Amgen Supply Chain Segmentation – The Journey to 2022

October 23, 2014
Introduction

- Rayne Waller
- VP Global Supply Chain at Amgen
- Responsible for:
  - Corporate and Regional Supply Chain Functions
  - Contract Manufacturing
  - Raw Materials and Device Supply
  - Operations Strategic Planning, Risk Management, PMO and Business Systems
- 20+ years of experience in Biotechnology
- Held various positions across supply chain and manufacturing globally for Amgen
About Amgen

• World’s largest biotechnology company
• More than 30 years of pioneering science and vital medicines
• Focused on discovering, developing, and making human therapeutics
• Key facts 2013:
  – ~ 20,000 employees
  – ~ $18.7 billion Revenues
  – R&D Expenses > 20% of revenues
• 10 innovative products and ~50 product candidates
• 6 Biosimilar product candidates
• Pipeline: Advancing medicines for diseases that matter
• More than 22 million patients served
For additional information about Amgen products, including important safety information, please visit amgen.com; Kyprolis® (carfilzomib) is developed and marketed by Onyx Pharmaceuticals (except in Japan), an Amgen subsidiary; NEXAVAR® (sorafenib) is developed and marketed under collaboration and co-promotion agreements between Bayer Healthcare and Onyx Pharmaceuticals.
Amgen’s Segmentation Journey – How to Increase Profits and Provide Better Service

• Impetus for Change
• Our Journey
• The Path Forward
Amgen has a strong track record in biologics manufacturing and ensuring supply

Reliable Supply

“Every Patient, Every Time” – Have never experienced a drug shortage

High Quality

Robust Quality Management System focused on driving towards six sigma processes to ensure quality control and compliance

Cost Effective

Rigorous Operational Excellence program focused on increasing productivity and lowering COGM
External and internal drivers require continued focus on improving the performance of our supply chain

Increase in products/SKUs has historically required linear growth in overhead

Industry Drivers
- Healthcare reform and impact on payors
- Increased competition including biosimilars entrants
- Industry consolidations through M&A
- Increased regulatory scrutiny for new products
- Increased regulatory concern for supply chain security

Amgen Drivers
- International expansion and complexity of supply requirements
- Maturity and imminent patent expiry of our commercial products
- Continued margin improvement and net expense reduction efforts
- Greater understanding and increased focus on mitigating supply risk
The mix of market types and complexity of managing the supply chain for our markets is increasing.

- **Canada**
  - Low volume, low mix
  - Distribution outsourced
  - Low Complexity

- **United States**
  - High volume, low mix
  - 80% of Distribution volume through 3 wholesalers, 2 regional DCs
  - Low complexity

- **CEE**
  - Low volume, low mix
  - Distribution through distributors, LSPs
  - Medium Complexity

- **Latin America**
  - Low volume, medium mix
  - Distribution through Affiliate, Distributors, LSP
  - Medium Complexity

- **Europe/Middle East/Africa**
  - Both high and low volume countries with high mix
  - Distribution through regional DC plus Wholesalers, Distributors and LSPs
  - High Complexity

- **Asia Pacific/Japan**
  - Both high and low volume countries with medium mix
  - Distribution models under evaluation
  - Alliance in Japan
  - High Complexity

- **Canada**
  - Low volume, low mix
  - Distribution outsourced
  - Low Complexity

- **Australia**
  - Low volume, low mix
  - Distribution through Affiliate and LSP
  - Low Complexity
Amgen plans to deploy demand driven value chains segmented based on market characteristics

**Objective** | Create an end-to-end segmented supply chain to improve profitability through strategically balanced flexibility and efficiency

**Scope** | The end-to-end supply chain is defined as information and physical flows related to PLAN, SOURCE, MAKE and DELIVER and related SUPPORT activities

**Outcomes** | A detailed understanding of the supply chain segments, the business case for segmentation, the capability gaps between current and future state and a roadmap for implementation

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Enable Growth
A segmented supply chain provides Amgen the platform to support growth in new and existing markets

*Benchmark: Up to 5% potential topline growth*

Maximize Profitability
Segmentation can unleash value for Amgen by optimizing operating expenses and working capital

*Benchmark: 5 – 10% potential COGM and COS reduction*

Balance Flexibility and Efficiency
When executed well, a segmented supply chain can serve customers at optimal performance levels

*Benchmark: 3 – 5x potential Supply Chain Performance Gain*
Cross-functional collaboration and alignment drives the success of demand driven segmentation process

1. **Analyzed Data**
   - Identified data requirements
   - Collected data
   - Performed grouping analysis
   - Identified segmentation options

2. **Engaged SMEs**
   - Conducted focus groups with cross functional teams from operations, commercial, finance, etc.
   - Refined segmentation options based on focus group feedback
   - Prepared leadership for Segmentation Alignment

3. **Gained Alignment**
   - Designed and conducted segmentation alignment with Commercial and Operations leadership
   - Selected segmentation option
   - Executed the fit gap working sessions to identify capability gaps

4. **Evaluation and Value**
   - Conducted and reviewed the value analysis with operations and commercial
   - Identified and prioritized capability gaps based on future state requirements across the value stream
   - Assessed impacted populations

5. **Next Steps**
   - Present to Amgen Leadership and reconfirm moving forward with detailed design
   - Next Steps:
     - Conduct detailed design workshops
     - Develop business case
Segmentation simplifies supply chain complexity by grouping products and customers with similar attributes into segments.

