On the FOREFRONT

A Quarterly Compilation of Outsourcing Best Practices and Case Studies

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Hayman Joins Arrow Medical as Managing Director

Rick Hayman

Rick Hayman joined Arrow Medical as Managing Director in June. He will also handle business development within the UK and EU.

"We are delighted to have Rick on board. He brings a wealth of experience from working within international sales, marketing, manufacturing, regulatory compliance, R&D, quality assurance, supply chain and commercial partner development with major medical supply companies," said Walter Tarca, Forefront Medical Technology's President.

Previously, Rick was Head of the Professional Division at Byotrol PLC and Managing Director of Medimark Scientific. He was previously Managing Director for Medichem International Limited and has a background in sales and marketing. In his spare time he serves as Acting Chair of the Board of Trustees for Dogstar Foundation, a non-profit focused on improving animal welfare in Sri Lanka.

Founded in 1989 and headquartered in Kington, Herefordshire, UK, Arrow Medical (www.arrowmedical.co.uk) provides contract manufacturing services for a variety of medical and mission critical customers. Arrow Medical maintains three ISO Class 7 (US Fed Std 10,000) clean room assembly facilities for the assembly of single use devices and other Class 2 and Class 3 products for use in anaesthesia, emergency and cardiac treatments. Two additional clean room facilities are dedicated to High Consistency Rubber (HCR) and liquid silicone rubber (LSR) moulding and RF welding, respectively. Arrow Medical is FDA registered and certified to ISO 13485:2016.

Understanding Contract Manufacturing Business Models

Contract manufacturing can deliver significant benefits to a medical product commercialization strategy. However, there are variations in contract manufacturing business models and that can impact the value a contract manufacturer is able to provide.

In medical contract manufacturing, the three most popular business models are:

- Manufacturer of engineered components who does larger scale projects through subcontract relationships
- Electronics contract manufacturer who subcontracts production requirements not within their capabilities
- Vertically-integrated, specialty contract manufacturer specializing in design through commercialization solutions

Each of these types of business models can have advantages depending on project requirements.

In the engineered components model, the suppliers may have dominance in specific manufacturing technology such as molding or extrusion. For products that require that technology for the bulk of the product, there may be savings in tooling or design costs. The downside is that design recommendations will center on that supplier's core manufacturing technology

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Mitigating Challenges

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and may not include optimization suggestions that involve subcontracted capabilities. Additionally, if the supplier manufactures its own proprietary line of products, those products may have priority for internal manufacturing capacity.

When the product is predominantly electronic, an electronics contract manufacturer may represent the best choice for the project. However, there may be less feedback on optimization choices involving engineered components or only a focus on engineered manufacturing capabilities that the contract manufacturer has in house. Additionally, given the limited redesign capabilities associated with medical products, the options for reducing cost within printed circuit board assembly (PCBA) or the processes associated with the PCBA may be limited.

The vertically-integrated, specialty contract manufacturer typically represents the best option for non-electronic products or electronic products with a significant percentage of engineered components. This is because much of the cost savings in engineered components comes in material and manufacturing technology selection, plus tooling design. A vertically-integrated contract manufacturer, such as Forefront Medical Technology, can recommend the best manufacturing technology for the product requirements rather than focus on a single core manufacturing capability. Additionally, because tooling complexity/efficiency and unit cost are related, having the supplier providing those services managing the program ensures that cost reduction focus will be applied in the areas likely to generate the largest savings.

In outsourcing, there is no one perfect solution. The best outsourcing processes align customer requirements with partner capabilities. In auditing potential contract manufacturers, questions to ask include:

Forefront Medical's vertically integrated, specialty contract manufacturing business model selects the best manufacturing process for the product's requirements.

- How closely do the contract manufacturer's core manufacturing capabilities align with my project?
- How important is product development engineering support to this program?
- Does the contract manufacturer have unique engineering or manufacturing capabilities that are relevant to my project?
- Are there projects of similar type and scope being built by this contract manufacturer?
- Do the contract manufacturer's quality systems and experience with regulatory agencies align with my product's requirements and end markets?
- Has the contract manufacturer solved challenges similar to those likely to happen within my program?
- Does the contract manufacturer's team interact well with my team?
- How does the contract manufacturer identify cost reduction opportunities?
- Do the contract manufacturer's facility locations align with my preferences?
- Does the contract manufacturer have well-defined processes?
- How will my program be managed?
- Does the contract manufacturer offer a similar time zone support option?

Asking questions about the way a contract manufacturer interacts with customer teams, ensures process repeatability, and achieves cost reductions over time ensures unique project challenges are addressed. It also helps better analyze that contract manufacturer's ability to support project requirements. While a quote response provides a comparative datapoint on initial pricing, the deeper exploration of the way each contract manufacturer does business may be more indicative of which one represents the best choice.

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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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Forefront Medical's Singapore Facility Expands ISO Certifications

In addition to ISO 13485:2016, Forefront Medical's Singapore facility is now certified to the following additional ISO standards:

- ISO 14001:2015 Environmental Management System
- ISO 45001:2018 Occupational Health & Safety Management System
- ISO 50001:2018 Energy Management System

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