APICS-ISPE Event, Operational Efficiency

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

Jim Curry, OpStat Group Inc.

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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?”

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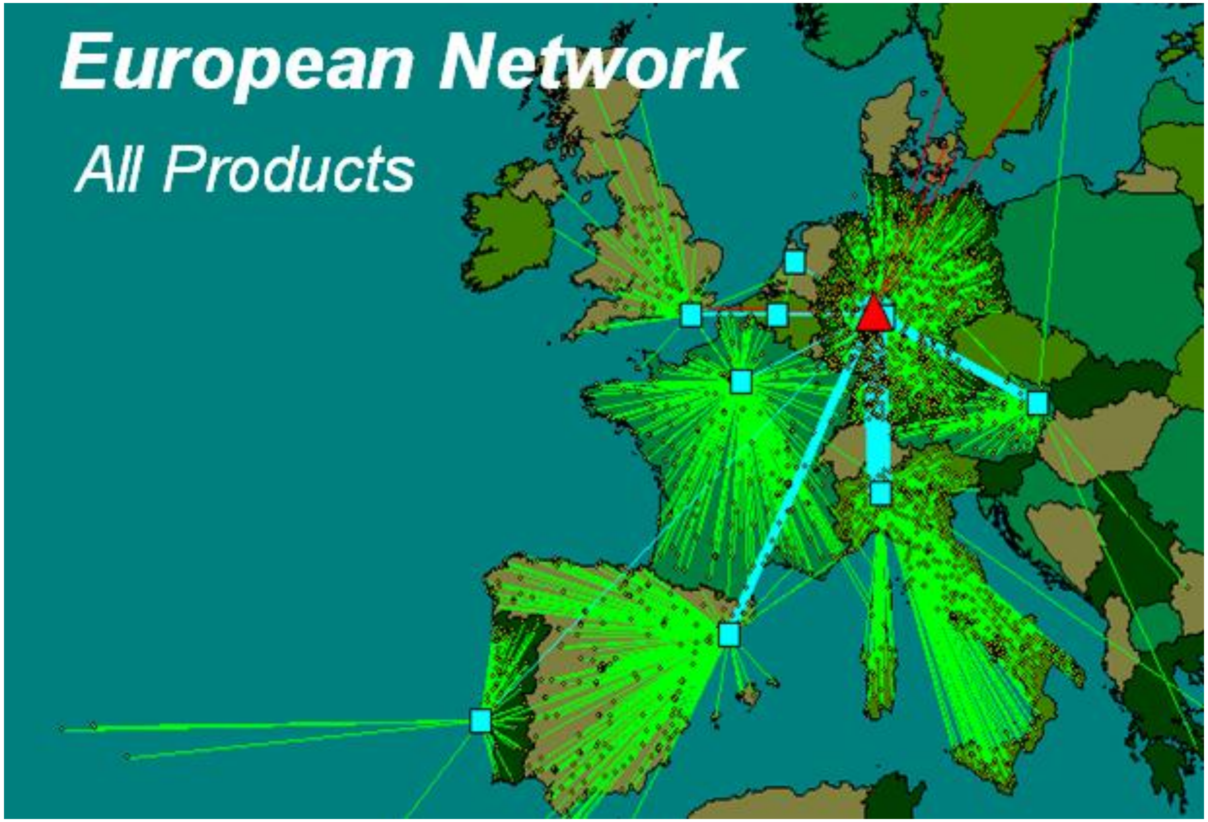
Case Study: Biopharma company



Plant in Germany

8 country DC's

58 products (bulk vials)
198 country items
(labeled skus)

~3,500 end customers
~1.5million vials

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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

