

Meeting the Aftermarket Service Requirements Of Medical Device Manufacturers

By Michael R. Blumberg

Executive Summary

The management of forward & reverse logistics supply chains has come under increased scrutiny in many manufacturing industries. The Medical Device Industry is no exception. However, efforts to improve the efficiency and productivity of the supply chain, particularly with respect to Aftermarket Service, have often taken a back seat to other strategic priorities and regulatory compliance issues within the typical Medical Device Manufacturer. As a result of the current status quo, Aftermarket Service organizations within the Medical Device Industry have experienced an environment characterized by excessive operational costs and inefficiencies.

With the marketplace for medical devices growing rapidly, increased demands for more affordable and accessible healthcare, will force Medical Device Manufacturers to explore opportunities to streamline processes and control costs in order to maintain operating margins and sustain high levels of quality and regulatory compliance. Business process outsourcing represents a viable strategy for achieving these goals. Manufacturers should begin to look outsourcing their supply chains to maintain high levels of quality, realize efficiencies, control costs and improve the overall customer experience.

The Current Status Quo

Management and coordination of forward and reverse logistics supply chains represents a critical challenge for Medical Device & Electronics manufacturers particularly as it relates to issues dealing with aftermarket service and support. A basic goal of any electronics equipment manufacturer is to optimize the quality, efficiency, and productivity of aftermarket supply chains via the implementation of strategies and tactics to ensure the following outcomes:

- High Availability of Service Spares Inventory
- High visibility and accessibility to inventory
- Rapid Delivery of Spare Parts within the context of end-customer Service Level Agreement (SLA) requirements
- High velocity of service inventory (e.g., spares, defects, loaners, demo units, etc.) return rates
- Effective testing & screening of defective units
- High quality and productivity of depot repair activities

Supply Chain organizations within Medical Device Manufacturers have a vested interest in achieving these outcomes as part of their quest to maintain high Quality Standards within their industry. Indeed, aftermarket logistics has an impact on quality. However, our analysis suggests that attention to these outcomes appears to be reactive at best. In essence, a great deal of effort is placed on resolving Aftermarket Service and Logistics

problems after they occur rather than establishing process and procedures to ensure they do not occur at all.

Most Aftermarket Service Executives and Managers in the Medical Device industry acknowledge the fact that Aftermarket Supply Chain functions have received limited attention. In contrast, these functions receive higher strategic priority within other industries involving Aftermarket Support of electronic (i.e., capital) equipment such as Information Technology and Telecom. As a result, Aftermarket Service Logistics operations within the Medical Device Industry operate less efficiently than their counterparts in other industries. The evidence to support this allegation can be found in the results of a benchmark analysis conducted by our firm which is contained in Figure 1. The data validates that Medical Device Manufacturers have higher costs and are less effective from a quality and productivity standpoint than their counterparts in other industries.

Figure 1
Benchmark Performance Metrics
- By Industry -

Metric	All Industries	Information Technology	Telecom Equipment	Medical Devices
Logistics Costs As a % of Total Aftermarket Support Costs	18.3%	21.2%	14.5%	36.5%
Dead On Arrival from Logistics	5.3%	6.5%	3.5%	5.0%
Percent of service requests requiring parts to complete transaction	43.4%	42.5%	28.8%	73.8%
Percent of service requests placed on hold due to lack of parts	10.7%	9.5%	6.4%	17.7%
No Trouble Found Percent of Returned Materials	14.7%	14.4%	11.1%	20.5%

The reason for the status quo within the Medical Industry may stem from the fact that capital equipment typically represents a small portion of the overall business of many Medical Device manufacturers. For many Medical Device companies, capital equipment becomes a tool for automating medical procedures that require the use of consumable and disposable supplies that these firms manufacture and supply. It is these consumable and disposable profits that represent the lion's share of revenues and profits for medical device manufacturers. In these situations, Aftermarket service needs and requirements are often not well understood or managed. Political issues and strategic priorities make it difficult for Aftermarket Service executives to obtain budgetary resources to ensure the necessary systems and procedures are in place for controlling the cost, quality, and productivity of Aftermarket Supply Chain.

