Panel Discussion – Contract Manufacture Organizations (CMO)

36th Global GS1 Healthcare Conference

New Delhi, India

Chaired by **Jeff Denton**, Senior Director Global Secure Supply Chain Digital Business Solutions, Amerisource Bergen
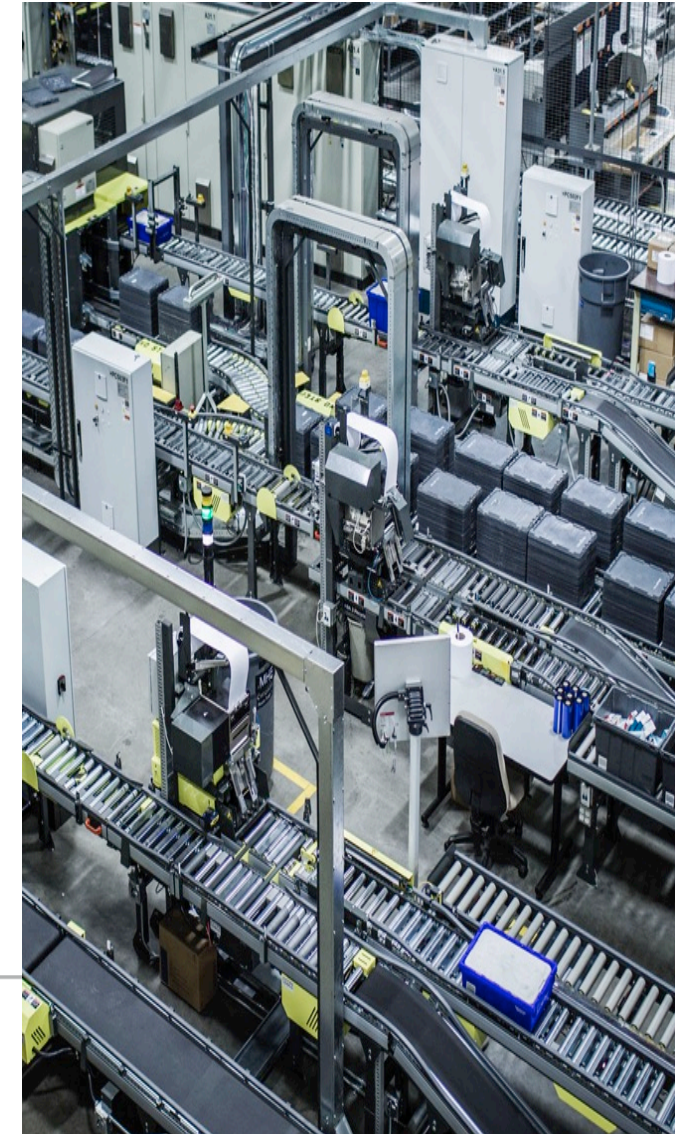
5 November 2019

What is contract manufacturing?

Pharmaceutical contract manufacturing is a huge sector with a large number of integrated services.

Some of the services include Active Pharmaceutical Ingredient (API) manufacturing, Final Dosage Form (FDF) manufacturing, advanced drug delivery products, OTC medicines and nutritional product, packaging, and others.

FDF comprises solid dose formulations, semi-solid and liquid dose formulations, and injectables.

