1 KEY ACTIVITIES
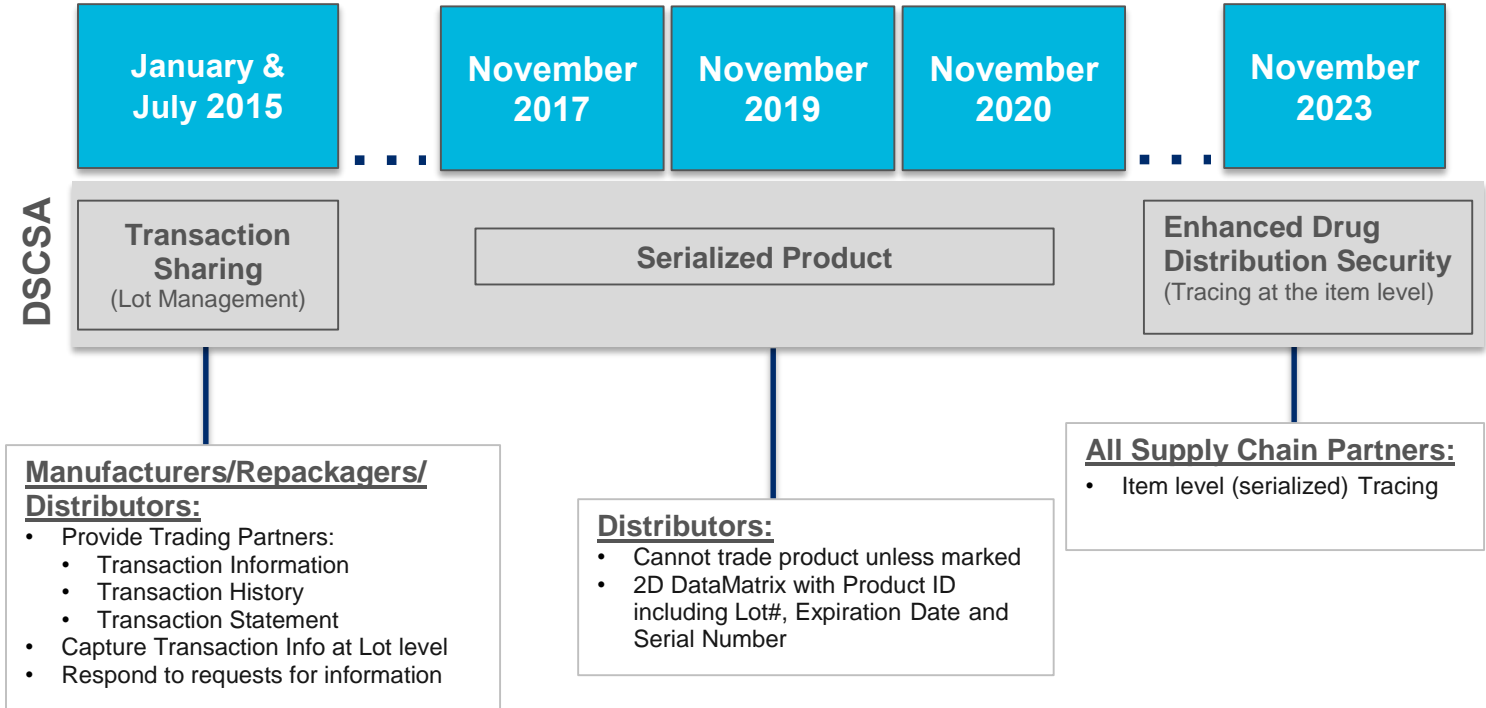
- Review the law with counsel at your company:
    - http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm20041041.htm

- Share it with key stakeholders in your organization such as:
    - Government Relations
    - IT
    - Logistics
    - Track & Trace/ERP vendor(s)

- Start budgeting and discussing how you will:
    - Create the new data
    - Receive the new data
    - Store the new data
    - Retrieve the new data for supply chain partners and regulators

2 GENERAL TIMELINE

Note: This section provides a brief summary of the major implementation phases of the DSCSA, please refer to the actual legislation for detailed information.