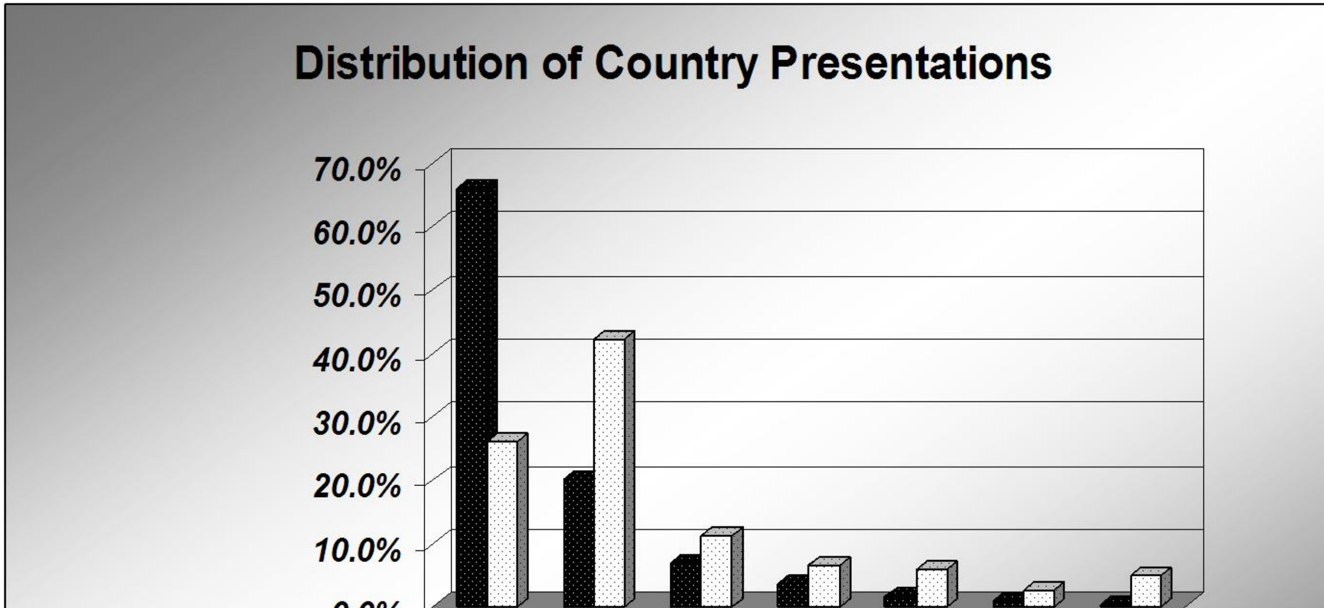
Statistical Analysis

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



Demand Category Vials per Week	> 1,000	200 - 1,000	100 - 200	48 - 100	26 - 48	11 - 26	< 11
% of Demand	66.1%	20.1%	7.0%	3.7%	1.8%	0.9%	0.4%
% of Inventory	26.2%	42.4%	11.2%	6.7%	5.9%	2.8%	4.9%
Number of Presentations	*14*	*28*	*28*	*28*	*28*	*28*	*44*

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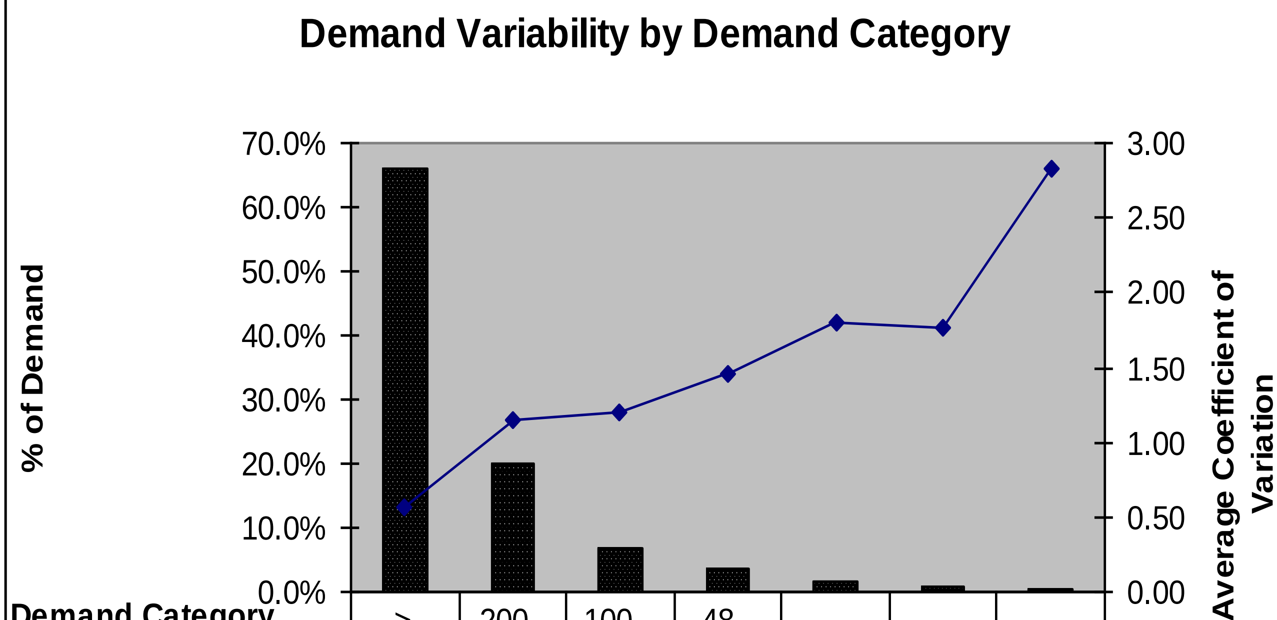
The Problem

- 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



Demand Category Vials per Week	> 1,000	200 - 1,000	100 - 200	48 - 100	26 - 48	11 - 26	< 11
% of Demand	66.1%	20.1%	7.0%	3.7%	1.8%	0.9%	0.4%
Demand Variability	0.57	1.14	1.20	1.45	1.80	1.76	2.83
Number of Presentations	*14*	*28*	*28*	*28*	*28*	*28*	*44*

