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Beyond Trade-offs:

How Medical Device Manufacturers can Balance Innovation, Quality and Compliance While Improving Profit

Comprehensive Findings Report

Primary Research Conducted in Conjunction with

Date: July 2012

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Contents

Cambashi Report #J3089 *Beyond Trade-offs in Medical Device Manufacturing: Balancing Innovation, Quality and Compliance While Improving Profit.*

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Executive Summary

The medical device industry has always been dependent upon product innovation to drive growth. With today's aging global population and expectations for living to an older age, the medical device industry is poised for a sustained period of extreme growth fueled by a level of innovation that is scheduled to accelerate. Most companies are growing. Nearly all are innovating at an increasing pace. The common challenge is how medical device manufacturers and their suppliers can simultaneously improve their financial performance, product innovation and quality while growing at a significant speed.

Cambashi and its partners conducted a market study to address this challenge, with an objective to seek out what best practices could be followed to maximize the chance for success – improving profitability within an environment of accelerating new product introductions while maintaining high quality standards. Based on the survey results, only a quarter of the respondents are able to achieve this level of performance.

Most companies instead made trade-offs, focusing on improved margins or product innovation. The top four factors that companies expect will improve their success are product design, development and introduction; the next two factors relate to product quality. There is an apparent trade-off between innovation and quality: the top inhibitors to quality improvement are regulatory and product changes. Other trade-offs abound, such as those between quality and supply chain complexity, and quality and concern about staff skills.

This report is based on primary research conducted during the first half of 2012, with responses from medical device and life science manufacturers and their suppliers. It includes fresh data from a representative cross-section of this industry. Included are several sets of information designed to assist the industry in crafting strategies to not only grow, but to simultaneously increase business performance in areas such as costs, earnings, net operating profit, and return on assets.

1. **Profile of "Advancers"** This set of data highlights differences between the quarter of respondents who both grew and made major improvements in business performance and others. The short answer: they focus on what customers care about, they innovate aggressively, and they have improved at the operational level in manufacturing, planning and development. Perhaps above all, Advancers have implemented measurement, production, and management processes and a wide array of information systems.

2. **Strategies for Success** The report pulls forward some of the strategies that appear to be effective to achieve specific goals and to balance trade-offs. For example, most respondents believe they conduct more quality process checks than are required, which is inefficient. To help focus on this and not only grow but also improve profitability, companies must measure and improve not just their quality, but the cost of quality and the cost of compliance. The final section has some recommended issues to consider in moving beyond trade-offs and into improvement across multiple areas at once.

3. **Quotes from Peers** Telephone interviews with professionals from several medical device makers and suppliers were competed as part of this research. Quotes were included from those that took the time to comment on their experiences. Most are from the Advancers group, so this feedback helps to clarify what steps were taken to grow and increase their business performance.

The medical device industry has enormous promise but is relatively immature in some of its business practices. As companies grow, mature and learn, we expect the competitive hurdles to rise. Advancers are already pushing higher expectations for customers, suppliers, employees, and shareholders. Every company in this industry must move beyond making trade-offs and into a culture of improvement and profitability to take full advantage of the unprecedented future worldwide opportunity.

Industry Context & Strategies

Saving, sustaining, and improving lives is the reason why the medical device industry exists – as more of the world's economies afford better healthcare, this growth will only expand. It is also highly dynamic as new medical devices are developed, technologies improve, regulations change, and treatments are adopted worldwide. Product innovation is an essential driver of success in this industry.

In fact, the top four opportunities to improve all relate to product innovation, as shown in Figure 1.

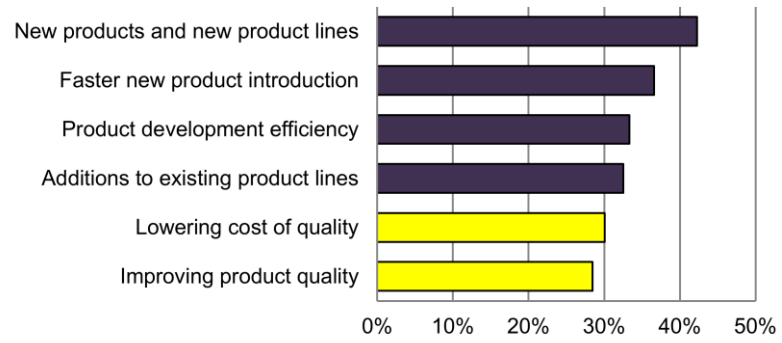

Figure 1: The top opportunities for future improvements relate to either product innovation (top four dark bars) or quality (yellow bars).

