INTRO TO BLOCKCHAIN AND HYPERLEDGER

REGULATION RESEARCH & IMPLEMENTATION - challenge 1

USE CASE: MEDICAL DEVICE TRACKING REQUIREMENTS AS PER [21 CFR PART 821]

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Selected Use Case for this challenge

USE CASE: MEDICAL DEVICE TRACKING REQUIREMENTS AS PER [21 CFR Part 821]

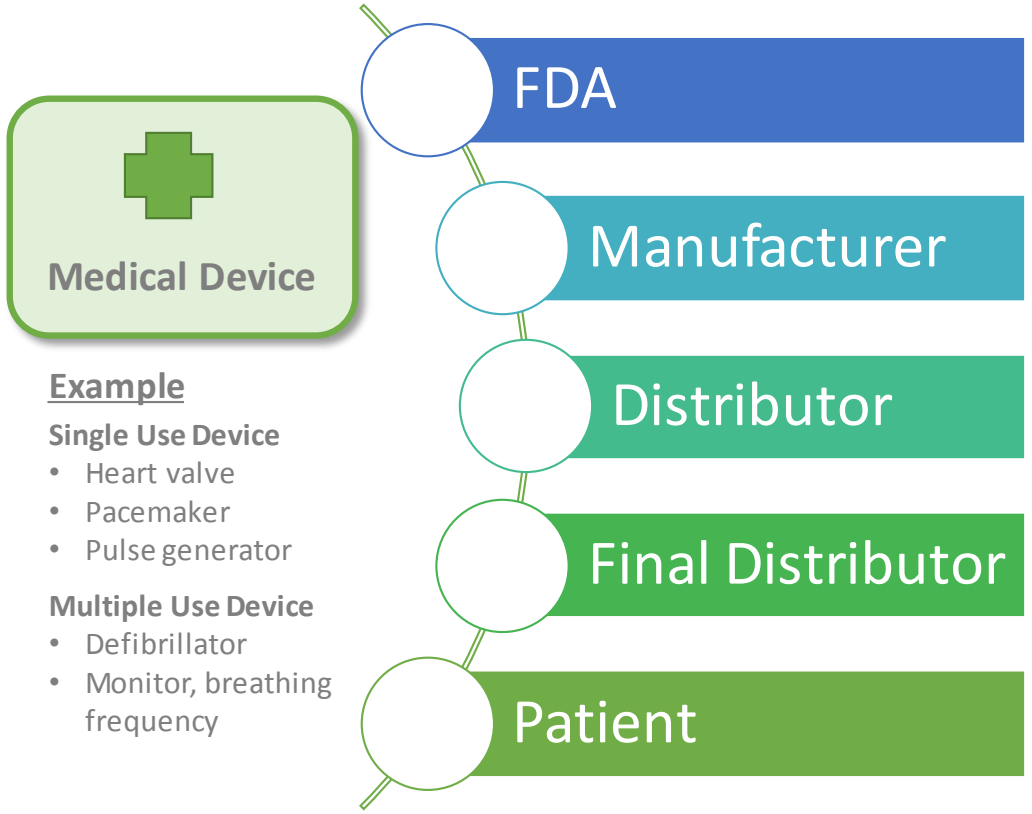
- Manufacturers are required to:
  - **Track** certain devices from their manufacture facility through the distribution chain up to patient level when they receive an order from the (FDA) agency to implement a tracking system for a certain type of (class II & III) medical device
  - **Report** critical information about the location of a tracked device within a short time frame. Manufacturers will have 3 working days to provide critical information about devices that have not yet been distributed to a patient and 10 working days for devices that have been distributed to patients
  - **Audit** periodically verify that the tracking method actually works and that the information collected is accurate

- Effective tracking of devices from the manufacturing facility, through the distributor network and, ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the agency (FDA), such as: patient notification (or) device recall

Code of Federal Regulations Reference:

