Minimizing Medical Device Technology Drift via Strategic Outsourcing

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Why do medical device companies choose to pursue vertical integration? How does vertical integration cause technology drift over time? How can outsourcing be used strategically in key circumstances to gain valuable access to otherwise unavailable and diverse solutions from non-medical industries? This article addresses all of these questions for medical device manufacturers.

Medium to large medical device companies often strive to become vertically integrated: they might own their own silicon fab, design their own hardware, engineer proprietary protocols, build their own testing and deployment equipment from scratch, and design their own custom manufacturing processes. Although there are good reasons for companies in regulated markets to become more vertically integrated (control over diverse processes, control of quality, and control of the supply chain), it can often cause a technology drift effect over time between the company's core competencies and industry trends.

Vertical Integration

Vertical integration refers to an approach whereby a company tries to control its upstream suppliers, its downstream buyers, or both. By controlling upstream suppliers, a company can ensure that there will be adequate supply in the face of changing market demands. By controlling downstream buyers, competing suppliers can be strategically excluded, and in addition, greater access to information about the end customer can be obtained, tracked, and controlled. From a medical device company perspective, vertical integration offers a number of perceived benefits.

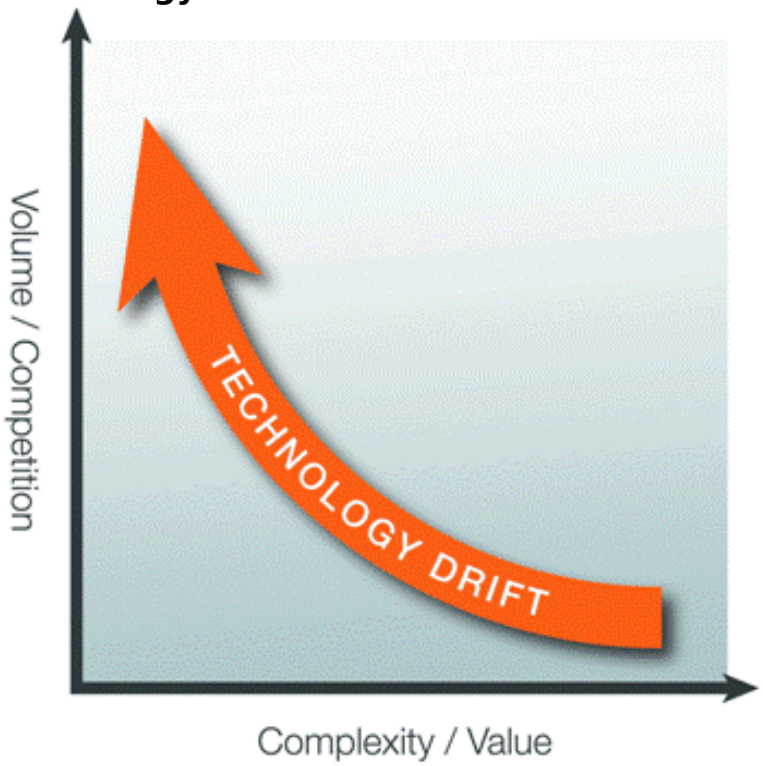
Control—One of the primary reasons medical device companies pursue vertical integration is to control the "system." Control in this case means many things: control of scarce resources, control of supply to reduce component costs and benefit from economies of scale, control of component quality, and control of the ability to react en mass to changing FDA regulations.

Quality—Another benefit of vertical integration is that it can allow complete control over the quality of the end product and the design, manufacturing, and deployment activities that contribute. In the medical device industry, the FDA exists to ensure that devices are safe and efficacious for consumers. The cost of getting through a PMA or a 510(k) is large, and the cost of making a safety mistake is massive. Although vertical integration does not often put medical device companies in a position to get through their PMA or 510(k) submittal process faster, it does give them a higher likelihood of producing a high-quality (safe + effective) product.

Efficiency—By controlling the supply chain, medical device companies can more easily control transportation and shipping costs by co-locating factories, design centers, and distribution warehouses. In addition, when regulations or markets change, the vertically integrated medical device company can make large scale changes that align the entire supply chain to a new regulation or strategy. Although higher organizational and management costs are incurred, vertical integration does increase transactional efficiency between in-house supply chain segments.

Immunity—If a medical device company has control over its supply chain and product quality, and has gained significant transactional efficiency through process and tool optimizations, the result is that it becomes reasonably immune to competitive threats. In other words, vertical integration can increase differentiation and, at the same time, increase the barrier to market entry for competitors. Warren Buffet says, “In business, I look for economic castles protected by unbreachable ‘moats.’” Vertical integration is one method a medical device company can employ that widens the moat.

