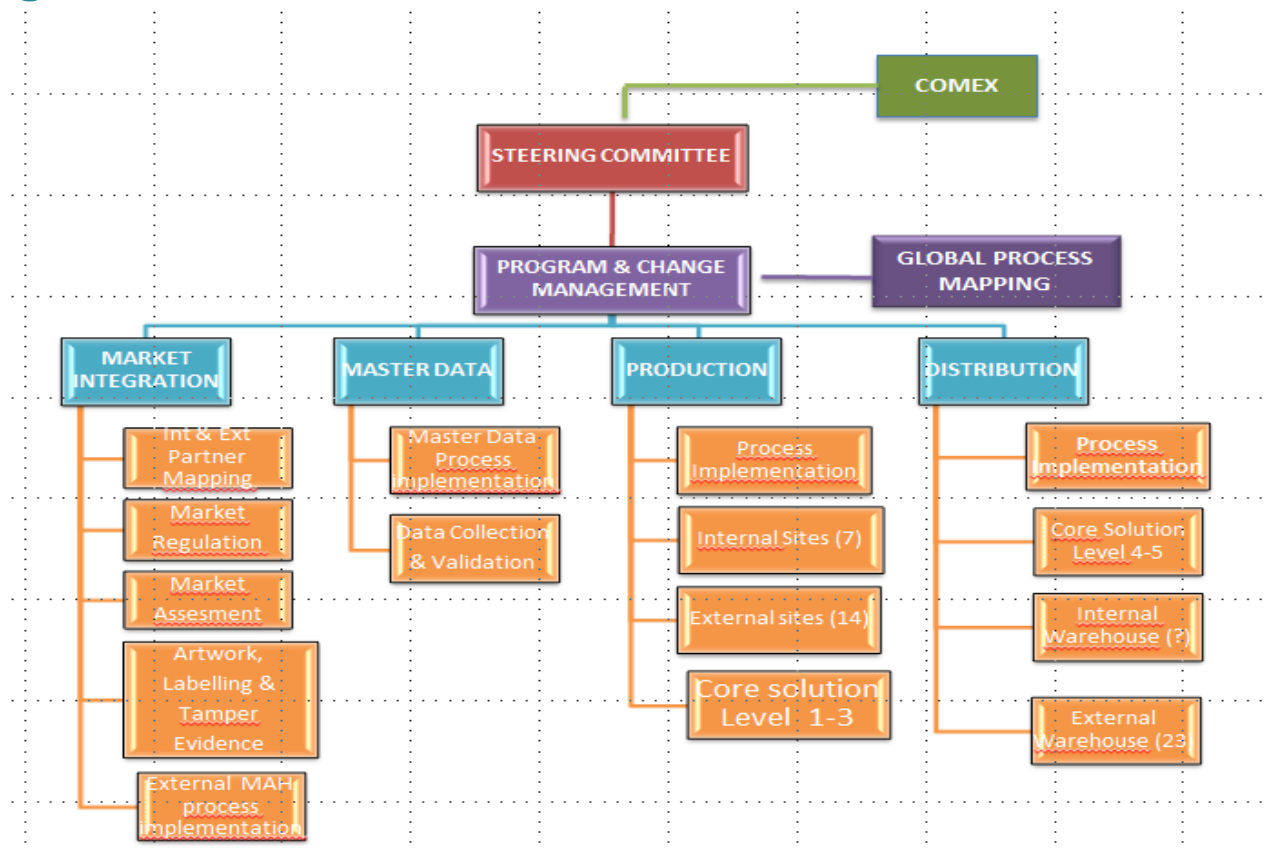
- Internal
- Servier group
- External

MATRIX Scope



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





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

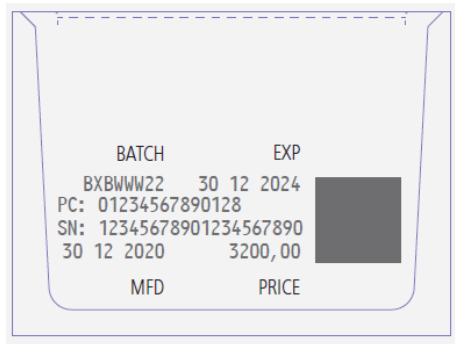
Bayer Standard

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

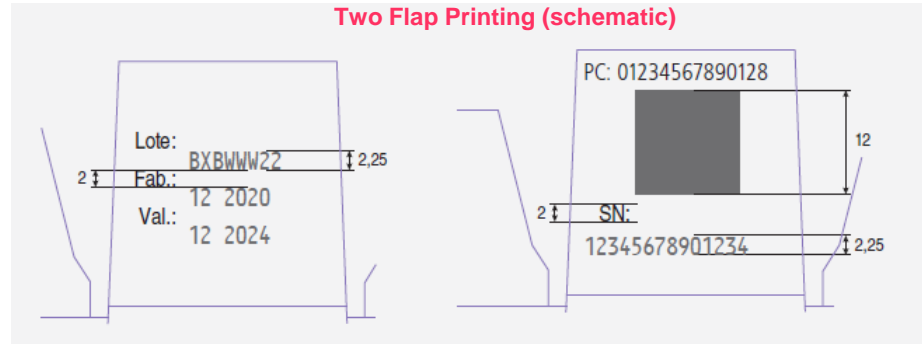
Variants

- // 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



Two Flap Printing (schematic)





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 registers