CFR Part 821	**: MEDICAL DEVICE TRACKING REQUIREMENTS**
Title 21	: FOOD AND DRUGS
Chapter 1	: FOOD AND DRUG ADMINISTRATION (DEPARTMENT OF HEALTH AND HUMAN SERVICES)
Sub-Chapter H	: MEDICAL DEVICES

Source: https://www.gpo.gov/fdsys/browse/collectionCfr.action?selectedYearFrom=2017&go=Go



Example

Single Use Device
- Heart valve
- Pacemaker
- Pulse generator

Multiple Use Device
- Defibrillator
- Monitor, breathing frequency

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Selected Use Case for this challenge

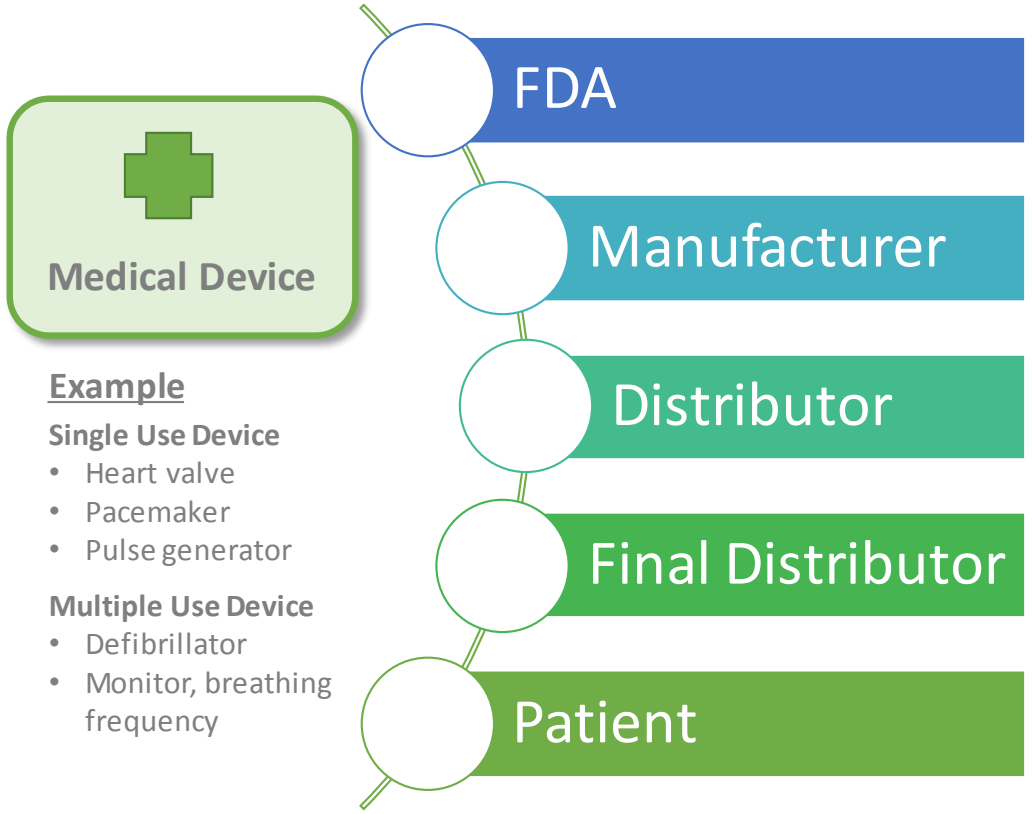
MEDICAL DEVICE TRACKING REQUIREMENTS – Stakeholders, Obligations & Responsibilities

- **FDA**
  - Issue device tracking order to manufacturer
  - Order critical information from manufacturer about the location of a tracked device
  - Order mandatory recalls and require notification of health professionals and patients

- **Manufacturer**
  - Adopt a device tracking method to ensure traceability from the device manufacturing facility, through the distribution network to the patient.
  - Ensure that the tracking system works
  - On demand report to FDA of critical information of a tracked device:
    - Within 3 days - prior to the distribution of a tracked device to a patient: the Unique Device Identifier (UDI), other device identifier details & Distributor details.
    - Within 10 days - after distribution to or implantation in a patient: the Unique Device Identifier (UDI), other device identifier details, Final distributor (physician) details & Patient details.