1/17/2012

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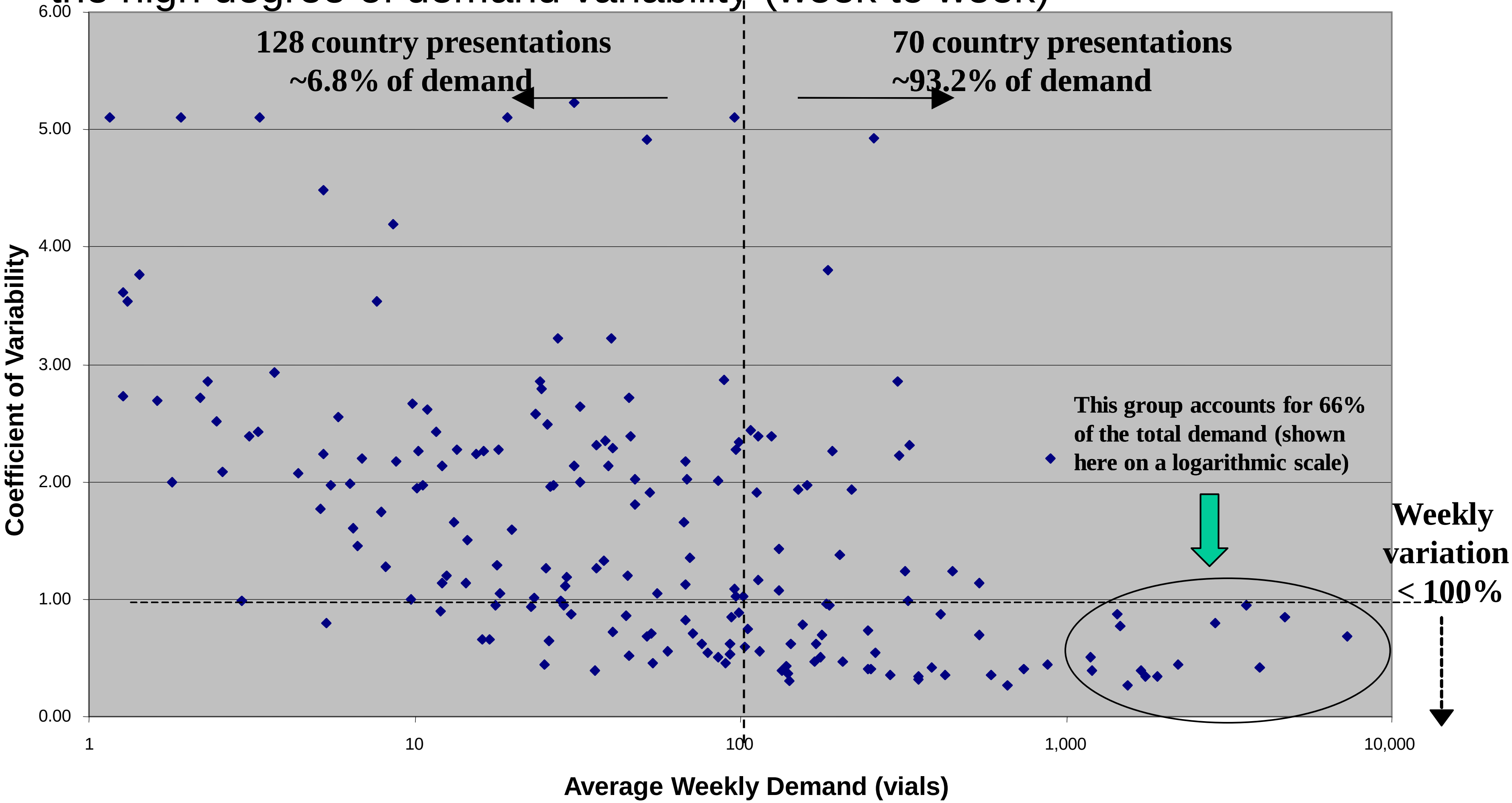
Statistical Demand Segmentation

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



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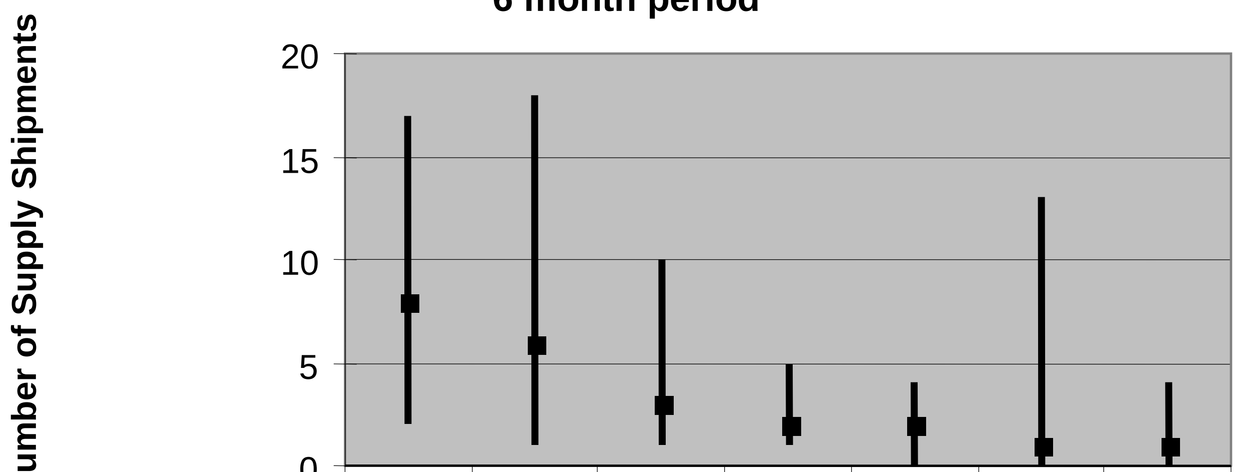
Statistical Supply Segmentation

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.

