

SUPPLY CHAIN MANAGEMENT: ENABLING BIOTECH, PHARMA & MED DEVICES GROWTH & PROFITABILITY

Devendra Mishra

Executive Director, BSMA

Adjunct Professor, Pepperdine University



FOUNDING PRINCIPLES OF BSMA

- “Minimize system-wide cost for supply chain management optimization”
.....J. W. Forrester
- End to end Supply Chain view
- Collaboration among stakeholders yields dividends for all
- Goal to achieve greater Productivity, Quality, Safety and Govt. Compliance

BSMA INDUSTRY INITIATIVES

- **SUPPLY CHAIN STRATEGIC SOURCING**
- **SUPPLY CHAIN CLINICAL SERVICES**
- **SUPPLY CHAIN INFORMATION MANAGEMENT**
- **SUPPLY CHAIN TALENT MANAGEMENT**
- **SUPPLY CHAIN RISK MANAGEMENT**
- **ENVIRONMENTALLY CONTROLLED LOGISTICS**
- **HEALTHCARE POLICY COMMITTEE**
- **MOLECULAR DIAGNOSTICS TESTING**

DRIVERS OF INDUSTRY GROWTH, EFFICIENCY & PATIENT CARE

- Scientific Discoveries
- Technology
- Governmental Regulations
- Supply Chain Management

PATIENT SAFETY: THE ULTIMATE GOAL

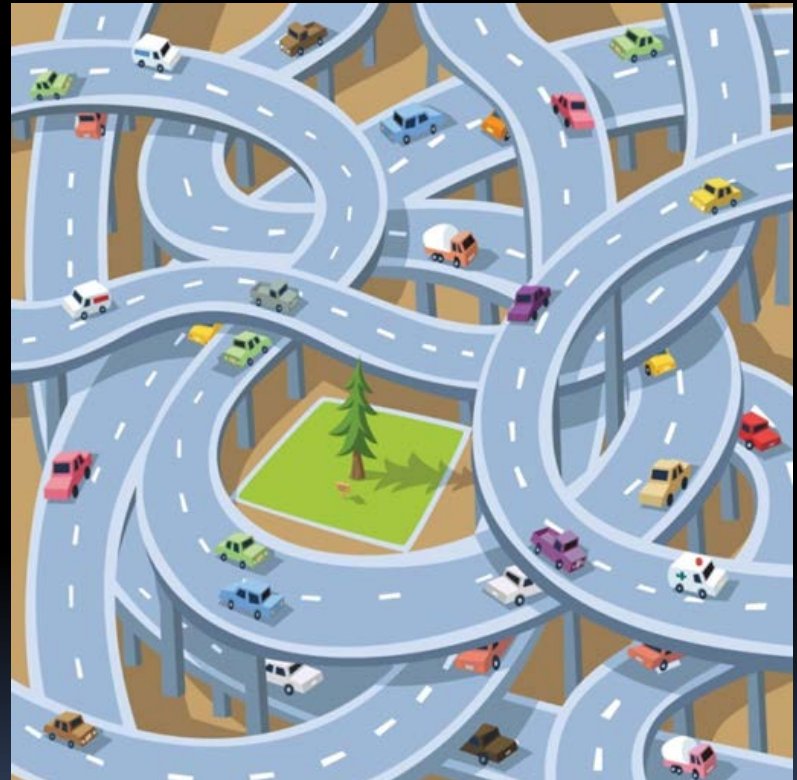
- Traceability has become a primary objective of many regulators around the world and is being applied to Food, Drugs and Medical Devices
- This leads to a few basic questions -
 - What is it?
 - Who owns it?
 - Where did it come from?
 - Is it authentic?
- **Increasingly the answers to the questions are required BEFORE the actual product is physically received.**

SITUATIONAL ANALYSIS

- 80 percent of the active pharmaceutical ingredients in medications sold here are manufactured elsewhere.
- Half of all medical devices used in this country are imported.
- Globalization is accelerating where manufacturing overseas for cost considerations is common place
- The threats of sub-par quality, counterfeit, adulteration, diversion, theft, contamination of drugs to patient care are unacceptable
- FDA's tools of Inspection have to be replaced with preventive and proactive approaches

SUPPLY CHAIN IS COMPLEX

- Thousands of ingredients
- Complex – APIs, Packaging, etc.
- Multiple Suppliers
- Various Transportation Methods
- Multiple Manufacturing Locations
- Third Party
- Multiple Distributors
- Inbound/Outbound
- Captive/Third party



