# **2019-09-19 Meeting notes**

#### Date

19 Sep 2019

## Group updates

· Marco Carvalho has agreed to be the Vice Chair

#### Introduction

Bob Celeste from the Center for Supply Chain Studies. Bob is the founder of the Center for Supply Chain Studies. His focus has primarily been in the Healthcare industry, specifically around its supply chain. He has also worked at GS1 US for 13 years. Bob will be completing the presentation he gave at our last Pharma/DSCSA meeting on August 20th. You can watch that presentation here. The last presentation focused primarily on the pharmaceutical supply chain, its challenges and the DSCSA. For this session, we plan to have a brief recap, discuss key takeaways and have an open Q&A discussion around blockchain being a solution to these challenges, DSCSA pilots, etc. so please bring your questions and ideas!

### Presentation

#### **DSCSA** challenges

- · Different points in time
- Implemented over 10 year period
- 2023 supply chain partners need to have their products serialized, but will need to get transaction information to show the history/lineage where the item has been in the supply chain
- Challenges are the supply chain itself
- 97% of all products are broken apart by 3 major pharma companies
- Need to track all the units as it breaks down in the supply chain
- One of the major issues
  - o Is it 1up 1 down?
    - FDA requires leading back to the manufacturer
  - o Criminals have operator as wholesalers to be able to counterfeit
  - o Potential:
- How does a dispenser actually find a manufacturer
- They are who they are and they should be able to have access to their requests
- Credentials for companies in BC
- Citizen access experiment
- Verifiable credentials Decentralized identity
- British Columbia government is providing email verification service
- Steps with credentials? Registered on the blockchain?
- Performed 2 years ago in a simulation, issues encountered:
  - Patterns of shipments, receipts
  - Too much data
  - Slow
  - Issues on confidentiality
  - All can tell about the enterprises based on the data
- $^{\circ}\,$  Group mentioned most of these issues have been addressed in the past year
- THE law requires that upon a request from a regulatory body, that anyone of the supply chain partners must be able to produce previous transaction information
- Trusting inquiries did the wholesaler actually own the product?
- Put information on the blockchain but it hasn't worked
- 150 million fine to large wholesaler by FDA for not taking steps
- Holding DSCSA transaction information (TI) does not working
- EPCIS is one of 5 technologies that FDA is looking into
- Similar to Food Safety Modernization Act (FSMA)
  - https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma
- Stuck on claims request
  - Disclosure request: "If you want this information, then this is what you need to give me"
  - I.e. Prove that I'm over 18. Please provide me your passport or license.

### Presentation