Number of Supply Shipments by Demand Category
6 month period



Demand Category Vials per Week	> 1,000	200 - 1,000	100 - 200	48 - 100	26 - 48	11 - 26	< 11
Max Shipments	17	18	10	5	4	13	4
Min Shipments	2	1	1	1	0	0	0
■ Avg Shipments	8	6	3	2	2	1	1

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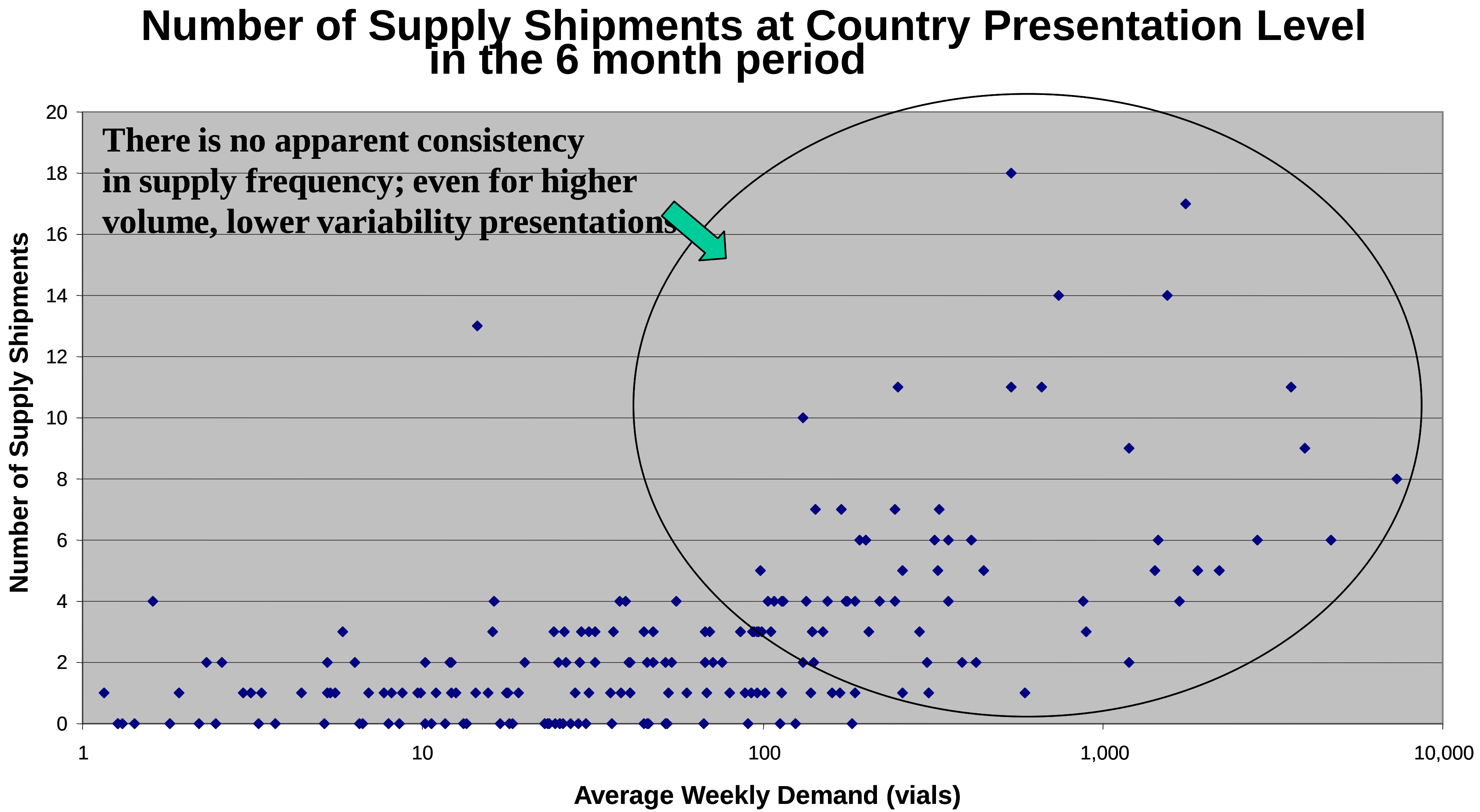
Statistical Supply Segmentation



