The Global Language of Business

Pharmaceutical Traceability – learnings from around the world

Panel Discussion

Chaired by Mr. Senthil Rajaratnam, Affiliate Serialization Account Manager, Eli Lilly and Company, U.S.

Mr. Lloyd Mager, Global Traceability Lead, AbbVie, U.S.

Mr. Pascal Aulagnet, Senior Manager, Global Serialization - EMEA Client Partner, Pfizer, France

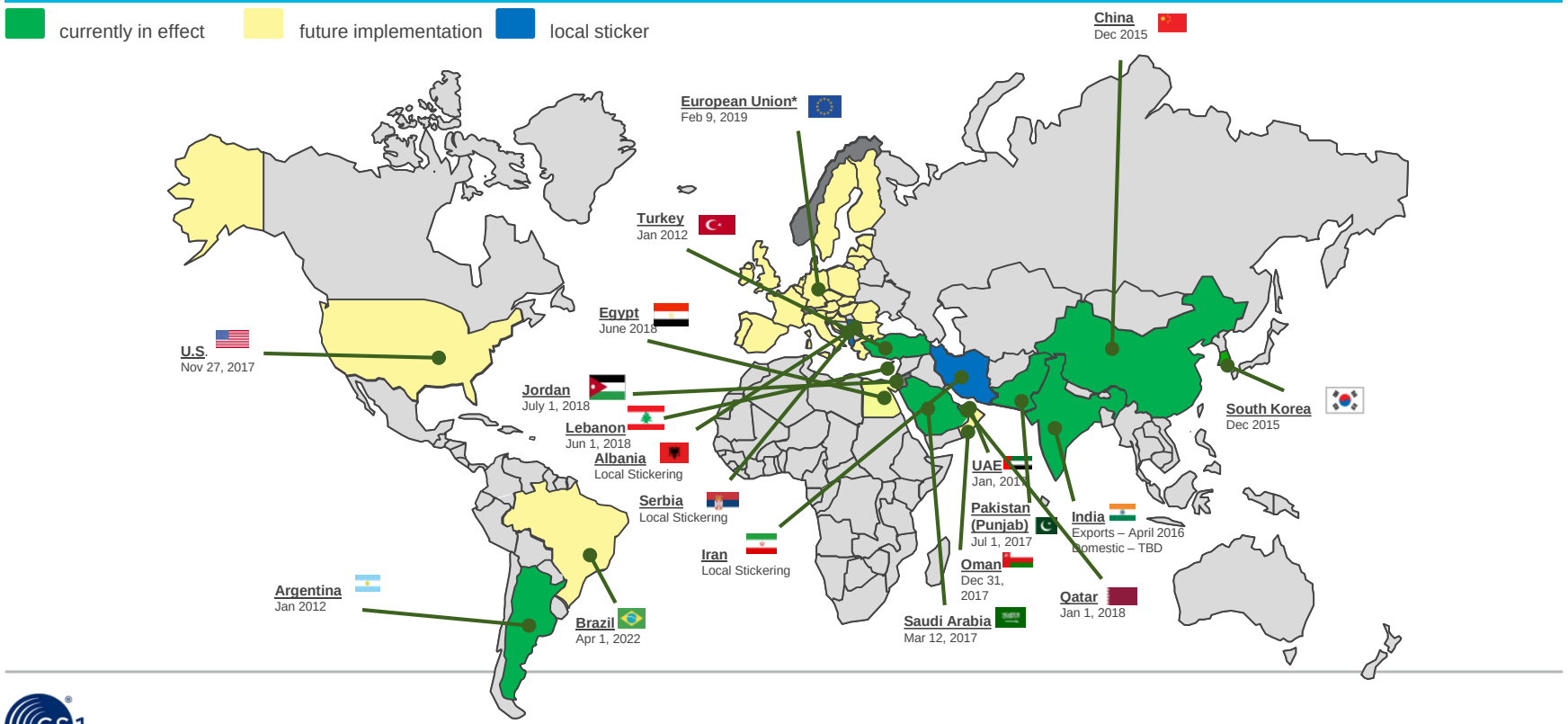
Mr. Stefan Artlich, Director, Track & Trace, Bayer, Germany

18 October 2017

Pharmaceutical Traceability – Learning from around the world

- Lilly, AbbVie, Pfizer and Bayer will present their approach to traceability from a manufacturer's perspective
- They will share their experiences, best practices, lessons learnt and offer advice for traceability implementation.
- The discussion will be chaired by Mr. Senthil Rajaratnam, Affiliate Serialization Account Manager, Eli Lilly, U.S.
- Panelists:
  - Mr. Lloyd Mager, Global Traceability Lead, AbbVie, U.S.
  - Mr. Pascal Aulagnet, Senior Manager, Global Serialization - EMEA Client Partner, Pfizer, France
  - Mr. Stefan Artlich, Director, Track & Trace, Bayer, Germany

