



# New Developments in Biopharma Supply Chain

**Atul Mohidekar**

CTO, SVP Products & Engineering, rfxcel

# Agenda

- 
- ◆◆ Introduction
  - ◆◆ Biopharma Products – Background
  - ◆◆ Supply Chains for Biopharma Products
  - ◆◆ Supply Chain Traceability and Monitoring for Biopharma Products
  - ◆◆ Raw Material Traceability for Biopharma Products
  - ◆◆ Summary
  - ◆◆ Q&A

# 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**
- **Allergens**
- **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.

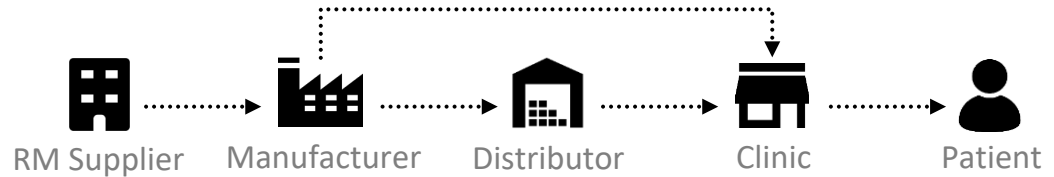
UPS is building two giant freezer farms capable of super-cooling millions of vials of a COVID-19 vaccine... The facilities will house a total of 600 deep-freezers that can each hold 48,000 vials of the vaccine at temperatures as low as -80 Celsius (-112 Fahrenheit).

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.

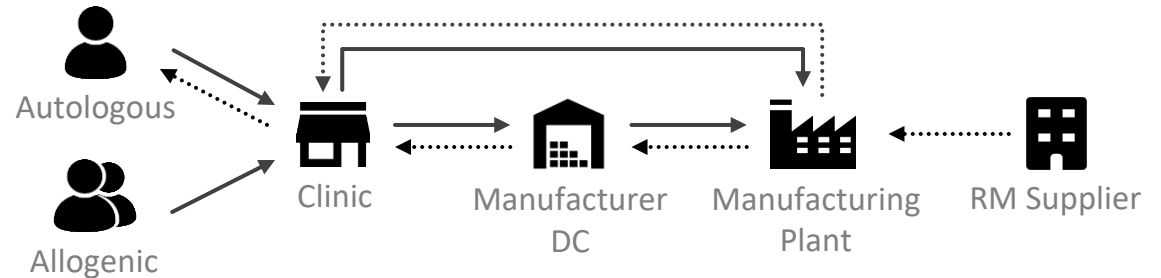


# The Biopharma Supply Chains

Products Created from  
Animals and Microorganisms



Products Created from  
Human Tissue/Cells/Blood



# Supply Chain Traceability and Monitoring for Biopharma Products



## Handle with Care



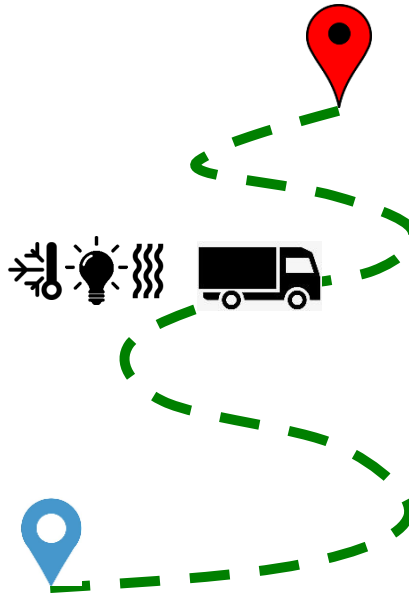
Temperature



Light



Vibration/  
Shock



## Accountability & Actionability



When?



Where?



Who?

# Supply Chain Traceability and Monitoring for Biopharma Products



## Handle with Care



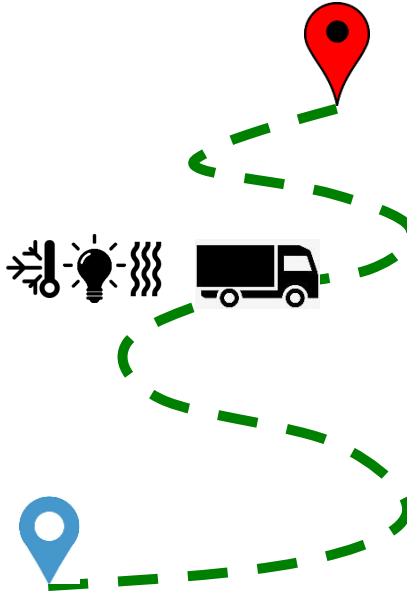
Temperature



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## Accountability & Actionability



When?