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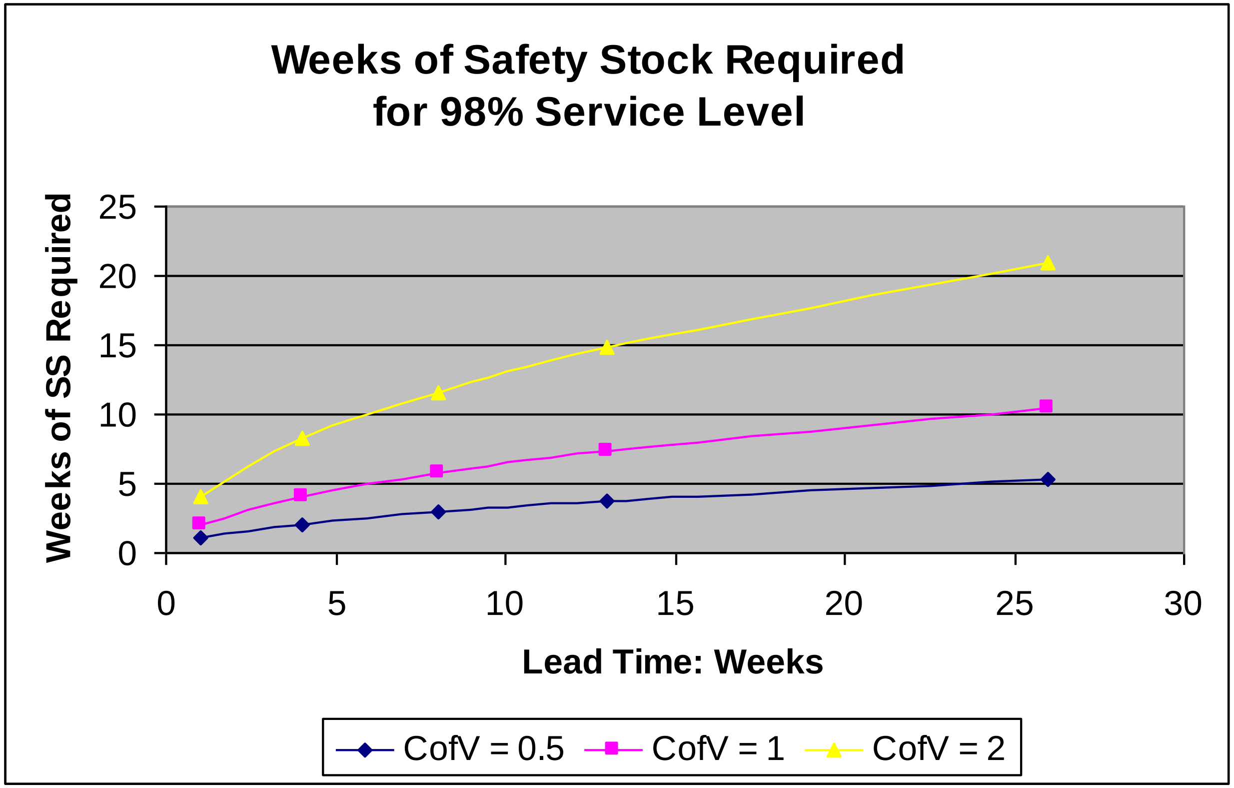
Service Level Theory:
Effect of Demand Variability & Lead-Time

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.

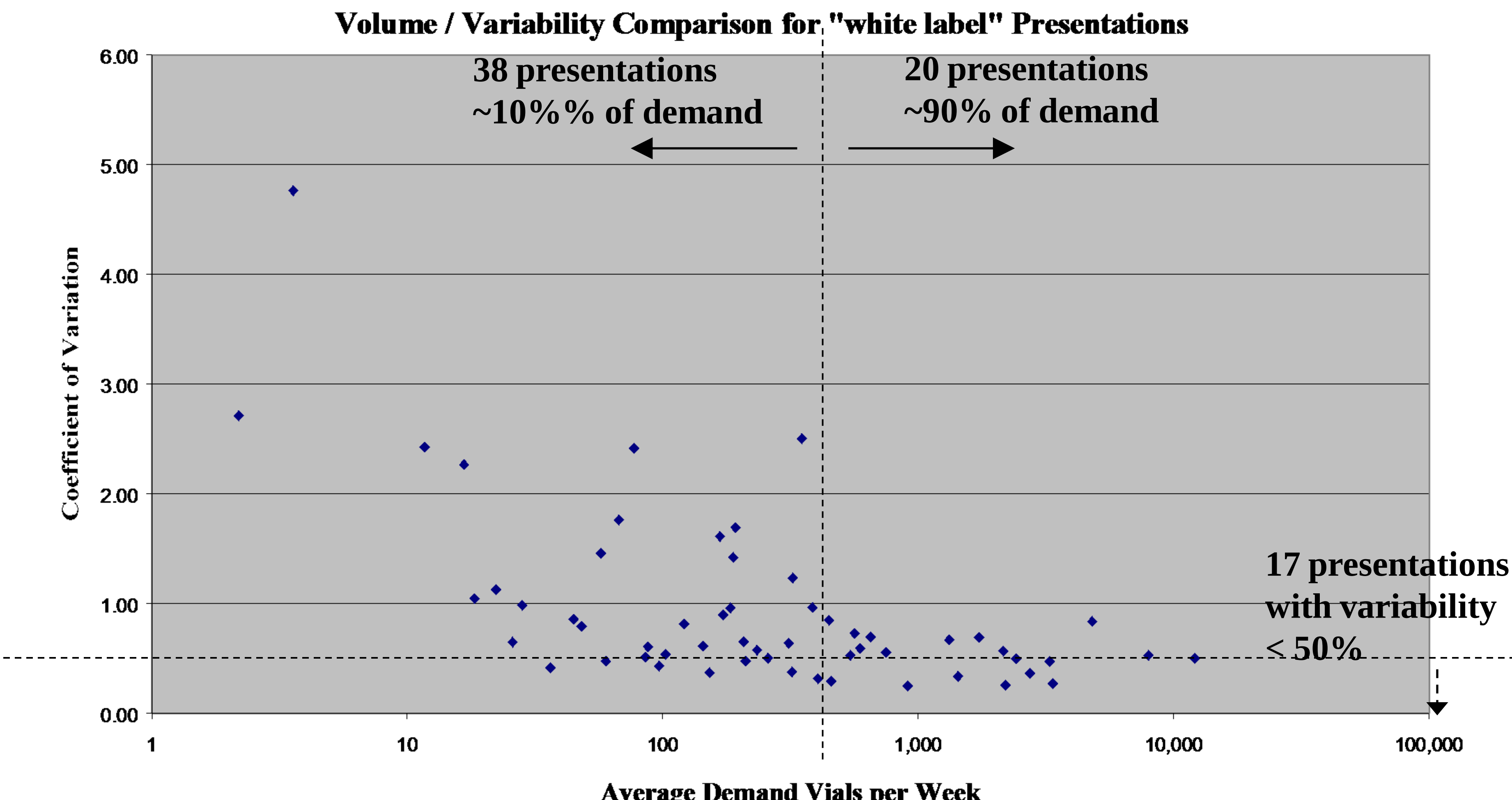
Supply variability adds to the safety stock required.