Expanding global market opportunities

The market for healthcare contract manufacturing is growing and is mainly attributed to factors such as patent protection expiration of major drugs and medical devices, competition and economics of production and trade to favor CMO, mutual benefits to both contract manufacturer and client, and lean manufacturing and agility. These factors are pushing the growth of the healthcare contract manufacturing market.*
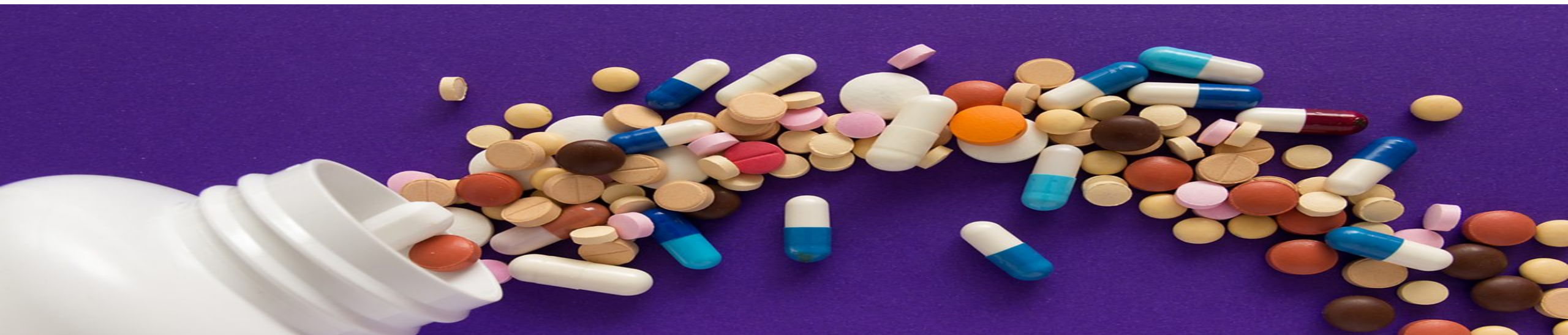
*Source: Market Watch April 2019

Expanding global market opportunities

On the other hand, certain factors are restraining the growth of the market. These include supply chain complexity and issues of control of third parties, standardization and interoperability issues, and growing cost of noncompliance and counterfeit medicines.*
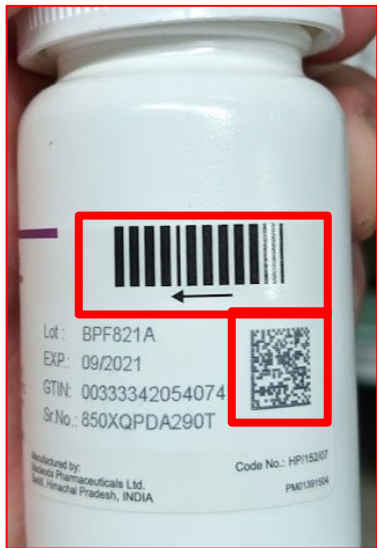
*Source: Market Watch April 2019

Drug Supply Chain Security Act (DSCSA)

Effective November 27, 2017(2018) - (1 Year Enforcement Discretion Provided)