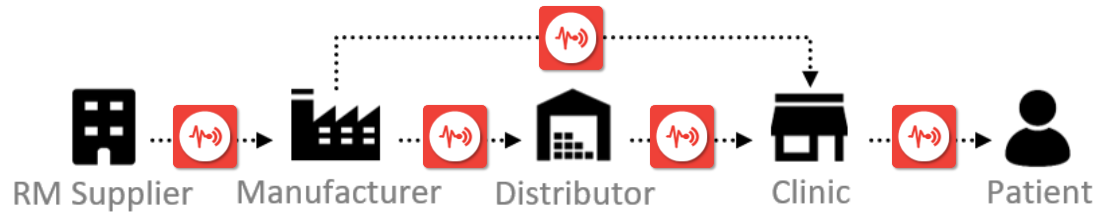
Where?



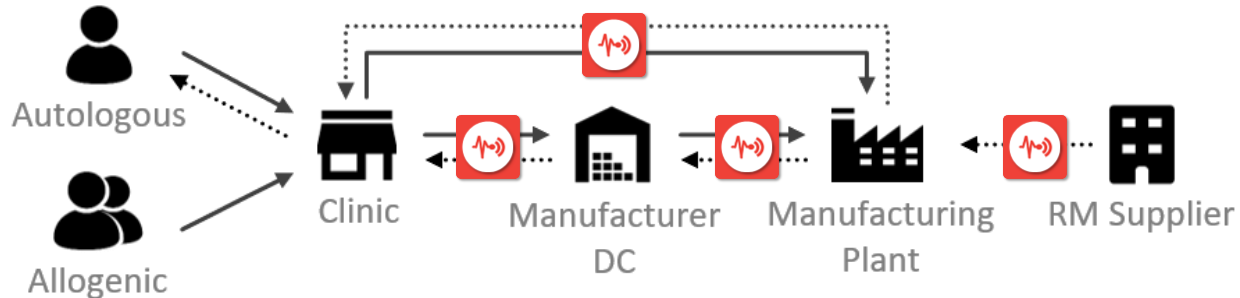
Who?