- **Distributors & Final Distributors**
  - Promptly provide the manufacturer tracking the device with the following information: distributor contact details, device details, physician (final distributor) & patient details

- **Patient**
  - Patient opt-in or opt-out to release personal information for tracking purposes



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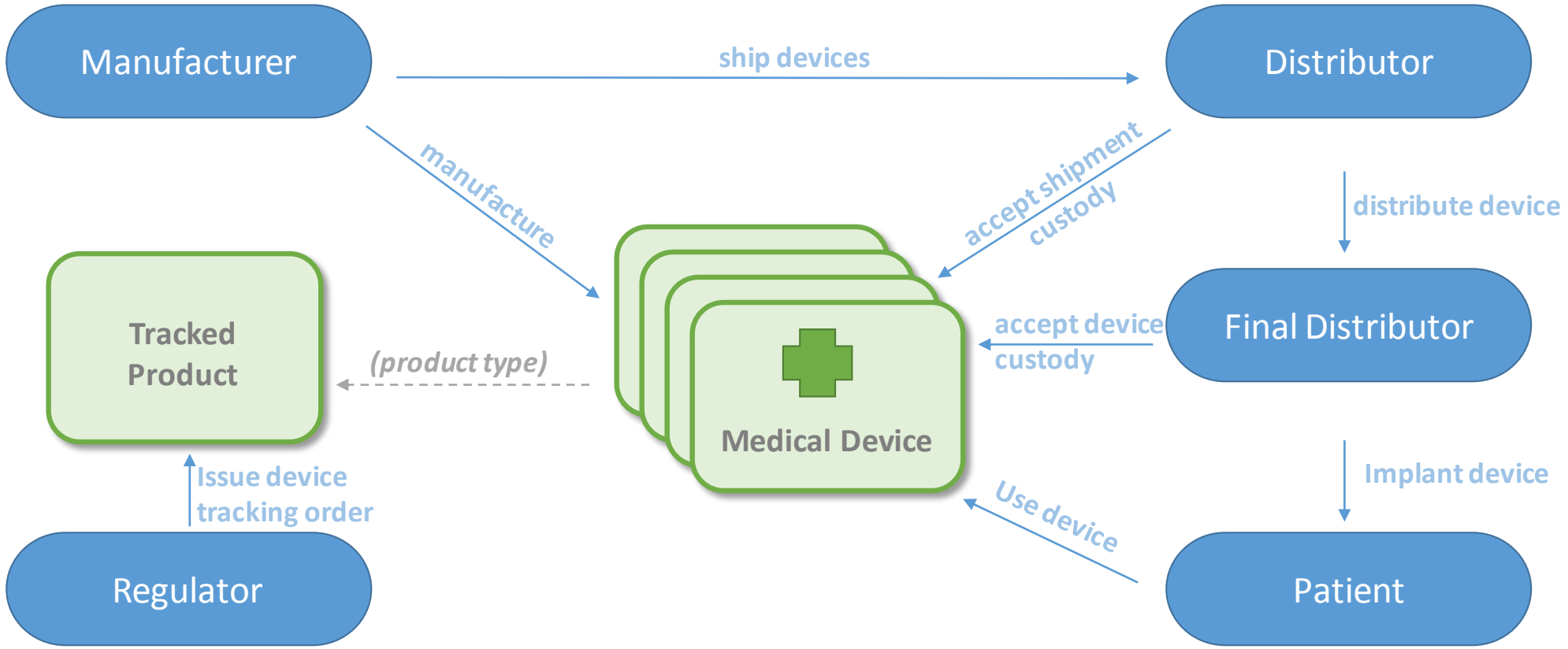
Solution

