



Is Your Contract Manufacturer Building a Resilient Organization?

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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 of the contract manufacturer in 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 operations 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 comprehensive compliance programs in these areas.

Forefront Medical Technology, a vertically-integrated specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, has been certified to ISO 13485 in all facilities for many years. Its Singapore facility was recently certified to:

- ISO 14001:2015
- ISO 45001:2018
- ISO 50001:2018.

This whitepaper looks at the benefits associated with each of these standards.

ISO 14001:2015

ISO 14001 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.

First released in 2004, the 2015 revision of the ISO 14001 standard expands environmental management system coverage and scope, lists required interactions with external parties, increases leadership engagement, expands legal compliance requirements, adds a risk-based planning and control element, revises documentation requirements, expands operational control requirements, changes internal audit requirements and is more closely aligned with ISO 9001 to facilitate integration of the two standards. It also integrates ISO 13485.

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 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

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.

A strong OH&S management system is critical to any manufacturing organization. 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 behavior/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

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 2018 revision improves compatibility with other ISO management system standards. There are also technical revisions to improve integration with strategic management processes, increase emphasis on the role of top management and provide greater detail on energy performance measurement and improvement.

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. 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.

Development and implementation of an EnMS under the standard, includes an energy policy, objectives, energy targets and action plans related to energy efficiency, energy use, and energy consumption while meeting applicable legal requirements and other requirements. The standard defines energy performance as a concept which is related to energy efficiency, energy use and energy consumption. Energy performance indicators (EnPIs) and energy baselines (EnBs) are two interrelated elements addressed within this framework to enable organizations to demonstrate energy performance improvement.

ISO 50001 also incorporates the same PDCA cycle previously outlined, making concepts easy to teach to employees already used to PDCA approaches in other management systems.

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 practices. 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.

About Forefront Medical Technology

Forefront Medical Technology is a global medical device contract manufacturer with five locations. Singapore is Forefront's headquarters, as well as home to our Design Engineering Center and specialty manufacturing. JiangSu and Xiamen, China, are additional manufacturing locations and are also China FDA Registered. Shanghai, China and Farmington, CT USA are regional Business Development offices which assure our technical sales teams are close to our customers for local, responsive assistance.

We have developed extensive capabilities with laryngeal mask airways, diagnostic devices, drug delivery systems, enteral feeding catheters, infusion sets, wire reinforced tubes, optically clear components, patient monitoring devices, electromechanical devices and other specialty products. Each of our locations has state of the art manufacturing capabilities that include class 100K clean rooms for extrusion and injection molding, complimented by class 10K clean rooms for assembly.

Forefront Medical's integrated technical approach provides customers the total manufacturing solution and global supply chain. Our facilities are TUV ISO 13485:2016 and FDA Registered. Forefront is a wholly owned subsidiary of VicPlas International Ltd, who is listed on the SGX Main Board, Singapore stock exchange.

Visit <http://forefrontmedical.com/> to learn more about our capabilities. For a confidential review of your project, please complete our enquiry form at: <http://forefrontmedical.com/contact-us/>, email us at: appl_dev@forefrontmedicaltechnology.com, or call +1 (860) 830-4637 (Europe and America's) / +86 21 6062 7177 (Asia).