

FORWARD-THINKING, INTELLIGENT HEALTHCARE



ADVANCING IN EVOLVING ENVIRONMENT SERIALIZATION

Mike Meakin, VP, Global Quality Regulatory & Compliance, DHL Supply Chain

The background of the slide features a futuristic medical visualization. It includes a translucent human head profile with glowing internal structures, a hand interacting with a digital interface, and various floating data panels showing network graphs, human head silhouettes, and molecular structures. The overall theme is advanced healthcare technology and data-driven innovation.

DHL Global Life Sciences & Healthcare Conference
2019, June 17-19, Miami

SERIALIZATION



NDC: 59148 011 13
SN: 100000000001
EXP: AUG 22 2015
Lot: AB100613



PROTECTING THE SUPPLY CHAIN ULTIMATELY PROTECTS PATIENTS

Offices of the United States Attorneys  United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE
EASTERN DISTRICT *of* VIRGINIA

FOR IMMEDIATE RELEASE

Friday, January 18, 2019

Medical Company Executive Sentenced for Smuggling \$18 Million in Misbranded Pharmaceuticals into United States

6 Canadians arrested in U.S. extradition request for allegedly selling fake cancer drugs online

CanadaDrugs.com founder, 5 others accused of illegally importing, selling counterfeit drugs to doctors in U.S.



Karen Pauls · National Reporter · [CBC News](#)
[June 19, 2017](#)

Department of Justice
U.S. Attorney's Office
Eastern District of Virginia

SHARE 

FOR IMMEDIATE RELEASE

Friday, May 9, 2014

Illegal Drug Company Gallant Pharma And Co-Founder Sentenced

Offices of the United States Attorneys  United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE
DISTRICT *of* MONTANA

FOR IMMEDIATE RELEASE

Friday, April 13, 2018

Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States

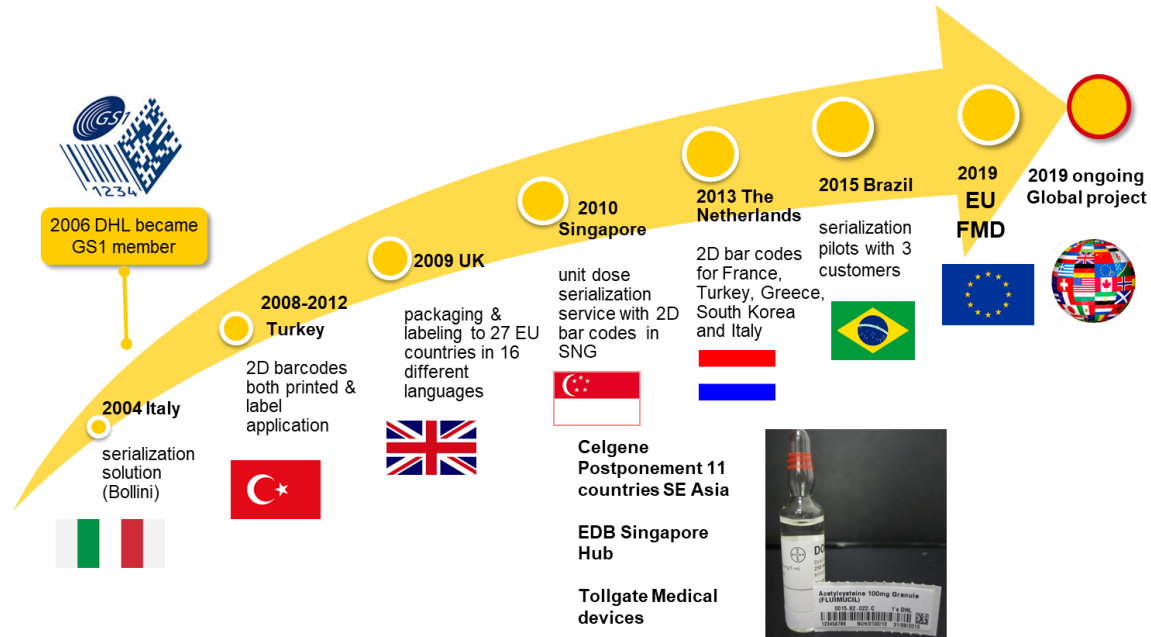
Counterfeit Version of Avastin in U.S. Distribution