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.



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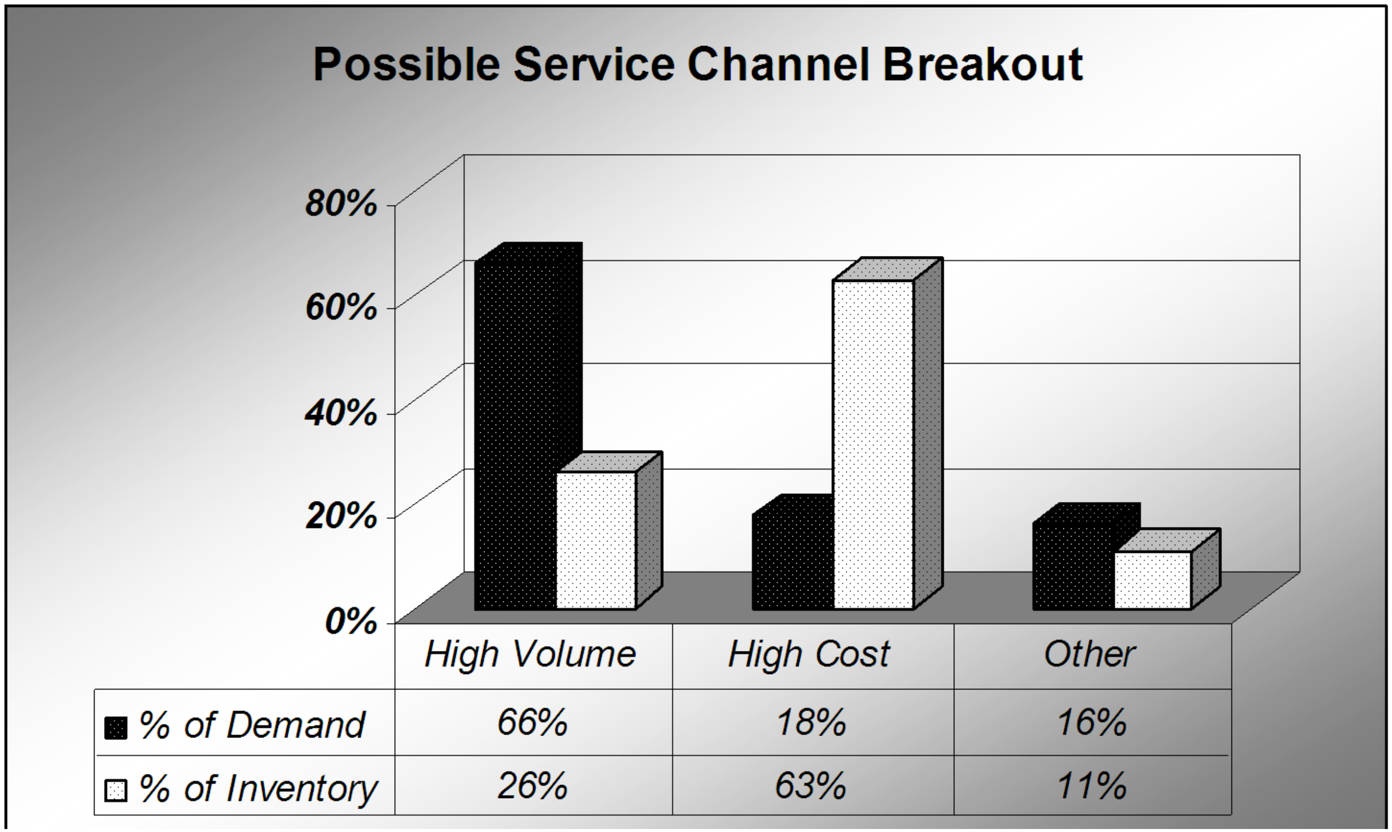
Service Channel™ Segmentation

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 have a wide range



White label Labeled	14	21 of 58 98 of 198 total	36

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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

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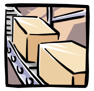
High Cost Channel

Before Process

Respond to Orders from Countries

API — QA Rel → Fill Finish — Lab test → Packaging & Labeling — QA Rel → Country Warehouses — Quarantine →



Patient Demand

98 finished products

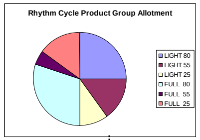
Inventory

Lead Time

?? Up to 6 months plus

New Process

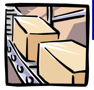
Triggered by KANBAN replenishment



EPEI Rotation Cycle with a KANBAN

Triggered by KANBAN replenishment

API — QA Rel → Fill Finish — Lab test → Packaging — QA Rel →



Inventory

21 "white label" products

→ Country Labeled Stock — Quarantine →

Inventory

98 labeled products

Patient Demand

Fill Finish is the main constraint

Lead Time

8-10 days

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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).