# Supply Chain Traceability and Monitoring for Biopharma Products

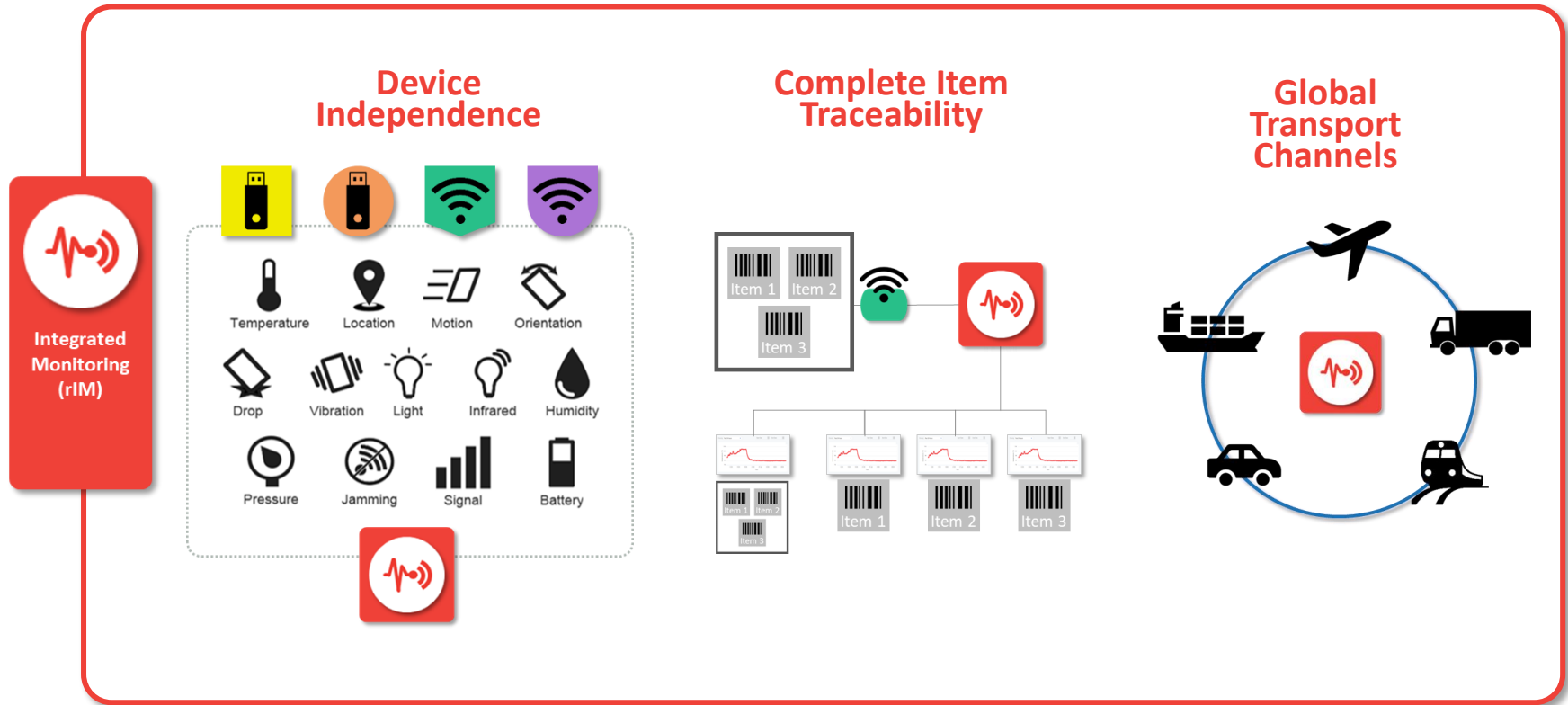
## Products Created from Animals and Microorganisms



## Products Created from Human Tissue/Cells/Blood



# Supply Chain Traceability and Monitoring for Biopharma Products





# rIM: Industry Recognition

## HDA Distribution Management Award

*“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.**”*

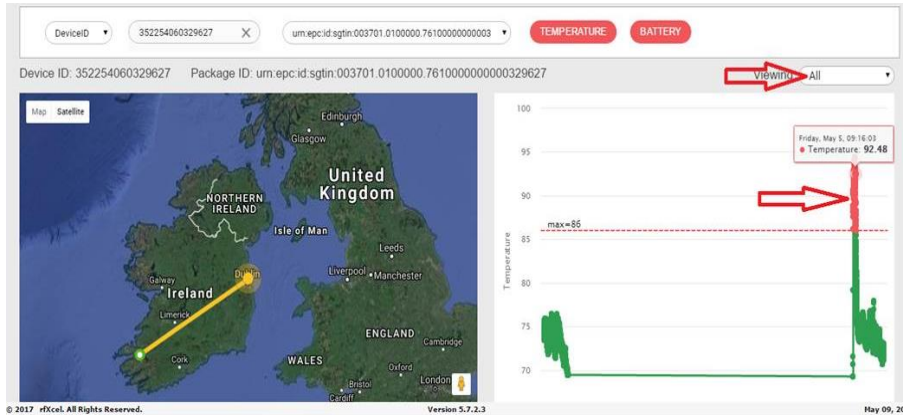


### 2018 DISTRIBUTION MANAGEMENT AWARD

Presented at HDA's 2018 Distribution Management Conference and Expo  
Tuesday, March 6, 2018 • JW Marriott Austin, Austin, Texas

# 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



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# 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.



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# 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



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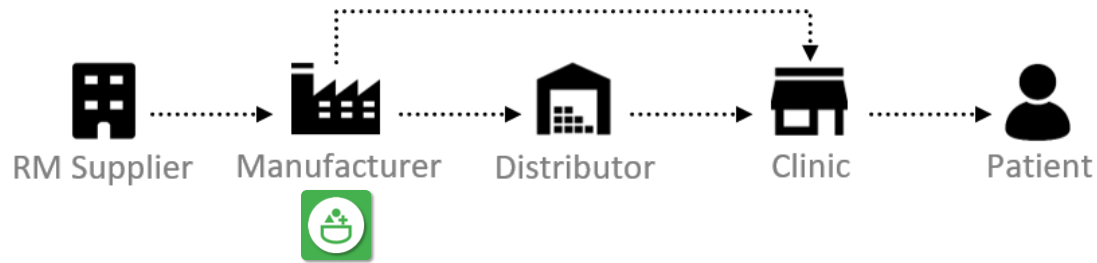
# Why Raw Material Traceability Is Important?

