

An Interoperable System: Could Blockchain be the Answer?



14 October 2016

Helping Companies Realize Prescription Drug Serialization



Presentation Overview

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- What is Blockchain?
- Does Blockchain matter?
- What does it have to do with DSCSA? How could it benefit industry?
- What do we have to do next?

What is Blockchain?



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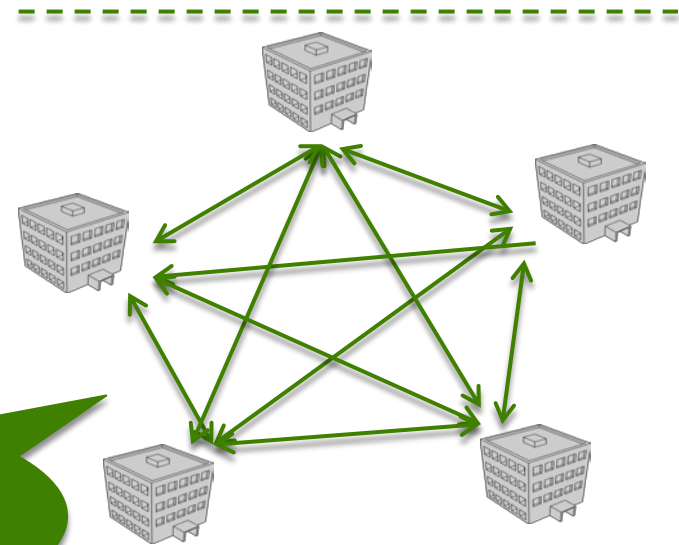
□ Blockchain:

- Is the technology that lies under the exchange of **Bitcoin**, a purely digital internet currency
- Is a digital ledger of transactions stored on a **distributed network** of computers
- Uses cryptography to allow participants on the network to add transactions to the network **securely without the need for a central authority**

Bitcoin (internet currency)



Blockchain (the technology that supports bitcoin)





Does Blockchain matter?

McKinsey&Company

How blockchains could change the world



Ignore Bitcoin's challenges. In this interview, Don Tapscott explains why blockchains, the technology underpinning the cryptocurrency, have the potential revolutionize the world economy.

FINANCE FINTECH

Blockchain Will Be Used By 15% of Big Banks By 2017

by Lucinda Shen @ShenLucinda SEPTEMBER 28, 2016, 1:08 PM EDT

Current State of Blockchain in Healthcare:

- The Use of Blockchain in Health IT and Health Related Research Ideation Challenge, public workshop Gaithersburg, MD Sept. 26-27, 2016 (sponsored by ONC)
- Distributed Health Blockchain Healthcare Conference, Nashville, TN Oct 3, 2016



DSCSA: An Interoperable System



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- Could a blockchain solution be the answer for the “interoperable system”?
 - ▣ **No central authority** (though standards would need to be developed)
 - ▣ **Immutable chain of transactions** for each serial number – completely secure
 - ▣ Would not allow any drugs into the system that did not come from originating manufacturer
 - ▣ Will the Blockchain be a public utility in the future?
- And the critics say:
 - ▣ Blockchain is designed for:
 - digital assets only
 - parties that do not trust each other
 - ▣ High energy requirements

Open Questions:

- Public or private?
- Where is the network hosted?
- US Only?
- Can it handle the volume of data?

What do we have to do next?



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- The LinkLab plans to conduct a Track & Trace pilot for serialized drugs using Blockchain
 - A prototype system will be created using an existing Blockchain system
 - The participants will include manufacturers, wholesalers, and dispensers
 - Expect 1 year program – would report back to industry / FDA on results

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appendix

Problem Statement:

Current US prescription drugs follow many paths with no visibility to where each drug unit has been



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Current US Legislation is looking to improve this visibility through the implementation of serialized product and track and trace requirements of those serial numbers through the full supply chain.

Who We Are



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Susanne Somerville

Founder and Principal



Susanne was most recently the Vice President of Supply Chain, North America, for Genentech/Roche. She brings over 25 years of pharmaceutical, biotech, and supply chain experience to The LinkLab. Her expertise includes:

- Supply Chain Strategic Planning
- Biotech and Pharmaceutical Manufacturing
- Warehousing and Distribution
- ERP and Systems Management
- Project Management and Leadership
- Logistics and Trade
- S&OP and Planning

Susanne was the program sponsor for implementation of serialization for the US market for Genentech, delivering serialized product to the market 3 years before regulatory deadlines.

