Up-Stream Supply Chain Management for Excipients through Distribution

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COMPANY BACKGROUND

- IPEC Americas member
- Quality Excipients distributor & co-marketer
- Pharma industry
- Technical, regulatory and quality know-how
- Offering valued-added services
“Up-Stream” Distribution is Critical

API

Up-stream

Excipients

Down-stream

Patients
• Discuss Supply Chain Security opportunities:
  – Sourcing
  – Transportation
  – Storage
  – Shipping to Customer
WHY EXCIPIENTS. . .

Excipient Distribution is new to cGMP & Regulation
WHY EXCIPIENTS...

• Concerns
  – Consistency and preservation of quality attributes
  – Security / Safety Risk
  – Supply
  – Cost
Basic of Excipient Distribution

- Source & qualify
- Sales Representatives (for suppliers)
- Purchase
- Transport
- Stock
- Deliver
EVOLUTION OF PHARMA DISTRIBUTION

Few distributors... Why?

Pharmaceutical Industry = HIGH MAINTENANCE

- Quality driven
- Slow-to-change
- No quick sale
EVOLUTION OF PHARMA DISTRIBUTION

• Few distributors... Why?
  – Considered as “sellers”
  – Work not always profitable
  – Requirements increased
    • 1970’s – Certificate of Analysis not required
    • 1980’s – Shipments without MSDS
EVOLUTION OF PHARMA DISTRIBUTION

SUCCESS = COMMITMENT TO SUPPLY CHAIN INTEGRITY
EVOLUTION OF PHARMA DISTRIBUTION

- Distributor = Asset to the Customer
  - Benefits
    - Multiple source alternatives
    - Local supply & smaller quantities
    - Logistic, technical & regulatory support
    - Tailored services & efficiencies
    - Consolidation of materials
    - Effective economics
EVOLUTION OF PHARMA DISTRIBUTION

FLEXIBILITY

Distributor  →  Extension of the Process
CUSTOMER  BASIC EXPECTATIONS ➔ SUPPLY CHAIN SECURITY
right product, quantity, functionality, regulations...  ON TIME
• Distribution starts here:

Long-term distribution relationships with quality Excipient manufacturers creates a partnership as an extension of their sales, regulatory, quality and supply chain teams.
SUPPLY CHAIN CONTROL PARAMETERS

- Risk assessment
- Contingency strategies
- Market & regulatory intelligence
- Supply chain mapping by product
- Communication & reliability
SUPPLY CHAIN CONTROL PARAMETERS

• Quality Controls
  – Documentation
  – Training
  – Metrics → KPI’s (Key performance indicators)
  – CAPA → Improvements
EXCIPIENT SUPPLY MAPPING

- Excipient Manufacturer
- Crystallization
- Fermentation
- Centrifuge
- Raw Material #1
- Raw Material #2
- Raw Material #3

- Supplier (Distribution Site)
- Distributor
- CUSTOMER
EXCIPIENT BACKGROUND

- Consider
  - Know original manufacturer
  - Assure that Manufacturer has a GMP compliant Quality System
  - Evaluate Chain Supply handled in compliance with GMP and GDP requirements
  - Excipient manufacturer quality certification
DISTRIBUTION CONTROLS

- Risk Assessment
  - Quantity of players in supply chain
  - Product shortages
  - Country of origin
  - Economics
  - Environmental factors
  - Repacking or labeling changes
  - Tampering or adulteration

Prior assessment ➔ Anticipation ➔ Risk Prevention
DISTRIBUTION CONTROLS

• Sourcing
  – Quality Suppliers
    • Who – How – Where
    • Specifications, samples, tech/regulatory documentation
    • Audits
    • Lead times & supply mapping
  – Qualify transportation (carrier & broker selection)
    • Dedicated containers
  – Supplier consistency builds supply credibility
DISTRIBUTION CONTROLS

