Modeling Regulatory Impacts on Medical Device Supply Chains

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Introduction: Changing regulatory requirements continue to be an increasingly complex issue in the medical device industry. Regulations place stress on supply chains around the world as companies work to stay internationally and domestically compliant. This research evaluates the impact of regulation changes by analyzing how activities in manufacturing and sourcing environments contribute to backorders. By taking a proactive approach to regulatory changes, firms can optimize supply chain flows to reduce cost, lead-time, and service level risks.

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KEY INSIGHTS

- ✓ **Modeling the impacts of regulatory changes before they go into effect can help supply chains reduce cost and mitigate service level impacts**
- ✓ **The number of activities and events present in supply chains can be complex-predictive analytics can help identify patterns which would otherwise go unseen**

Introduction

The medical device industry has been burdened with increasing amounts of regulation for decades. While regulation helps to ensure patient safety and efficacy, it has also created significant burden on the supply chain. In order to stay compliant, manufacturers and distributors have had to reconsider network design. This in turn raises cost and increases product lead times.

In April of 2017, the European Union implemented the Medical Device Directive (MDD). This legislation represents the largest regulatory change to the European medical device industry in thirty years. The directive establishes additional requirements and makes current requirements much more stringent.

The MDD presents a number of challenges that are not clearly outlined or have been left to medical device industry players to interpret and enact. Decisions will need to be made regarding how to design the new physical and informational flows in the supply chain. The purpose of this research is to:

1. Explore different approaches to model the impact of regulatory changes on global supply chains
2. Develop a model that can predict the impact of regulations on supply chains by analyzing different attributes and events

Methodology

This analysis utilizes twelve months of historical SKU level data from a medium sized medical device company. Included in the analysis are 3,000+ items ranging from implants to instruments to consumables. The sizes and features of implants include very small and very large, packaged and kitted, and sterilized and unsterilized. Product type also ranges from plates and screws to injectables, grafts, and wedges. Figure X illustrates the different physical attributes of each device.

The inventory footprint for these products differs by market. Some are stocked in pooled global distribution centers, while others are stocked via both regional distribution centers and small forward stocking locations. Almost all products are simultaneously present in hospital consignment locations and/or carried by reps in their trunk stock.

Most products have a single regulatory approved location filed as the official “manufacturer of origin” and is globally exported to other international markets. A product’s manufacturing assembly could range from a simple single raw material component to upwards of eighty raw material components. The product could be manufactured internally or it could be a hybrid of both outsourced vendor operations and international processing. To make it even more complicated, sterile, non sterile, single pack, and bulk pack SKU’s are all simultaneously stocked.

Figure 1: Multi-layered, Surgical Implant Kit with Instruments

This analysis gathers the following supply chain attributes and performance outcomes as input variables for the model.

- ITEM NUMBER
- ITEM CLASSIFICATION
- FORECAST DEMAND
- MANUFACTURING CELL
- SALES VOLUME
- ITEM MONTHLY DEMAND
- ITEM INVENTORY FINISHED
- ITEM INVENTORY SEMI-FINISHED GOODS
- DISTRIBUTOR DEMAND
- INSTANCES OF BACKORDERS
- AVERAGE LEADTIME
- MAKE VS BUY
- MANUFACTURING OPERATION
- MANUFACTURING PLANT LOCATION

Model Overview
The model applies predictive analytic techniques to find relationships within supply chain flows and backorders.

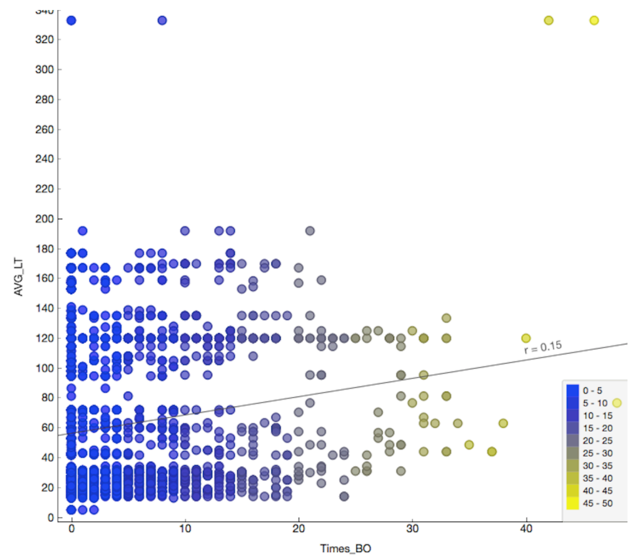


Figure 2 Graphical Correlation between Average Manufacturing Lead-time and Instances of Backorders

The first method, Linear Regression, looks at a set of *n* inputs (independent variables) and predicts a specific outcome y (the dependent variable). A general form of a Linear Regression equation is shown below.

$$y = c + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_n x_n$$

Where:
y = predicted dependent variable
c = a constant
β_n *= regression coefficient of independent variable* x_n
x_n *= independent variable n*

In the case of this analysis, the dependent variable y is the service level (i.e. number of instances an item goes on backorder in twelve months). The independent variables, x_n, are the attributes and of the operations within the medical device supply chain. Linear regression, upon analyzing the historical data inputs, will output a function for future predictions.

