



How ESI is Helping Move New Medical Device Product to Market Quicker & More Cost Efficiently

Benefits of Early Supplier Involvement (ESI) greater today as result of market globalization and increased pressure to commercialize innovations at faster pace



ENGINEERING YOUR SUCCESS.

Introduction

The whirlwind pace of breakthrough innovation is having a profound impact throughout the medical industry. To stay competitive, OEMs need to rethink how they develop and commercialize new products. Almost daily headlines are being made about new technologies and groundbreaking products. So much is changing so fast—faster than at any other time in the history of medical device and clinical research according to a January 2019 article in massdevice.com.¹ That's why 2019 is being predicted to be a transformational year in which OEMs will need to employ more creative approaches in how they innovate.

Early Supplier Involvement (ESI) has long been a valuable strategy manufacturers deploy to help produce new products more effectively and efficiently. After decades of thorough research and study, ESI continues to demonstrate significant value to OEM bottom lines, because decisions made in the design phase have a major effect on product quality and costs. Although many OEMs talk about ESI, they do not effectively implement it.

Bringing a new medical device to market is challenging, especially when engaging a strategic supplier at the earliest stage of the design cycle who can offer standard, modified standard or custom components and subsystems while collaborating to provide

long-term cost stability during production. Compounding this challenge are an array of changing market forces, including the rapid rate of technological innovation, globalization, reduced product life cycles, increasing market fragmentation and demand for shorter lead times.³ Manufacturers can offset some of these challenges and added risks in new product development by relying on experienced partners to design, develop and manufacture their medical devices.

But how should suppliers be evaluated to determine who is the best fit for collaborating? When should a supplier become involved in the development process? And to what degree? These are the

questions that have been the basis for volumes of research dating back nearly half a century around the concept of ESI.

Despite all the data and a growing recognition of the value of ESI, truly successful buyer-supplier collaboration is still considered rare. According to the same article on middionline.com,³ the forming of many of these alliances has been difficult with many failing to recognize the benefits of the approach.



This paper discusses the many facets of ESI and addresses the following questions:

- *Why is ESI more valuable today than ever before?*
- *What challenges exist to limit the benefits of ESI?*
- *What variables affect the timing and success of ESI?*
- *What criteria should be used to choose the supplier and manage the relationship?*
- *What does success look like?*
- *How is cost impacted?*

How ESI Keeps Manufacturers Competitive in Today's Fast-Paced Market

ESI is defined as the vertical collaboration between supply chain partners in which the manufacturer involves the supplier at the earliest stage of the product development process. Its value proposition is based on the premise that at least 80% of the total cost of a new product is locked in by the first two stages of the product development process.⁴ In addition, the right supplier involved early on can explore all possible opportunities for value engineering and cost reduction.

However, the success of an organization in today's highly competitive medical device market isn't simply about reducing R&D and engineering costs. Rather, it mandates the ability to quickly ramp up the development and full commercialization of quality products that offer a differentiated technology without compromising product quality. Assuming the right supplier is involved at the earliest stage, concurrent engineering between the manufacturer and supplier teams has proven to save time and result in a cost-effective and innovative product. It is critical, however, that a strategic partner is chosen early on and that all of its engineering and technical capabilities are fully utilized.

The drive to bring new products to market quickly is

not unique to 2019. However, it has been accelerated and exacerbated—especially in the medical device manufacturing industry—as a result of market globalization, increased regulatory requirements, enhanced consumer education and a general mentality in our culture that demands results and satisfaction now.

In order to remain competitive in this fast-changing environment, OEMs have come to accept the notion of outsourcing various activities. Savvy OEMs understand the benefits of treating key suppliers which possess a strategic vision more like partners than vendors. Working closely with strategic suppliers at the right time in the development process can create more value across the board by improving quality, reducing total time to market and identifying cost-effective and innovative technologies.

The concept of ESI is not new. Already in the 1980s it was being credited as a key reason behind the success of Japanese auto makers. Reaching out and collaborating with their suppliers early on, Japanese auto makers gained a major advantage over American manufacturers by being faster, cheaper and more innovative in their development efforts.⁵

Since that time, ESI has been gaining in importance and implementation as a result

of increased costs, more sophisticated technologies and market demand for faster turnaround. At least one researcher—Thomas Johnsen, who performed a rigorous analysis of major research regarding supplier involvement and subsequently published his findings in the *Journal of Purchasing & Supply Management*⁶—additionally points out that the need for and benefits of ESI continue to increase as products become more complex.



Choosing the Right Supplier and Optimizing Results

ESI is not a straightforward process and cannot be implemented easily. This is evident from the numerous case studies that have been documented of companies in an array of industries trying and failing.

Involving suppliers in the new product development process can be a resource-consuming activity, especially if the chosen supplier has little or no history with the manufacturer. Expanding the scope of existing relationships with trusted suppliers mitigates the effort required to establish a working knowledge of specialized manufacturing processes and business operations. The ESI process encompasses many internal and external variables and, to be implemented effectively, formal strategic supplier assessment procedures and protocols need to be developed. Programs that lack specificity and a formal approach are usually inadequate and ineffective, as are those that lack the support and involvement of top management since major decisions regarding product design and strategic material development often require approval from senior leadership.¹²

The criteria for choosing a supplier needs to focus on more than technical capabilities and competency in product development. To achieve success, manufacturers must identify suppliers that they know

have compatible cultures and communications processes, as well as the capacity to ramp up quickly.