One set of innovation factors focus on expanding the product set by rolling out new products and product lines or adding to existing product lines. Another focuses on timeliness with speeding up the new product introduction (NPI) process or improving efficiency in product development. These are followed by quality-related opportunities to improve. Innovation and quality are top of mind and the pathway to success. The survey included nine other factors, but these were selected by fewer than one in five respondents.

With various aspects of R&D representing the most important improvement opportunities, most companies expect the rapid pace of product innovation to not only continue, but to increase in the future.

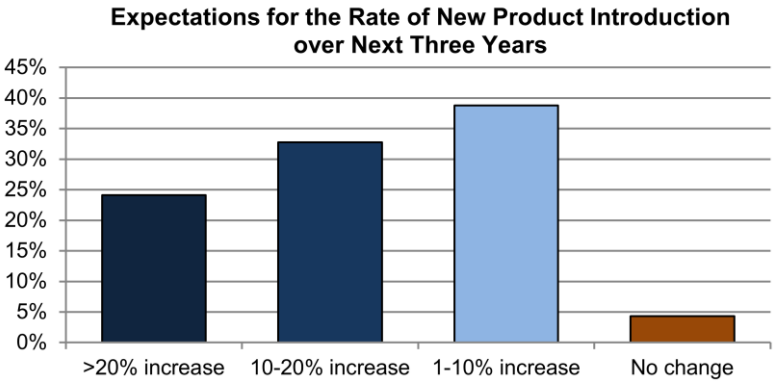

Figure 2: Nearly all medical device companies expect to introduce new products at a faster rate in the future, some dramatically.

Figure 2 shows that most companies expect the rate of NPI to accelerate by at least 10% per year over the next several years. That flood of new products is likely to drive continued growth and success in the medical device industry – yet it will also pose challenges with operational planning, manufacturing, quality and compliance.

Trade-off: innovation vs. quality and compliance

Quality and compliance are essential to the safety and efficacy of devices so they can't be ignored. To remain profitable, medical device manufacturers and their suppliers must become more agile so as to better manage the right balance between quality, compliance and innovation. This balance is a state that some companies have achieved, but most have not.

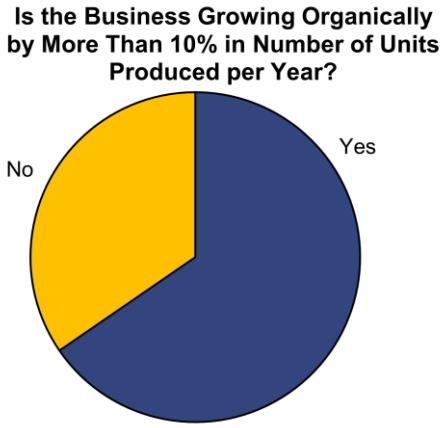

Figure 3: About two-thirds of the respondents to this study report that their companies are experiencing increased demand and growing.

"Our growth is so fast; it's like holding a tiger by the tail and trying to control it. We moved into this triple sized building a year ago, and are looking for more space already. It takes a team effort to get quality processes in place, and it also takes someone with the vision and ability to prioritize. A team including regulatory, quality assurance, production quality, and quality control meets two hours once a week to hash everything out. In addition, we hold a monthly Management Review meeting with all senior managers to resolve any outstanding issues."

- Hall Christman, Quality Assurance Manager, Amendia

Trade-off: growth vs. compliance, manufacturing, supply chain

Most companies have achieved growth. As is shown on Figure 3, most companies are shipping significantly more products each year. The combination of new products and higher volume is usually an indicator of increased revenues. It can also point to increased operational challenges. Innovation rates hit the R&D team. New products and higher volume create unprecedented challenges for the regulatory, production and supply chain departments. In some cases growth can actually hurt profits. This is particularly true if processes and systems are not designed thoughtfully.

Many medical device companies are research and development (R&D) driven. Particularly in the early years, some of these companies do not create scalable processes in plant and supply chain operations. It is not surprising, then, that some of the top strategies for coping with growth have to do with improving plant efficiency, planning and logistics capabilities. Figure 4 shows that over half of respondents are focused on improvements to plant operations and planning, and 40% are improving logistics and training.