Problems, Pain Points, & Solutions

Service Executive have told us that without the proper systems and processes in place to proactively deal with Aftermarket Supply Chain issues, the focus of medical device manufacturers becomes overly focused on compliance issues. If and when problems occur, such as in the case of repeat failures with a spare part, there is an attempt to isolate and identify why the problem occurred, assign responsibility for the problem, and ensure that the problem is not inherit to the quality system. There is a lot of finger pointing and blame with respect to quality and little attention to business costs and productivity, or implementation of strategies and tactics to minimize risk. "It's all misaligned" as one manger who we interviewed describes it, *internal groups fight and point finger at one*

another but no one's looking very hard out what's really failing!" As this statement implies, FDA compliance is both a legitimate concern and a hindrance to quality and productivity improvement of the aftermarket supply chain.

We have attempted to identify (see figure 2) some of the common problems or pain points that are the result of the current status quo within the Aftermarket in order to understand their significance and impact on financial and operational performance. Each pain point is described in terms of the observed symptom, probable cause, and potential solutions. The problems typically related to the effectiveness of inventory management, test & repair, logistics operations

FIGURE 2
MAJOR SERVICE "PAIN" POINTS AND RELATED SOLUTIONS

"PAIN" POINT/PROBLEM	SYMPTOM	PROBABLE CAUSE	POTENTIAL SOLUTIONS
INABILITY TO MANAGE OR CONTROL PARTS INVENTORY ON DAY-TO-DAY BASIS	<ul style="list-style-type: none"> LITTLE OR NO ACCURACY ON TIMELY DATA LIMITED VISIBILITY TO LOCATION OF PARTS 	<ul style="list-style-type: none"> INFORMATION SYSTEMS DO NOT TRACK CRITICAL DATA RELATED TO PARTS & AFTERMARKET LOGISTICS 	<ul style="list-style-type: none"> RECOGNIZE IMPORTANCE OF DATA CAPTURE AND INFORMATION SYSTEMS
LOGISTICS AND INVENTORY COSTS TOO HIGH OR INEFFICIENTLY USED	<ul style="list-style-type: none"> CONSTANTLY BUYING NEW PARTS PARTS NOT AT RIGHT PLACE AT RIGHT TIME 	<ul style="list-style-type: none"> INABILITY TO PROPERLY PLAN, FORECAST, & TRACK PARTS USAGE LABOR NOT OPERATING EFFICIENTLY DUE TO EXCESSIVE MANUAL PROCESSES 	<ul style="list-style-type: none"> FULL CLOSED LOOP LOGISTICS MANAGEMENT SYSTEM
LACK OF REAL-TIME CONTROL OVER PARTS	<ul style="list-style-type: none"> EXCESSIVE DELAYS IN RETURNS PARTS NOT DELIVERED IN A TIMELY MANNER SHRINKAGE AND OBSOLESCENCE 	<ul style="list-style-type: none"> LIMITED ACCOUNTABILITY FOR PARTS MANAGEMENT ACROSS COMPANY LACK OF MECHANISMS IN PLACE TO ENSURE TIMELY DELIVERY 	<ul style="list-style-type: none"> PROACTIVE AND ACCURATE REPORTING, TRACKING, AND FOLLOW-UP
QUALITY & PRODUCTIVITY ISSUES ASSOCIATED WITH DEPOT REPAIR OPERATIONS	<ul style="list-style-type: none"> HIGH OF NTF AND DOA RATES TIME & COST OF REPAIRS TOO HIGH 	<ul style="list-style-type: none"> PROCESSES AND PROCEDURES NOT OPTIMIZED LIMITED INVESTMENT IN TEST DIAGNOSTICS AND QUALITY SCREENING 	<ul style="list-style-type: none"> INVEST IN TEST EQUIPMENT & QUALITY PROCESSES
LOGISTICS OPERATION NOT OPTIMIZED	<ul style="list-style-type: none"> LOW PROFITABILITY AND/OR CUSTOMER SATISFACTION ASSOCIATED WITH AFTERMARKET SERVICE LOW LEVELS OF EFFICIENCY & PRODUCTIVITY 	<ul style="list-style-type: none"> LACK OF PROPER SYSTEMS TO AUTOMATE PROCESSES AND STREAMLINE OPERATIONS LOGISTICS WORKFORCE NOT AVAILABLE ON PROPERLY TRAINED ON AFTERMARKET ISSUES 	<ul style="list-style-type: none"> ON-LINE REAL TIME CONTROL OF LOGISTICS PIPELINE DOWN TO FIELD LEVEL
INABILITY TO CONTROL AND MANAGE FINANCIAL ASPECTS OF AFTERMARKET LOGISTICS	<ul style="list-style-type: none"> DELAYS IN ISSUING CREDITS DELAYS IN CASH FLOW OR BILLING FREQUENT BUDGETARY DISCREPANCIES 	<ul style="list-style-type: none"> INFLEXIBILITY OF SYSTEMS AND PROCEDURES LOGISTICS SYSTEMS NOT ABLE TO CAPTURE FINANCIAL DATA SYSTEMS NOT ACCESSIBLE TO ALL USERS 	<ul style="list-style-type: none"> EXPAND SYSTEM FUNCTIONALITY IMPROVE INTERFACE BETWEEN FINANCE & LOGISTICS