The following questions should be asked as part of the evaluation process.⁹

- What are the supplier's core technological competencies?
- Does the supplier have relevant product or production knowledge for this particular part?
- Can the supplier do the development work more efficiently than the manufacturer?
- Can the supplier handle full product development, including research and design?
- Does the supplier have rapid prototyping and prototype tooling to shorten the development cycle, minimize tooling costs and improve design flexibility?
- Does the supplier have the necessary certifications and approvals in place for the application?
- Is the supplier capable and willing to identify product designs that simply are not feasible as designed?
- How has the supplier dealt with confidential information in the past?
- How willing and able is the supplier in investing resources?

In projects involving breakthrough technologies, it is often more difficult to

properly assess potential technologies to determine which one is the most suitable. However, by selecting a known supplier with a proven track record for collaboration, flexibility and responsiveness, as well as a solid history with the organization, manufacturers can reduce the risk of selecting an incompatible supplier. Partnering with a known supplier also minimizes issues with trust, communication, knowledge sharing, cooperation and commitment.

There may be multiple suppliers with the technological capabilities required, but the key is to focus on the relational capabilities.¹³ If the two organizations can't work together, it will be difficult to realize any cost or time savings.

It's also important to evaluate the extent of the supplier involvement early on. Both the OEM and supplier need to understand their roles and manage expectations. For example, will the supplier simply be providing manufacturing or basic consulting or actually be a part of the innovation development? The degree of innovation of the product determines, to some extent, the level of involvement of the supplier. Not every project will require the same level of involvement.

Choosing one key supplier that provides the broadest coverage of technologies and application expertise simplifies the process and often results in superior and more consistent results, because it is more difficult to manage and communicate with multiple key suppliers.

When assembling project teams, manufacturers should ensure that all necessary disciplines are represented and that one full-time ESI project manager is appointed and held responsible for results. All relevant departments should be included in each design review to ensure the product can actually be manufactured effectively and reliably. Project team members should be appointed based on their technical expertise as well as their ability to work well with others. For project success, all team members from both

companies need to work seamlessly and unselfishly as one team.

Ideally there will be a single program manager from the supplier identified early on in the process. This person is not only responsible for managing the supplier's work but also managing customer expectations.

The value of good communication cannot be overestimated throughout the development process, as it is critical for soliciting cooperation, better use of resources, better understanding and execution of deliverables, ability to make improvements throughout the entire design, development and manufacturing process. Encourage feedback and create an environment that rewards listening and the discussion of new ideas.

As the project team continues to meet, it's important to avoid "design creep" which is the veering off of the original course and making a product more complex than necessary by adding functionality or enhanced performance. All these extras can add to the final cost of the product or make it too complicated to produce or take more time to launch. ESI can help keep the project on track by providing input, expertise and guidance.

Make sure the supplier has a clear understanding of the product's end use. An experienced, well-informed supplier can suggest material substitutions where appropriate to reduce cost and/or improve performance, as well as recommend common processes for greater manufacturing efficiency and faster time to market.

| Concept | Feasibility | Design | Pilot | Production | Sustaining |
|--|---|---|--|--|--|
| <ul style="list-style-type: none"> Collaborative Engineering One Contact Across All Parker Technologies | <ul style="list-style-type: none"> Early Supplier Involvement Design for Mfg. & Assembly (DFMA)/Failure Mode and Effect Analysis (FMEA)/Advanced Product Quality Planning (APQP) | <ul style="list-style-type: none"> Rapid Prototyping Initiate Documentation, Drawing Package & Components Engineering | <ul style="list-style-type: none"> Release Final Design Deliver Documentation, Test Plans & Drawing Package | <ul style="list-style-type: none"> Release Plan for Logistics Inventory Management Systems (JIT, Kanban, MRP or Kitting) Quality Metrics/Quarterly Check Points | <ul style="list-style-type: none"> Productivity Metrics/Quarterly Check Points Identify Mutual cost Reduction Opportunities |
| <p>Parker works as a valuable source of innovation, using our engineering, manufacturing, and quality planning expertise to critically evaluate design concepts.</p> | <p>We eliminate development risk factors using collaborative engineering and rapid prototyping. This upfront work uncovers any initial design discrepancies so we can ensure that production will meet feasibility requirements and any regulations governing production.</p> | <p>By working alongside our customers during their product development, we can deliver extra value in the areas of prototyping, data validation, design for manufacturing and assembly and documentation.</p> | <p>As a process-driven, lean enterprise, Parker thoroughly tests its products to achieve a smooth transition from concept to production, which is important for the successful launch of our customers new products.</p> | <p>By using productivity metrics and maintaining uncompromised quality control, we ensure that our solutions match customer specification.</p> | <p>Throughout the entire product lifecycle, Parker works to ensure our customers' return on investment and drive advancements in the life sciences industry.</p> |

Evaluating Success

Was the right supplier chosen?

Sometimes the answer to this question becomes obvious early in the development process, especially if the wrong supplier was chosen or if the process was mismanaged. Numerous case studies have been identified over the years in which product introductions were delayed, costs increased and quality compromised as a direct result of the complexities involved in managing ESI development projects. In some cases, a manufacturer may have recognized a savings in engineering time but that savings was overshadowed by increases in management and communications time.

According to Wynstra's study published in the *European Journal of Purchasing & Supply Management*,⁹ a win-win situation occurs when a project is completed with an optimal amount of "management capacity" (time and money spent on communications, coordination, etc) while making optimal use of a supplier's expertise. The result is a new product representing breakthrough/ differentiated technology that

was brought to market at a competitive cost before the competition could provide a similar offering.

Because when it comes to successfully introducing medical devices, you have to be smarter, faster and cheaper in order to stay competitive. A well-implemented and managed ESI program can make that all possible.

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