DSCSA

VirtualShowcase™

at the HDMA 2015 Traceability Seminar

A visual representation of the US drug supply chain, DSCSA requirements and the products and services available to implementing companies.

CSCS

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SUPPLY CHAIN STUDIES™

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Background

As an increasing number of supply chain trading partners attempt to comply with the intricacies of the Drug supply Chain Security Act (DSCSA), they are in need of better tools to educate themselves on their responsibilities and the companies available to help them implement – via products and services developed for DSCSA compliance.

Goal of the VirtualShowcase™

In response to the challenges of implementing DSCSA requirements through the various phases identified in the law, the DSCSA VirtualShowcase was initiated by Solution Provider companies to provide **thought leadership and promote deeper understanding** of the US drug supply chain, DSCSA requirements and the products and services that are available to them.

DSCSA VirtualShowcase at HDMA 2015 Traceability Seminar

This VirtualShowcase depicts the movement of product through a virtual supply chain and highlights key dates and responsibilities within the DSCSA. It provides a **virtual world** where HDMA attendees can interact with and learn about the intricacies of the pharmaceutical supply chain. They will also see how medicines safely make their way from the manufacturer to the pharmacy.

The Rx Supply Chain meets Pharmacy Practice

Using patent-pending simulation software and techniques, medicines are depicted flowing through a virtual supply chain making use of a number of real world scenarios. The scenarios end within the hospital and retail pharmacy, where they will continue their journey to the patient. This VirtualShowcase:

1. Depicts the movement of product through a virtual supply chain
2. Highlights key dates and responsibilities within the Drug Supply Chain Security Act (DSCSA)
3. Promotes deeper understanding of products and services that are available to implementing companies.

CollaborationLab™

Working with a team of industry leaders and facilitators, CollaborationLabs enable participants to virtually come together to share in all Lab findings.

Many Labs set out to generate publishable white papers and in-depth reports, some work on verification of concept and theories, while others are designed to come to a consensus on an issue or ideation.

Participants are able come together to explore, experiment and test while saving on the fixed costs of traditional buildings and laboratories.

The origin of the VirtualShowcase

VirtualShowcases were created as a way to bring together thought leaders from industry, academia, regulatory and other arenas to demonstrate complex industry issues and explore new ideas and methods to address them.

Using simulation and other documentation that comes out of a CollaborationLab, a VirtualShowcase contains a VirtualPoster™ and a ReferenceModel(s) that has been further developed to lead the viewer through a visual demonstration of that Model.

VirtualShowcases are fine-tuned and custom-tailored for any setting. They can be presented via webinar or other online sites, through video conferencing, or at in-person installations or presentations (large or small venues.)

ReferenceModel™

A ReferenceModel is a simulated model that represents a real-world or projected scenario and can be used to visually demonstrate a finding, point of view or just to educate on a topic. Some ReferenceModels may even serve as baselines for future discovery or experimentation.

The ReferenceModels that are output from a CollaborationLab are in the form of **process simulations**. While the learnings from a particular simulation can be captured in tables, diagrams and papers, the simulations themselves are interactive computer systems that allow the viewer to **interact with the topic at hand** and watch the result of that interaction play out before them.

VisualResults™

Once the data from the ReferenceModel is analyzed and understood, a VisualResults screen is designed to allow you to **visually convey the findings**.

This allows for more engaging presentations and clearer dissemination of information.

ReferenceModels and Simulation

Simulated ReferenceModels capture and analyze complex systems in context to **real-world scenarios**, provide a means of verifying processes and information with designated representatives from companies, and assess the impact of large or small changes to the overall system.

This approach produces models that operate as **living systems** and can be used and altered to test any number of ideas, variations or modes of solving real-world problems.

Lab participants are encouraged to think freely about the experiment with new ways of solving today's and tomorrow's challenges and explore new opportunities.

VirtualPilot™

VirtualPilot simulation modeling provides a means to experience key supply chain phases. Essential test data is produced allowing for assessment of certain scenarios, including impact of suspect and illicit product, recalls, receiving of medication and others.

Physical, information technology and/or financial environments are modeled in a virtual world using real-world scenarios to provide key learning and test data to accurately predict the performance expected in live production. VirtualPilots allow for safe experimentation for implementation planning and provide increased efficiency and decreased costs based on assessments of empirical evidence gleaned from simulation.

Funding a CollaborationLab or VirtualShowcase

Labs and Showcases are individually funded by participating companies and do not require memberships or recurring annual fees. While funding is not the only contribution a participating company makes, it is fundamental to being able to organize and present a Lab or Showcase at an event.