Our analysis suggests that the root causes of these issues are often systemic and procedural in nature, and while they may have an impact on FDA regulatory compliance and quality, they are not caused by a break down or gap in the quality system but instead through a gap in back office systems and processes. This assessment reinforces the points made earlier with respect to manufacturers trying to solve basic business challenges as though they were solely the result of failures within the Quality System. Even more problematic from the perspective of Aftermarket Service is that sometimes the challenges have no impact on quality compliance and thus continue to manifest, ultimately hitting bottom line profitability and customer satisfaction.

As indicated in Figure 1, the problems/pain points identified above can be resolved by adapting systemic and procedural improvements to key functional areas within the Aftermarket Logistics Supply Chain such as Order Management & Fulfillment, Inventory & Warehouse Management, Reverse Logistics & Returns Management, Depot Repair, and Logistics Planning. Our research indicates that these improvements can improve efficiency and productivity by as much as 30% to 40% depending on the functional area under consideration. The most dramatic impacts can be found in the following areas:

- Reduction in order fulfillment processing time (40% to 50%)
- Improvement in returns rates and velocity (time) of returns (40% to 50%)

- Improvement in the forecast accuracy of service parts and returns (20% to 35%)
- Reduction in NTF & DOA rates (30% to 35%)
- Improved productivity & efficiency of workforce (20% to 30%)
- Reduction in cost and time associated with depot repair (30% to 40%)
- Reduction in Inventory costs (30% to 35%)

Clearly, the impact on bottom line profitability as well as customer satisfaction can be quite significant from the implementation of systemic and procedural improvements. However, a great of time, effort, and investment is required to achieve these types of improvements. Furthermore, conflicting strategic priorities over the allocation of limited resources make it difficult, if not almost impossible for real and substantial change to occur within the typical Aftermarket Service organization.

Strategic Benefit & Value of BPO

Business Process Outsourcing (BPO) represents a practical way to resolve Aftermarket Logistical Support challenges. (BPO) provides the Medical Device Manufacturer with state of the art system functionality and best in class, quality, compliant processes. The benefit is speed to market and reduced cost of implementation. In essence, a manufacturer can quickly gain capability without the need for major capital investment in infrastructure or disruption to the current business environment common when implementing new systems and procedures.