Global Serialization and Traceability Landscape




Lilly
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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

14 Contract Manufacturers impacted by serialization

55 packaging lines globally

~2000 SKUs Globally Impacted by Serialization

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

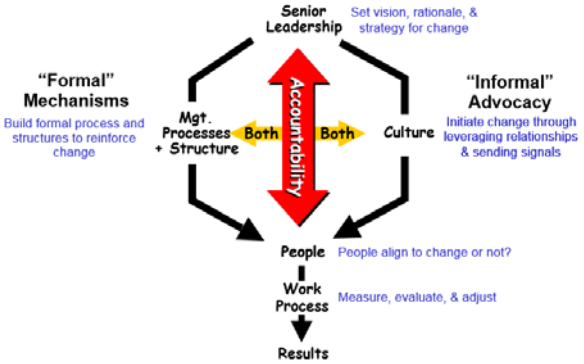
- Central serial number repository.
- Utilize enterprise system for Lilly produced data.
- Utilize a data broker for contract manufacturer produced data (feeding into Lilly enterprise).
- Utilize a data broker for transmitting to downstream partners and MoH systems.

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 throughlevel-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.

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The Global Language of Business

Pharmaceutical Traceability – learnings from around the world
GS1 Global Healthcare Conference - Chicago
An Industry perspective

Lloyd Mager, Global Traceability Lead, AbbVie

18 October 2017

Traceability Approach

- Serialize all products prioritized by market to assure continuity
  - Package line technology to serialize and aggregate where feasible
  - Third party collaboration
  - SKU conversion
- Distribution readiness
  - DC technology
  - 3PL collaboration
- IT System
  - Serial number generation and management at the enterprise level
  - System of record
- Quality System Integration