- Transportation
  - Internal coding of material, supplier, packaging
  - Logistics confirmation at-all-stages
  - Import & transport regulatory compliance
  - Coding transparency on all documentation & check-lists
  - Incoming inspection
  - Bar-coding
DISTRIBUTION CONTROLS

• Storage
  – Re-palletize
  – Shrink-wrapped
  – Segregation specific to material
  – Ambience monitoring
DISTRIBUTION CONTROLS

• Shipping
  – Unit labeling (customer PO, code, specifications)
  – Final cleaning & inspection
  – Coding verification & check-lists, internal sign-off
  – COA’s, B/L, packing list consistency
  – Inspection of carrier, check-list, sign-off
DISTRIBUTION CONTROLS

• Customer Receiving
  – Verification of material, documentation & sign-off
  – Problem-free delivery
DISTRIBUTION CONTROLS

• Evaluation
  – Quality Manager dedicated to verification of operation
  – Internal self-auditing
  – Trainings → Metrics → Goals
  – Review → Improvements
  – Demonstrate reliability
  – Audits from customers
DISTRIBUTION CONTROLS

• Non Conformance Events
  – Internal investigation tracking system
  – Customer complaints (full investigations reports, CAPA)
  – Internal deviation of NCE’s

• Change controls → Customer communication

• Security
  – Guarded facility, video monitoring & recording
  – Controlled-area access only (training required)
HOW DISTRIBUTORS ARE QUALIFIED BY PHARMA?

• Product availability outweighs other factors (lead time)
• Reputation in business (vs. true verification)
• Audits are usually done later (resources?)
• Purchase order is the only agreement

Limited time & resources → Need for 3rd Party Audits
CUSTOMER AUDITS

• Housekeeping & Pest Control
• SOP compliance & training
• Storage temperature & humidity
• Inventory accuracy, receiving & shipping verification
• Heat-treated pallets
• Damaged materials (storage & disposal)
EXCIPIENT DISTRIBUTION OF THE FUTURE

• Multiple-global locations & creation of “pharma facility”
  – Government registration (FDA)
  – Electronic “track & trace” (tamper chips)
  – Start-to-Finish transparency
EXCIPIENT DISTRIBUTION OF THE FUTURE

• Multiple-global locations & creation of “pharma facility”
  – Photo libraries (product, packaging, labeling, seals)
  – Id / RAMAN product identification
  – Valued-added services & efficiency creation
BUILDING EFFICIENCIES INTO SUPPLY CHAIN

“Production Ready” Excipients

Sampling, Dispensing, Repacking & Testing

INTEGRATING COST EFFICIENCIES TO PROCESSES
BUILDING EFFICIENCIES INTO SUPPLY CHAIN

AVS = Shorter Manufacturing Current Process Manufacturing Cycle

...The whole is greater than the sum of the parts
QUALITY NOT SACRIFICED...

• What is expected
  – Equivalency ISO Class 8 & Class 100,000 PC
  – ISO 9001 & IPEA Certification
  – Customer certification
  – Excipient manufacturer’s certification
REGULATORY COMPLIANCE

- cGMP – CFR 21 Part 210, 211
- Supply Chain Integrity
- Robust Customer Qualification
- Ownership of quality process
- Risk management

Manufacturers ultimately responsible for qualifying suppliers
SUMMARY ON EXCIPIENT DISTRIBUTION

- Product availability & performance are priority (not how it got there)
- Pharma manufacturers’ risk tolerance is still high
- Pharma distributors are “setting the bar” for their supply chain
- Monitoring, documentation, evaluation are the tools
- Time, resources, support are the fuel
SUMMARY

PRODUCT INTEGRITY

PATIENT SAFETY

Excipient Manufacturers

Pharmaceutical Manufacturers

Product Transparency

Excipient Distributor

Product Traceability

PRODUCT INTEGRITY

PATIENT SAFETY
A good investment starts with a relationship of quality, integrity & trust