Growth strategy: consistency and efficiency

Some of the strategies used to cope with growth can deliver consistent efficiency. Training can improve any process by helping staff understand and consistently execute standard operating procedures (SOPs). Further benefits come from employees understanding what their role is and how they can impact outcomes. Based on the survey responses, outsourcing is a strategy that many small companies are now pursuing. This is a way to improve production, planning, and operations without developing those systems and competencies internally. Implementing software systems can also have a significant impact on the consistency, efficiency, reliability and speed of key processes.

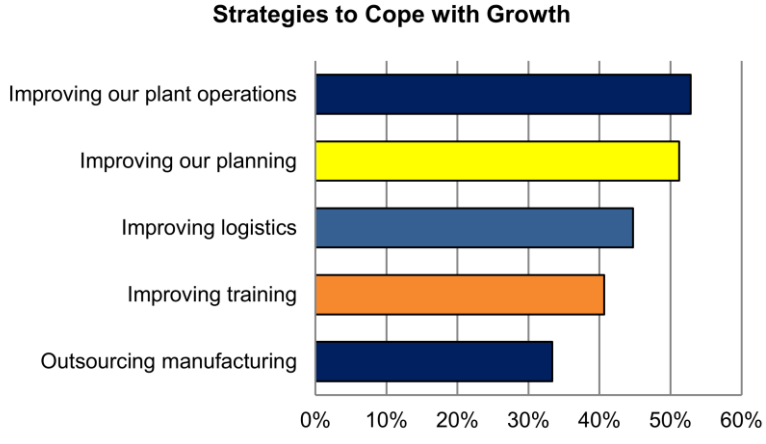

Figure 4: The most common strategies to cope with growth focus on improving various operational areas and training employees.

Beyond those strategies listed in Figure 4, we offered seven other possibilities in the survey. The next two were implementing new end-to-end processes and improving analysis across sites, each an

effective strategy to support growth by helping companies understand what works in order to establish sound business processes. Other strategies to cope with growth mostly relate to geographic expansion.

According to the survey, the top two strategic priorities line up well to these growth strategies. Half of the respondents report that strategic priorities are to improve efficiency of manufacturing operations or to align operational performance with corporate objectives. A third of the respondents are promoting collaboration across locations and functions as a strategic priority; about a quarter are focused on building compliance and traceability into production processes.

"For a while, harmonization allowed you to get CE Mark then just register, pay fees and submit a summary document about the product. Then you could start selling. Now, that's all fallen apart. Countries are all going back to national regulations and insisting that you be audited to those regulations."

- David Netzley, Sr. Quality Systems Engineer, Abiomed

Quality & Profit Challenges

Respondents report that the top challenge to maintaining high quality is one entirely out of their control: changes in regulatory compliance requirements. Figure 5 shows this result. As regulations change, so too must the reporting on these changes, which may force changes to a process, consuming time that quality and regulatory staff might otherwise devote to keeping quality high.

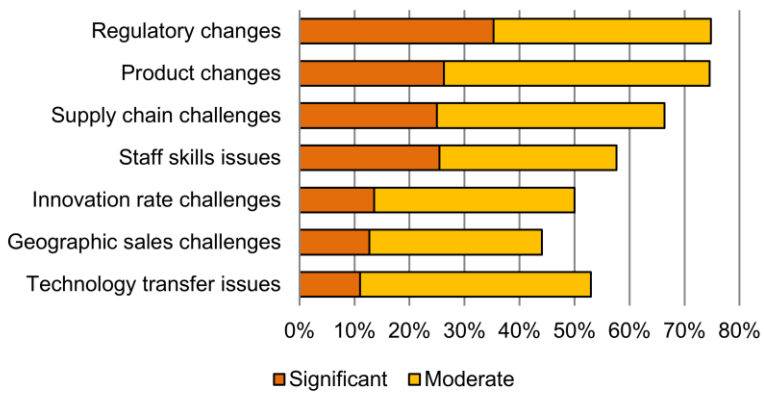

Figure 5: Keeping quality high is difficult in the face of changes to regulations and products, complex supply chains, and staff skills.

Trade-off: Regulatory changes and quality

Changing regulations are most likely to be a significant challenge to quality in part because there are quite a few of them. Healthcare regulators in each country have their own requirements that change independently of each other. Examples include the new good manufacturing practices (GMPs) being developed in Brazil and Australia. For those with electronics, IEC 60601 3rd edition just became effective in May 2012.

