

# On the FOREFRONT

A Quarterly Compilation of Outsourcing Best Practices and Case Studies

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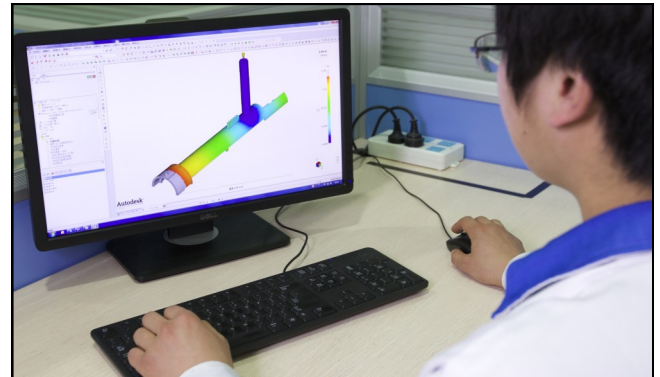
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## Mitigating Current Manufacturing Challenges

The imbalance between supply and demand continues to challenge medical device manufacturers. Rising costs, materials constraints and logistics delays have become “givens” in today’s manufacturing environment. In the outsourcing realm, contract manufacturers are being tested as never before. However, there is one major difference. Most OEMs’ business models revolve around product innovation and an ability to dominate their market niches. Conversely, the con-

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*Forefront’s design team focuses on manufacturability during design or redesign. 3D modeling tools ensure that tooling assumptions can be tested prior to fabrication.*

## Are You Asking Enough Questions About Tooling?

Tooling for molded parts is an area that many medical device manufacturing sourcing teams see simply as a line item in non-recurring engineering costs. However, anticipated project volumes, complexity of tool, tooling vendor selection and tool maintenance strategy are all issues that can impact product quality, tooling cost and overall project cost. Forefront Medical Technology believes that educating its clients in tooling basics is fundamental to achieving lowest total cost of ownership in contract manufacturing. This article looks at the cost elements of key decision points in tooling strategy development.

### Anticipated Project Volumes

Tooling metal composition or “hardness” is determined by the projected product volumes desired tool life. Questions to ask in determining the best strategy include:

- How firm is the projected volume forecast?
- How mature is the product design?
- Are there constraints on upfront project costs?

Hard tools are generally more expensive than soft tools. Forefront’s hard tools are made from Stavax steel and are guaranteed for a mini-

mum of one million shots. In some cases, a lower cost “soft” tool may be utilized for market evaluation parts because the design is expected to be modified. However, the tradeoff to be considered with a soft tool is that it will show wear in its cavities faster than a hard tool. When there is wear in a tool, the parts that tool molds are often not as precise in tolerance.

### Complexity of Tool

Product design choices, product cost targets and quality considerations drive tooling options.

Often there are multiple choices to be considered. For example, a complex mold can eliminate secondary production operations and the higher production costs that can come with those operations. Eliminating secondary operations also improves quality by eliminating the variation associated with manual processing. However, complex molds are higher cost and often have higher maintenance costs over time.

Questions to ask in determining the best strategy include:

- Do the projected project volumes generate enough savings to justify a tool that

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## Mitigating Challenges

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tract manufacturing business model revolves around manufacturing expertise and the ability to rapidly transform customer orders to delivered products. As a result, there is greater incentive in the contract manufacturing model to find ways to mitigate current challenges.

Forefront Medical Technology feels there are four areas where a contract manufacturer's capabilities may be able to improve outcomes in the current market:

- Product launch
- Vertical integration
- Continuous improvement
- Logistics management.

### Product Launch

In an era of material and logistics challenges, having a disciplined process for product launch is critical. Both Forefront's product development and product launch processes are designed to fulfill this need.

Forefront's team works with customers who have new products in development or mature products requiring a shift to a lower cost labor market. When either product design assistance or redesign for cost reduction is involved, Forefront's design engineering group works under a Design Development Plan (DDP) process designed to assess customer requirements and define a detailed product specification.

Once the customer specification is approved, 3D CAD models are developed and analyzed to test assumptions related to the design and manufacturing process. Tooling performance and throughput assumptions are tested via software modeling. Design reviews which include functional analysis and risk evaluation are completed. After the customer's team approves the design, prototyping and



**Forefront Medical's level of vertical integration provides scalable options. In some cases, projects move from non-tooled options to tooling options as volumes grow.**

verification begin. This phased process enables an evolutionary path to be taken should analysis or a review step indicate a change in approach would be beneficial. Use of rapid prototyping technologies ensures that the customer team is able to see and handle a prototype as an additional check and balance in the process.