Model: Participants, Assets & Transactions



Implementation

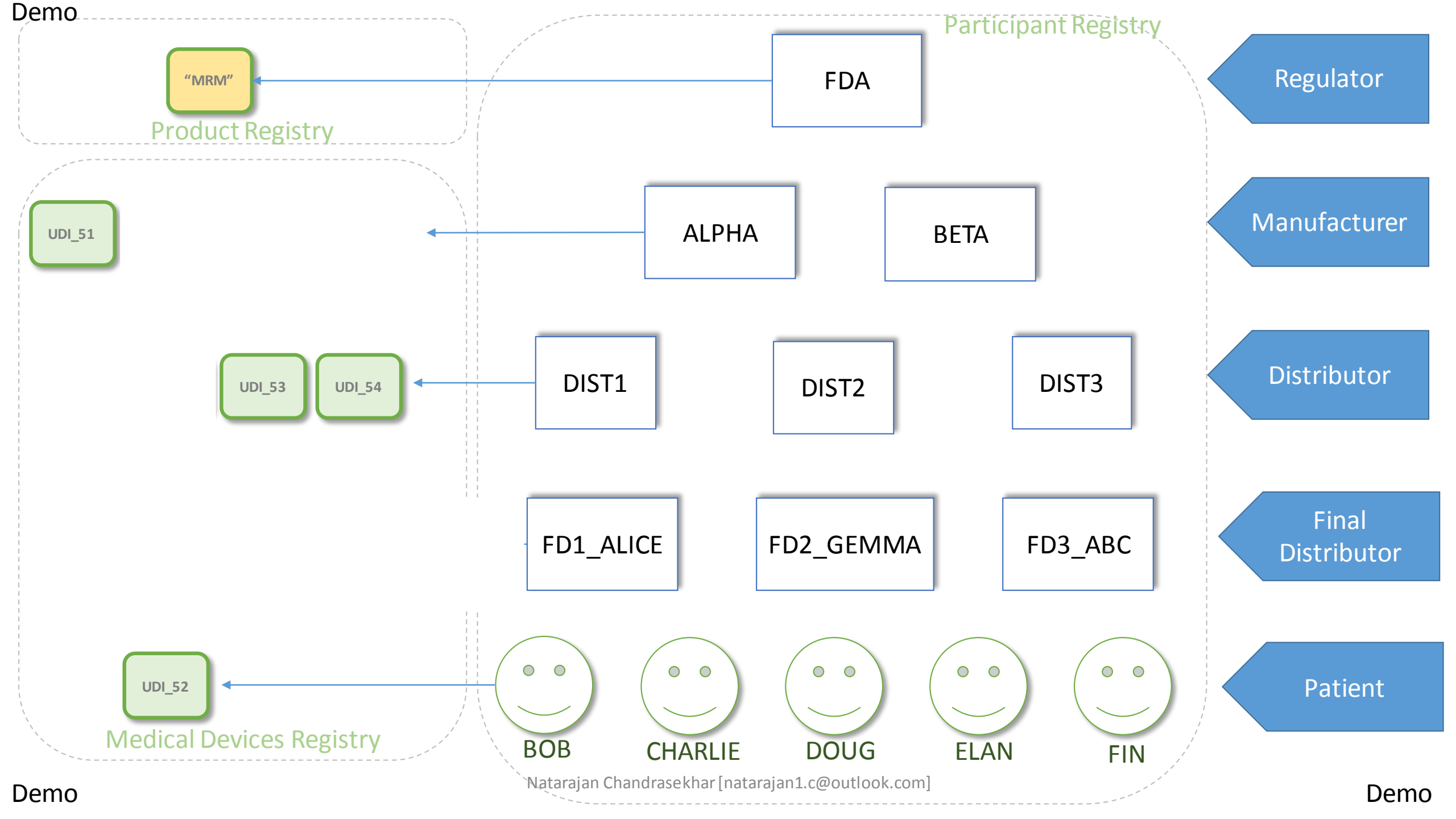
- Tools
  - Hyperledger Fabric
  - Hyperledger Composer [https://composer-playground.mybluemix.net/editor]

- Source Code
  - medical-device-tracking.bna

Demo

Link to video:
https://youtu.be/o5Z85GOiP-Q

Demo



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Demo

Thank You!

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