APICS-ISPE Event, Operational Efficiency

Simulations for improved production cycles using a lean supply chain postponement strategy

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Background

- How do we design an optimized supply chain in which all the functions and operations are synchronized?

- Issues to deal with
  - Demand variability
  - Production campaigning & changeovers/cleaning
  - Quality testing & QA documentation

- How many operations have we all seen that focus on “when will that batch be released?”
Case Study: Biopharma company

European Network
All Products

Plant in Germany
8 country DC’s
58 products (bulk vials)
198 country items (labeled skus)
~3,500 end customers
~1.5million vials
The Problem

• Symptoms
  ▫ High inventory - how high?
  ▫ Missed orders - how many?

• Some root causes
  ▫ Organizational disconnects
  ▫ Country orders
    • “Over the wall” to plant
    • Vials packaged/labeled at time a batch is created
Approach

• The solution - benefits from:
  ▫ Reduced demand variability
  ▫ Consistent production
  ▫ Reduced lead times

• Design concepts:
  ▫ One size does not fit all
  ▫ Keep inventory as far back as possible

Methodology
- Statistical Analysis
- Simulation
- Implementation
The Problem

- **Overall Product Demand & Inventory**
  - Demand at the country label presentation level was categorized by average weekly volume levels
  - The categories were classified as a % of both demand volume and inventory cost

![Distribution of Country Presentations](chart.png)

<table>
<thead>
<tr>
<th>Demand Category</th>
<th>% of Demand</th>
<th>% of Inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 1,000 Vials</td>
<td>66.1%</td>
<td>26.2%</td>
</tr>
<tr>
<td>200 - 1,000</td>
<td>20.1%</td>
<td>42.4%</td>
</tr>
<tr>
<td>100 - 200</td>
<td>7.0%</td>
<td>11.2%</td>
</tr>
<tr>
<td>48 - 100</td>
<td>3.7%</td>
<td>6.7%</td>
</tr>
<tr>
<td>26 - 48</td>
<td>1.8%</td>
<td>5.9%</td>
</tr>
<tr>
<td>11 - 26</td>
<td>0.9%</td>
<td>2.8%</td>
</tr>
<tr>
<td>&lt; 11</td>
<td>0.4%</td>
<td>4.9%</td>
</tr>
</tbody>
</table>

| Number of Presentations | 14 | 28 | 28 | 28 | 28 | 28 | 44 |
The Problem

- A good comparative index of variability is the standard deviation of weekly demand divided by the average; it is called the **Coefficient of Variation (CofV)**

- CofV is a key driver of the amount of inventory required to meet demand

- A CofV $> ~.5$ indicates demand that is difficult to predict

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Demand Variability by Demand Category