- // 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

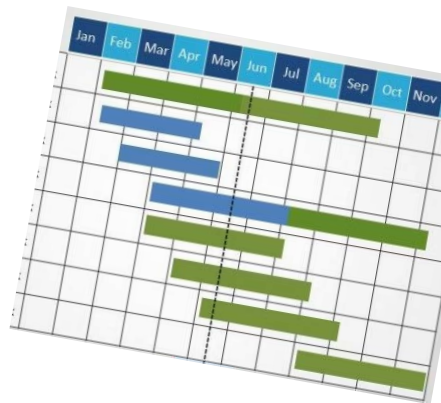
Nominate Country Project Manager

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)

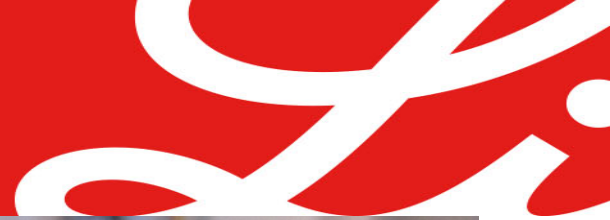
- // Packaging line not ready for serialization or aggregation (in particular if OTCs are in scope) → 12-15 months
- // New CMO in scope → up to 24 months
- // New Application Identifier (AI) required → 6-9 months
- // Usage of 2D code other than GS1 DataMatrix code → 12-18 months
- // Execute change 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

