On the FOREFRONT

A Quarterly Compilation of Outsourcing Best Practices and Case Studies

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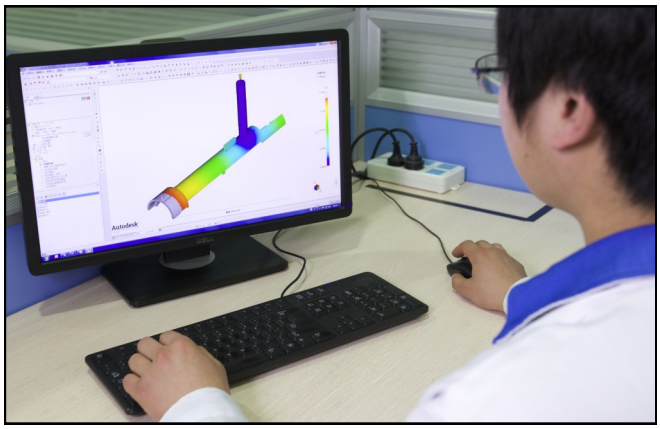
The Value Equation: Benefits Beyond Manufacturing

Outsourcing manufacturing is a good way to reduce production costs by accessing shared manufacturing resources. That said, when the benefits a contract manufacturer can bring to the product commercialization process are fully analyzed, there is often significant value beyond access to shared manufacturing resources. This value equation can also include:

- Reduction in product development cycle time
- Improved design for manufacturability
- A continuous improvement focus over the life of the product
- Supply chain and logistics expertise.



Software simulations help optimize product and tooling design in Forefront's product development process.

The combination of these elements can help improve competitive advantage, control costs and ensure that quality goals are consistently achieved. Supplier selection should evaluate not only assembly capability, but also the ability of each contract manufacturer to provide a solution that encompasses these additional points of value.

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The Importance of Process Repeatability

Product Launch or new product introduction (NPI) is the point where manufacturing assumptions are validated through pre-production and/or qualification runs. It is also a point where manufacturing learning curve issues become evident. This phase can represent a hidden cost in the outsourcing process if resolving learning curve issues requires significant OEM team presence and interaction, particularly if the OEM team and contract manufacturer are in different parts of the world.

Forefront's SafeLaunch™ process helps ensure a robust production validation process, verifying product and process stability in an organized manner through audits during the validation process.

Areas audited include:

- Material receiving and incoming inspection
- Material storage conditions and security
- Work order issuing
- Material issuing and accountability
- Set-up, line clearance and first article inspection
- Production record of good vs. scrap
- Production run with 100% inspection on critical points
- Work order closure to determine if actual quantity aligns with system quantity.

The output of this audit process is a gap analysis on commercial run readiness which leads to development of an action plan. Data collec-

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The Value Equation

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Reduction in Product Development Cycle Time

For contract manufacturers with internal product development engineering capability, product development is a disciplined and repeatable process. The benefit of collaborating with this type of team can be elimination of many of the learning curve issues that can slow the commercialization process.

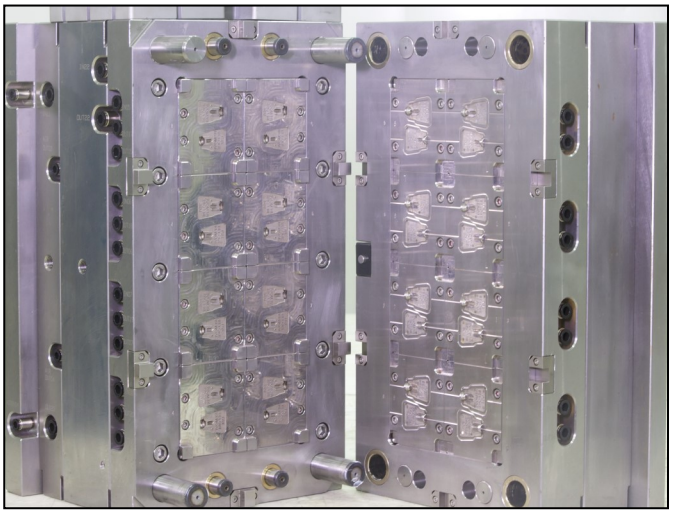
Forefront's process helps reduce cycle time in several ways:

- Use of its standardized Design Development Plan (DDP) to gather all critical information needed for the project
- A design team capable of addressing all design needs
- CAD modeling and simulation software to optimize tooling and test design assumptions
- Internal database of materials that have previously been tested and approved within the regulatory environments associated with the product
- A U.S. Technical Center to facilitate project communication
- A focused NPI effort that considers risk mitigation and all necessary validation steps.

Improved Design for Manufacturability

One of the benefits of team collaboration during the product development phase is the ability to optimize the design to improve efficiency in the manufacturing process.

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. Communication is streamlined, which minimizes time and cost. Forefront Medical enhances this by having standardized software tools in its US Technical Center, Singapore Design Center and China full-scale commercial tool room. During product development, design for manufacturability (DFM) recommendations are made to ensure minimal secondary processing. Tooling and assembly lines are optimized for efficiency.



Mold design considers volumes, product cost targets and elimination of unnecessary manual labor.

A Continuous Improvement Focus Over the Life of the Project

It is common for OEMs with electronic products to change contract manufacturers multiple times over the life of a product because assembly line equipment is interchangeable. Conversely, products with customized tooling and assembly/packaging automation often stay with a single contract manufacturer. That said, changes in demand, market advantage or external costs often drive a need for improvement in the cost equation to balance the cost impact these variations drive. Selecting a contract manufacturer with a disciplined approach to improving production efficiency can help in that effort.

Six Sigma Green Belt training is in place in all Forefront facilities, creating teams with enhanced problem solving skills to lead continuous improvement focus in each facility. The core tools used to drive this process include:

- 7S workplace organization
- Poka Yoke mistake proofing technique
- 8D systematic approach problem solving methodology
- Risk management & Process Failure Modes and Effects Analysis (PFMEA)
- Statistical process control.

Supply Chain and 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.

Partnering with a contract manufacturer to optimize the product commercialization process ensures that inefficiency and non value-added costs are eliminated. Decisions made in the product development phase are particularly beneficial in this regard. Working with a contract manufacturer's team to continue this focus on eliminating unnecessary cost in production and logistics further improves competitive advantage.

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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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Repeatability

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tion 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 SafeLaunch™ and begins normal production.

In developing each SafeLaunch™ 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. Forefront's team then develops a control plan with checks and balances to prevent defects from occurring where possible, plus inspects critical to quality (CTQ) elements to ensure only defect-free product leaves the factory.

Visual inspection of incoming material helps ensure material conformance. Environmental issues that could impact product quality such as storage temperature and relative humidity are also monitored. Products are visually inspected to ensure conformance to product specification following assembly and that required finished goods packed quantities meet customer requirements. When indicated in the control plan, samples are pulled from each production lot for packaging and sealing strength tests. Potential sources of contamination are identified, and measures are taken to ensure that work-in-process (WIP) and finished product will be handled, packed and stored in ways that prevent this contamination issue from occurring.

Forefront's SafeLaunch™ process helps ensure a robust production validation process, verifying product and process stability in an organized manner through audits during the validation process.

The SafeLaunch™ process also considers Device History Recordkeeping requirements and ensures that required inventory inspection and control, production process tracking, and quality data is recorded and stored per customer and appropriate regulatory requirements.

A focus on process repeatability eliminates unnecessary cost and improves quality.