- Encode the GTIN (NDC), serial number, expiration date, and lot number in a 2D GS1 DataMatrix
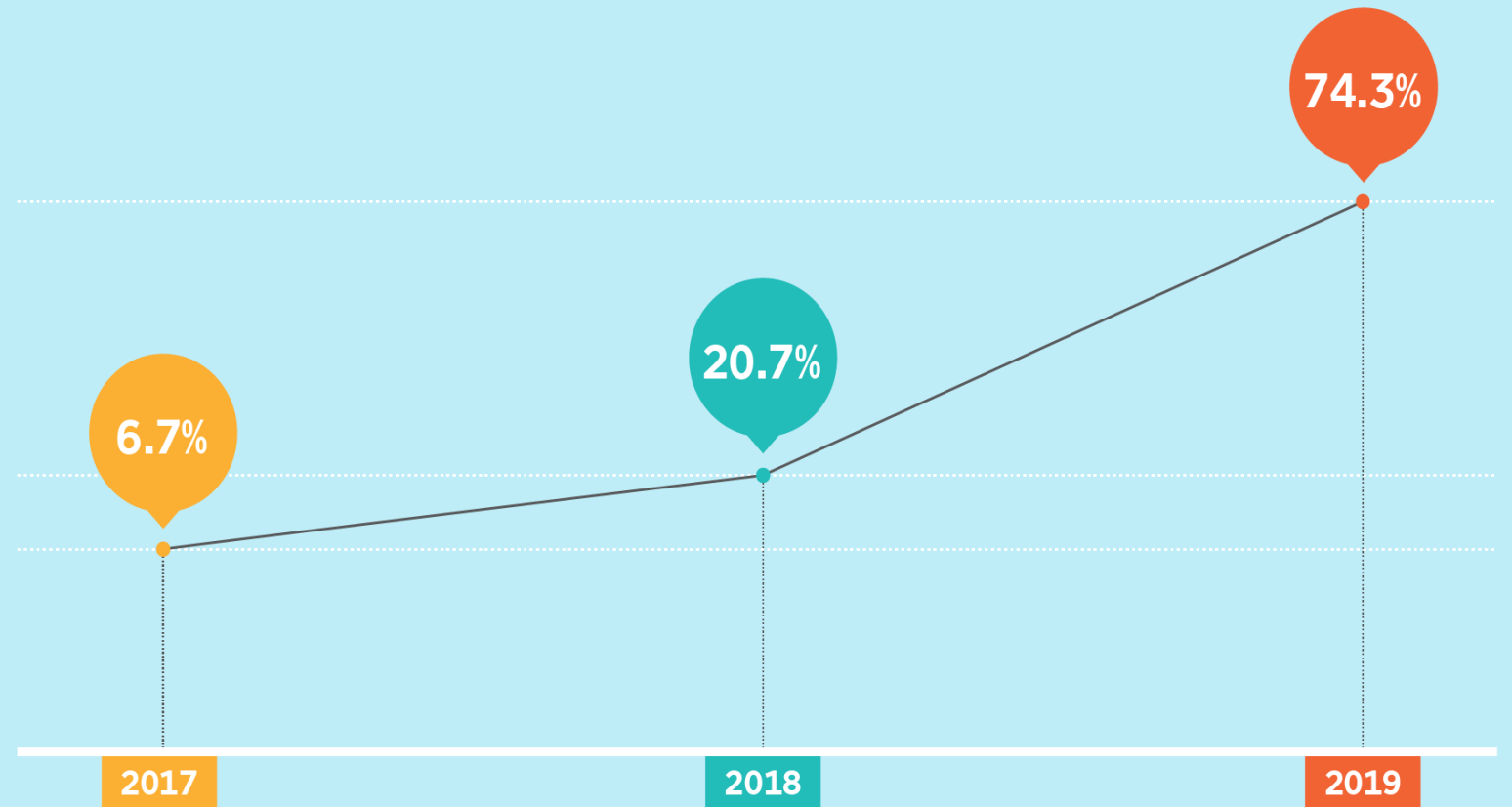
- Assign a unique serial number to each saleable unit and case

Excellent Three-Year Progress

Three-Year Progression of Serialized Products With a GS1 DataMatrix Containing Four Application Identifiers

6.7% — 2017
20.7% — 2018
74.3% — 2019

Today's panel of Healthcare professionals

Scott Mooney
VP Distribution Operations Supply Chain Assurance, **McKesson** (US)