Eric Garvin

Founder and Principal



Eric founded Global Technical Partners (GTP) in 1997 with a mission to provide industry-best project management services to Pharmaceutical, Biotech, and Medical Device companies. His expertise includes:

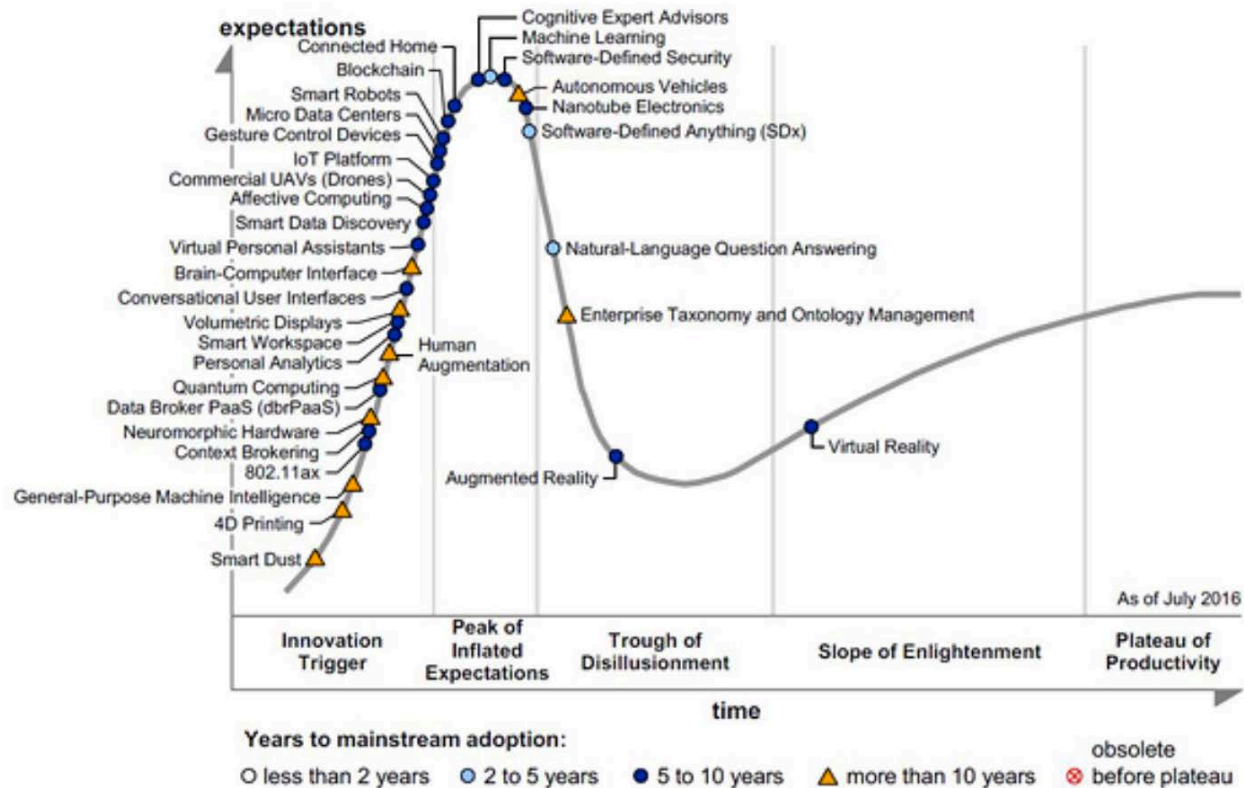
- Management of Enterprise level IT programs
- Merger and Acquisition Integration
- ERP Implementation
- Project and Program Management
- Biotech and Pharmaceutical Manufacturing
- Warehousing and Distribution

Eric has spent the last 3 years leading serialization implementation programs, both for the US and globally and has full understanding of the current solution providers, global regulations, and systems architecture in the space.

Blockchain Hype



Figure 1. Hype Cycle for Emerging Technologies, 2016



Source: Gartner (July 2016)

Source: Gartner (August 2016)