The second Supervised Learning technique applied in this model is Logistic Regression. Logistic Regression is used to predict binary outcomes (e.g. 0 or 1, YES/NO, etc.) Logistic regression predicts the probability of an independent variable belonging to a certain class. The general equation for logistic regression is given in Equation 2.

$$logit(p) = c + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_n x_n$$

Where:

$$logit(p) = \ln\left(\frac{p}{1-p}\right)$$

p = probability of an event occurring in twelve months

c = *a constant*
β_n = *regression coefficient of independent variable* x_n
x_n = *independent variable n*
Equation 2. [ ]

As data availability improves, so does the model, and so does the risk of over-fitting. Therefore, Primary Component Analysis (PCA) is used to convert the set of observations of *possibly* correlated variables into a set of values of linearly uncorrelated variables. In other words, when a lot of data is available, PCA reduces the dimensionality to only those features which are "most informative" or most important. These are the features which account for most of the variability.

The output of the PCA is a transformed dataset with weights of individual instances for each feature, or weights of combinations of those features.

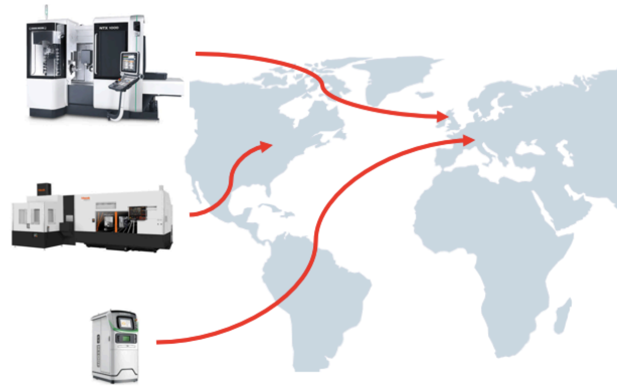
Results
The model's performance is indicated by the Coefficient of Determination (R^2), which measures how closely the data is fitted to the regression line. Using Linear Regression, the number of instances a SKU will go on backorder is only predictable with an R^2 of 22.4%. This means realistically predicting the number of instances a SKU will go on backorder with a good level of certainty is not likely.

However, by transforming the data to a Logistic Regression, and transforming the number of instances a SKU will go on backorder to a binary, categorical variable-the odds of forecasting accurately is much greater. The new Logistic regression increases forecast accuracy from 22% to 82.9%.

Given the current set of data, making a general prediction of whether or not a SKU will go on backorder, with a good level of certainty, is possible. Using this classification technique, the prediction would be accurate approximately 83% of the time.

Application
We can now apply this Logistic Regression to a real-world example. Assume an item requires a unique device identifier on both the packaging and the physical product. The current manufacturing facility does not have this capability and the supply chain manager must choose the best location to conduct this operation. Given three options shown in the following figure, a service difference can be seen.

In the existing process, prior to regulation change, there is a 74% probability this item will go on backorder. Given the performance and lead times of



the three separate locations, the model gives the following results:

- *Option 1*, reduces the probability that there will be instances of backorders from 74% to 62%.
- *Option 2*, increases the probability that there will be instances of backorders from 74% to 77%.
- *Option 3*, increases the probability that there will be instances of backorders from 74% to 76%.

Because it reduces the instances of backorders from 74% to 62%, moving production to the location for Option 1 is the most desireable. Moving manufacturing to this location reduces the lead-time, improves service level, and provides a better customer experience.

Conclusion
The goal of this thesis was to develop a model to help supply chains understand the impact of regulatory changes, and be able to react. The model is effective, but with several key considerations.

First, data quality and availability is integral to the effectiveness of both the model and the outcome. As data availability improves over time, so will the model.

However, in order to make this a sustainable, repeatable process in day to day operations some investment needs to be made in data cleansing and master data maintenance. A significant amount of work went into making such a large data set usable for programming. Even more work went into filtering it down to only usable parts. This is partially because both master data and sales history were dispersed among several different ERP systems. It would be beneficial to include more historical data of the same nature, as well as a wider set of attributes.

Second, while the application of predictive analytics can bring valuable information to the supply chain, there is a law of diminishing returns. Without appropriate data integrity, the results are not informative. Without the correct level of data attributes available, significant hours are put into creating a model with very little predictive power.

Moving forward, with some systems maturity and integration, this model has the potential to become much more robust. The benefits are improved supply chain efficiency, profitability, and a positive customer experience.