FDA: PATHWAY FOR GLOBAL PRODUCT SAFETY & QUALITY

- Partner with foreign counterparts to create global coalitions of regulators
- Build a global data-information system and network and proactively share data with peers
- Expand its capabilities in intelligence gathering and use, with an increased focus on risk analytics and thoroughly modernized IT capabilities
- Leveraging the combined efforts of government, industry, and public- and private sector third parties

PRODUCT INTEGRITY STARTS WITH SUPPLIER

- Good Manufacturing Practices
- Good Import Practices
 - CBP 10+2
 - Temp. Monitor
 - Good Cold Chain Practices
- Supplier Quality Management
 - Secondary Suppliers
 - Tertiary Suppliers
 - Risk Management
 - Quality Agreements
- Good Distribution Practices

INFORMATION TECHNOLOGY



- Ways of connecting, sharing, collaborating, and doing business become richer, more varied, and more powerful.
- Progress in information technology is transformative.
- Every year brings faster processing speeds, greater storage capacity, and more advanced software.

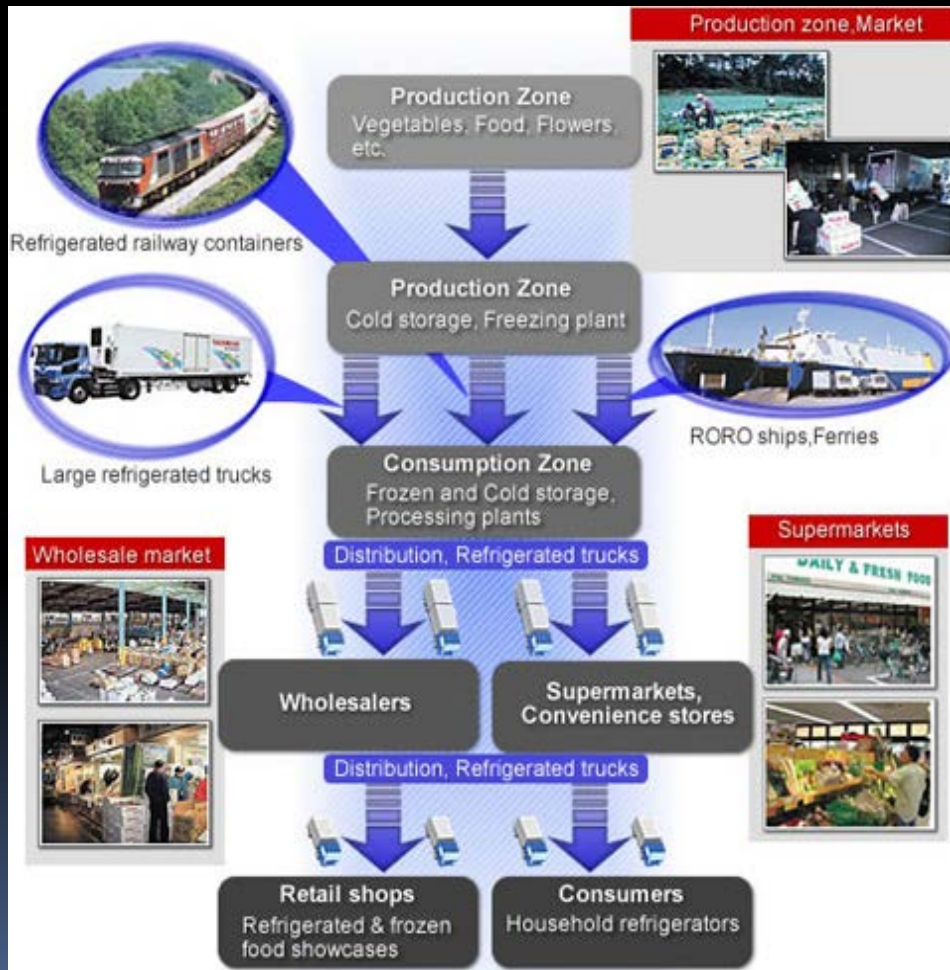
SERIALIZATION



- Visibility in the Supply Chain End to End
- Accountability
- Elimination of Counterfeit Drugs and Leakage
- ROI



COLD CHAIN TECHNOLOGY



Ensure Drug Quality from Manufacturer to Patient

Monitoring for Govt. Compliance

Enabling New Drugs

FINAL NOTE

Let Us Collaborate and Build a Community of
SCM Professionals!

Thank You!