 SHARE  TWEET  LINKEDIN  PIN IT  EMAIL  PRINT

Statement Update Issued: July 10, 2012

DHL

DHL SERIALIZATION JOURNEY



GS1 Healthcare LT 2018 / 2019



Tri-Chairs:

- Scott Mooney, McKesson
- Feargal Mc Groarty, St. James's Hospital
- Mark Hoyle, Teleflex

LT Members

- Charity Hovey, 3M
- Cyndi Poetker, Abbott
- Jeff Denton, Amerisourcebergen
- Volker Zeinar, B. Braun
- Stefan Artlich, Bayer
- Dennis Black, BD
- Patrick Main, Cook Medical
- Kevin Downs, University Hospitals of Derby and Burton NHS Foundation Trust
- Mike Meakin, DHL
- Sébastien Langlois-Berthelot, F. Hoffmann-La Roche
- Karen Conway, GHX
- Grant Courtney, GSK
- Jean-Michel Descoutures, IHF
- Gerry Collins, Johnson & Johnson
- Jackie Elkin, Medtronic
- Pascal Aulagnet, Pfizer
- Mark Hoyle, Teleflex
- Grant Hodgkins, Smith & Nephew
- Dr. Hajo Reissmann, University Hospital Schleswig-Holstein
- Catherine Koetz, GS1 Australia
- Marcelo Oliveira, GS1 Brazil
- Arthur Smith, GS1 Canada
- Valérie Marchand, GS1 France
- Hans Lunenborg, GS1 Netherlands
- Rami Habbal, GS1 UAE
- Glen Hodgson, GS1 UK
- Greg Bylo, GS1 US

EU FALSIFIED MEDICINES DIRECTIVE

DHL implementation

- Deployed in Feb 19
- **11** countries
- **22** sites
- **93** customers

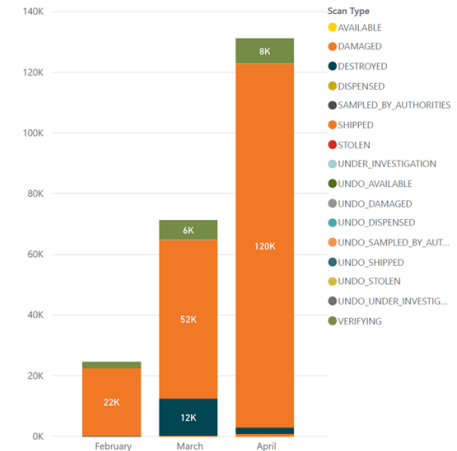
3 Phase Deployment

2 Models:

- 10% Full track & trace
- 90% EU Minimum Compliance QTAs



Scan Volume by Type & Month



Scan Type	Count of Scan Type
SHIPPED	194504
VERIFYING	16395
DESTROYED	13754
DAMAGED	1278
SAMPLED_BY_AUTHORITIES	597
UNDER_INVESTIGATION	218
Total	226943

DHL EU FMD - IMPLEMENTATION LESSONS LEARNED

- Complex serialization landscape demands **flexibility from all parties**, 3PL, IT Vendors and MAH – **everyone is learning** on this journey and not every scenario can be foreseen
- **IT vendors are still learning too**, development plans are hard to track and resourcing projects is a challenge, Continuous Risk Assessments and Design Reviews are critical
- Document **as many use case scenarios** as you can and add to them continuously - NEED to **keep everyone aligned** to operating scenarios
- This journey requires **strong and continuously engaged Sponsorship & Stakeholder Management** – *don't leave anyone behind*
- **Connectivity is KEY** - interfaces are the highest area of risk to schedule – **Start early!**
- EMVO – period of grace but DRAs ie MHRA different view on decommissioning –
- **Start QTA process early too!**

