How the Global Supply Chain Organization is Managing the Transition at Eli Lilly & Company

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Answers That Matter.
“… global research based pharmaceutical company dedicated to creating and delivering innovative pharmaceutical based health care solutions…”

$12.3B

$20.3 billion sales
19% reinvested in R&D

Human Health Products: Strattera, Cialis, Zyprexa, Cymbalta, Prozac, Humulin, Evista, Xigris, Gemzar, Alimta, Fosteo, Humalog, Byetta

Animal Health Products:

40,500 employees in 146 countries

21 manufacturing sites
92 contract manufacturers
160 Sales affiliates / DC’s
Lilly’s Supply Chains

Supply Chain Complexities:

- # of products – 420 dosage formulations going into 2850 SKU’s
- technology (tablets, capsules, vials, cartridges, patches, devices)
- bulk technology (fermentation, recovery, biotech’s)
- Quality model (laboratory, regulatory reqt’s)
- Product protection – distribution, storage, anti-counterfeit serialization, tampering
- Product life cycle
Product Life Cycle is all about making the “right” decisions at the right time

Supply Chain Design

- Must happen during development to support regulatory requirements
- Must balance risk of clinical failure with speed to market of successful products
- Must enable a robust and responsive supply after launch

Supply Chain Operation

- Must ensure 98% customer service in all scenarios
- Must effectively utilize fixed assets and working capital
- Must adapt to the marketplace in spite of regulatory influences
- Must optimize capacity and inventory across the supply chain

On the average we are looking at a time period of 10 years prior to launch.
Supply Chain Operations: maintaining 98-99% customer service level and maximizing profitability

Global Supply Chain Operations

1. Demand Management
2. Inventory, risk & Customer Service Level
3. Supply chain planning
4. Global Capacity Balancing and Profit Maximization
5. Launch Management
6. Operational Excellence
Issues Facing Lilly Today

- Gap in the pipeline of new products along with loss of key patents will reduce demand
- Pressures for health care reform create uncertainty
- Worldwide recession puts pressure on spending
- Cost reductions required to fund research
- Emerging markets require investment
- New Products require investment
- Increased product requirements for safety
- Lilly desires to meet worldwide health care issues
What is Global Supply Chain Doing?

• Maintain excellence in operating the Supply Chain Processes

Operating Standards for Supply Chain Excellence
What is Global Supply Chain Doing?

- Maintain excellence in operating the Supply Chain Processes

Operating Standards for Supply Chain Excellence

- Assure Sales & Operations Planning (S&OP) processes are maintained
**OBJECTIVE**
Assure global supply is optimized across the supply chain to meet the total global demand

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**OBJECTIVE**
Assure demand realization and high levels of customer service are achieved considering all sources of supply

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**OBJECTIVE**
Managing capacity and cost to assure all demands pointed there way are met on-time and in-full
What is Global Supply Chain Doing?

• Maintain excellence in operating the Supply Chain Processes

Operating Standards for Supply Chain Excellence
• Assure S&OP processes are maintained
• Streamline the processes - (Lean Six Sigma)
Lean Six Sigma at Eli Lilly & Co.
What is Global Supply Chain Doing?

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- Reduce complexity
  - Synchronized Lean
Results in:

An increase in Packaging orders by 76%

While simultaneously the average order size decreases by 34%

This means packaging will experience more packaging setups while each order spends less time on the equipment
One Typical Solution

Add 40% more direct and indirect labor

Add 4 more packaging lines

Bottom line: Cost per pack increases by 14% when the market demands less cost
Alternative to Managing Complexity

Implement a Synchronized Lean program to meet the increase in demand without adding cost

Lean principles applied in manufacturing attack the sweet spot of the “usually” conflicting objectives

June 19, 2009  R Bohl GSC
Creating a Lean Vision

Current State:
# products – 958
Volume: 65,000,000
# orders – 5000
A replenishments – 10
B replenishments – 6
C replenishments - 3
Set up time – 2.5 hours
Set up hours – 11,960
Direct labor hours – 116,700
Indirect to direct hdct – 3/1
Lead time – 34 days
Cycle time – 13 days
Remaining shelf life – 84%

Future State:
# products – 1100
Volume: 75,000,000
# orders – 7700
A replenishments – 10
B replenishments – 8
C replenishments - 6
Set up time – 1.2 hours
Set up hours – 11,500
Direct labor hours –154,000
Indirect to direct hdct – 1.5/1
Lead time – 10 days
Cycle time – 3 days
Remaining shelf life – 92%

Path forward requires
1. Commitment
2. Vision
3. Consulting / Education
4. Governance
5. Tools / Processes along the transition

Lean, Flexible Cow
Synchronized Lean Flow in Packaging

Implement pull system (Kanban capacity signal) to trigger authorization to produce

Daily / shift Dispatch List for each of the twelve packaging lines sets priority and triggers the pull.