<table>
<thead>
<tr>
<th>Demand Category</th>
<th>% of Demand</th>
<th>Average Coefficient of Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vials per Week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 1,000</td>
<td>66.1%</td>
<td>0.57</td>
</tr>
<tr>
<td>200 - 1,000</td>
<td>20.1%</td>
<td>1.14</td>
</tr>
<tr>
<td>100 - 200</td>
<td>7.0%</td>
<td>1.20</td>
</tr>
<tr>
<td>48 - 100</td>
<td>3.7%</td>
<td>1.45</td>
</tr>
<tr>
<td>26 - 48</td>
<td>1.8%</td>
<td>1.80</td>
</tr>
<tr>
<td>11 - 26</td>
<td>0.9%</td>
<td>1.76</td>
</tr>
<tr>
<td>&lt; 11</td>
<td>0.4%</td>
<td>2.83</td>
</tr>
</tbody>
</table>
```

Number of Presentations: 14 28 28 28 28 28 44
Statistical Demand Segmentation

Combining the variability vs. the weekly demand for all presentations shows the high degree of demand variability (week to week)

128 country presentations
~6.8% of demand

70 country presentations
~93.2% of demand

This group accounts for 66% of the total demand (shown here on a logarithmic scale)

Weekly variation < 100%
The number of re-supply shipments for the same demand categories over the 6 months were compared, showing wide variation in the number of shipments.
There is no apparent consistency in supply frequency; even for higher volume, lower variability presentations.
Service Level Theory: Effect of Demand Variability & Lead-Time

This example demonstrates the additional safety stock requirement as weekly demand variability and supply lead times increase.

This example uses 98% service level; increasing or decreasing the service level changes the safety stock exponentially.

Supply variability adds to the safety stock required.

Coefficient of Variation (CofV) for weekly demand, equal to Standard deviation / mean demand is an indicator of comparative variability.
Statistical Segmentation

At the packaged unlabeled level, the demand variability looks better. However, there is still significant demand variability even at the Europe-wide level.

Volume / Variability Comparison for "white label" Presentations

- 38 presentations (~10% of demand)
- 20 presentations (~90% of demand)
- 17 presentations with variability < 50%
One Size Does Not Fit All

In addition to demand and supply patterns, high unit cost is also a driver of overall inventory cost, with unit costs having a wide range.

Possible Service Channel Breakout

- **High Volume**
  - % of Demand: 66%
  - % of Inventory: 26%

- **High Cost**
  - % of Demand: 18%
  - % of Inventory: 63%

- **Other**
  - % of Demand: 16%
  - % of Inventory: 11%

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Service Channel™ Segmentation

• Replenishment/production design
  ▫ High volume channel with level frequent supply:
    • Produce on a biweekly level cycle
  ▫ High cost channel with postponement:
    • Produce “white label” product every 4 weeks
    • Kanbans for country labeled stock
  ▫ Low volume/low cost channel with level supply:
    • Produce twice per year on a regular schedule
High Cost Channel

Before Process

Respond to Orders from Countries

- API
  - QA Rel
- Fill Finish
  - Lab test
- Packaging & Labeling
  - QA Rel
- Country Warehouses
  - Inventory
  - Patient Demand
  - 98 finished products

Lead Time
- ?? Up to 6 months plus

New Process

- Triggered by KANBAN replenishment
- EPEI Rotation Cycle with a KANBAN
  - Inventory
    - 21 “white label” products
    - 98 labeled products
  - Lead Time
    - 8-10 days
- Fill Finish is the main constraint

- Country Labeled Stock
  - Inventory
  - Patient Demand
  - 80 Light
  - 55 Light
  - 25 Light
  - 80 Full
  - 55 Full
  - 25 Full

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Some Definitions

Sources: *Apics Dictionary 12th Edition*; and *Design & Analysis of Lean Production Systems*

- **Kanban** – a method of Just-in-Time production that uses standard containers or lot sizes with a single card attached to each. It is a pull system in which work centers signal with a card that they wish to withdraw parts from feeding operations or suppliers.

- **Every Part Every Interval (EPEI)** – is the time period over which every member of the product family can be produced, including the changeover between products.

- **Rhythm or rotation cycle** – sequences production orders in a repetitive pattern of quantities for a mix of products within the overall EPEI. Also referred to as “level schedule” or heijunka.

- **Drum-buffer-rope (DBR)** The theory of constraints method for scheduling and managing operations that have an internal constraint or capacity-constrained resource.

- **Drum schedule**—The detailed production schedule for a resource that sets the pace for the entire system. The drum schedule must reconcile the customer requirements with the system’s constraint(s).
### Postponement: 1 product example

Current process: lots produced approx every 6 months

<table>
<thead>
<tr>
<th>Lot Size</th>
<th>Weekly Demand</th>
<th>CofV</th>
<th>Combined Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,800</td>
<td>273</td>
<td>.65</td>
<td></td>
</tr>
</tbody>
</table>

**Est Lead-time**
- “white label”
- labeled stock

- **Plant**: 6 Weeks
- **Postponement Site**: 1-3 Days + 7 Day quarantine

<table>
<thead>
<tr>
<th>Country</th>
<th>CofV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain</td>
<td>1.03</td>
</tr>
<tr>
<td>Germany</td>
<td>.95</td>
</tr>
<tr>
<td>Sweden</td>
<td>1.98</td>
</tr>
<tr>
<td>France</td>
<td>2.85</td>
</tr>
<tr>
<td>Netherlands</td>
<td>2.28</td>
</tr>
<tr>
<td>Italy</td>
<td>1.20</td>
</tr>
<tr>
<td>Great Britain</td>
<td>2.11</td>
</tr>
</tbody>
</table>

A lot of 1800 units produced every 6 weeks reduces overall lead times & lead time variability.
The Modeling Process

Today’s Demo

Validate Model with Actual Data & Metrics
- Ran w/ 6 months demand

Validate Statistical Patterns vs. the Metrics
- Patterns from the demand

Try Process Changes at Summary Level
- Ran w/ Forecasts

Check them vs. the Actual Detailed Data
- Ran w/ 6 months demand
- Check them w/ statistical demand projections
- Some sampling to get statistical data

Add full variability & downtimes
- Patterns from the demand

Ran w/ 6 months demand
- Patterns from the demand

Ran w/ Forecasts
- Patterns from the demand

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### SC Planning System Overview

<table>
<thead>
<tr>
<th>Structure of the system</th>
<th>Deployment to Depots</th>
<th>Finished drug requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Master Matrix</td>
<td>• Site days coverage</td>
<td>• Planned &amp; actual</td>
</tr>
<tr>
<td>• Item Master</td>
<td>• Replenishment rules</td>
<td>• Lead times &amp; lot sizes</td>
</tr>
<tr>
<td>• Production /quality variability</td>
<td>• Depot inventory replenishment</td>
<td>• 3rd party or in-house</td>
</tr>
<tr>
<td>• 3PL activity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Forecasting capabilities</th>
<th>Labeling by molecule/study (for clinical)</th>
<th>API requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Statistical demand</td>
<td>• Inventory tracking</td>
<td>• Planned &amp; actual</td>
</tr>
<tr>
<td>• Actual vs. forecast updates</td>
<td>• Expiration tracking</td>
<td>• Resource scheduling for in-house manufacturing</td>
</tr>
<tr>
<td>• Clinical study forecasts</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Labeling by molecule/study (for clinical)**
  - Inventory tracking
  - Expiration tracking

- **API requirements**
  - Planned & actual
  - Resource scheduling for in-house manufacturing
Measureable Benefits

• Simulation results
  ▫ High volume channel with level frequent supply:
    • 99.9+% service level
    • 60% reduction in inventory
  ▫ High cost channel with postponement:
    • 97+% service level
    • 30% reduction in inventory
  ▫ Low volume/low cost channel with level supply:
    • Improved service levels with same inventory level
Probabilistic Demand

From the actual demand, probability demand distributions are developed and replace the actual demand to allow multiple monte carlo simulation runs. Below are examples for one of the products, with its statistical histograms for each of the 5 countries where sold.
More Information


- ISPE Operations Management Community of Practice [http://www.ispe.org/omcop](http://www.ispe.org/omcop)