"Our flagship life science instrument has 2500 unique components, about 60% electronic or electrical. With the EU regulations coming, I saw the writing on the wall that we would need data on all of them. With some careful research, we found reliable third party data sources for component material content and implemented automated data management processes to help us be even more efficient."

- George Valaitis, RoHS Program Manager, AB SCIEX

Beyond those regulations, companies must also comply with changing environmental regulations. For example, medical device makers have been exempt from the European Union (EU) Restriction of Hazardous Substances (RoHS), which is changing next year. Companies have been subject to Regulation, Evaluation, Authorization, and Restriction of Chemical Substances (REACH) limits, though medical device makers don't truly know whether their products comply. The criminal penalties for offenders can be up to €55M EUR in Belgium, and some EU countries have prison sentences for serious breaches. So, companies using certain electronics and chemicals in their products must go through the process of documenting and in some cases re-designing, testing, and creating new quality processes for those products.

Innovation Pathway

The US FDA's Innovation Pathway 2.0 released in April 2012 "ultimately aims to shorten the overall time and cost it takes for the development, assessment and review of medical devices, and to improve how FDA staff and innovators work together." In this model, the manufacturer (or innovator) and regulators begin to work together to identify issues, additional data requirements, clinical trial issues, and engage experts prior to pre-investigational device exemption (pre-IDE) rather than after IDE.

Innovation Pathway 2.0 has two main goals:

1. Shorten the time to develop safe and effective products, based on earlier contact and a stronger balance of benefit and risk.
2. Improve collaboration, with a "Collaboration Phase" — a "loosely structured timeframe where innovators and FDA staff map out the future regulatory pathway for a product."

This builds on the core iterative development process the FDA outlined in its total product life cycle (TPLC) model. The TPLC model shows the critical input to the development process from trials, marketing, manufacturing, commercial use, and obsolescence. Companies need to build on TPLC across their enterprises and share data through the lifecycle for the development process to be rapid and effective.

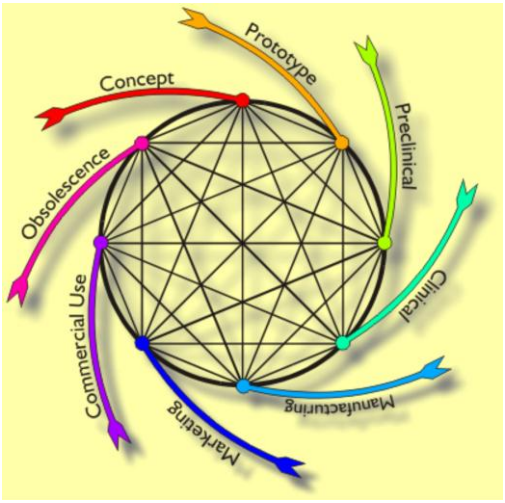

Figure 6: The Total Product Life Cycle or TPLC concept shows the iterative nature of medical device development and the need for information sharing.

Trade-off: Product changes and quality

The second most significant challenge to quality has to do with product changes – and the resulting engineering, technology or material changes. Clearly, as product specifications change, so too do quality targets, testing protocols, and an array of processes. This is at the core of the innovation conflict with quality – it's difficult to get beyond a baseline and document the processes in the face of constant change.

Product change ripples through every aspect of the organization, not just quality and regulatory compliance. The FDA's Innovation Pathway framework aims to help support companies in sustaining innovation and speeding approval processes by involving the agency earlier in the cycle. (See Sidebar: *Innovation Pathway.)* This approach follows on from and expands on the Total Product Lifecycle (TPLC) concept (see Figure 6).

"A founding factor of our company was to automate a process and take out the potential for human error. We started out making distraction pins for minimally invasive surgery in a fully automated way over three and a half years ago. Because our manufacturing costs are substantially lower than anyone else, we have now captured a significant share of the market."

- Hall Christman, Quality Assurance Manager, Amendia

Trade-off: Supply chain complexity and quality

Supply chain issues are number three on the list of challenges to quality. Product and regulatory changes also impact suppliers. The FDA and other regulators make it clear that device makers are also responsible for the quality and compliance of their suppliers. Respondents indicated how often their suppliers caused various types of problems, as shown in Figure 7. The good news is that most respondents say suppliers rarely or never cause audit findings or compliance issues. Still, the fact that

they sometimes or frequently cause problems in quality, obsolescence, manufacturing, costs, and delays is cause for concern. We also suspect that most companies do not have full visibility into materials compliance issues and may incur extra costs if they don't catch environmental issues early in design.