- **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

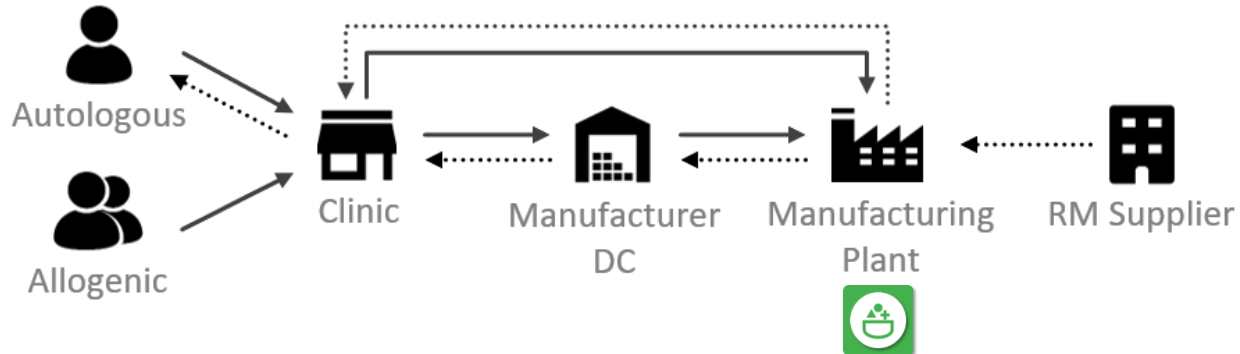


# Raw Material Traceability for Biopharma Products

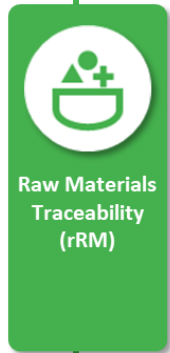
## Products Created from Animals and Microorganisms



## Products Created from Human Tissue/Cells/Blood



# Raw Material Traceability for Biopharma Products

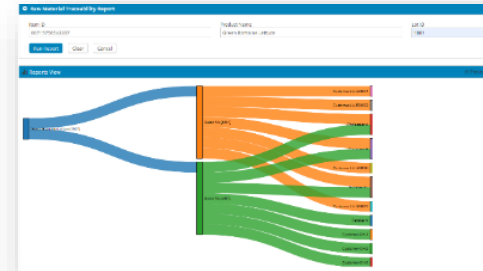


## Product Recipe

Input Product	Product Name	Quantity	Lot Status	Manufacture/Release Date	Action
Input Product	Input Product	10	ACTIVE	2023-01-01	
Input Product	Input Product	10	ACTIVE	2023-01-01	
Input Product	Input Product	10	ACTIVE	2023-01-01	
Input Product	Input Product	10	ACTIVE	2023-01-01	