Matt Sample
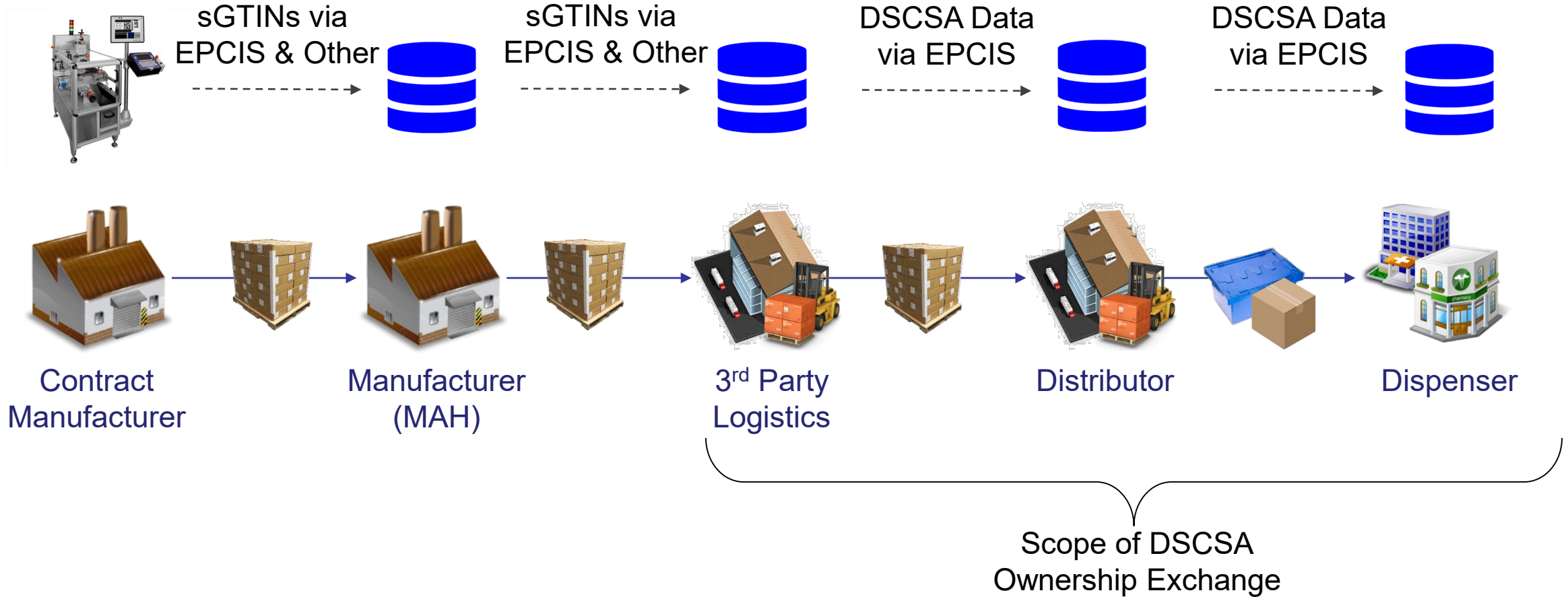VP Manufacturer Operations, **AmerisourceBergen** (US)

Dr. Oliver Nuernberg
Chief Product Owner SAP Life Sciences, **SAP** (Germany)

Anand Garg
Senior Director, Head India Supply Chain, **Dr. Reddy's** (India)

RX USA Product and Data Flow

sGTINs via EPCIS & Other

sGTINs via EPCIS & Other

DSCSA Data via EPCIS

DSCSA Data via EPCIS

Contract Manufacturer

Manufacturer (MAH)

3rd Party Logistics

Distributor

Dispenser

Scope of DSCSA Ownership Exchange

Conflicting Application of Standard

Packaging Levels	U.S.	DGFT
Pallet, Partial, & Mixed Case Meant for transport/ logistics. (Tertiary)	• **No DSCSA Requirement** • US Supply Chain requirement – SSCC	Tertiary: GTIN 14*, Expiry Date, Batch Number & SSCC
Homogenous Case Intended for logistics & sales. Contains inner packs and/or quantities of lowest unit of sale. (Tertiary/Secondary)	• GTIN 14 (NDC encoded) • Expiry Date • Batch Number • Unique Serial Number	Tertiary: GTIN 14*, Expiry Date, Batch Number & SSCC Secondary: GTIN 14, Expiry Date, Batch Number, & Unique Serial Number
Inner Pack** (Secondary) Packaging level containing multiple lowest unit of sales Used for convenience & handling	• **No DSCSA Requirement**	Secondary: GTIN 14, Expiry Date, Batch Number, & Unique Serial Number
Lowest Unit of Sale (for sale to pharmacy). Bottle, blister carton, large vials, cartons of vials, etc. (Secondary/Primary)	• GTIN 14 (NDC encoded) • Expiry Date • Batch Number • Unique Serial Number	Secondary: GTIN 14, Expiry Date, Batch Number, & Unique Serial Number Primary: GTIN 14*, Expiry Date, Batch Number, Unique Serial Number (Deferred)
Primary level (for sale to consumer). Packaging in direct contact w/medicine. E.g., strip, vial, etc.	• **None (if not lowest unit of sale)**	Primary: GTIN 14*, Expiry Date, Batch Number, Unique Serial Number (Deferred)