DSCSA

| January & July 2015 | November 2017 | November 2019 | November 2020 | November 2023 |

Transaction Sharing (Lot Management)

Serialized Product

Enhanced Drug Distribution Security (Tracing at the item level)

Manufacturers/Repackagers/Distributors:
- Provide Trading Partners:
    - Transaction Information
    - Transaction History
    - Transaction Statement
- Capture Transaction Info at Lot level
- Respond to requests for information

Distributors:
- Cannot trade product unless marked
- 2D DataMatrix with Product ID including Lot#, Expiration Date and Serial Number

All Supply Chain Partners:
- Item level (serialized) Tracing

Please note that the above illustration is for informational purposes only, and provided as a convenience, and is not legal advice or a substitute for legal counsel, nor does it constitute advertising or a solicitation. GS1 US is not a representative or agent of the FDA, and this content has not been reviewed, approved or authorized by the FDA.

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3 TOPICS TO ADDRESS IN YOUR PLANNING

DSCSA INTERPRETATION

The Drug Supply Chain Security Act (DSCSA) was signed into law on November 27, 2013. Key provisions of the law went into effect for certain supply chain participants on January 1, 2015 (see timeline). Although the law required that the FDA develop draft standards (guidance) on the law by November 27, 2014, certain FDA standards are still in development. Understandably, this presents a challenge to your company to implement for the law while specific FDA guidance is still pending. It is crucial that your company acquire a working knowledge of the law in order to understand your risk and develop policies and internal guidelines for operations.

PROGRAM PLANNING MANAGEMENT AND CONSULTING

Lot level information sharing, product serialization and item traceability as documented in the DSCSA will cause your company to make changes to quite a few business processes and information systems throughout your organization. You may want to take advantage of the growing knowledge base of consultancies, peers and others within the US pharmaceutical industry.

STANDARD OPERATING PROCEDURES (SOPs)

As business, operational and I.T. processes and systems change, a large number of SOPs will need to be changed over the next ten years. Impact to your business may be mitigated by developing a solid plan and roll-out schedule to keep existing SOPs in compliance with requirements of regulators and other certifying bodies (FDA, DEA, Joint Commission, etc.).

DSCSA INFORMATION SHARING (TS, TI & TH)

The DSCSA specifies certain dates for each participating trading partner in the supply chain to share or make available Transaction Statements, Transaction Information and Transaction History with their upstream trading partners. The granularity, format and choreography of information flow may change as the timeframe transitions from Lot Level to serialized item level information. Due to the tight timeframes defined in the law, you would benefit from a short term and long term plan that includes the vast transition period from 2015 – 2023.

BARCODE PRINTING & VERIFICATION

The DSCSA requires that manufacturers and repackagers mark their products with a 2D DataMatrix barcode and include the NDC (GTIN in GS1 Standard), Serial Number, Lot Number and Expiration Date. Given multiple production lines, manufacturing geographies and increased use of contract manufacturing, a plan for managing this data to and from the production line is crucial. Also, the process and equipment needed to print clear, readable barcodes needs to be planned accordingly.

INVENTORY MANAGEMENT

The law requires each company to manage inventory, first at the Lot level and then at the individual serialized item level. This will require significant changes to all inventory management systems and related processes. Understanding the implementation strategy of the companies that supply inventory management systems and services may be crucial to your success.

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LINE LEVEL SERIALIZATION SOLUTIONS

Serializing individual products may require physical equipment changes to your company's production lines. Different printers and visual systems may be needed to keep line speeds and production yields at current rates.

SECURITY, STORAGE AND RETRIEVAL

The DSCSA includes provisions for protecting data, storage time periods and time permitted to retrieve data based on a regulator's request. Current Security, Storage and Retrieval plans may need to be augmented or updated for each product.

