

EXPANDING OPPORTUNITIES WITH A SIMPLIFIED SUPPLY CHAIN

*Transformational strategies for improving
outcomes and cost along the medical device chain*

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EXPANDING OPPORTUNITIES WITH A SIMPLIFIED SUPPLY CHAIN:

***Transformational strategies for improving outcomes
and cost along the medical device value chain***

In the era of cost-conscious, value-based healthcare, medical device original equipment manufacturers (OEMs) are under intense cost pressures to find ways to reevaluate their operations and supply chain strategies. To this end, an approach that procurement professionals are progressively employing is to consolidate the supply chain. Managing a complex, multi-vendor supply chain in an increasingly regulated and competitive healthcare environment has become expensive, time-consuming, and precarious.

Conversely, many medical device OEMs have found that, by partnering with carefully selected vendors that can offer complete supply chain solutions, they are able to free up capital, better control quality, cost, and lead times, and strengthen their global competitive advantage.

This white paper will review some of the market trends driving supply chain consolidation within the medical device industry and examine the benefits of collaborating with a supplier that can provide complete solutions for every step of the value chain.

MARKET DRIVERS IMPACTING SUPPLIER CONSOLIDATION

The FDA and global regulatory bodies have raised the bar on supplier controls. OEMs must now bear more responsibility for every step of their global supply chain. This requires the OEM to delve deeper into their supplier's business in order to ensure that the supplier's validation and qualification processes operate within a state of control. More detailed records must be kept, more audits and on-site visits must be conducted, and ongoing reviews of process control data must be performed.

Essentially, OEMs now need to think of their suppliers as part of their in-house production facility and have extensive safeguards in place to verify that all of their supplier's procedures meet the regulatory and product requirements of the manufacturer's quality system. This increased responsibility and complexity puts a strain on OEM's purchasing and quality teams and makes managing a vast supply chain network all that more difficult.

In addition to the ever-evolving regulatory demands, another driving force behind supplier consolidation is the push and pull of financial and market pressures. Across the board, payers (i.e. Medicare, Medicaid, private insurance, etc.) are cutting and capping their reimbursements to hospitals. Since hospitals are the largest purchasers of medical devices, the ramifications of these reimbursement reductions trickle down through the supply chain.

For example, if the price of an orthopedic implant is \$6,000, but payer reimbursement is only \$3,000, the hospital is faced with absorbing the remaining cost. As a result, the growing trend is that hospitals and Group Purchasing Organizations are increasingly renegotiating – and lowering – the amount they are willing to spend on medical devices. Their vendor evaluation process is also getting more stringent.

In addition, OEMs face greater demand to improve devices and surgical procedures so that patients will recover more quickly and have shorter hospital stays. A primary catalyst behind this demand is the move toward value-based purchasing (VBP). VBP is a program established by the Patient Protection and Accountable Care Act of 2010 and gives the Centers for Medicare and Medicaid Services the power to base a portion of

hospital and provider reimbursement payments on how cost-effectively they can provide high-quality care.¹

The intention is for payers to depart from their fee-for-service payment system and reward value over volume. By linking payments to improved performance, cost and quality, VBP holds healthcare providers—and their medical device suppliers—more accountable for improving the cost and quality of care.²

CHALLENGES WITH MANAGING A LARGE, FRAGMENTED, MULTI-VENDOR SUPPLY CHAIN

The status quo has long been for OEMs to piecemeal their outsourcing, with the primary focus being on each suppliers pricing as opposed to overall capabilities, costs, and quality. As a result, one supplier was responsible for machining the product, another for coating it, and yet another for packaging and sterilization.

The issue with this supply chain structure is that, in addition to being complicated, arduous, and inefficient, it actually increases costs overall.

Compounding Costs

The incremental costs associated with managing multiple vendors add up quickly. With global quality regulations more stringent than ever before, OEMs must outlay considerable time, cost, and manpower to ensure that all their suppliers adhere to not only Current Good Manufacturing Practices (cGMP) requirements, but also to the quality requirements of the OEM – which are often even more meticulous and demanding.

To help their suppliers meet the necessary requirements, including validation, gage repeatability and reproducibility, shop floor concepts (5S, etc), the OEMs must send their Quality people to each supplier for site visits and performance audits. This takes a significant time and financial toll – even more so when there are hundreds of suppliers involved. For a large company, auditing the entire vendor base could mean doing several hundred audits per year, at a cost of thousands of dollars per audit (not including personnel costs).

In addition to ensuring that each supplier's technology, quality, responsiveness, and lead times are where they need to be, OEMs incur sizeable costs managing the entire supply chain. This involves everything from hiring staff to oversee multiple facilities, to writing and sending multiple purchase orders and recording and maintaining in-depth supplier control documentation.