These problems are not likely to vanish quickly, particularly since most of the respondents only use a supplier scorecard to help ensure supplier quality, as Figure 8 shows. A scorecard is the basic foundation to measure a supplier's success and communicate your perspective to them. However, the other processes can help a supplier to actually improve. The respondents were asked to indicate all of the options they use. A minority use all of the other processes listed.

More mature manufacturing industries that make products whose quality can impact human safety such as automotive and aerospace are more likely to use some of these supplier quality processes. The major US automotive OEMs developed the Production Part Approval Process (PPAP); aerospace companies commonly have supplier quality personnel who go on site with suppliers for improvement projects.

Bringing better practices to lower costs and improve quality is a way of life for those industries. Of course, that is challenging to do unless the company has its own quality processes that are well established and run effectively. Other industries are also working to master materials environmental compliance. Consider whether you can find suppliers that also sell into those industries, as strong capabilities can be a positive selling factor for them.

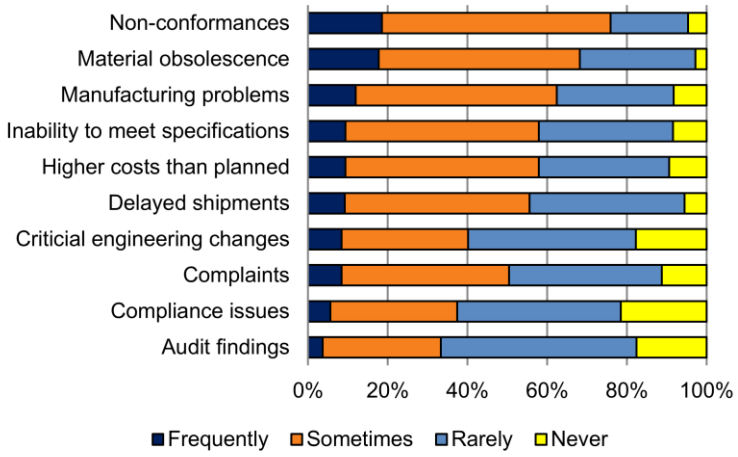

Figure 7: Suppliers rarely cause audit or compliance problems, but do at least sometimes create a range of other issues for medical device manufacturers.

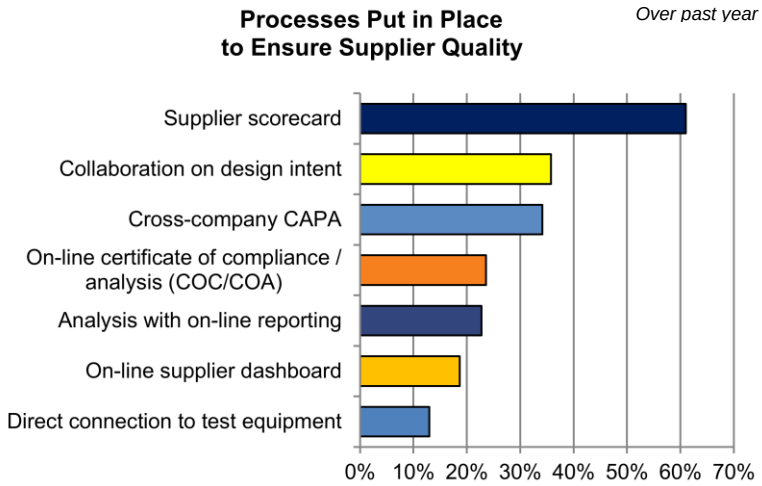

Figure 8: Of the seven supplier quality processes in the survey, most respondents use only one, supplier scorecards.

"Many people recognize that all of the checks and balances in the quality process are overdone. Yet the fear is perfectly understandable. The consequences of being found deficient are so high you can't afford to face them. People in this industry feel they have to overequip with these quality process controls. And, those attracted to regulatory affairs and quality tend to, by nature, be risk-averse."

- Carl Heeder, Director of ERP Systems, IDEV Technologies

"Many companies appear to lack a detailed awareness of what regulations require. With the uncertainty of what needs to be done, companies often layer in far more checks and balances than they need, which drives up costs. Companies that can streamline their compliance needs are more competitive and flexible."