4 WHO CAN HELP?

The following list is provided by GS1 US as a convenience and does not constitute or imply an endorsement, recommendation, or favoring by GS1 US of any of the identified companies, products, or services. GS1 US does not warrant or guarantee any of the products or services identified here, nor does it assume any legal liability or responsibility with respect to them.

WHO CAN HELP?		
DSCSA INTERPRETATION	**Associations**: HDMA [HC] GPhA [HC] NACDS [HC] NCPD [HC] PhRMA [HC]	**Solution Providers:** Axway [HC, SPP] rfXcel Corp. [HC] Deloitte Consulting LLP [HC] TraceLink Inc. [HC, SPP] Dirk Rodgers Consulting, LLC & RxTrace[HC] USDM, LLC [HC] Ken Traub Consulting LLC [SPP] Pharma Logic Solutions, LLC [HC, CBP]
PROGRAM PLANNING / MANAGEMENT / CONSULTING	1WorldSync [HC, SPP] Deloitte Consulting LLP [HC] Dirk Rodgers Consulting, LLC & RxTrace [HC] Ken Traub Consulting LLC [SPP]	Pharma Logic Solutions, LLC [HC, CBP] TraceLink Inc. [HC, SPP] USDM, LLC [HC]
STANDARD OPERATING PROCEDURES	Deloitte Consulting LLP [HC] Pharma Logic Solutions, LLC [HC, CSP]	
DSCSA INFORMATION SHARING (TI, TS, TH)	1WorldSync [HC, SPP] Axway [HC, SPP] Deloitte Consulting LLP [HC] Dirk Rodgers Consulting, LLC & RxTrace [HC] Ken Traub Consulting LLC [SPP]	Oracle [HC, SPP] Pharma Logic Solutions, LLC [HC, CBP] rfXcel Corp. [HC] TraceLink Inc. [HC, SPP]
SECURITY STORAGE AND RETRIEVAL	1WorldSync [HC, SPP] Deloitte Consulting LLP [HC] Oracle [HC, SPP]	Pharma Logic Solutions, LLC [HC, CBP] rfXcel Corp. [HC] TraceLink Inc. [HC, SPP]
BARCODE PRINTING	Bar Code Graphics, Inc. [SPP] Deloitte Consulting LLP [HC]	Omega Design Corporation [HC] Pharma Logic Solutions, LLC [HC, CBP]
INVENTORY MANAGEMENT	1WorldSync [HC, SPP, CSP] Deloitte Consulting LLP [HC, SPP, CBP]	Oracle [HC, SPP, CBP] TECSYS Inc. [HC, SPP, CBP]

Legend:

HC – GS1 Healthcare US Member   **SPP** – Solution Partner Program   **CBP** – Certified Barcode Professional

5 SOLUTION PROVIDER CONTACT INFORMATION

SOLUTION PROVIDER CONTACT INFORMATION
1WorldSync www.1worldsync.com Contact: Kelly Kucera, kkucera@1worldsync.com Serves: Large, Medium and Small Companies Areas: • Program Planning / Management / Consulting • DSCSA Information sharing (TS, TI, TH) • Inventory Management • Security / Storage & Retrieval
Axway http:www.axway.com/industries-customers/industry/life-sciences Contact: Atif Chaugtai, achaughtai@axway.com Serves: Manufacturers – Large & Medium companies Areas: • DSCSA Interpretation • DSCSA Information sharing (TS, TI, TH) • Line Level Serialization Solutions • Security / Storage & Retrieval • Pharmacy Systems
Bar Code Graphics, Inc. http://www.barcode.graphics/ Contact: Andy Verb, averb@barcode.graphics Serves: Manufacturers & Wholesalers of all sizes Areas: • Barcoding (origination & testing
D2 Pharma Consulting http://www.d2rx.com/ Contact: Dan Steiber, dan.steiber@d2rx.com Serves: Medium & Small companies Areas: • DSCSA Interpretation • Program planning / Consulting • Standard Operating Procedures