Forefront's Safe Launch™ process helps ensure a robust production validation process, verifying product and process stability in an organized manner through audits during the validation process. The output of this audit process is a gap analysis on commercial run readiness which leads to development of an action plan. Data collection is used to determine if critical defects are detected. Once all the gaps are closed and pre-defined critical customer and product requirements are met, the team exits Safe Launch™ and begins normal production.

In developing each Safe Launch™ Plan, Forefront's team and the customer's team collaborate to assess potential defect opportunities and define a list of requirements that help prevent defects from occurring. Fore-

front's team then develops a control plan with checks and balances to prevent defects from occurring where possible, plus inspects CTQ elements to ensure only defect-free product leaves the factory.

This highly disciplined process helps eliminate the learning curve issues and miscommunication that can otherwise slow down the product launch process. The focus on quality assurance helps ensure production yield goals are achieved. It also makes it easier to discuss alternative options should current market constraints create unforeseen issues.

### Vertical Integration

Vertical integration streamlines lines of communication and priorities. Even in a normal market, a group of suppliers often has varying priorities, capacity constraints and different recommendations on design modifications. All of these issues can impact the targeted

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## Mitigating Challenges

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timeline for product development or start of production. Conversely, a vertically integrated contract manufacturer has one set of priorities and a multi-disciplinary team. If demand needs to increase rapidly, a vertically-integrated contract manufacturer can re-prioritize internal resources more rapidly than a company dependent on multiple suppliers for the same processes. Finally, a contract manufacturer with a broad range of capabilities is more able to suggest manufacturing solutions that are ideal for the project, rather than limiting options to a single internal production technology.

Forefront Medical's capabilities include Selective Laser Sintering (SLS) and Multi-Jet Modeling (MJM) systems, injection and blow molding, extrusion, metal fabrication, electromechanical assembly, and clean room assembly capabilities.

This range of capabilities opens the door to use of processes requiring minimal tooling when a fast start-up is needed with a conversion to lower cost, tooled options as volumes increase.

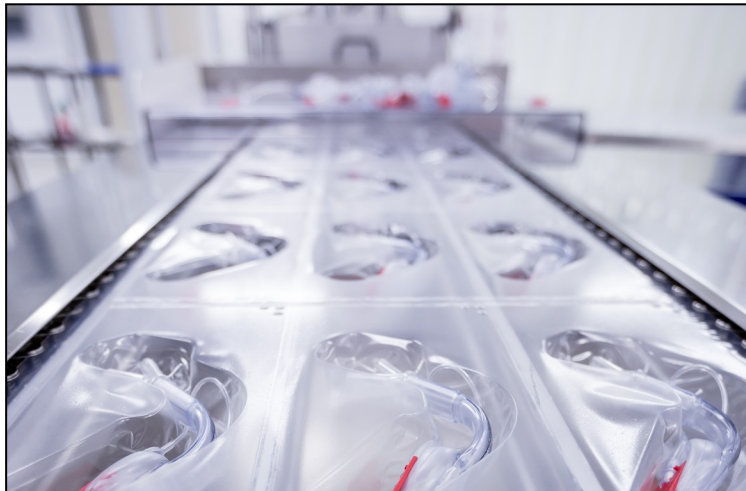
### Continuous Improvement

While no contract manufacturer can completely eliminate the issues caused by supply/demand imbalance in global markets, it is possible to mitigate that impact by improving internal efficiencies in the manufacturing process.

Six Sigma Green Belt training is in place in all Forefront facilities, creating teams with enhanced problem solving skills to lead a continuous improvement focus in each facility.

The teams start by developing a project charter which defines the problem statement, clear business objectives and ben-

efits drivers. A Gemba workshop is then conducted with participation from various functions to identify potential areas of improvement, together with a time study to pinpoint bottlenecks. In Lean philosophy, Gemba means the place where value is created, and the technique is derived from the Toyota Production System. A more commonly recognized corollary in the management world would be Tom Peters' concept of "management by walking around." The Green Belt teams learn from observing the process and talking with production operators about their perspectives. Following Gemba, a focused DMAIC (Define, Measure, Analyze, Improve, Control) methodology is used to initiate the improvement process.