Push product through based upon lean six/sigma tact time

Dispatch list without dates determine next item to produce only triggered through kanban pull signal

Eliminate by incorporating in Schedule. Identifying capability across 12 packaging lines and incorporating shipping sub optimization to align weekly packaging schedules. Use calendar logic in SNP to accommodate.

Total Lead time 10 days
The journey to a Synchronized Lean finishing environment

Current status

- Use of SOQs
- Each SKU managed individually (unique & time-consuming plans every time)
- Sub-optimization of different steps leading to long and variable lead times
- Complicated shipment consolidation

Implementation of Replenishment Repetitive Cycles

After a first round of improvements

- Use of POQs (variable Qty)
- Fixed schedules in Mfg (product wheel)
- Synchronization of Mfg and Shipping: shorter lead times and easier shipment consolidation

Decision?

- Change-over time reductions (SMED) and additional improvements derived from the repetition of the fixed schedules mean less capacity requirements. As a result:
  - Capacity constraints alleviated and/or no need to invest in capacity (cost avoidance).
  - Alternatively, more volume can be managed with existing resources.
- The frequency of replenishment is increased. This means more orders to fill the available capacity that would help to reduce inventories, improve shelf-life and less dependency on sales forecast accuracy. These benefits would be realized at the expense of the manufacturing capacity to manage more orders, although higher levels of repetitions may deliver other benefits faster.

Leverage local and external opportunities: Synchronized Lean environment

Local benefits (Mfg) External benefits (DCs)
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  – Project Tango
Communications with Contract Manufacturers

- Lilly has 92 Contract Manufactures, approximately 60% are strategic in our supply and demand realization processes.
- Gathering information is difficult and resource/time consuming.
- Creating a collaborative environment where data can be shared and information flows are timely does not exist.
- “Who’s driving and who’s riding?”
Collaboration Vision

CMOs and Suppliers

LillyNet Toolbox

Collaboration Services
- Identity Management
- Access to Web Services
- Business Process Management

Quality Management
- Non-Conformance Management
- CAPA Management
- Product Complaint Management
- Adverse Event Management
- Batch Release
- Certificate of Conformance

Demand & Supply
- Demand Management
- Planning
- Supply PO or Process Orders
- Inventory Management

Material Testing
- Test Methods & Specifications
- Sample Management
- Test Request / Results
- Certificate of Analysis

Technical Transfer
- Mfg. Process (MBR, Tickets)
- Engineering Change
- Process Validation
- CM Approval

Document Management
- Mfg. Requirements (Contracts)
- Quality Agreement
- SOPs
- Batch Records

Regulatory Affairs
- Submissions
- Variances
- Annual Product Review

All provided in a configure to CM package

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Project Tango
Overall Implementation Strategy

**Elements**

- **Face of Lilly**
- **SNC - sap**
- **Life Cycle**
- **Document Management**
- **Regulatory Affairs**
- **Material Testing**
- **Quality Management**
- **Technical Transfer**

**Design to Pilot**

- Design
- Develop
- Test
- Validate

- Document
- Dev. Education / Training / user manuals
- Dev Go no/go

**Global Implementation**

- CMO & CM
- Operate Pilot / s
- Evaluate Go no/go

**Pre-operation**

- Selection
- Approval
- Training
- IT requirements

**Operation**

- Support
- Governance
- Problem ID
- Resolution

**Stabilization**

- Evaluate go no / go
- Assure “walk away”

**Ready for Prime Time**

Global implementation into CMO and CM’s
### High Level Implementation Plan

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  – Project Tango
  – Postponement / Distribution
AH Postponement / Distribution Strategy

Base sites producing unlabeled bags based upon demand signal coming from Central Supply Chain

Base Site Molecule Mfg

Safety stock of unlabeled bags is kept at the base sites to protect against the variability of supply

Safety Stock at RDC based upon variability of demand and over the replenishment lead time

Finishing RDC’s producing labeled product based upon short term sales order demands

Regional Distribution Center - Finishing
AH Postponement / Distribution Strategy
Keeping Inventory Where it is Most Flexible

Base Site Molecule Mfg

Send me more Monesin

Regional Distribution Center - Finishing
IN SUMMARY

“How is the Global Supply Chain Organization Managing the Transition”

1. Maintain the Basics
2. Maintain the Core Processes
3. Improve Productivity and Reduce Cost
4. Reduce Complexity