Funding is offered at three levels: **Underwriter, Sponsor or Supporter**. Each level has contribution recognition and benefits commensurate with the funding level. This allows companies to initiate, participate and benefit from Labs and Showcases fairly, and ensures that their overall value stands on their own.

Beyond the VirtualShowcase

Ongoing education and exploration opportunities

This VirtualShowcase has brought together some of the best and brightest experts across industry, regulatory, supply chain, technology, and standards arenas to support clients in navigating today's complex business world.

Based on additional education needs for pharmacists and feedback from the HDMA event, there could remain scenarios or trading partner relationships that all or some Showcase team members would like to pursue.

In that event, a second Lab or Showcase may be proposed based on the new areas of interest.

DSCSA ReferenceModels for your consideration:

- **2015: Non-serialized product and data** (lot or batch level)

- **2023: All serialized product & tracing back to manufacturer**

So, what's next?

Five CollaborationLabs have been initiated and are currently in their funding stages. *They are:*

1. **Global Track & Trace Pharmaceutical Backbone**
2. **DSCSA Recall**
3. **UDI in the Hospital**
4. **DSCSA in the Hospital**
5. **Master Data Management** (DSCSA or UDI)

Please contact The Center for Supply Chain Studies to participate in one of these CollaborationLabs.
Or, if you have an idea for another Lab, we welcome your suggestions!

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On behalf of The Center for Supply Chain Studies...

Thank you again to the Underwriters for making this VirtualShowcase
presentation at the 2015 HDMA Traceability Seminar a success.

This VirtualShowcase
was made possible by:

Underwritten by:

www.1worldsync.com

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1WorldSync is the leading product information network and data pool solutions provider.

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Omega Design Corporation is a global provider of innovative packaging solutions. Since 1969, Omega has specialized in the design, manufacture, service, and support of a broad range of packaging equipment systems.

Omega's brand protection division, Unit Level, specializes in deploying and servicing serialization solutions along packaging lines. Ensuring the serialization process operates correctly and reliably is a cross-functional mix of product handling, controls integration, purposed devices, and data management software. Omega is the nexus of a serialization solution – bringing all points into contact – delivering a complete solution.

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SIMUL8

www.simul8healthcare.com/drugsupplychain

Welcome to Simul8

For over 20 years, SIMUL8 Corporation has been providing powerful simulation software that is helping companies to:

- Improve processes
- Reduce costs
- Create an evidence base for decisions
- Transform services

Healthcare systems and their supply chains are complex, experiencing high levels of variation, uncertainty and continuous change. Poor processes will affect patient outcomes, increase costs and required resources – and decisions need to be right first time. Simulation allows users to test changes in a risk-free, virtual environment to identify and implement the best solution.

Our healthcare team teaches and supports clients to use the software effectively to drive forward improvements in their organization and its supply chains.

Find out more at **www.simul8healthcare/drugsupplychain**

"Trials have shown that modelling and simulation could reduce medical error costs by up to $17 billion across the country."

- J. Randy Forbes, Congressman

Welcome to RxTrace.

RxTrace is a comprehensive exploration of the intersection between healthcare supply chains, track and trace technology, standards and global regulatory compliance. It is a website that contains free, unbiased information and analysis of healthcare serialization and track & trace regulations and the potential solutions necessary for meeting them.

RxTrace publisher, **Dirk Rodgers,** is the CEO of Dirk Rodgers Consulting, LLC, an independent consultant and author of "***The Drug Supply Chain Security Act, Explained***". An Electrical and Computer Engineer by education, Dirk has worked as a consultant, software architect and automation engineer during a career spanning 30 years. In 2002 he became employed by Cardinal Health, one of the big 3 U.S. drug distributors, where he studied many approaches to applying serialization and track & trace technology to solve supply chain integrity problems and improve supply chain efficiencies at the same time.

Overall, Dirk's thought leadership has helped to expose hidden complexities and reveal surprising consequences and implications of drug serialization and pedigree laws.

Underwritten by:

Ken Traub Consulting LLC

www.kentraubconsulting.com

Welcome to Ken Traub Consulting LLC

Ken Traub Consulting LLC is a Massachusetts Limited Liability Company founded in 2007 to provide services to software product companies and to enterprises that rely on advanced software technology to run their businesses. Its founder, Ken Traub, is an experienced CTO, entrepreneur, and software architect. Ken Traub Consulting offers services including architecture of large-scale software systems, on-call consulting on a variety of technical topics, and educational seminars on standards for supply chain traceability, product identification, and automatic identification.