**Forefront Medical's team is expert in optimizing automation strategy, plus utilize Lean Six Sigma core tools to assess options for improvement as project variables change.**

A DMAIC spreadsheet is used to capture information in a concise form. The benefit of this approach is that each identified improvement opportunity is thoroughly analyzed and tested to ensure root causes are correctly identified and the magnitude of the improvement benefit of implementing the corrective action is thoroughly understood.

Lean Six Sigma provides well-trained teams with a focused process and core tools for evaluating and prioritizing improvement opportunities. Even the best planned projects can have room for improvement when production

requirements increase significantly. In the current environment of increasing cost and imbalance between supply and demand, Lean Six Sigma provides Forefront Medical's team with the resources to help mitigate increasing costs while increasing throughput and process yield.

### Logistics Expertise

Logistics management expertise has never been more critical. A contract manufacturer's expertise in regional supply chain identification plus an ability to determine the best shipment strategy for support of the end market can provide substantial savings.

Forefront Medical's team has significant experience in supply chain realignment to reduce logistics costs. Its facility locations have been selected for their proximity to major shipping hubs and support infrastructure such as contract sterilizers. This increases the options it can consider when logistics constraints are impacting delivery times.

One of the advantages of outsourcing is that most contract manufacturers are developing different types of solutions to fit a variety of customer requirements. The skillset needed to do this well drives a combination of staff

expertise and creative thinking that works well in addressing challenges within the current environment. When OEMs partner with their contract manufacturers to identify potential solutions to developing challenges, improved outcomes are possible. Forefront Medical's combination of disciplined processes, experienced team, breadth of manufacturing technologies and supply chain relationships help ensure flexibility in addressing current market challenges.



# On the FOREFRONT

## A Quarterly Compilation of Outsourcing Best Practices and Case Studies

Forefront Medical Technology focuses exclusively on the medical device industry and thoroughly understands the needs of this market. As a specialty contract manufacturer with a focus in disposable diagnostic, drug infusion and medical device systems, Forefront Medical has extensive expertise with injection molding, extrusion, assembly and packaging of specialty medical disposable devices. In addition, Forefront Medical Technology's technical expertise extends into collaborative product design and development, rapid SLS prototyping, in-house tool making and isolated clean rooms for manufacturing, assembly and packaging. Capabilities also include sterilization and global logistics to provide one integrated source for the total supply chain. This world class supplier has the expertise to custom design a new product... or redesign the current one...from a conceptual drawing into a completely manufactured, packaged and sterilized product, ready for global shipment.

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## Tooling Questions

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eliminates secondary processes?

- What impact will required tool size have on machine choices?
- Are there quality considerations that drive the need for eliminating manual processes?
- Will the tooling budget support the cost of a complex tool?

When tooling design and fabrication are integrated into the product development process, tooling options, costs and constraints can be evaluated concurrently with product design decisions.

### Tooling Vendor Selection

Tooling fabrication can be simple or complex. Tooling metal specifications, operations performed inside the tool or budget considerations may make the choice of a specific tooling manufacturer or region attractive. Questions to ask include:

- Do tooling material composition requirements make a specific re-

gion more attractive?

- Which vendors have the most expertise in desired tool internal operations?
- Are there cost constraints on the tooling budget?

Forefront has internal tool fabrication capability, but also works with outside vendors. The team's manufacturing expertise ensures that tooling vendor selection is driven by analysis of the right mix of variables. The team's expertise as a tooling fabricator ensures that when outside vendors are selected, the tooling fabrication process is carefully managed to required specifications.

### Tooling Maintenance Strategy

Tooling maintenance strategy should also be considered in tool design. The more complex the tool, the more preventive maintenance the tool is likely to need. Questions to consider include:

- Does the contract manufacturer have an in-house tool room or will the mold need to be sent out for preventive maintenance?

- How much downtime will offsite maintenance typically require?
- Will that impact production capacity to the point where an additional tool is needed?

Complex tools may have more frequent maintenance and repair requirements than less complex tools, but any tool that doesn't have routine preventive maintenance will wear inappropriately and develop quality issues over time.

Forefront Medical operates a full scale commercial tool room. This provides the resources necessary to maintain tooling on-site. A robust preventive maintenance program that extends the life of each tool, helps minimize unscheduled downtime and contributes to high product quality.

Tooling cost can often be a large investment. Working with a vertically integrated contract manufacturer with tooling design and fabrication capability helps ensure the right questions get asked to provide the best value for project requirements.