BIOMEDICAL SCIENCES - VIBRANT INDUSTRY IN SINGAPORE

Singapore as a Gateway to Asia



>50 Manufacturing Plants

>\$26B output
>18,000 employees

>50 R&D Centres

>\$500M BMS BERD¹
>2,000 Private Sector Researchers

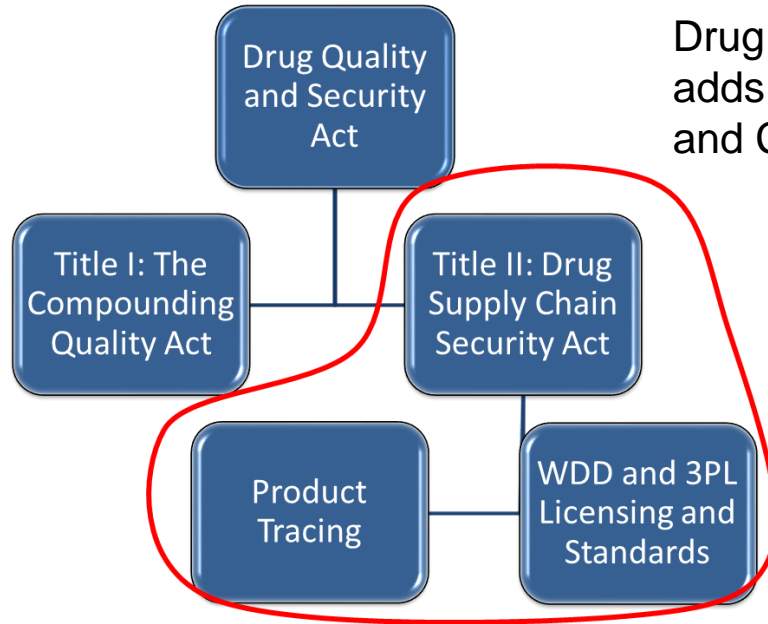
>30 Leading RHQs

>7,600 employees

Companies with Regional Hubs in Singapore (Non-exhaustive)



DRUG SUPPLY CHAIN SECURITY ACT



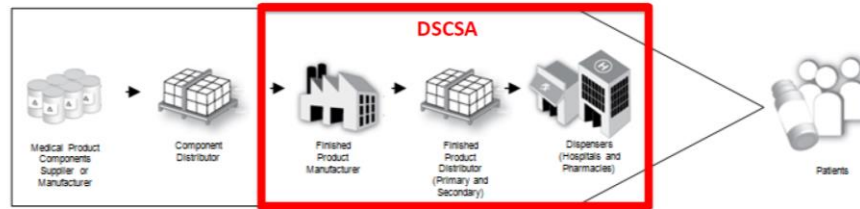
Drug Supply Chain Security Act (DSCSA) adds new sections in the Federal Food, Drug and Cosmetic Act (FD&C Act)

- 581 – Definitions
- 582 – Requirements (product tracing, product identification, verification)
- 583 – Standards for licensure of wholesale distributors
- 584 – Standards for licensure of third-party logistics providers (3PLs)
- 585 – Uniform national policy

DRUG SUPPLY CHAIN SECURITY ACT



Pharmaceutical Supply Chain



Maintaining integrity from manufacturer to patient(s)

- Who touches the product?
- Where are the vulnerabilities?
- What are the threats?

