New Developments in Biopharma Supply Chain

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About the Speaker

Atul Mohidekar
Chief Technology Officer, Senior Vice President Products & Engineering, rfxcel

• Responsible for rfxcel’s technology vision, product vision and product delivery.
• Involved in key customer acquisitions, architecting customer solutions and customer implementations.
• rfxcel’s SaaS products span multiple supply chain solutions: serialization, supply chain traceability, supply chain visibility, compliance with global supply chain laws, raw material traceability, real-time supply chain monitoring using IoT/sensor devices, supply chain analytics, recall management, system integrations & external trading partner integrations.
• Over 25 years of cross-functional experience – engineering management, software architecture & delivery, product strategy, product management, sales, professional services, customer support, acquisitions and capital raising.
• Prior experience: Oracle, Velosel (acquired by TIBCO), Intel, Symantec, etc.
“rfxcel is founded upon an extreme commitment to customer satisfaction & continuous innovation.”

Glenn Abood, CEO & Cofounder

Highlights

Over 17 years of continuous operation
- Life Sciences
- Government

Global serialization & compliance for pharma

+92% rfxcel spend dedicated to product & customer facing Teams

$30M (Series B) in 2017

2020

“Software Company of the Year” (2020)

Certified ISO 9001-2015

FDA Pilot for Saleable Returns

HDA Recognition for Innovation

Partnership with Verizon

2003
Biopharma/Biopharmaceutical/Biologics/Biological Products

“Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. **Biologics are isolated from a variety of natural sources—human, animal, or microorganism**—and may be produced by biotechnology methods and other cutting-edge technologies.”

“A biological medicinal product is a product, the active substance of which is a biological substance. A biological substance is a substance that is **produced by or extracted from a biological source** and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing...”

**Biopharma products are created from biological sources**
Biosimilars/Similar Biologics Products

“A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. A manufacturer developing a proposed biosimilar demonstrates that its product is highly similar to the reference product by extensively analyzing (i.e., characterizing) the structure and function of both the reference product and the proposed biosimilar. A manufacturer must also demonstrate that its proposed biosimilar product has no clinically meaningful differences from the reference product in terms of safety, purity, and potency (safety and effectiveness).”

“A biosimilar is a biological medicine highly similar to another biological medicine already approved in the EU. The biosimilar has physical, chemical and biological properties highly similar to the reference medicine’s. No differences are expected in clinical performance.

Biosimilars/Similar Biologics are Biopharma/Biological products
Common Biopharma Products

- Vaccines
- Cell therapies
- Gene therapies
- Allergenics
- Other
The Biopharma Supply Chain Is Bracing for the “Vaccine Surge”

UPS predicted in July 2020 that biologics will soon represent nearly half of all global pharmaceutical sales.

The World Health Organization (WHO) is aiming to deliver 2 billion COVID-19 vaccine doses in 2021.

DHL estimated that delivering 10 billion COVID-19 vaccine doses over two years would require
• 15,000 flights
• 200,000 movements by pallet shippers
• 15 million deliveries in cooling boxes.

UPS is building two giant freezer farms capable of super-cooling millions of vials of a COVID-19 vaccine... The facilities will house a total of 600 deep-freezers that can each hold 48,000 vials of the vaccine at temperatures as low as -80 Celsius (-112 Fahrenheit).

India’s Serum Institute is building a new plant to manufacture COVID-19 vaccines that will be capable of producing 1 billion vaccine doses when it opens in 2022.
The Biopharma Supply Chains

Products Created from Animals and Microorganisms

RM Supplier → Manufacturer → Distributor → Clinic → Patient

Products Created from Human Tissue/Cells/Blood

Autologous

Allogenic

Clinic → Manufacturer DC → Manufacturing Plant → RM Supplier

Human Tissue/Cells/Blood → Product/RM
Supply Chain Traceability and Monitoring for Biopharma Products

- **Handle with Care**
  - Temperature
  - Light
  - Vibration/Shock

- **Accountability & Actionability**
  - When?
  - Where?
  - Who?
Supply Chain Traceability and Monitoring for Biopharma Products

Handle with Care

Temperature

Light

Vibration/Shock

Accountability & Actionability

When?

Where?

Who?
Supply Chain Traceability and Monitoring for Biopharma Products

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Supply Chain Traceability and Monitoring for Biopharma Products
The award highlights innovative collaborations between distributors and manufacturers that enhance processes, reduce costs and leverage advanced technologies or logistical practices.

"Recipients are models for leadership and innovation in the pharmaceutical distribution industry and demonstrate the power of successful trading partner relationships."
rIM Case Study: Result 1
Temperature Excursion

- International shipment had temperature threshold of 30°C/86°F
- Was stopped at a location without temperature control
- As the temperature rose, a notification was sent to authorized users
- The manufacturer intervened immediately
- Prevented any loss in product and quality
rIM Case Study: Result 2

Product Diversion

- Shipment scheduled to London Heathrow by the 3PL provider
- Geo-point showed shipment at airport without the proper facilities to handle the product
- 3PL was out of compliance and in breach of contract.
- Diversion was corrected and damage avoided.
- 3PL’s contract and processes were corrected.
rIM Case Study: Result 3
Risk Management

- A high-value shipment sat on airport tarmac for 6+ hours and was at risk for a temperature excursion
- Manufacturer informed airport of the issue
- Airport quickly relocated shipment
- Manufacturer observed the movement in real time
- Longitude and latitude values confirmed that the cargo was once again being handled properly
Why Raw Material Traceability Is Important?

• **Improve Product Quality by Continuous Improvement** – Increase process repeatability, reduce variation, increase production throughput and reduce defects

• **Reduce Recall Exposure and Recall Costs** – Prevent recalling unaffected product/units to minimize recall costs and limit customer dissatisfaction

• **Compliance Laws** – Mandated by Governments
Raw Material Traceability for Biopharma Products

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Raw Material Traceability for Biopharma Products
Backward Traceability:
A Finished Good SN/Lot to all its Raw Materials Lots/SNs

RM: A
Lot: 1001

RM: B
Lot: 2105

RM: C
Lot: 3209

FG: Product
GTIN: (01)01234567890128
Lot: (10)55084482
Expiry: (17)221030
SN: (21)3400472894
Forward Traceability:
Select one Raw Material Lot to start Forward Traceability

RM: C
Lot: 3209
Forward Traceability:
A Raw Material Lot to all its Finished Goods Lots/SNs
Advancing the Biopharma Supply Chain

Compliance laws in many countries have forced the industry to digitize the finished goods supply chain.

New developments are happening that enhance the biopharma supply chain: integrated monitoring and raw material traceability to finished goods.
Thank You