Portescap

WHITE PAPER

EFFECTIVE MOTOR SUPPLIER MANAGEMENT IN MEDICAL DEVICE DEVELOPMENT

The benefits of early engagement during the concept and ideation stages

Medical device companies are under extreme pressure to deliver new or improved products to doctors and patients ahead of the competition. While the overall process for a medical device takes years, most of this timeline is absorbed by tooling and component lead times, market feedback, life testing and regulatory approval. Device engineers must often wait to begin design updates until these inputs are received, leaving them tight windows to complete their next deliverable before the deadline.

Immediately after management greenlights the project, device engineers need to rapidly build proof-of-concept (POC) samples for internal review and market feedback. It can then take weeks or months before finance approves funding and marketing confirms the target specifications, at which point engineers must quickly produce more robust and sophisticated prototypes for further testing. This cycle repeats itself through verification testing and regulatory approval.

Unfortunately, this time pressure can compromise the end result. To meet early stage deadlines, it is a common and accepted practice to design the POC sample around readily available standard components with the intention to fine-tune the design using customized parts during the next round of prototyping. However, similar time pressure during subsequent iterations can again make custom component lead times prohibitive. As a result, concessions made even in the most rudimentary prototypes frequently survive to production, lowering product performance and increasing total costs.

Staying on track while delivering an optimized design requires choosing supply partners that can help manage the evolution of a component from concept to launch. They must be able to provide rapid standard prototypes that are close enough for POC development, capable of fast customization for future iterations and positioned with the right price and quality for production. It is far