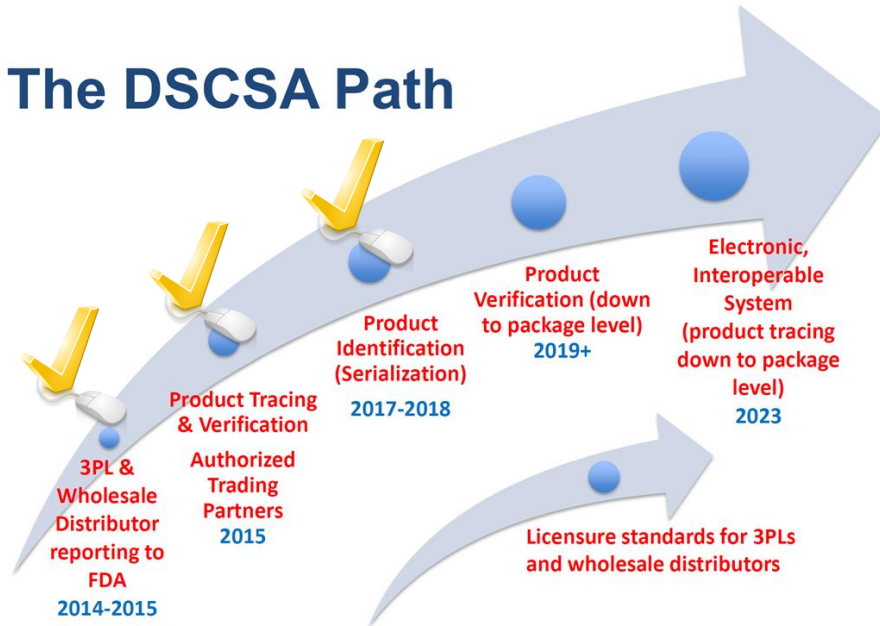
Protect the product → Protect the patient

DRUG SUPPLY CHAIN SECURITY ACT

Key Supply Chain Milestones – 2019+

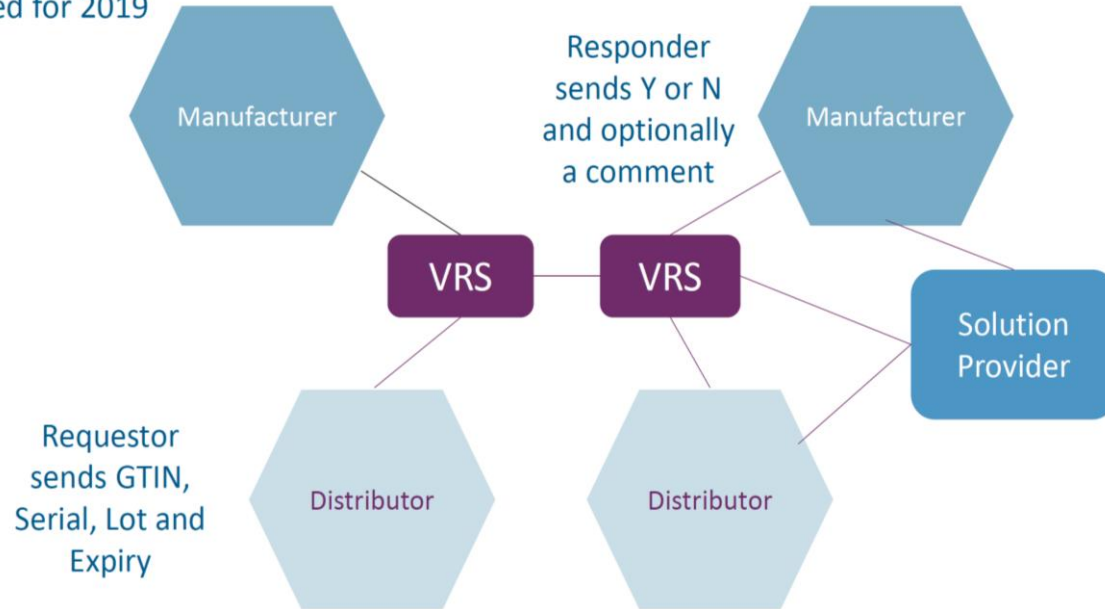
- Product Verification
- First phase is Saleable Returns Verification

The DSCSA Path



DSCSA – VERIFICATION ROUTER SERVICE

Needed for 2019



DSCSA – NEXT STEP

2023 PILOT PROJECT PROGRAM

In Feb 2019, the FDA announced its pilot project program to help inform planning for 2023 interoperable electronic, package-level traceability requirements.

The pilot program will be designed to explore issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, identifying the system attributes that are necessary to implement the requirements established under the DSCSA and other issues identified by FDA.

THERE ARE ALWAYS QUESTIONS LEFT ON SERIALIZATION