CMO Network Collaboration

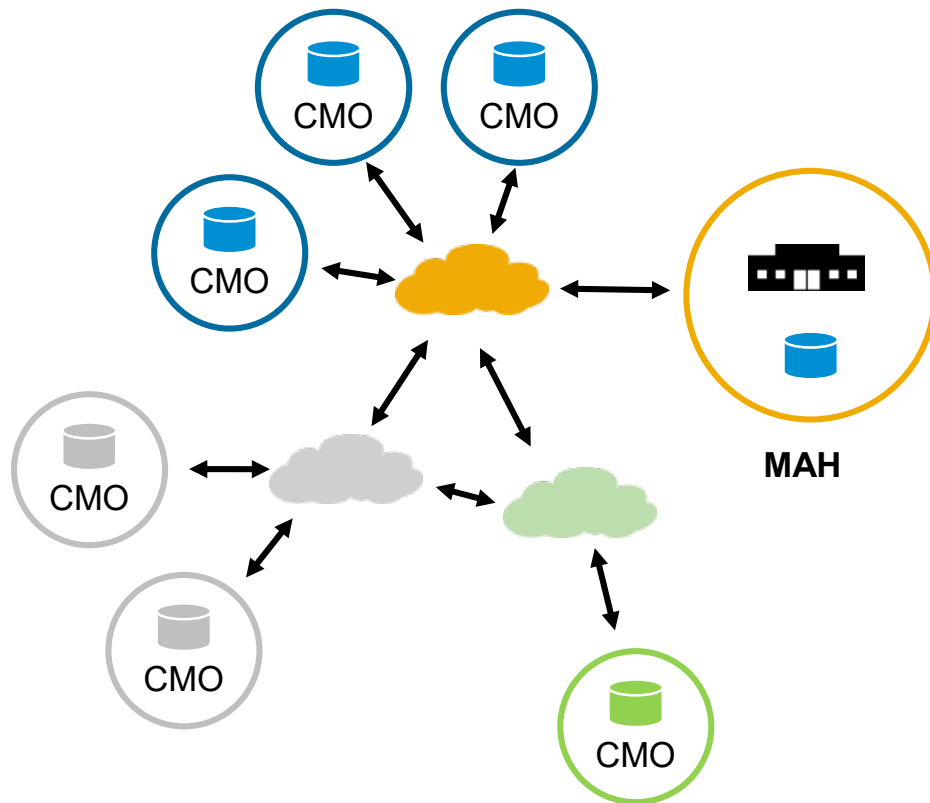**Connect Once – Collaborate with the entire ecosystem,**

- either with business partners connected to the network directly, or
- with business partners connected through third party cloud solutions.

Challenges in cross vendor collaboration

- Lack of Standards (or Implementation Guidelines) beyond the EPCIS scope
- Orchestration
- Semantics
- Business Rules

Opportunities

- Enter into an entirely electronic exchange of process related data: order, order confirmation, ASN, invoice, …, connected to the serialization data exchange

Efforts to enhance Traceability across geographies for preventing counterfeiting

	U.S.A	E.U.	China	Russia	India
1 Serialization rollout across GUs with customized country requirements (11 digit vs 91 digit)	✔	✔	✔	Jan'20	✖
		FMD Controlled Tamper Evident	SFDA Controlled	FDA Controlled	
2 Advanced implementation of complete unit level traceability including aggregation/ de-aggregation throughout supply chain	✔	✔	✔	Jan'20	✖
3 Implemented 7 digit authorization code for our biggest brands however seen very few responses					✔

We have an opportunity to leverage our experience of Serialization for Indian Market which can be propelled by building adequate infrastructure & capabilities

Dr.Reddy's

GS1 Resources

https://www.gs1us.org/industries/healthcare/standards-in-use/pharmaceutical/dscsa-barcode-assessment

https://api.fdsys.gov/link?collection=plaw&congress=113&lawtype=public&lawnum=54&link-type=html

http://www.gs1us.org/barcode-readability

http://www.gs1us.org/pharma-gln

https://www.gs1us.org/industries/healthcare/standards-in-use/pharmaceutical/implementation-guideline

http://www.gs1.org/1/gtinrules/en/healthcare

https://www.gs1us.org/documents?Command=Core_Download&EntryId=1908

https://www.gs1.org/standards/epcis/epcis-cbv/1-0

https://www.gs1.org/epcis