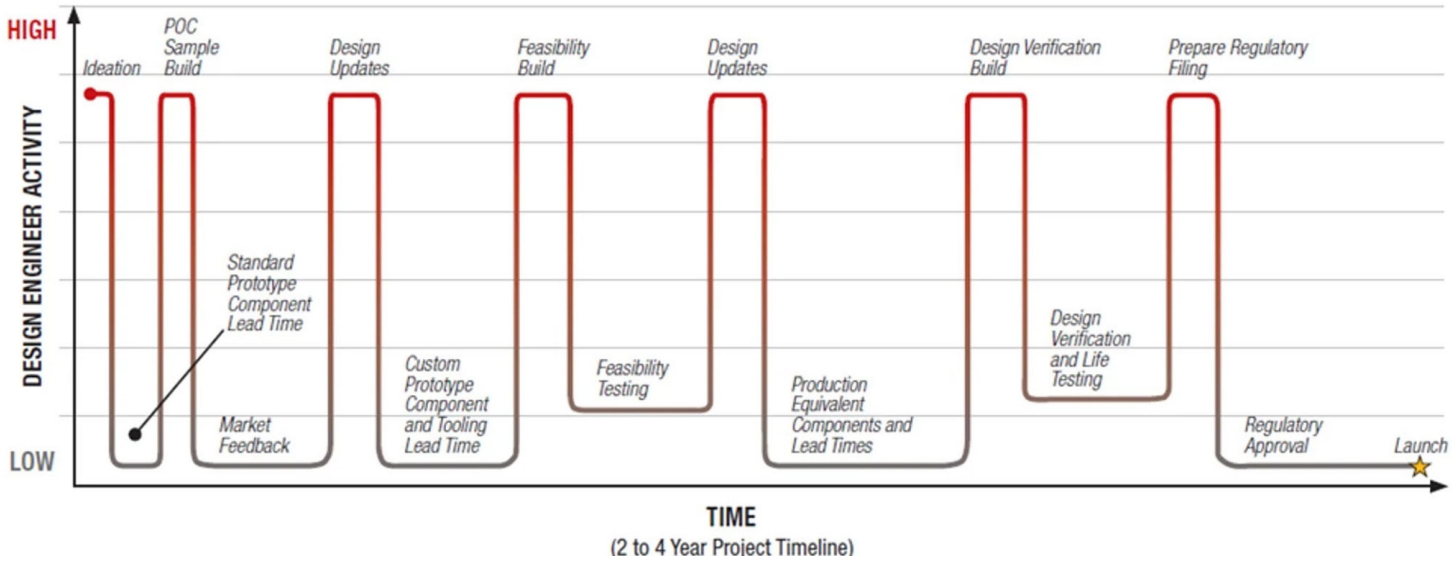


Figure 1 – Timeline Constraints

more preferable to use a consistent partner throughout the process because the supplier can learn more from the concept testing if its own product was used, and it can execute each stage while considering the big picture. If a supplier not viable for production must be chosen for the POC, then it is critical to also engage with the strategic supplier at that time. An effective strategic supply partner can help the device engineer prepare to incorporate the custom component both by consulting on the POC design and beginning work on the customization in parallel.

The criticality of supplier selection during early development stages is compounded by the reality that most medical devices fail in their initial goal of qualifying multiple sources for critical components. As deadlines approach and issues arise, designers are forced to eliminate as many moving pieces as possible. Attempting to herd competing suppliers to conform to the same specification and timeline is an added challenge that can rarely be supported. As a result, medical products are typically submitted for regulatory approval with only one supplier per component. Qualifying a second supplier once production is underway is rarely successful because resubmission to regulators is most often required, a prospect that is generally rejected by management as too expensive, resource intensive, and risky. And of course, qualifying two suppliers means double the development cost and reduced scale for volume pricing in production.

Given the difficulty in qualifying two suppliers and in switching suppliers at any point during the process, it is critical to choose strategic supply partners at the concept phase based on the following criteria:

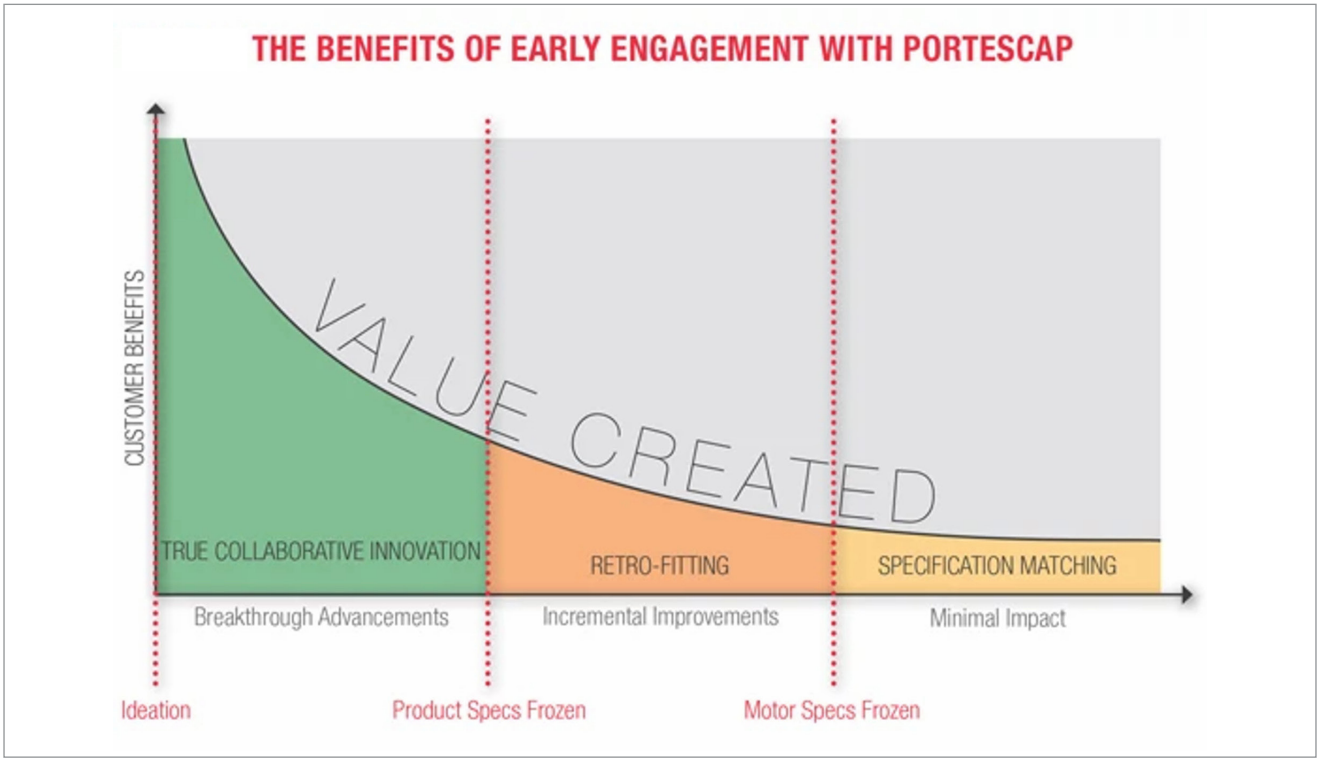
- Standard products available for shipment within a matter of days that are carefully selected and optimized for the POC build
- Industry experience to anticipate and resolve common traps and contribute design suggestions for improvement
- Design and manufacturing engineers readily available for customer collaboration at all stages
- Prototype and new product development capabilities structured to support the unique requirements of medical device development
- Facilities with robust validation and change control processes that regularly pass leading medical device company quality audits
- A clear plan to achieve the target production price
- A wide array of technology options that do not restrict the product design