Global Serialization Program

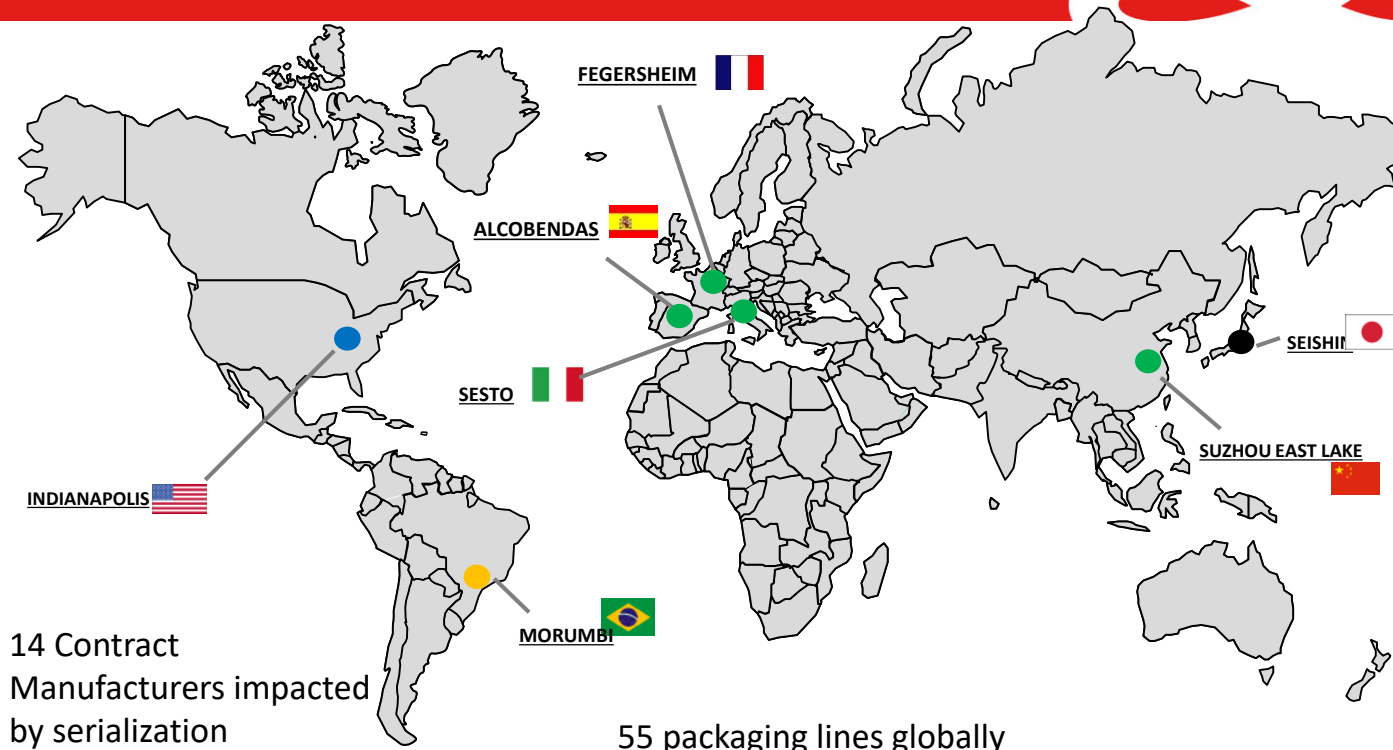


Lilly Snapshot

- 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



Traceability Models overview

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:

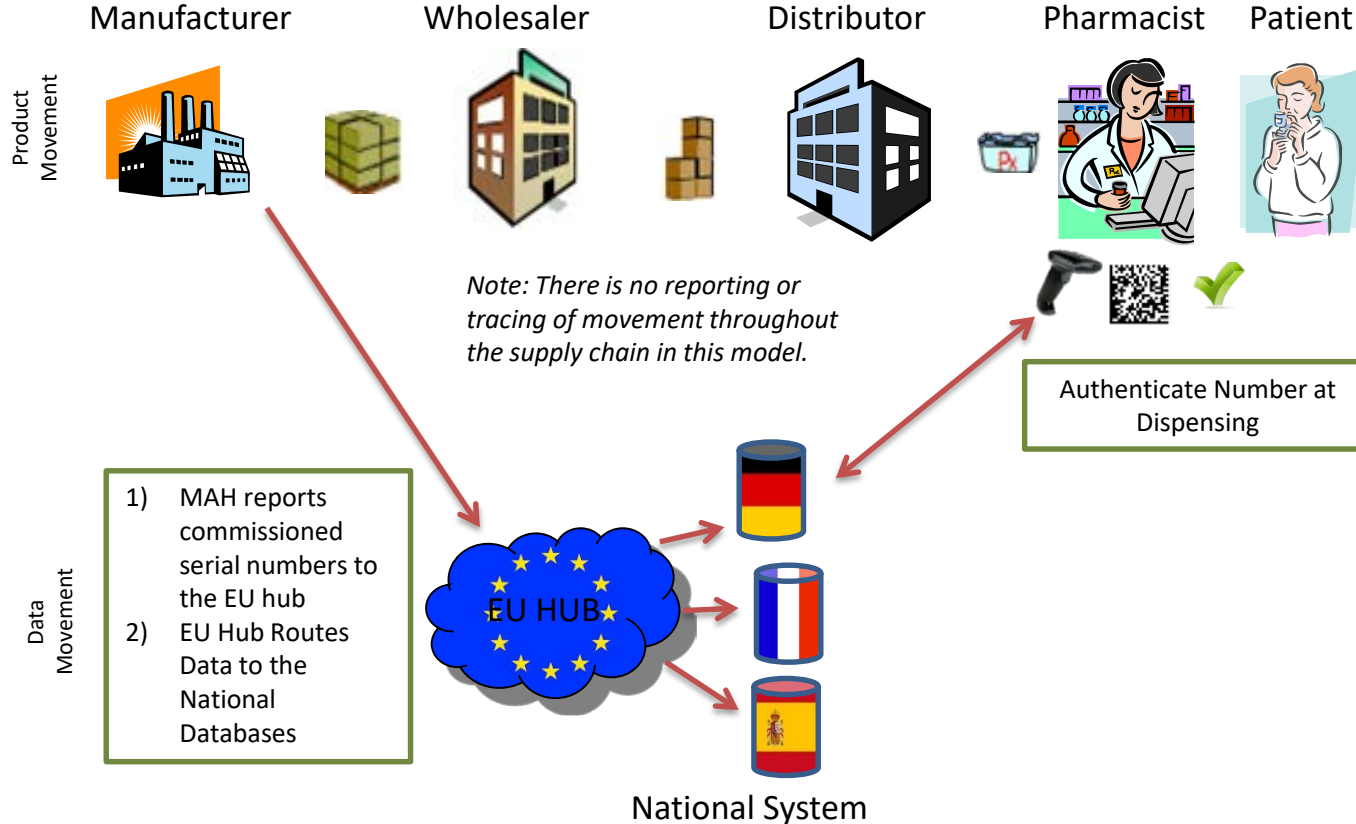
1. Point of Dispensing Verification



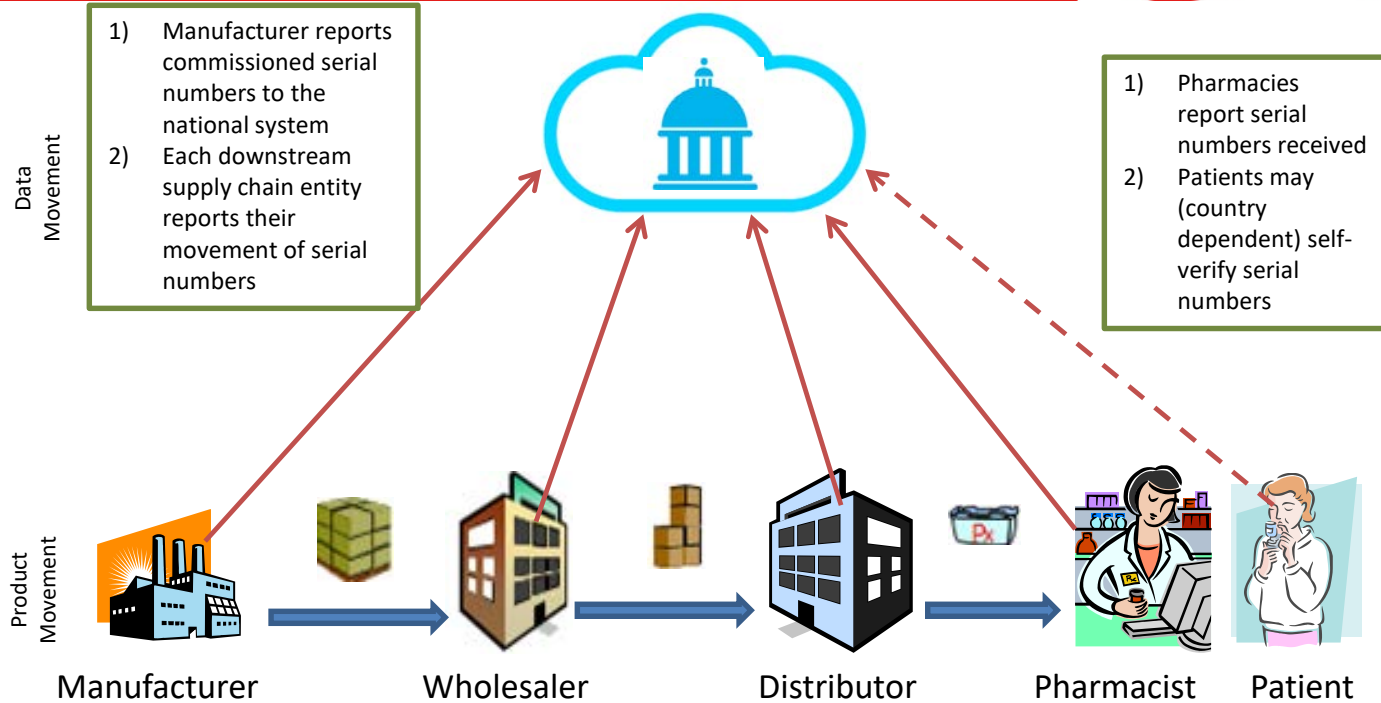
2. Track and Trace



Model 1: Point of Dispensing Verification



Model 2: Track and Trace with a national system



Lilly's approach

Single Technical Solution

- Single technical solution, centrally supported, locally operated.
- Prioritized based on market deadlines.
- Aggregate at the case and pallet level, even if not required by the market.

Data Management

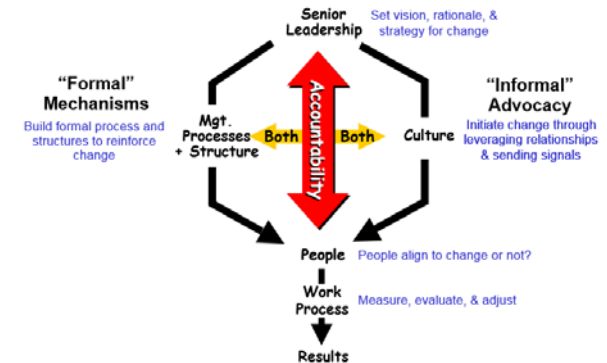
- Central serial number repository.
- Utilize enterprise system for Lilly produced data.
- Utilize a data broker for contract manufacturer produced data (feeding into Lilly enterprise).
- Utilize a data broker for transmitting to downstream partners and MoH systems.

Operating in a Serialized State

- Modify existing systems at Lilly to handle serialized products.
- New lines will be built with serialization integrated.
- Warehouse Management systems designed to work with serialization processes.

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.





A word cloud featuring the phrase "thank you" in numerous languages, arranged in a circular pattern. The words are in various colors and sizes, with "thank you" being the largest and most central. The languages include:

- danke
- 謝謝
- ngiyabonga
- tesekkür ederim
- gracias
- tapadh leat
- hvala
- asante
- manana
- obrigada
- murakoze
- tenki
- chokrane
- maith
- agat
- arigatō
- takk
- dakujem
- merci
- euχαριστώ
- xiexie
- 감사합니다
- terima kasih
- rahmah
- rahmet
- tanemirt
- kop khun krap
- gracias
- gratias ago
- chnorakaloutioun
- sukriya
- sagolun
- mes
- didi madloba
- kam sah hamnida
- tosake shlyabad
- obrigado
- bedankt
- enkosi
- bayarlalaa
- nandri
- kiitos
- dankie
- dhanyavad
- hvala
- maururu
- köszönöm
- spas
- wellalin
- tack
- dank je
- misaotra
- matondo
- paldies
- grazzi
- malalo
- chokrane
- maith
- agat
- arigatō
- takk
- dakujem
- merci
- euχαριστώ
- xiexie
- 감사합니다
- terima kasih
- rahmah
- rahmet
- tanemirt
- kop khun krap
- gracias
- gratias ago
- chnorakaloutioun
- sukriya
- sagolun
- mes
- didi madloba
- kam sah hamnida
- tosake shlyabad
- obrigado
- bedankt
- enkosi
- bayarlalaa
- nandri
- kiitos
- dankie
- dhanyavad
- hvala
- maururu
- köszönöm
- spas
- wellalin
- tack
- dank je
- misaotra
- matondo
- paldies
- grazzi
- malalo

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 9:30pm until 12:00am,
running on a loop

Dress code: business casual.

PLEASE WEAR YOUR EVENT BADGE 😊