SOLUTION PROVIDER CONTACT INFORMATION

Deloitte Consulting LLP
www.deloitte.com
Contacts:
- Michael Delone, Principal mdelone@deloitte.com
- Mark Lutostansky, Principal mlutostansky@deloitte.com
- Rajesh Singh, Senior Manager rajessingh@deloitte.com

Serves: All size companies
Areas:
- DSCSA Interpretation
- Program planning / Consulting
- Standard Operating Procedures
- DSCSA Information sharing (TS, TI, TH)
- Barcode printing/reading
- Inventory Management
- Line Level Serialization Solutions
- Security / Storage & Retrieval
- Pharmacy Systems

**Does not sell hardware; assists in designing barcode per GS1/HDMA standards and obtaining hardware vendor.
** Does not sell hardware; assists in designing serialization manager components and obtaining hardware/software vendor

Dirk Rodgers Consulting, LLC
http://www.rxtrace.com/ http://www.dirkrodgers.com/
Contact: Dirk Rogers, Dirk@DirkRodgers.com
Serves: All size companies
Areas:
- DSCSA Interpretation
- DSCSA General Program Consulting

Ken Traub Consulting LLC
www.kentraub.com
Contact: info@kentraub.com
Serves: All size companies
Areas:
- DSCSA Interpretation
- DSCSA General Program Consulting
- DSCSA Information sharing (TS, TI, TH)

Omega Design Corporation
www.omegadesign.com
www.unitlevel.com
Contact: info@kentraub.com
Serves: All size companies
Areas:
- Barcode printing/reading
- Line Level Serialization Solutions

SOLUTION PROVIDER CONTACT INFORMATION

Oracle

http://www.oracle.com/us/products/applications/life-sciences/pedigree-serialization/index.html

Contact: John Danese, john.danese@oracle.com

Serves: Large & Medium companies

Areas:
- DSCSA Information sharing (TS, TI, TH)
- Inventory Management
- Security / Storage & Retrieval

Pharma Logic Solutions

http://www.pharma-logic.com

Contact: info@pharma-logic.com

Serves: All size companies

Areas:
- DSCSA Interpretation
- DSCSA General Program Consulting
- Standard Operating Procedures
- DSCSA Information sharing (TS, TI, TH)
- Barcode printing/reading
- Line Level Serialization Solutions
- Security / Storage & Retrieval

rfXcel Corp.

http://www.rfxcel.com

Contact: Jack Tarkoff, jtarkoff@rfxcel.com

Serves: All size companies

Areas:
- DSCSA Interpretation
- DSCSA Information Sharing (TS, TI, TH)
- Line Level Serialization Solutions
- Security / Storage & Retrieval

TECSYS

http://www.tecsys.com/

Contact: Rick Watkinson, rick.watkinson@tecsys.com

Serves: Medium to large companies (wholesaler, 3PL, and dispenser)

Areas:
- Inventory Management

TraceLink Inc.

http://www.tracelink.com

Contact: Brian Daleiden, bdaleiden@tracelink.com

Serves: All size companies

Areas:
- DSCSA Interpretation
- Program planning / Consulting
- DSCSA Information sharing (TS, TI, TH)
- Line Level Serialization Solutions
- Security / Storage & Retrieval

SOLUTION PROVIDER CONTACT INFORMATION

USDM, LLC
http://www.usdm.com/
Contact: Grant Hodgkins, ghodgkins@usdm.com
Serves: All size companies
Areas:
- DSCSA Interpretation
- DSCSA General Program Consulting
- Label Design and Implementation
- GS1 Conversion Planning (for structuring programs to drive GS1 barcodes, transactions, and master data adoption)

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