**Sample Demand Dimensions**
- Market Access Index
- Customer Volume by SKU
- Lead Time Expectation by Customer
- Channel Characteristics
- Customer Margin %
- Average Price paid per SKU by Customer

**Sample Supply Dimensions**
- Product Volume
- Volume Volatility
- Product Complexity
- Number of Suppliers per Raw Material
- Manufacturing Capacity
- Packaging Complexity

**ILLUSTRATIVE SEGMENTS**

- **“Efficient” segment**
  - (e.g., High Volume, Mature Products, Stable Demand, Premium Customers)

- **“Agile” segment**
  - (e.g., Low Volume, Growth Products, Variable Demand, Regular Customers)

- **“Dedicated” segment**
  - (e.g., Low Volume, Growth Products, Stable Demand, Premium Customers)

- **“Responsive” segment**
  - (e.g., High Volume, Mature Products, Variable Demand, Regular Customers)

**Product Groups**

**Customer Groups**

1. Segment names are an example to demonstrate the combination of product and customer groups
2. Sample demand and supply dimensions are examples of data points that can be used for a segmentation analysis
Analysis is powered by large datasets and statistical tools to identify suitable segmentation options for Amgen.

Over 300 Variables of Supply & Demand Data

Variable Reduction (14 product variables & 10 customer variables)

Cluster Analysis

Multiple segmentation options created

Decide on final segmentation type

Aggregated data from multiple Amgen sources, functional areas, and systems

Statistically reduced variables to 10-14 significant variables to perform cluster analysis

Statistical clustering of SKU’s and customers using statistical methods

Overlaid clusters (SKU and customer) to create segmentation options

An alignment process was used to decide on a final segmentation type in the Segmentation Alignment Lab.
Select the right segmentation option based on data, relevance to the business, and ability to ‘simplify-the-complex’

No one option is “right”, Amgen selected the strategy that best fits our growth in the next 5-10 years.

Option A
- Stable and Profitable: Matures products with low demand variability, mainly in the US.
- Highly Variable: Products with high demand variability and wide geographic footprint.
- Unique Needs: Dedicated segment with products (i.e., non-US, non-US, non-US, etc.) in specific regions.

Option B
- Regional focused segmentation option optimizes the supply chain based on geographic presence and future expansion.

Option C
- Product focused segmentation option optimizes the supply chain based on product life cycle considerations.
The selected option creates value for Amgen by integrating product complexity and demand driven needs

**Advantages**
- Optimizes physical and information supply chains
- Accommodates Amgen's product lifecycle shift in the coming 5-10 years
- Implies minimal changes in supply chain in select segments
- Enables geographic nuances and demand driven value streams across segments
- Provides the landscape for future products

**Challenges**
- Requires investments in new capabilities to close gaps in specific segments
- Requires commercial engagement for potential re-negotiations in customer expectations
Potential sub-segments may require distinct changes to value streams and the operating model

**Segment Refinement**

**A  Stable and Profitable**
- **Top Channels**
  - Wholesaler
  - Hospital
- **Stable Tender Markets**
  (e.g., UK)

**B  Highly Variable**
- **Top Channels**
  - Wholesaler
  - Other
  - Hospital
- **Home Health Care Customers**
- **Variable Tender Markets**
  (e.g., MEA-EE)

**C  Unique Needs**
- **Top Channels**
  - Wholesaler
  - Hospital
- **Biosimilars**
- **New Products**
- **Unique Handling Requirements**

**D  Diverse Low Volume**
- **Top Channels**
  - Retail Pharmacy
  - Other
All supply chain functions will be reviewed to determine the right alignment with each segment

