Supply Chain Challenges in the Life Sciences Industry

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2007 Northeast Supply Chain Conference & Educational Exhibition

Supply Chain Challenges in the Life Sciences Industry

Our objective today is to understand the unique challenges of the Life Sciences supply chains

- Biotech
- Pharmaceutical
- Medical devices

Agenda

- Background
- Comparison of Supply Chains
- Unique Challenges and Implications

Pharmaceutical vs Biotechnology Drugs

	Pharmaceutical	Biotechnology
Discovery	Chemical synthesis and biological extracts	Design, modify and synthesize biological compounds
Molecule size	Small	Large
Delivery	Oral (tablets, capsules), Injectable (sterile), topical	Injectable (sterile), skin patches, inhalation
Manufacturing	Chemical processes	Biological processes

Supply Chain Structures

Biotech

RM & Components → Cell Culture & Purification → Fill/finish → Package → Distribution → Customer

Pharmaceutical

Active pharmaceutical ingredient & components → Drug Product → Fill/finish → Package → Distribution → Customer

Medical Device

RM & Components → Discrete Manufacturing → Package → Distribution → Customer → Repair

Life Sciences Supply Chains

	Pharma	Biotech	Med Devices
Manufacturing Process	Mixing/Blending	Biologic Process	Discrete Manufacturing
Product Technical Complexity	Med-High	High	Low-Med
Product Value ($/g)	~$5	$100 to $1,000+	Varies
Regulatory Focus	Process Control	Product Control	Process Control
Capacity	Incremental	Highly Capital Intensive	Incremental
Supply Chain Scope	Global	Global	Global
Experience/Maturity	High	Low	High

Challenges and Implications
Unique Materials and Components

Many raw materials and critical components are very difficult to obtain …

Implications

- Single sourcing is more common
- Higher level of inherent risk

Recommendations

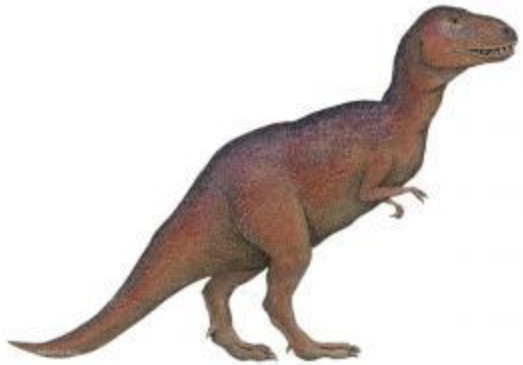
- Structured, formalized risk identification and management
- "Belts and suspenders"
- Strategic partnerships with key suppliers

Examples

- Cell Lines
- Solutions
- Buffers
- Active pharmaceutical ingredients

Challenges and Implications
Long Cycle Times

Supply cycle times typically run 4-8 months from production to distribution…



Implications

- Difficult to link supply with actual demand (MTO, replenishment)
- Slow to react to trends, events, problems
- High inventory levels; more at risk
- Increase complexity of materials mgt.

Recommendations

- Aggressive management of cycle times through both production and quality
- Identify and manage key constraints
- Move to replenishment where possible

Challenges and Implications
Fragile Products

Many pharmaceutical and biotech drugs are very fragile and degrade quickly …

<u>Implications</u>

- Environmental parameters must be tightly controlled (i.e.”cold chain”)
- Drug delivery often requires IV injection

<u>Recommendations</u>

- Understand customer requirements for storage & use…based on good scientific data
- Plan early for controlled shipping & handling
- Include transport & storage considerations in development
- Consider end-to-end product tracking and environmental monitoring

Challenges and Implications Product Expiry

Expiry imposes additional constraints on a supply system.

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Implications

- Strict limitations on inventory levels
- FEFO (not FIFO) inventory management
- Adds complexity to planning process (Concept vs. expired)

Recommendations

- Consider expiry in positioning of strategic inventory
- Reduce cycle times where possible
- Utilize advanced simulation modeling for scenarios
- Maintain multiple options for storage capacity

Challenges and Implications Inconsistent Regulatory Requirements

Requirements vary across jurisdictions.

Implications

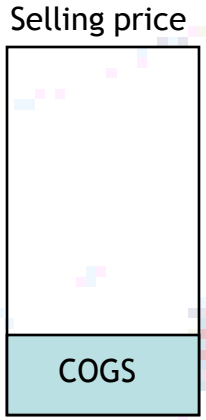
- Product label
- Acceptable specifications
- Product expiry
- Packaging requirements
- Unauthorized product movements
- Brand security & counterfeiting

Recommendations

- Apply “postponement” strategies where possible
- Consider advanced constraint-based optimization tools

Challenges and Implications
Minimal Cost of Goods

Production costs are typically a very small percentage.