Elevated Regulatory Exposure

The more vendors in the supply chain, the more liability an OEM takes on. With limited manpower to sufficiently manage a vast supply chain, the OEM faces increased risk that the FDA and/or a global regulatory body will find fault in their supplier control process. This could lead to increased FDA audits, citations – even fines and recalls.

High Inventory Levels

Generally, each time a supplier completes their part, the product must be sent back to the manufacturer for inspection. If it passes inspection, it is then sent out to the next supplier in the supply chain, and inspected again. Managing the logistics of these multiple touch points means longer lead times and more inventory tied up in the supply chain.

Long Lead Times

Since each supplier must wait for the part to be inspected by the OEM before they can apply their capability, time between processes takes even longer. For example, if a purchaser contracts with three suppliers to machine, coat, and package their hip implant, the OEM must ship the component to the supplier and then wait for the supplier to ship the machined part back. Once the OEM receives the part, they must conduct a quality audit on the machined part before shipping it out to the next vendor in the chain. This process is repeated again for the coating supplier and the packaging supplier.

Dealing with three separate vendors not only adds time, it also requires three separate accounts payable and three separate quality audits before the product is packaged and on the shelf.

Competitive Disadvantage

The process of managing, auditing, and paying multiple suppliers often ties up an OEM's cash flow, which can limit their ability to innovate, grow, and effectively compete in the global marketplace.

THE COMPLETE SUPPLY CHAIN SOLUTION

To overcome the challenges associated with an increasingly complex medical device manufacturing process, more and more, OEMs are relying on suppliers that have the expertise and comprehensive capabilities to provide solutions for every part of their value chain.

This means that, from concept, design, FDA submission, all the way through to packaging and sterilization, the supplier handles each step of the process for the OEM, including supplier auditing and inventory management.

IMPORTANT BENEFITS OF FULL-SERVICE PARTNERSHIPS

OEMs realize a number of important benefits when they simplify their supply chain and partner with a company that can offer complete value chain solutions, including:

Fewer vendors to manage – Partnering with a full-service provider can help an OEM reduce 20-30 percent of their approved supplier list. Fewer suppliers' means that less time and funds are needed for the OEM to sufficiently oversee each supplier. The OEM is also better situated to strengthen and streamline their supplier controls, ensure quality, and reduce their risk of regulatory action.

Overall cost containment – A condensed, strategically structured supply chain can save OEMs significant time and money on things such as travel, paperwork, parts inspection, handling of the device history record, shipping, auditing, processing purchase orders, and other supplier-management logistics.

Better purchasing power – When more business is moved to a highly capable and qualified supplier, a deeper, more advantageous service relationship develops. This bundling effect can make it possible for a supplier to help their OEM partner leverage volume and improve their bottom line in the process. Greater purchasing power also gives the OEM better visibility over their supplier's operations and more control over where the supplier invests their resources.

Faster Lead Times – A full-service supplier that has the willingness and ability to work jointly with their OEM partner can make it possible for the OEM to get their ordering process closer to their actual selling process through reduction of lead times, inventory reduction and the application of lean principles (e.g., Kanban).

Greater Competitive Advantage – OEM's do business leaner, faster, and more productively when they partner with a supplier that provides services for every step in the supply chain. The time and capital that this partnership frees up enables the OEM to hire more highly-skilled people, acquire state-of-the-art machinery, and create sustained competitive advantage.

WHAT TO LOOK FOR IN A FULL-SERVICE SUPPLY CHAIN PROVIDER

When seeking a partner that can provide complete supply chain services, many factors should be considered, including:

Lean principles: A supplier whose employees and management team embrace Lean manufacturing principles create greater overall value for their OEM customers. A Lean supplier is able to remove waste, decrease cost, and reduce lead times in a way that requires less effort, investment, inventory and logistics on the part of the OEM.

Technology: Suppliers who employ technology that automates processes help ensure process stability, reduced labor costs, better quality, and rapid response times.

Quality systems: The most efficient pathway to commercial success is to partner with a supplier that has broad and in-depth quality system expertise. This can help OEMs simplify their existing system so that it is more efficient and productive, and

manage risk by ensuring continued compliance to ISO 13485, FDA Quality System Regulation for Medical Devices 21 CFR Part 820, and/or MDD requirements.^{3 4 5}

Regulatory expertise: A full-service supplier with a skilled regulatory team provides the knowledge, preparation and process needed to develop submission strategies that ensure compliance and regulatory clearance. A supplier adds even more value if their regulatory team is able to effectively communicate with the FDA and obtain clarification on all elements of a 510k before it is submitted.

Design and development process: Whether it's idea generation, design risk assessment, project management, or design transfer, a supplier with a finely tuned product development process and on-site prototype facilities accelerates successful product launches.