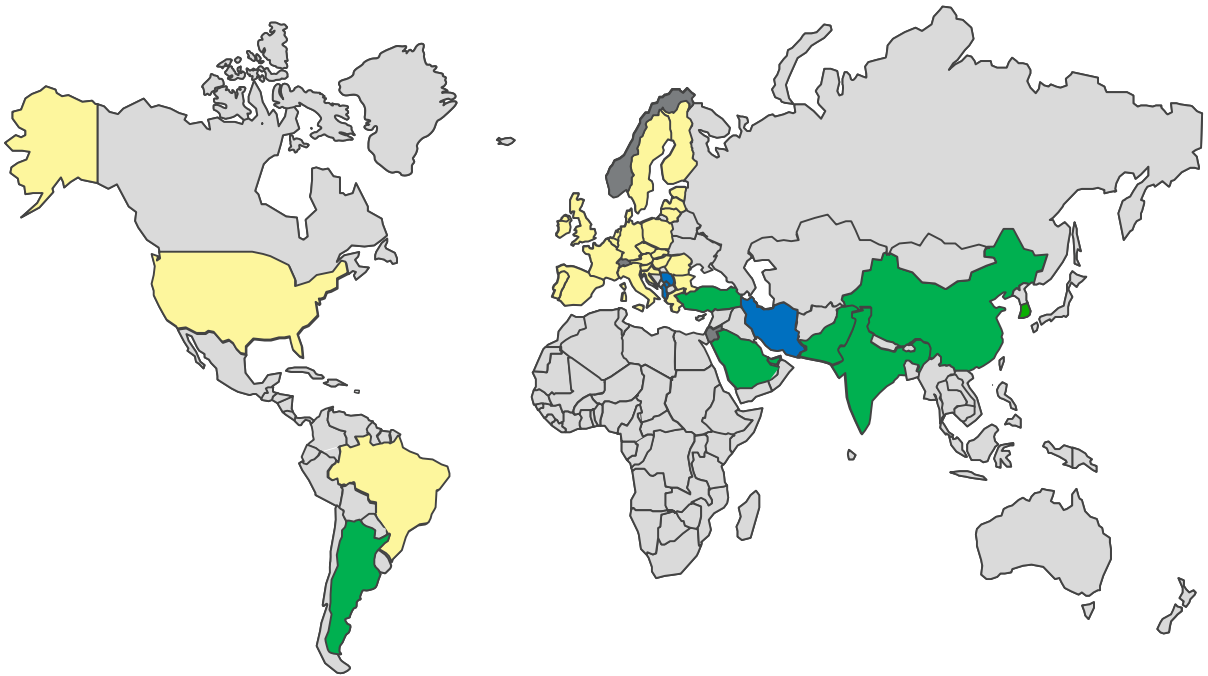
Experiences

- Executive buy in and understanding was ongoing and very important
- Standards were developed and leveraged in limited application
  - Identify, capture, share
- Consultants were learning but helped rationalized best practices
- Customer alignment on interoperability is significant and continues
  - Inference impact and risk yet to be rationalized
- Master data solutions needed to be addressed
- Third party technology service providers were overwhelmed
  - Solutions were not as configurable or flexible as needed
  - Created solutions without direction or full understanding

Lessons Learned

- This is a new paradigm and we are all continuing to learn
  - Make strategic decisions and move forward
- An operational impact was realized in multiple organizations
  - Process rationalization and change is significant
- A *“Digital Supply Chain”* emerged
  - Data integrity is critical
- Collaboration and communication with trade partners needs to continue to achieve interoperability
  - Inference practices must not create risk for patients who need the medicines they depend on

AbbVie is Serializing 100% of it's Product to Protect Patients in All Parts of the World



- Verification services can be provided to everyone through mobile applications
- "Share" Standards need additional development to achieve interoperability

Thank You

Pharmaceutical Traceability – learnings from around the world

Pfizer Global Serialization Program

GS1 Global Healthcare Conference - Chicago

Pascal Aulagnet, Senior Manager Business Technology, **Pfizer Inc**

18th of October 2017 - Chicago

Disclaimer: *This presentation outlines a general technology direction. Pfizer Inc. has no obligation to pursue any approaches outlined in this presentation or to develop or use any functionality mentioned in this presentation. The technology strategy and possible future developments are subject to change and may be changed at any time for any reason without notice.*

The views and opinions expressed in this presentation and any related discussion(s) are solely those of the individual presenter(s) and may not express the views of and opinions of Pfizer Inc.

Company Overview

- $52.8 Billion in revenue
- 96,000+ employees
- 63 Internal Manufacturing Plants
- ~ 450 Contract Manufacturers
- ~ 13,000 Supply Partners
- 850+ major product groups
- 25,000+ SKUs
- Diverse Operating Units covering key product areas such as:
  - Bio Pharmaceuticals
  - Vaccines
  - Solid Oral Dose
  - Aseptic
  - Sterile Injectables
  - Consumer Healthcare

Serialization Footprint

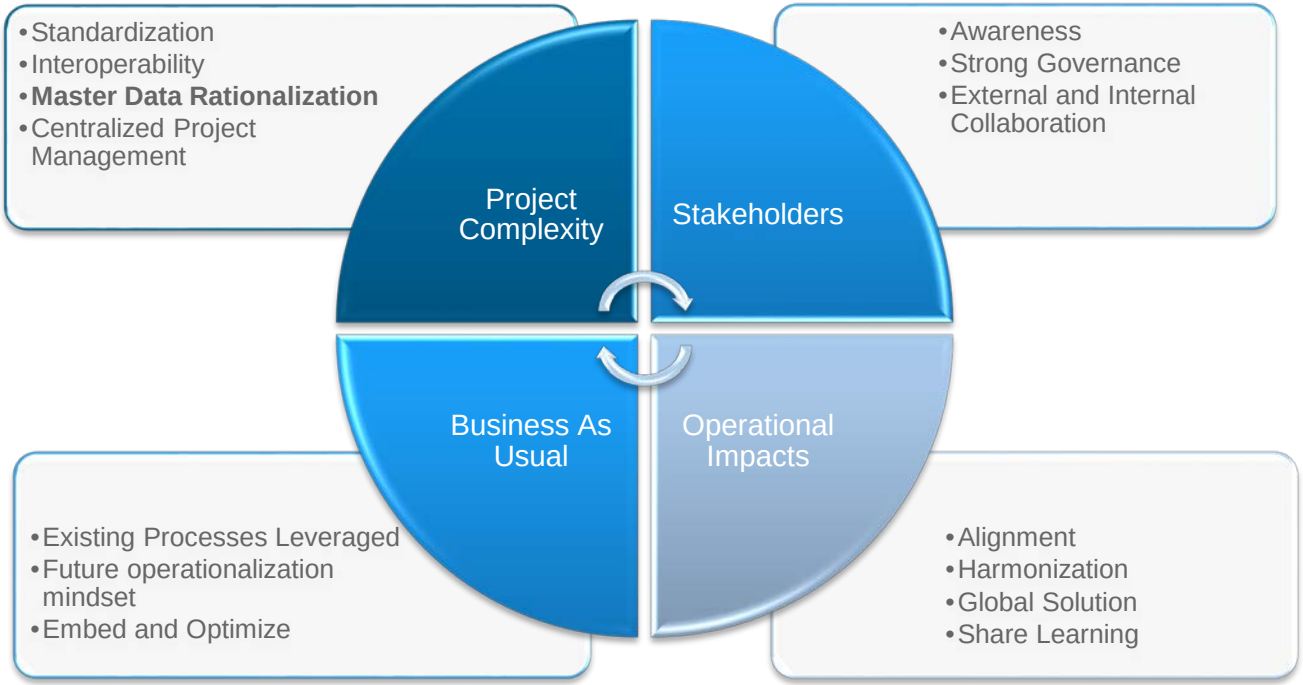
	NETWORK SCOPE	INCREASE IN SCOPE (CURRENT)
Supply	PGS LINES	50%
	ES LINES	42%
	SSPs	100+ %
Logistics	Plant Warehouse	45%
	LSPs & DCs	100+ %
	Trading Partners	100+ %
Compliance	Regional Mandates	43%
	SKUs	33%
BT	Deployments	100+ %
	Interfaces/Instances	30% / 100+ %
	Stored Transactions	30%