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Postponement: 1 product example

Current process: lots produced approx every 6 months

Combined Volume

Lot Size	**Weekly Demand**	**CofV**
1,800	273	.65

Est Lead-time "white label"

Est Lead-time labeled stock

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

	CofV
Spain	1.03
Germany	.95
Sweden	1.98
France	2.85
Netherlands	2.28
Italy	1.20
Great Britain	2.11

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

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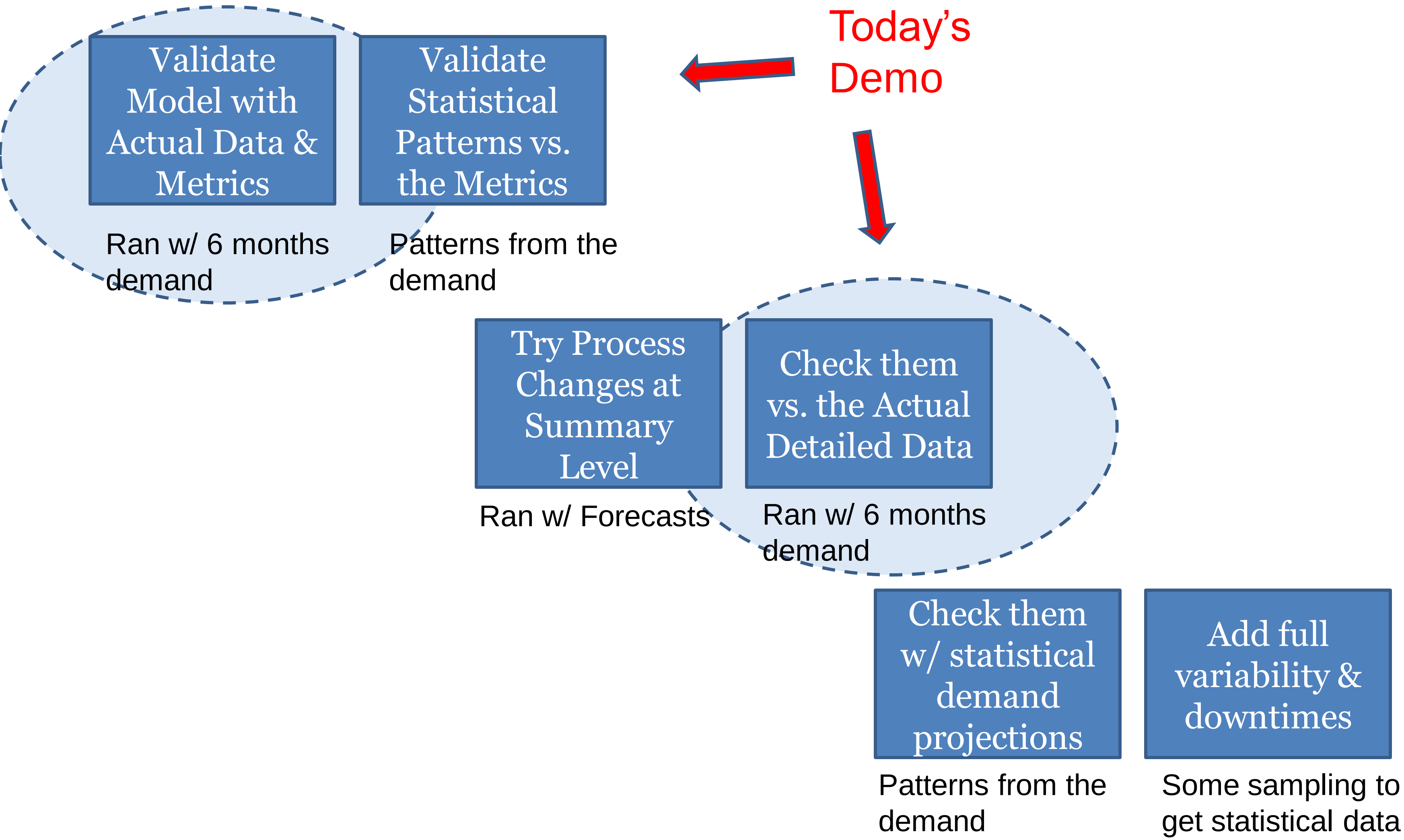
The Modeling Process