<table>
<thead>
<tr>
<th>PLAN</th>
<th>SOURCE</th>
<th>MAKE</th>
<th>DELIVER</th>
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</thead>
<tbody>
<tr>
<td><strong>Stable and Profitable</strong></td>
<td><strong>Efficient</strong></td>
<td></td>
<td></td>
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<tr>
<td>Stable, repeating schedule</td>
<td>Vendor Managed Inventory</td>
<td>Large batch sizes</td>
<td>Increase minimum order quantity</td>
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<tr>
<td>Increased planning cycle / frequency</td>
<td>High order quantities</td>
<td>Optimized line capacity</td>
<td>Low priority / low cost transportation</td>
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<tr>
<td>Decreased cycle stocks</td>
<td></td>
<td>Continuous production</td>
<td>Mature lanes</td>
</tr>
<tr>
<td><strong>Highly Variable</strong></td>
<td><strong>Agile</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequent planning process &amp; improved planning accuracy</td>
<td>Postponement strategies</td>
<td>Make-to-order</td>
<td>Combination of low priority and high priority transportation</td>
</tr>
<tr>
<td>Streamlined revision process to variation changes</td>
<td>High level of input/ raw material safety stocks</td>
<td>Decreased lot sizes</td>
<td>Creation of Hubs</td>
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<tr>
<td>Decentralized planning</td>
<td></td>
<td>Small scale labelers and manual packing</td>
<td>Potentially high complexity</td>
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<tr>
<td><strong>Unique Needs</strong></td>
<td><strong>Dedicated</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Defined roles and resp. for new products and LCM</td>
<td>High level of input/ raw material safety stocks</td>
<td>Customized formulations</td>
<td>Combination of service levels</td>
</tr>
<tr>
<td>Risk-based policies and procedures</td>
<td></td>
<td>Specialized packaging requirements for special handling</td>
<td>Varying levels of customer service depending on needs</td>
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<tr>
<td>On-demand schedule</td>
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<tr>
<td>Accurate forecasting (e.g. statistical models)</td>
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<tr>
<td><strong>Diverse Low Volume</strong></td>
<td><strong>Responsive</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Efficient planning process</td>
<td>High input safety stocks</td>
<td>Decreased lot sizes</td>
<td>High priority transportation</td>
</tr>
<tr>
<td>Accurate forecasting (e.g. statistical models, customer-focused, multiple approaches)</td>
<td></td>
<td>Small scale labelers and manual packing</td>
<td>High-touch customer service</td>
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Realignment with segmentation will leverage a robust fit-gap assessment that prioritizes changes based on benefits

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<tr>
<td><strong>Problem Statement</strong></td>
<td>• Cycle time is extended by challenges with rigorously structured processes, manual work, inaccurate data, and unclear accountability across forecasting, jurisdictional control planning, and the product LCM for NPI</td>
<td>• Forecast reliability is questioned because the data is not consistently updated and accurate</td>
<td>• Speed to market is impeded by challenges with no standardized platform for packaging requirements, inflexible production lines, and coupled IDP and FDP processes</td>
</tr>
<tr>
<td><strong>Future State Requirements</strong></td>
<td>• Need simplified and flexible forecasting, planning, and product LCM processes, forecasting accuracy metrics, and defined ownership of forecast</td>
<td>• Need ownership of data accuracy in SAP for NPI, BOM and material for test lots</td>
<td>• Need pack configuration policy, dedicated production line for high mix low volume, and decoupled IDP and FDP processes</td>
</tr>
<tr>
<td><strong>Assessment</strong></td>
<td>Gap Assessment</td>
<td>Segments Impacted</td>
<td>Gap Assessment</td>
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<td></td>
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<td>S</td>
<td>U</td>
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**Critical**
- Critical to success (e.g., new capabilities that does not currently exist required)

**Minor**
- Minor improvement (e.g., best practice exists in some regions)

**Segments Impacted**
- S: Stable & Profitable
- U: Unique Needs
- V: Highly Variable
- D: Diverse Low Volume

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Detailed value stream and operating model design will follow the segmentation assessment

### Assessment
- Analyze product, customer and demand data
- Create segmentation options
- Select and align on segmentation option
- Create segmentation value proposition

### Design
- Define changes to value stream by segments
- Identify operating model and change readiness implications
- Build detailed business case for segmentation

### Execution
- Phased execution
Key takeaways at this point in the journey

• **Data is critical**, need to build the analytical model once and refresh periodically

• Incorporate the “**Voice of Customer**” into the analysis

• **Challenge biases** based on the current way of working

• **Allow for time to debate options** and acknowledge the hurdles so that they can be addressed

• Recognize the need to change before it is mission critical – **segmentation takes time**
We have been assisted in our journey by Deloitte

**Impact**

**Deloitte delivers significant results for clients**
- Over 30% of projects are on an incentive fee structure

**Representative Projects:**
- Identified >$100M in cost savings through supply chain transformation
- Supply chain redesign improved service levels by 28%, and scrap reduction in excess of $15M

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**Analytics**

Combining deep industry and supply chain expertise with **advanced analytics** allows Deloitte to turn everyday information into **useful and actionable insights**

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**Innovation**

Deloitte brings **innovative approaches and ideas** to address the most challenging business problems
- Deloitte Greenhouse – an advanced, immersive environment designed to accelerate breakthroughs

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**Industry Leadership**

Deloitte Consulting provides supply chain services to leaders within the industry and is recognized by analysts as a **leader within both Life Sciences and Operations consulting**

**Representative Clients:**
- Abbvie
- Allergan
- Amgen
- Astra Zeneca
- Baxter
- Bayer
- Celgene
- Grifols
- GSK
- Novartis
- Merck
- Patheon
- Pfizer
- Sanofi
- Roche
Q & A