46% increase in Total Number of Packaging Lines

400+ Deployments in current scope

5+ Government Reports

Challenges and Lessons Learned



Serialization “Master” Data Consumption

SOURCE
Data is cleansed, collected and governed

MANAGE
Data is centralized and prepared Serialization operations

USE
Data is leveraged by many business functions

Mandates and Operational Needs

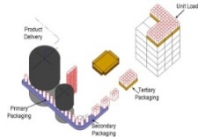
Maintained in various tools: Excel, SAP, …)

Corporate Systems

Manufacturing Systems

SME Knowledge

Product - ***~40 elements per SKU*** Used to provide unique identifiers and attributes required for Track and Trace capability
Location Standard to identify Company, Functional entities and Physical locations
Customer – ***direct or dropships (US)*** Used to provide unique identifiers, address, and other attributes for Trading Partners/ Customers
Lines – ***~40 elements per Line*** Information used to configure line level data for packaging operations
Miscellaneous MD Metadata required in support of serial number management, mandates, reporting, etc



Operational Systems

SCT

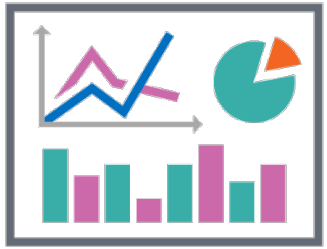
- External
- Government Reporting
- CMOs
- Distributors
- Customers
- National Databases

Warehouse Operations


thank you!

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

Science For A Better Life

Pharmaceutical Traceability – Bayer’s learnings from around the world

Subheadline

Chicago 18 October 2017 / Dr. Stefan Artlich

Our Mission
Bayer: 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

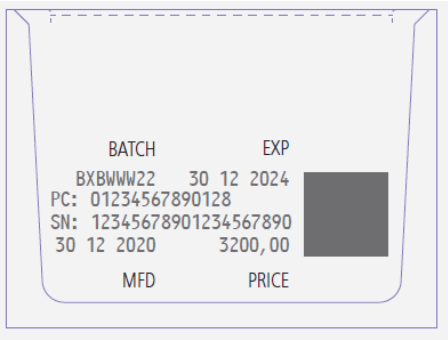
Bayer Standard

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

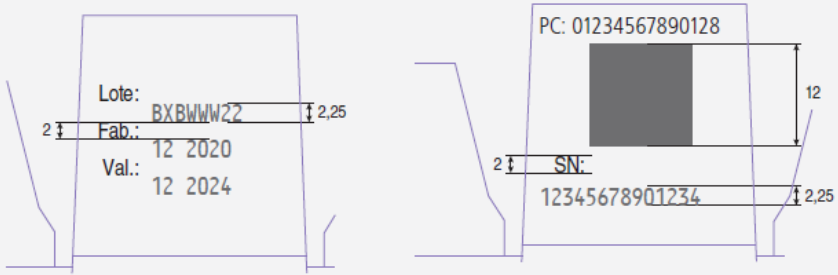
Variants

- 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.)