- Larry Dube, VP of Operations, medical device supplier

"When I write a quality procedure I make it the minimum to be compliant. I'll have the debate with the auditor if it arises and if I don't win, I'll write an ECO for my procedure. Auditors will always push you to tighten up the system more, so if you start with a really tight system, they will lock you down. No point in putting the burden in place until you are absolutely forced to do it."

- David Netzley, Sr. Quality Systems Engineer, Abiomed

Trade-off: Checks and balances vs. efficiency and speed

This research shows that companies may be spending too much time and effort on checks and balances and not enough on processes that might better improve the quality rather than let the most risk-averse sleep well. Other than regulatory affairs professionals, ***the majority of every other response group believes that their company has more cumbersome processes than required by the regulations***. In fact, over 40% of regulatory affairs respondents believe that they are overdoing it.

Clearly, these checks and balances are protection mechanisms against problems. When processes are not reliable end-to-end, this is a traditional response. However, it is also costly not only in pure monetary terms for the time, but also because it is after-the-fact rather than preventive. Even more insidious, these non-value added tasks limit agility and damage a company's ability to handle the frequent change inherent in the industry. Making matters worse, once in place, these quality control checks often remain, even after a process is more capable and less likely to create problems.

These checks and balances may also relate to the staff skills issues that rank number four in challenges to quality (Figure 5). While many discuss staff training and empowering the employees, automation is also playing a role. Finding the balance will be different for each company. However, we suspect a combination of better training to truly empower staff to take appropriate action along with automation in both equipment and software will be important.

Medical device makers cannot afford to risk being non-compliant, but from a business standpoint, having so many checks and balances is a heavy burden. The innovation and growth of companies in the industry appears to be "choked" by process checks and an overzealous approach to regulatory compliance.

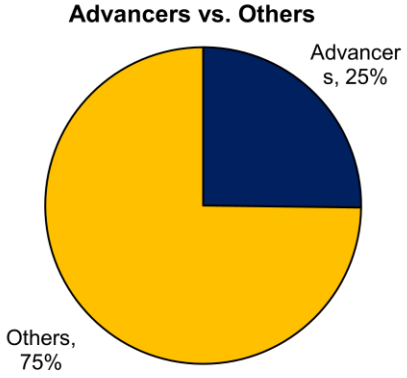

Figure 9: A quarter of respondents both grew and improved on most business metrics.

Advancers Show What's Possible

This research begs the question, "How can medical device companies lower costs and increase agility while remaining compliant?" What is the formula that enables a company to grow and improve financial outcomes at the same time? To find out, we separated out a group of respondents who had achieved both growth and dramatically improved business performance. Figure 9 shows that these "Advancers" make up a quarter of the response base.

Definition: The Advancers are companies that both grew organically by 10% per year in units produced and also made either modest or major improvements

on at least four of the six business metrics in the study. Respondents determined what major and modest improvements were. Those business metrics are:

- Net operating profit
- Market share of key products
- Earnings before interest, taxes, depreciation and amortization (EBITDA)
- Return on assets or return on net assets (ROA/RONA)
- Cost of quality
- Cost of regulatory compliance

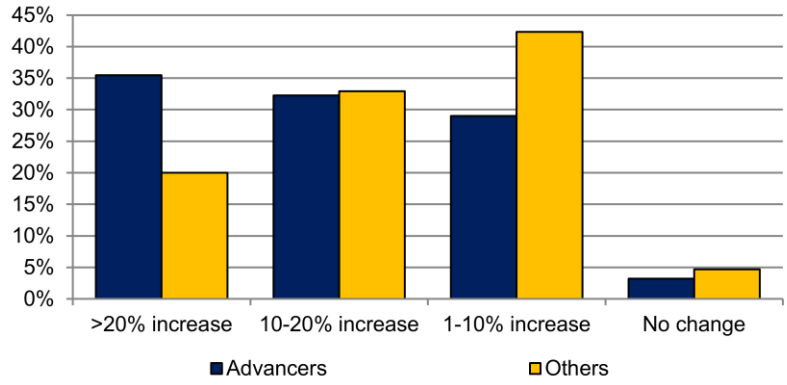

Figure 10: Advancers expect a rapidly increasing stream of new products and appear to have disciplines to make those profitable.