Sterile packaging skillsets: The expertise and resources required for packaging sterilization and validation are extensive. Partnering with a complete solutions supplier that has the ISO 7 (class 10,000) qualified clean rooms,⁶ state-of-the-art automated packaging and test equipment, and highly experienced team members is essential to bringing a product to market quickly, safely, and cost-effectively.

Point of manufacture packaging: The most effective way for OEMs to reduce handling, lead times and Work in Process inventory is to partner with a supplier that has the capabilities to sterile package coated and/or finished products at their facility, as opposed to shipping it to another location. Point of manufacture packaging closes the loop on the supply chain and helps protect an OEM's product from getting scratched, damaged, or even contaminated before it gets to the end user.

Value chain management: A full-service partner with the resources and proficiency to audit and maintain an entire value stream (including other suppliers) simplifies the OEM's purchasing process and reduces waste and cost along their supply chain.

ORCHID ORTHOPEDIC SOLUTIONS

Orchid Orthopedic Solutions takes the role of strategic supply chain partner to a whole new level. From product concept to product launch and every step in between, the Orchid team has the capabilities and experience to provide complete supply chain solutions for the orthopedic and medical device markets.

Orchid's 1,700+ team members have unparalleled expertise in the design and manufacture of joint reconstruction, trauma, spine, sports medicine, extremities, craniomaxillofacial, dental, cardiovascular and general surgical devices.

Orchid's unique advantages and proprietary solutions include:

- **Lean culture** that is committed to simplifying processes, minimizing waste, and increasing value.
- **Multiple full-service facilities** to ensure an uninterrupted supply chain and risk mitigation.
- **Automation technology** at multiple facilities including robots that handle parts through different processes; CNC machining; and automated inspection systems within machines that measure the part and make adjustments before machining to ensure good capability.
- An **ISO 13485** certified quality system with reliable, consistent results.
- Specialized strategies **for regulatory submissions and developing customized quality systems**.
- A regulatory team in **direct communication with the FDA** and that receives prompt clarification on 510k submissions.
- Award-winning **casting, forging, machining and plastic injection molding** expertise.
- Dedicated team with experience designing, prototyping, and manufacturing a range of **cutting instruments** and **assembling complex instruments**, including drills, burrs, taps, reamers, blades and more.
- **Implant coatings and surface treatment expertise** to meet any market need.

- **Packaging and sterilization validation expertise** that protect customers from the cost and complexity of validation.
- **RediPak™** – an **off-the-shelf, turn-key, pre-validated** (up to 5 years shelf life) **sterile packaging system** for numerous product families and formations that accelerates time to market at a fraction of the cost.
- **Point of Manufacture Packaging Process** that protects the product and minimizes lead times.
- A **Supplier Consolidation Program** that streamlines the management of the entire value chain.



To learn more about how **Orchid** can help you strategically consolidate your supply chain, reduce risk, improve quality, and strengthen your competitive advantage in the new medical device economy, call us at **(517) 694-2300** or visit us online at www.orchid-ortho.com.

ENDNOTES

¹ Nelson, Bryn, PhD, *Value-Based Purchasing Raises the Stakes*. The Hospitalist. http://www.the-hospitalist.org/details/article/1056049/Value-Based_Purchasing_Raises_the_Stakes.html.

² Keckley, Paul H. PhD, Coughlin, Sheryl, PhD, MHA, Gupta, Shiraz, PharmD, MPH, Underwood, Howard, R. MD, FSA. *Value-based Purchasing: A strategic overview for health care industry stakeholders*. Deloitte. 2011. http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/Health%20Reform%20Issues%20Briefs/US_CHS_ValueBasedPurchasing_031811.pdf

³ ISO 13485 is an International Organization for Standardization (ISO) standard, published in 2003, that represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.

⁴ The FDA's Quality System Regulations (QSR) are documented in the Code of Federal Regulations Title 21—Food and Drugs, Subchapter H—Medical Devices part 820. FDA QSR states that manufacturers must establish and follow quality systems, known as current good manufacturing practices (CGMP's), to help ensure that their products (food, drugs, biologics, and devices) consistently meet applicable requirements and specifications.

⁵ The Medical Devices Directive (MDD) covers the regulatory requirements of the European Union for Medical Devices.

⁶ ISO clean room classifications are rated according to how much particulate of specific sizes exist per cubic meter and must follow specified international standards for cleanliness and contamination prevention. For ISO 7 (class 10,000) qualified clean rooms, the maximum concentration limits for particles is 352,000 per 0.5 micron of air. Involved tests must be conducted on a frequent basis to monitor the environment and clean room processes to ensure that the device will remain sterile. Tests involve monitoring: bioburden (population of microbes on or in a product or package), airborne particles (including viable particulate), temperature, humidity, water quality, etc.