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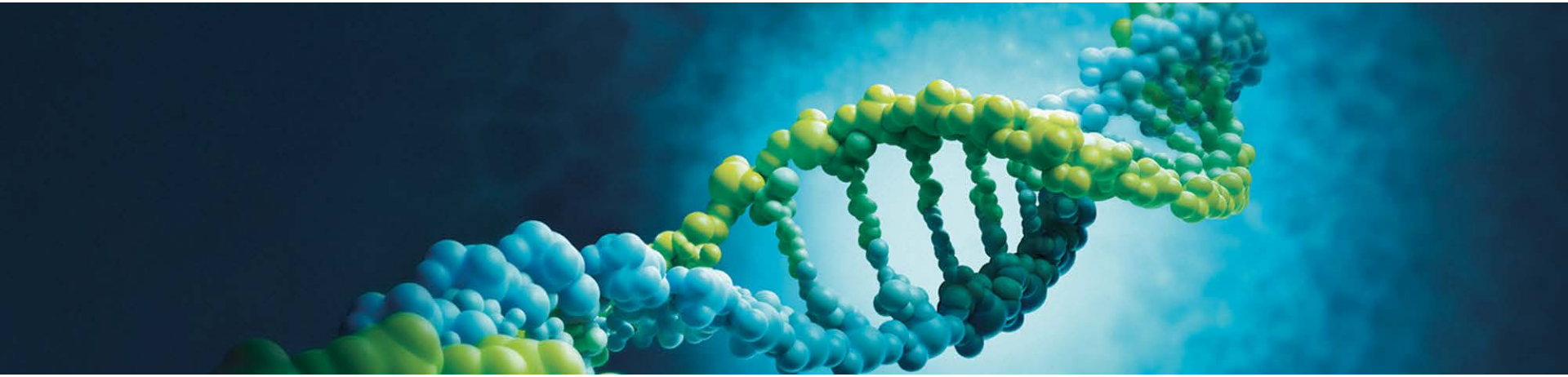

Thank You!

EU-FMD @ Bayer: Implementation Challenges

Coding of Multi-Market Packs / Shared Packs

Description

- Multi-market pack / shared pack is a product that is marketed with the same artwork in multiple countries e.g. Germany/Austria, Poland/Bulgaria/Romania
- Today, sometimes multiple barcodes on same pack
- In future, only one GS1 DataMatrix code allowed → Easy where packs bear only one EAN code already today

Solution

- Usage of GS1 GTIN allows for marketing of a product in several countries using the same product code

Challenge

- Harmonize product codes for multi-market packs that today bear multiple barcodes
  - Identify relevant products
  - Assign unique GTIN considering nat'l constraints w.r.t. product code changes
  - Process and synchronize change applications across countries incl. update of nat'l master data registers

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

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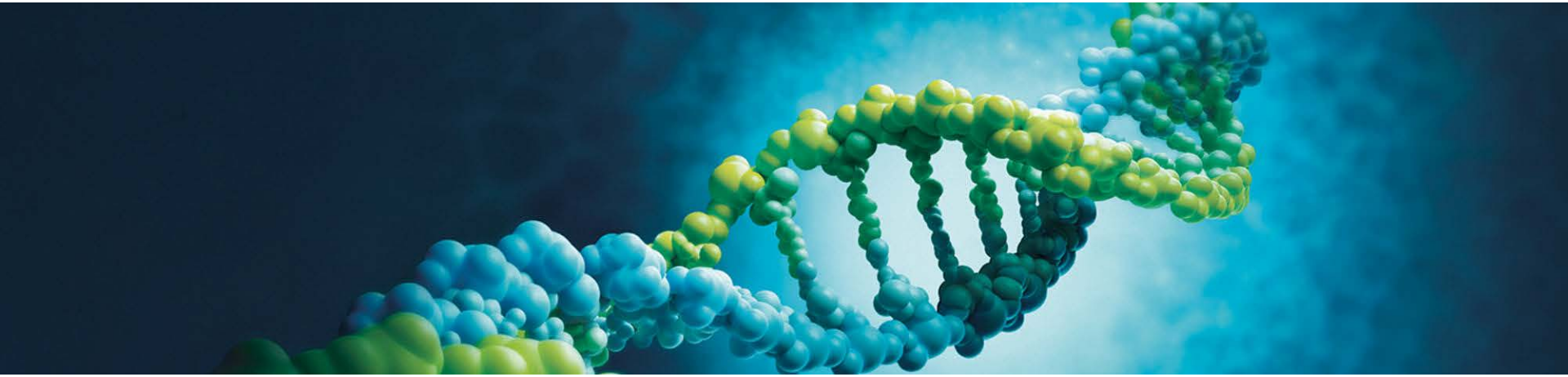

Thank You Again!