Trade-off: Growth vs. financial performance improvement

This Advancers group that grew and improved business performance is significantly smaller than the two-thirds portion of the response base that is growing. What differentiates this group from others?

Our first thought was that smaller companies had a better opportunity to grow organically and might be over-represented in this type of analysis. However, the opposite was true. The balance tipped slightly toward the largest companies and away from the smallest. While the rapid volume growth from larger companies is somewhat counterintuitive, improvement to financial metrics may not be. Larger companies are often public and have the profit disciplines in place to drive business improvements.

Profit strategy: innovation

Actually, the Advancers appear to be more aggressive on innovation than others. They are far more likely to have more than five variants, configurations or stock-keeping units (SKUs) for each product, when compared to the other companies. While 40% of others have one to five variants typically per product, only 13% of Advancers do. This may have to do with larger companies getting approval to sell in more countries. In any case, it makes compliance much more complex.

As Figure 10 shows, Advancers expect the rate of innovation to accelerate more dramatically than others. So while product changes are a challenge to quality for most respondents (shown in the second bar of Figure 5), these companies know how to both grow and improve business performance by leveraging this rapid pace of change. While a typical mindset is that R&D driven companies are not as focused on profit, there are quite a few achieving both rapid innovation and increased profitability.

> *"We are a very data-driven company. Our CEO is really into metrics. This approach has helped the company a lot. We have a history of being an R&D company – and now it's a manufacturing company with a strong drive to be a profitable and growing business. This has been a big philosophical and style change over the last seven or eight years."*
>
> - David Netzley, Sr Quality Systems Engineer, Abiomed

One key to that success may be that fewer of the Advancers are overdoing it on process checks and balances. A majority (58%) of the Advancers believe that not all of the checks, balances, and fool-proofing they have in place is strictly required by regulations.

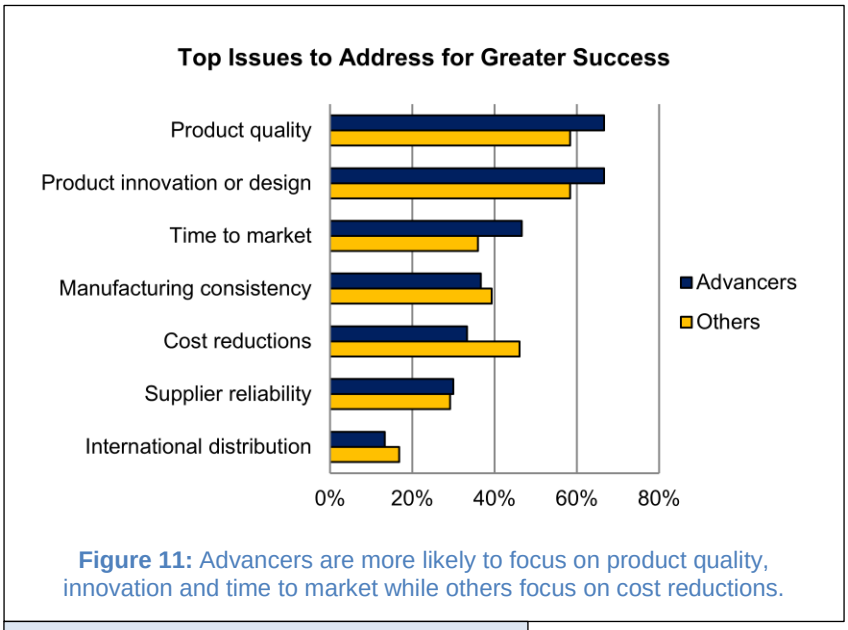

Figure 11: Advancers are more likely to focus on product quality, innovation and time to market while others focus on cost reductions.

Advancers: QbD in Practice

Advancers are aggressive about new product introduction; to have succeeded as they did financially the constant product change clearly did not disrupt the operation. The data suggest that they have mastered incorporating quality in the product and process design. Another term for this is practicing quality by design (QbD).

Advancers and the Others have some different issues they focus on, and what else they have improved to drive those improvements in business outcomes. The Advancers got better results on costs and profitability – but not by focusing strictly on cost reductions. Figure 11 shows that Advancers are more likely to care about product quality, design and time to market – and less likely to focus on cost reductions. Perhaps this difference reflects a thought that higher quality and product innovation will take care of cost reductions.

