

On the FOREFRONT

A Quarterly Compilation of Outsourcing Best Practices and Case Studies

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Are You Asking the Right Supplier Audit Questions?

Achieving total lowest cost in outsourcing is rarely accomplished by selecting the contract manufacturer with the lowest unit price. Instead, it often is the result of selecting the contract manufacturer with the best focus on eliminating non value-added cost through well-defined processes and efficient commercialization strategies. This latter type of contract manufacturer is often identified during the plant tour phase where audit teams can see how the contract manufacturer has managed programs of similar manufacturing technology, size and scope.



Supplier audits that discuss how programs of similar size and scope are managed provide a better understanding of a contract manufacturer's ability to deliver best value.

Areas where contract manufacturer efficiency or expertise improves outcomes include:

- Product development
- Product launch
- Manufacturing capabilities
- Logistics support
- Continuous improvement

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Utilizing ISO Standards to Create the Framework for a Sustainable Organization

Much of the focus on outsourcing is on contract manufacturer capabilities, on-time delivery track record and ability to provide a competitive, superior quality solution over the life of the project. As outsourcing has grown as a mainstream supply chain solution, the role the contract manufacturer plays its customers' reputations has also drawn more scrutiny. Supplier selection and monitoring audits look not only at processes, but also workplace safety, environmental stewardship and elements of operational efficiency. Just as pre-ISO 9001 and ISO 13485, every customer developed their own quality management system (QMS) audit checklist, much of the focus on audits beyond QMS have been unique to the auditing sourcing team or simply relied on the statement that opera-

tions were in compliance with local regulations. While this type of audit helps reassure the auditing entity that the potential supplier meets minimum standards, it doesn't necessarily ensure that the contract manufacturer has put all the needed building blocks in place to create a resilient organization.

ISO 14001 - Environmental Management System has been gaining in popularity as a roadmap for developing sustainable, environmentally friendly practices. ISO 45001 - Occupational Health & Safety Management System and ISO 50001 - Energy Management System are two additional standards designed to help companies establish compre-

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ISO Framework

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hensive compliance programs in these areas.

Forefront Medical Technology's Singapore facility was recently certified to ISO 14001:2015, ISO 45001:2018 and ISO 50001:2018. This article looks at the benefits of these standards in greater detail.

ISO 14001:2015 is the international standard that specifies requirements for an effective environmental management system, providing a framework that an organization can follow. It is part of the ISO 14000 family of standards, and one of the most widely used. The framework in the ISO 14001 standard can be used within a plan-do-check-act (PDCA) approach to continuous improvement, which aligns well with Forefront's internal approach to continuous improvement.

Originally associated with W. Edwards Deming, as part of the Deming cycle for continuous improvement, the PDCA methodology provides an easy-to-understand approach. Within the standard, the Plan phase focuses on determining and assessing risks and opportunities and establishing the objectives and processes necessary to deliver results in accordance with the policy. The Do phase focuses on process implementation. The Check phase monitors and measures and the activities and processes with regard to the policy and objective. The Act phase drives actions focused on improving measured performance to achieve intended outcomes.

The overall benefit of the framework is its ability to create an organizational vision for a comprehensive environmental management system with a standardized approach to assessing environmental impact, driving continuous improvement, ensuring compliance with legal requirements, and increasing stakeholder and customer trust. It also makes it easier to



ISO 45001: 2018 provides a framework for occupational health & safety, enabling organizations to build a model for a safe and healthy workplace that can be deployed worldwide.

replicate a consistent system among multiple facilities over time. From a customer perspective, having a third-party audited, well-documented environmental management system in place at suppliers typically reduces overall audit time by providing a standardized approach to assessing supplier competency in this area.

ISO 45001:2018 specifies requirements for an occupational health and safety (OH&S) management system, and gives guidance for its use, to enable organizations to provide safe and healthy workplaces. A key point is that it is the first international standard on OH&S management and incorporates best practices from around the world. Forefront Medical previously addressed OH&S under its 7S program which simplified the transition to ISO 45001:2018.

ISO 45001 drives not only a leadership/management responsibility, but also communication and employee participation components. Ultimately, workplace safety requires commitment from everyone in the organization to adhere to internal policies and report and/or correct unsafe behav-

ior/conditions should they arise. As with the other standards discussed here, development of an ISO 45001 OH&S management framework facilitates a comprehensive, standardized approach to occupational health & safety across facilities and simplifies customer audits. The standard also incorporates a PDCA cycle of improvement and has been structured to integrate with other standards such as ISO 13485.

ISO 50001:2018 provides the framework for establishing, implementing, maintaining and improving an energy management system (EnMS). The intended outcome is to enable an organization to follow a systematic approach in achieving continual improvement of energy performance and the EnMS.

The primary benefit of adoption of ISO 50001:2018 is its focus on establishing the systems and processes necessary to continually improve energy performance, including energy efficiency, energy use and energy consumption.

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Audit Questions

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- IP protection.

Here are questions to ask in each area of the audit process.

Product Development

- What does the product development process entail?
- What type of interaction occurs among product development engineers and manufacturing engineers?
- How is manufacturability ensured?
- How are customer requirements documented?
- Are cost improvement suggestions made or do designs simply follow a purely customer-defined scope of work?
- How is tooling efficiency ensured?
- Who owns the design?

Product Launch

- What does the product launch/NPI process entail?
- How are potential issues documented and communicated to ensure they are corrected rapidly?