## RM Lot ↔ FGs Lots/SNs Forward & Backward Traceability



**Backward Traceability:**  
A Finished Good SN/Lot to all its Raw Materials Lots/SNs

RM: A  
Lot: 1001



RM: B  
Lot: 2105



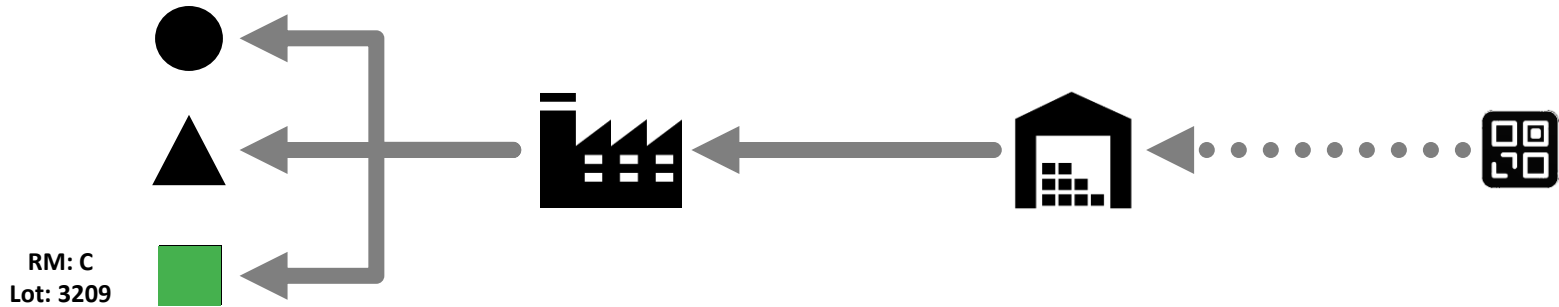
RM: C  
Lot: 3209



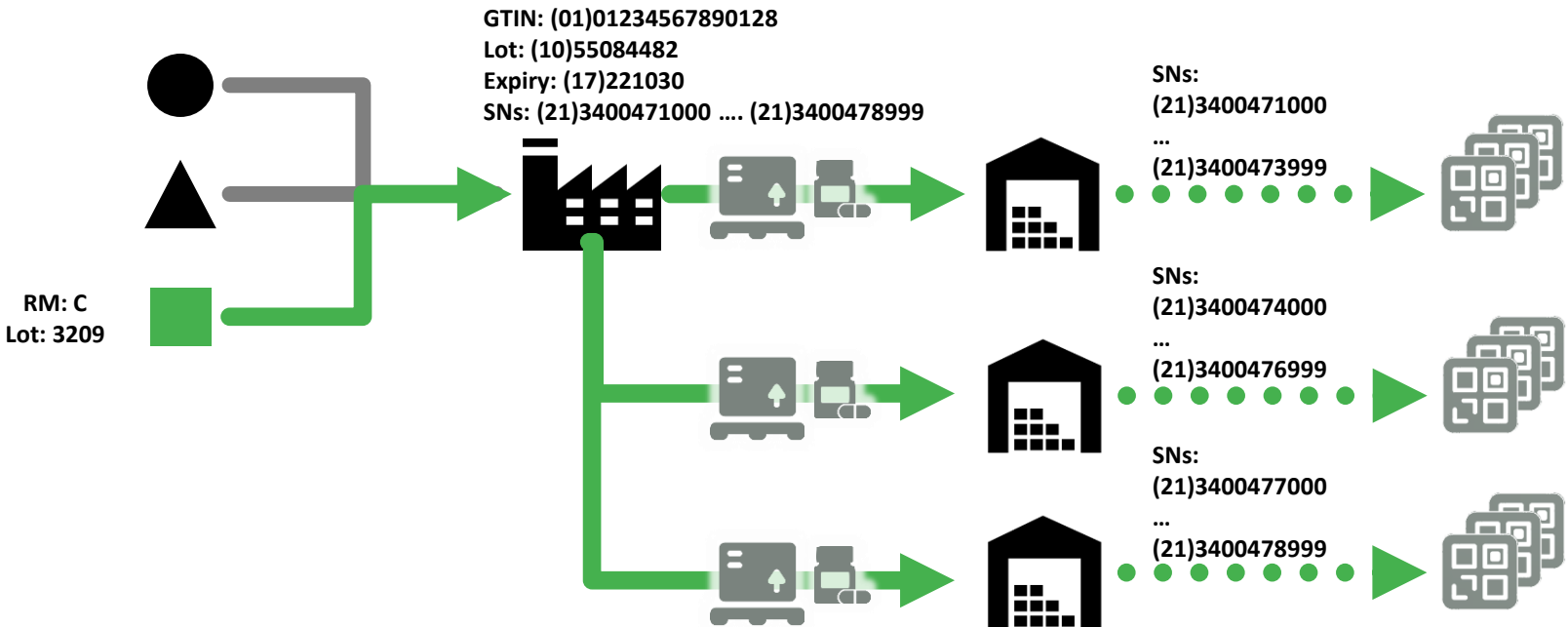
FG: Product  
GTIN: (01)01234567890128  
Lot: (10)55084482  
Expiry: (17)221030  
SN: (21)3400472894

## Forward Traceability:

Select **one** Raw Material Lot to start Forward Traceability



# 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