 Since 2002 Ken Traub has been deeply involved in the creation and implementation of software standards for the Electronic Product Code (EPC), traceability, and RFID, as the principal author of key GS1 global standards including EPC Information Systems (EPCIS), Application Level Events (ALE), and the EPC Tag Data Standard. Ken Traub Consulting operates free services for the community of EPCIS users including the Visibility Data Workbench (www.vizworkbench.com), FREEPCIS (www.freepcis.com), and the EPC Encoder/Decoder suite (www.kentraub.com/aidc).

Welcome to USDM Life Sciences

Complete Life Sciences Solutions and Services

USDM Life Sciences is a leading global professional services firm focused on strategic consulting, regulatory consulting, technology, and compliance solutions for the regulated life science and healthcare industries, including Pharmaceuticals, Medical Devices, Biologics, Vaccines, and Supplements. USDM has industry leading capabilities to help Manufacturers, Distributors, and Healthcare Providers implement the processes and technologies required to meet the global product identification initiatives including the US DSCSA and US UDI Final Rule.

USDM offerings also include proven capabilities in ERP, PLM, MES, QMS, Manufacturing Systems, auditing and managed compliance services. These offerings are integral to USDM's US DSCSA and US UDI Final Rule solutions.

Serialization and DSCSA Services

USDM Life Sciences offers a complete framework of services to plan, execute and audit your pharmaceutical serialization and medical device UDI programs. Our services include both the technology and procedural controls required by the Drug Supply Chain Security Act (DSCSA). These services address the needs of Pharmaceutical, Medical Device and Biotechnology manufacturers and Healthcare Providers.

USDM was recently awarded the FDA contract for the
"Pilot Projects for Drug Supply Chain Security Act."
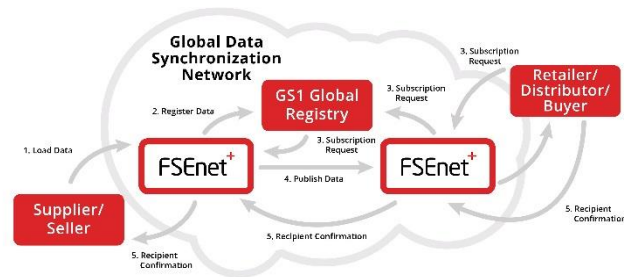
Welcome to FSEnet[+]

FSEnet[+] is the leading provider of supply chain solutions that facilitate the exchange of e-business communications to ensure **perfect data in every system.**

With a balance of expert customer service and innovative technology, we have fulfilled the data management needs of over 2,500 companies around the world. Our web portal allows transparent collaboration between buyer and seller, and our solutions satisfy regulatory, industry, and sector requirements throughout the world.

Global Presence
With offices throughout the world, FSEnet+ thinks globally, but acts locally. Whether regional or multinational, enterprise or small business, we make satisfying global and local needs simple and simultaneous.

Certifications
FSEnet+ is a Certified GDSN Data Pool. FSEnet+ fully supports the GDSN and its mission to assure that the data exchanged between trading partners is accurate and compliant with universally supported standards.

Underwritten by:

Welcome to RC Partners.

RC Partners monitors, interprets and clarifies healthcare industry trends, including legislative and regulatory changes and forecasts. We carefully study the implication of these developments in our work to assist our clients in interpreting them for their individual needs. Our healthcare consultancy, simulation modeling and educational modules focus primarily on clarification of and navigation through the Drug Supply Chain and Security Act (DSCSA) and Unique Device Identification (UDI).

We've developed a patent-pending VirtualPilot™ service that allows pilot teams to accelerate the process of learning, discovery and decision-making. We also advise companies in the areas of Business Process Re-engineering and Systems Integration.

Making it our business to stay ahead of yours.

VirtualPilot™

CollaborationLab™

VirtualPoster™

VirtualShowcase™

Who we are

The Center for Supply Chain Studies was created as a forum for thought leaders in supply chain industries to come together and exchange ideas, share knowledge and generate meaningful, evidence-based research. Through collaboration and exploration, the Center and its members create openly-published educational content on a wide range of issues and challenges facing the US and global supply chains. The Center for Supply Chain Studies was formed with one overall mission: to improve supply chain efficiencies, enhance practices and improve overall patient and consumer safety.

Contact Us

Your questions and comments are important to us. Please feel free to reach out to us via the contact information below.

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