Today, many manufacturers handle Aftermarket Logistical Support through a centralized operation often with limited capabilities in terms of systemic capability, which in turn does not allow them to effectively perform certain processes that must be automated in order to perform at all. There are situations abound were Aftermarket Support operations do not have access to the right functionality to capture and track key data associated with business processes. For that matter, we have found examples where some organizations do not have any automated functionality at all. Instead, they rely on spreadsheets and manual processes to capture and track information.

Outsourcing not only solves internal operating challenges but provides access to new service options and/or more efficient and streamlined service which not currently available there internal capabilities such as:

- Critical Spare Parts Inventory Management
- Centralized Distribution of Spare Parts
- Inventory Replenishment
- Advanced Exchange
- Reverse Logistics & Returns Management
- Asset Recovery
- Repair & Refurbishment
- e-Waste & e-Recycling
- Reporting & Business Analytics
- On-going Process/Quality Improvements

Manufacturers who have access to these capabilities from a 3rd Party Service provider can in turn offer new services to their end-customers to generate new sources of profitable revenue.

Indeed, while many Medical Device Manufacturers are interested in outsourcing, there exist some obvious concerns with respect to the knowledge and expertise that 3rd Party vendors possess regarding regulatory compliance and quality systems. In addition to robust systems and processes, the ideal 3rd Party Outsource provider must be willing to have a scalable solution that fits any size operation in terms of equipment population.

This is a particular concern since many Medical Device Manufacturers support a relatively small installed base of equipment but none the less can benefit significantly from outsourcing Aftermarket Service Logistics functions. *“This represents a big opportunity for us to save money and become more efficient”* notes one executive.

Summary & Conclusions

In Summary, Aftermarket Logistics represents a critical challenge area for many manufacturers within the Medical Device Industry. Far too many organizations spend a great deal of time and attention on ensuring regulatory compliance and far too little effort and investment on the business end of aftermarket support. As a result, pain points and problems associated with inventory availability, quality outcomes, and financial management are common. The implementation of state of the art logistics management systems and leading edge business processes is critical to eliminating pain points and problems. Although significant improvements in quality, productivity, and efficiency are available, most manufacturers lack the resources and know-how required to achieve long term sustainable improvements.

Business Process Outsourcing represents an effective strategy for obtaining improvements on a rapid and cost effective basis. Characteristics that Manufacturers should look for in a 3rd Party Service provider include 1) a robust systemic infrastructure, 2) knowledge of industry best practices, and 3) a scalable solution that fits any size operation in terms of equipment population. In essence, the ideal 3rd party service provider should be able to combine state of the art technology with quality processes, in order to deliver best in class performance on metrics critical to the Medical Device Manufacturer such as order accuracy, order processing time, rate of return, return velocity, turnaround time, NTF & DOA, customer satisfaction and reduced cost of logistics operations.

Whether the situation calls for a total outsourcing of all Aftermarket Logistics functions or a hybrid of in-sourced and selected outsourced functions, a 3rd party business partner with demonstrated flexibility, control, quality assurance and creativity to ensure that Medical Device Manufacturers get exactly what they expect, plus substantial value-added benefits that enable the Manufacturer to expand the services offered to end customers and develop new sources of profitable revenue. By working with a reputable, credible, and qualified 3rd Party Service Provider, a Medical Device Manufacturer can realize a high level of assurance that their supply chain operations can be successfully outsourced to achieve optimal levels of quality and productivity, and costs can be reduced dramatically all while improving the end-customer experience.

About the Author

Michael R. Blumberg is a Certified Management Consultant (CMC) and President & CEO of Blumberg Advisory Group, Inc. His firm focuses on providing strategic and tactical assistance to client organizations for improving the overall profitability and quality of aftermarket service operations. Mr. Blumberg has established himself as an expert and industry authority on Reverse Logistics and Closed Loop Supply Chain Management. Mr. Blumberg also serves as a Chairman of the Reverse Logistics Association's Medical/Pharmaceutical Focus Committee