Manufacturing Capabilities

- How closely do the contract manufacturer's core manufacturing capabilities align with my project?
- Does the contract manufacturer have unique engineering or manufacturing capabilities that are relevant to my project?
- Have there been any recent supply chain disruptions with suppliers fabricating parts that are outside internal competencies?
- How rapidly can unplanned demand increases be supported?

Logistics Support

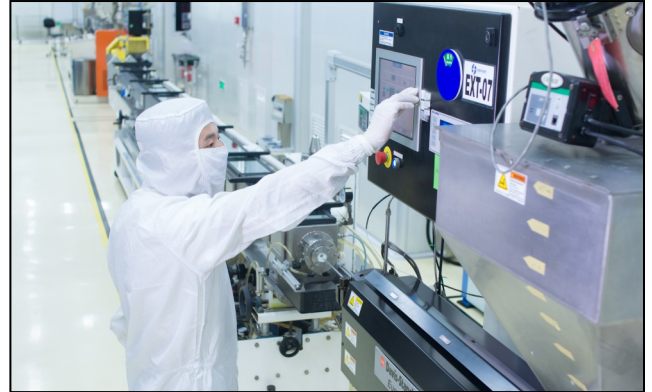
- Does your team have a process for evaluating optimum logistics strategy?
- What examples can you give of situations where logistics costs were reduced or at least kept at parity through a logistics strategy you've developed?

Continuous Improvement

- What processes are in place to drive continuous improvement activities?
- How are personnel trained in issue identification and problem solving techniques?
- What examples can you provide of situations where continuous improvement activities improved quality or reduced cost?

IP Protection

- What criteria are used in identifying and selecting key suppliers?
- Are suppliers audited for IP protection processes and contractually required to protect sensitive information?
- What processes are in place to limit the proprietary design information shared with any one supplier?
- Does the contract manufacturer's headquarters country have strong penalties related to IP theft?
- How does the contract manufacturer's headquarters country score in global reports focused on IP protection?
- Will your current legal team be able to adequately evaluate the contract or will you need to retain a firm doing business in that country?



Different contract manufacturers have different capabilities. The ability to consider multiple production process options helps identify lowest total cost of ownership.

- What language must contracts be written in to be enforceable in the contract manufacturer's headquarters country and what checks and balances are in place to ensure the translation adequately reflects agreed upon terms?
- What is the typical timeframe for resolving contractual disputes in the contract manufacturer's headquarters country?
- Is there any evidence of bias against foreign companies in legal decisions?

Taking the time to evaluate the way a contract manufacturer interacts with customer teams, ensures process repeatability, achieves cost reductions over time and assures 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, a more thorough exploration of the way each contract manufacturer does business can be a better gauge of which supplier represents the best choice.



On the FOREFRONT

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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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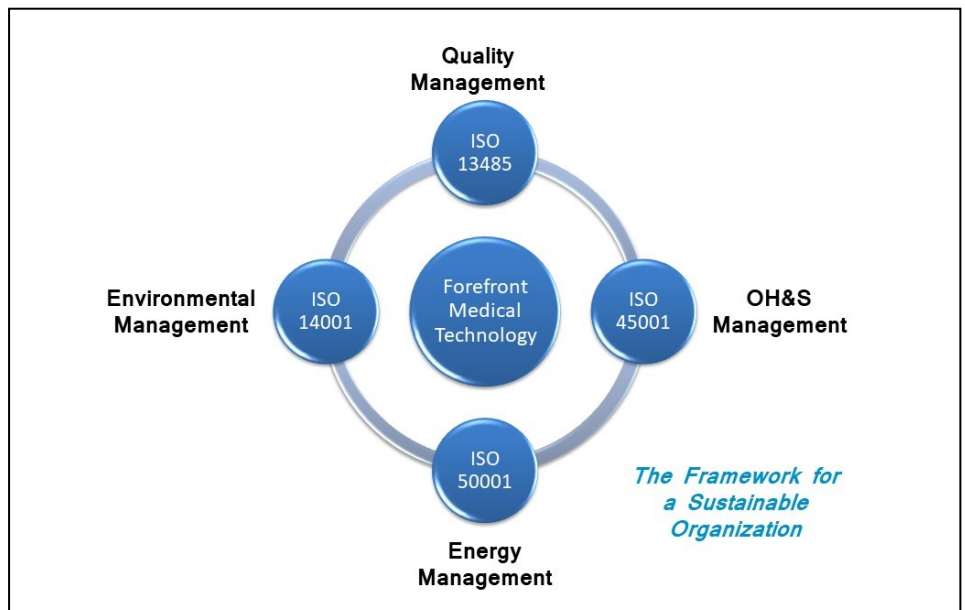
ISO Framework

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Successful implementation of an energy management system (EnMS) helps create a culture of energy performance improvement throughout an organization. Like OH&S management, creating an ideal environment requires participation throughout the organization and this standard helps provide the foundation for the procedural and educational efforts necessary to achieve that goal.

From a customer benefit perspective, suppliers with well-defined energy policies and energy performance strategies have more efficient and sustainable business models.

While quality management standards such as these provide a comprehensive framework for creating a relevant management system and a third-party auditing process that assesses whether an appropriate system has been put in place, organizations adopting these standards ultimately create the system through development of policies and procedures. Forefront Medical has



long had internal initiatives related to environmental stewardship, OH&S and EnMS throughout its organization. Adoption of these standards at its Singapore headquarters has enhanced existing management systems and ensured their alignment with international best prac-

tices. Most importantly, placing strategic management focus on these areas is helping to ensure a resilient organization compliant with the legal requirements associated with its facilities, that also embraces best practices in corporate social responsibility.