Technology Drift



Technology Drift—Products that were once created as high value and high complexity invariably drift along the curve towards low value and low complexity. This technology drift effect enables new competition and implores companies to continuously increase value and competitive differentiation to remain relevant.

Vertical integration has many benefits, but there are also considerable drawbacks.

Higher organizational overhead costs—The larger and more diverse a company becomes, the higher the organizational overhead costs. Having a product design team requires a layer of management to oversee product development activities. If a medical device company decides to buy or build a silicon fab, they not only need to appoint personnel and a management team to run the silicon fab, but they need to ensure that there is a layer of management above the silicon fab and the product development organization that oversees it all. This, of course, is in addition to the increased cross-departmental communication costs, potentially fragmented employee culture, and a more complex enterprise IT infrastructure.

Potential for decreased flexibility due to previous investments in people, processes, product designs, or capital equipment—Once a company grows large and continues to grab and own more pieces of the supply chain, it garners momentum that is difficult to change. If a previous investment was made, for instance, in a formidable and highly-structured quality management system, if the market demands change too quickly, it may be quite difficult to re-arrange the design process to be more flexible, and may hinder the ability of the company to remain agile and relevant. For the purposes of this article, any discussion surrounding organizational overhead costs will be bypassed, and instead, the heart of the issue to be tackled will be addressed, which is why the pursuit of vertical integration for medical device companies can lead to a drift away from current technology trends.

Some medical device companies will design their own silicon, often purchasing some core intellectual property, and then wrapping additional silicon, memory, peripheral interfaces, and packaging around it. integrated circuits (ICs) that will sometimes fall into this category for medical device companies are application-specific integrated circuits, field-programmable gate arrays, microcontrollers, capacitors, accelerometers, magnetometers, and gyroscopes. The rationale for creating custom ICs are primarily to reduce cost for high volume use, have complete control over the IC’s quality and performance, and reduce unnecessary features to save power and space that would otherwise be found in commercial off-the-shelf parts.

The problem here is that when these custom ICs are initially created, there are very good market reasons to do so: the IC that a medical device company really needs does not exist, is too costly, consumes too much power, or does not meet required performance standards. Over time, as technology moves forward quickly, these ICs that were once considered high value, become commoditized, and subsequently, become low-value. This phenomenon, referred to as technology drift, affects all technology companies. However, in the unique case of medical device companies, the desire to become more vertically integrated accidentally causes a perverse incentive to increase stability, quality, reliability, and brand strength. These are all good things but happen to be counter to the type of agility that is necessary to stay current with rapidly changing technology trends, advances, and innovations.

Strategic Outsourcing

Strategic outsourcing can be used as a complementary technique to support organizational strategic planning and alignment activities where the organization

focuses on identifying and developing core competencies internally, and identifies and pursues outsourcing activities that are necessary for the operation of the business, but are not core competencies that drive the company's most important value propositions.

Another type of strategic outsourcing, which can significantly minimize susceptibility to technology drift for vertically integrated medical device companies, is to bring in a professional design service firm that has experience in multiple industries (medical and non-medical) to evaluate and be involved in new product designs, to bring a type of experience to the table that is informed about technology trends in diverse industries such as industrial, mil-aero, automotive, energy, or consumer, which would otherwise be unavailable.

Although one could argue that all outsourcing should be strategic, here are some examples when strategic outsourcing to professional design firms for the express purpose of augmenting and informing strategies surrounding the evolution of core competencies and minimizing technology drift should be considered.

- When internal skills or knowledge sets start drifting away from current technology trends
- When new platforms are being architected for long lifecycle use, and a key characteristic of the design is to be easily able to be adapted or evolved over time to increase features, increase performance, lower power consumption, and lower cost by leveraging new technology that is presently unclear
- When core competencies start to become commoditized and need to be re-invented, re-aligned, re-tooled, or rethought
- When old thinking and habits unnecessarily limit innovation, and a fresh look at a design, approach, or strategy would be beneficial by outside, independent, and trusted technology advisors who can act as unbiased reviewers

Conclusion

Within the context of vertical integration and strategic outsourcing, it's important to understand that there will always be a tension and a set of tradeoff decisions that must be made between flexibility and control. What might start as a desire to gain market share, reduce transactional costs, increase profit margins, and control quality and supply chain activities can become a serious threat if changes in technology, market, business, political, or user trends require a new degree of flexibility and agile adaptation that challenge conventional corporate wisdom that was conceived when the current generation of technology was not yet available.

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