To take full advantage of such a supplier's capabilities, the relationship must begin to be built at the concept or even ideation stage. The right supply partner will be able to provide valuable insight to choose the best path

from the outset. Just a few hours spent up-front with the supplier's experts can reduce future design hours many-fold, cut overall development time by months, and ultimately deliver a more optimized and valuable product to the market.

To illustrate the benefits of concept phase collaboration with a strategic supply partner, consider the following example of a device engineer selecting the supply partner for the motor in a medical product. He or she needs to build a POC in 3 weeks, complete testing for regulatory submission in 6 months and begin building high volumes for production in 2 years. The deadline for the POC clearly dictates an off-the-shelf motor, but the designer chooses a concept stage supplier it knows can also deliver the necessary custom version and meet the right price and quality level for production.

Within days or even hours of initial contact, the motor supplier's design engineers support a conference call to discuss the long-term goals of the design. They recommend a standard motor that can be delivered within a week but also is already tailored to the application requirements based on industry experience.



Incorporating common customization requests into application specific products results in a POC build that is closer to the final design criteria. This can avoid an extra iteration before design freeze, potentially saving many weeks or months, unnecessary engineering effort and thousands of dollars. Any remaining customizations needed (output shaft configurations, dialed in windings and gear ratios, feedback systems, etc.) are planned during this initial discussion so the Device Engineer can account for the differences during POC testing.

Once the POC testing is complete, a strategic motor supplier can then provide custom prototypes in as little as 4 weeks when there is a cohesive development strategy that allows design work and long lead time component or tooling to be preemptively initiated. This leaves the device designer with ample time to complete product design work, iterate on the motor design or resolve other issues before the 6-month regulatory filing deadline. After testing is completed on each iteration of prototypes, the motor supplier sends its engineers to the customer's site for detailed design reviews of the motor and system.

When it comes time to move to production, it is assured that the motor supplier can execute the design. If the design engineer needed to switch suppliers at this time, it is unlikely that a new supplier would be able to meet the unique requirements of the application without a design change that would derail the regulatory approval. In the end the successful incorporation of a custom motor maximizes power and efficiency while eliminating extra components and therefore reducing cost, size and complexity. The total development time is also shortened thanks to the seamless transition between motor iterations and the elimination of surprises that could have rippled through the device design.

Portescap produces precision motors, gearheads, encoders and assemblies for medical applications such as surgical power tools, infusion pumps and ventilators. Its products and services are carefully developed to provide the advantages to its customers described in this document. **P**

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