Implications

- Little emphasis on cost reduction
- Typical service/cost tradeoffs techniques rarely apply directly
- Cost of stockouts much greater than cost of holding inventory (NPV of a day on the market of a product with a finite patent life)

Recommendations

- Prioritize service and quality over cost in tradeoffs
- Focus OE efforts on improving quality, service and compliance rather than reducing cost

Challenges and Implications Regulatory Environment

Regulatory bodies demand compliance for safety, integrity, and quality.

Implications

- Processes directly impacting products are tightly controlled
- Changes and improvements can be difficult to make…Cost and time to modify supply chain are large
- Single supply chain supplies global requirements

Recommendations

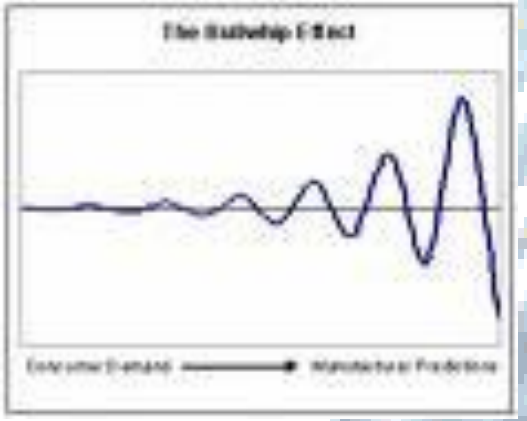
- Plan early for alternate sources and contingencies
- Develop contingency plans for multiple likely outcomes
- Actively build and manage flexibility into the supply chain
- Be VERY careful when choosing partners

Challenges and Implications
High Uncertainty

Key variables and decisions can have dramatic impacts on supply.

Implications

- Plans (& forecasts) can be wildly off
- Due to high cost and long time to switch supplier, BULLWHIP EFFECT is exacerbated.
- Significantly different planning scenarios may result from single decisions/outcomes

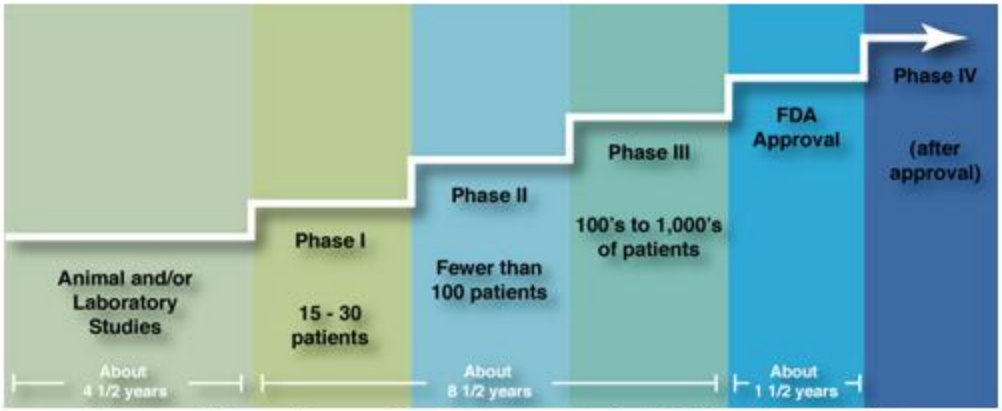


Recommendations

- Identify, track, and manage key variables
- Develop contingency plans for multiple likely outcomes
- Actively build and manage flexibility into the supply chain

Challenges and Implications Clinical Trials

All new drug and many medical devices must go through a clinical trial process before approval.



The Drug and Approval Process in the 1990s as reported by the National Cancer Institute.

Implications

- Product supply is uncertain due to new process, new suppliers, long lead times
- Many factors impact supply and are in a state of flux (e.g. number of sites and patients, dosage level)

Recommendations

- Identify, track, and manage key variables
- Ensure commercial interests are considered in sourcing decisions

Challenges and Implications
Pedigree and Mass Serialization

Federal and (especially) state regulations are forcing the industry to take anti-counterfeiting measures

Prove "chain of custody" throughout supply chain

Mass serialization of items

Implications

- Significant investments needed in IT, packaging, and related areas
- Additional process steps will need to be implemented

Recommendations

- Develop readiness plans for meeting regulations
- As regulations are constantly evolving, implement solutions when exact requirements are well understood

Questions