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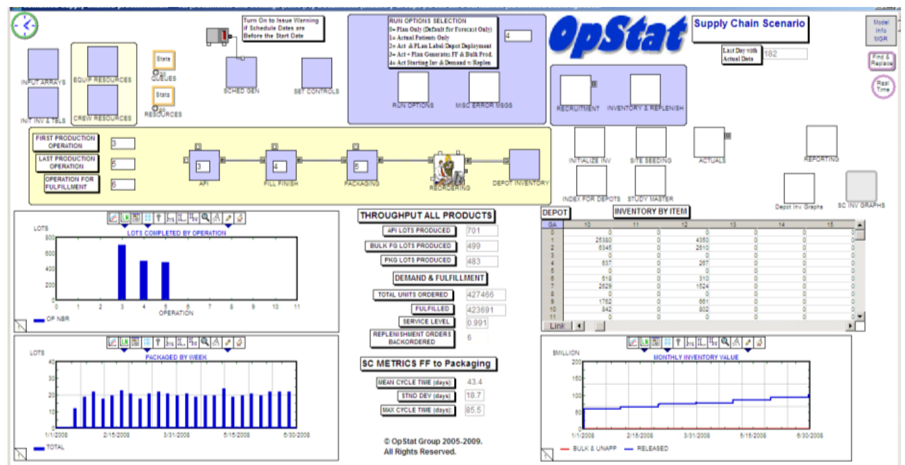
SC Planning System Overview

- Structure of the system
  - Master Matrix
  - Item Master
  - Production /quality variability
  - 3PL activity

- Deployment to Depots
  - Site days coverage
  - Replenishment rules
  - Depot inventory replenishment

- Finished drug requirements
  - Planned & actual
  - Lead times & lot sizes
  - 3rd party or in-house



- Forecasting capabilities
  - Statistical demand
  - Actual vs. forecast updates
  - Clinical study forecasts

- 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

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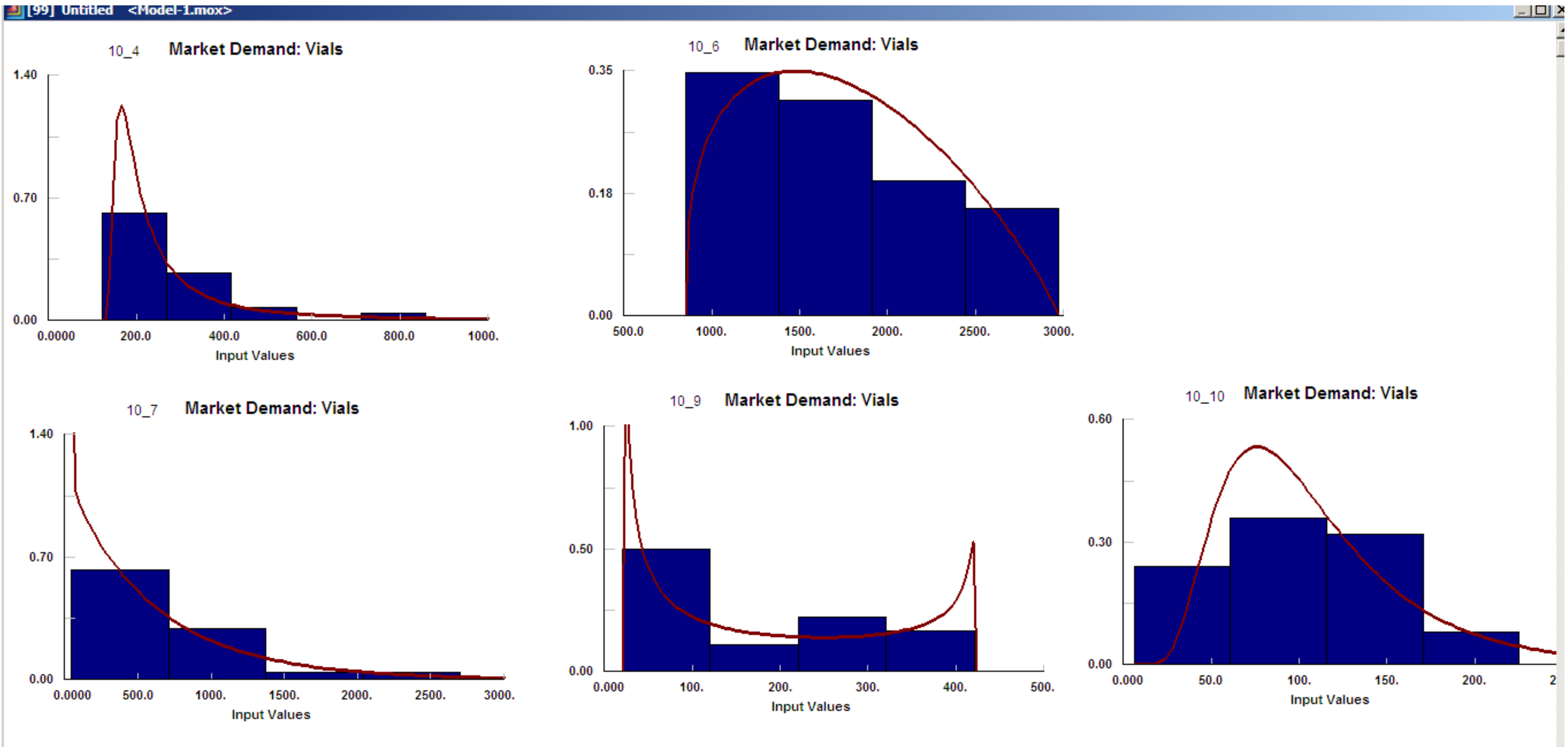
Probabilistic Demand

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 *Pharmaceutical Engineering* magazine: "Successful Use of Simulation as a Tool in a Lean Six Sigma Program" 2010 with J&J http://magazinevolume.com/7008ISPE
- Examples of models: www.OpStat.com
- ISPE Operations Management Community of Practice http://www.ispe.org/omcop

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