"With complaints, are you really getting to root cause, or just writing things up in a file in case the FDA shows up? There is a difference there. If you are really trying to get to root cause and find out what you can do on the preventive side, it takes more time on the front end, but saves you pain and money down the road too."

- Dave Empey, Director, Regulatory and Compliance Zynex Medical, Inc.

Strategy for profit: improve on issues customers see

Product quality is a highly visible attribute – customers notice quality and design. They also often respond to first-in-market products. Once they get to know a pioneering product, they may stick with it, at least until the next compelling new product enters the market. While customers may be price-sensitive, cost reductions are not typically the source of growth and success in the market. In contrast, strong product quality and design can actually lower costs while boosting revenue.

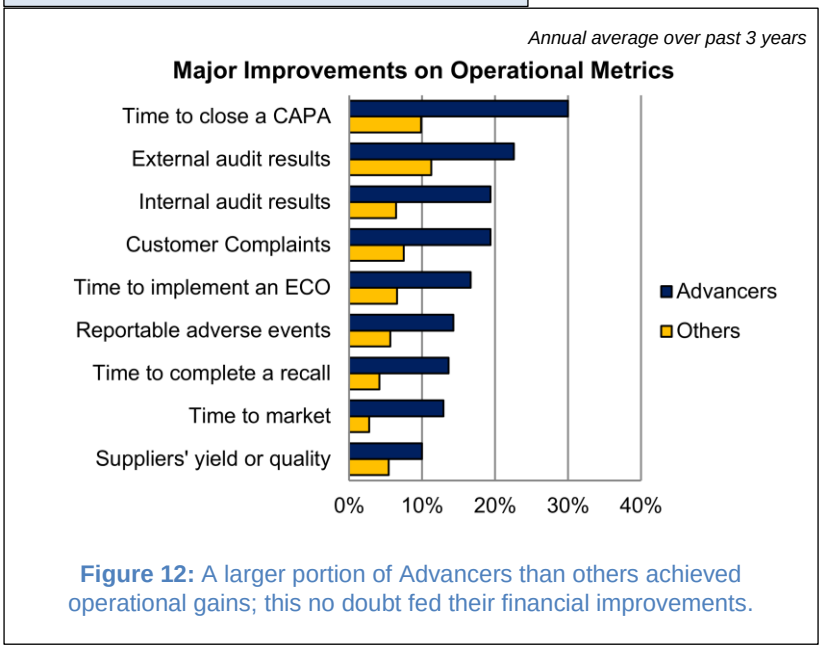

Figure 12: A larger portion of Advancers than others achieved operational gains; this no doubt fed their financial improvements.

This is not to say that the Advancers were not concerned with internal improvements. In fact, what appears to have driven their business performance gains are improvements at the line and operational level. Figure 12 shows some of those operational results. Similar dramatic differences hold in the proportion of

Advancers vs. Others achieving any gains in these metrics. These primarily focus on quality and time to complete key tasks. Notice that the largest ratio differences are in metrics that require both multi-disciplinary cooperation to achieve and that also impact market perception and success: time to market and time to complete a recall. Product innovation and in-field problems are two ends of the process that touch the market most directly.

Quality strategy: process capability improvement

How did the Advancers achieve these major gains in quality and timeliness? It appears they are focused on improving metrics that are closer to the Quality by Design (QbD) concept. That concept is: quality is inherent to the product design and the production process, not necessarily achieved through additional steps or checks. This is often measured as process capability. Those with a more capable process are able to handle change and variety far more successfully than others. Note that in addition to having a well-designed product and process, process quality refers to the execution reliability of the process. So quality by execution is just as important as quality by design. Advancers practice this, as shown in Figure 13, as well as focus on other line level metrics where they were more than twice as likely to achieve major improvements. It is no coincidence that the largest difference in proportion is the key process capability metric. With that level of process understanding and capability, QbD is also designed to allow companies to make changes confidently without re-validating the processes.

Improving process capability goes beyond the individual metrics from a piece of equipment or line. The foundation is to understand how the production process reacts in various situations and then analyze what changes actually alter the outcome. This is a process that many companies may not have the staff to conduct effectively, particularly since there is not a large qualified pool of quality engineers, due in part to the lack of an academic curriculum for that discipline. One interviewee reports that they are setting up mentoring to hire other types of engineers out of universities to enable them to become successful quality engineers.

Metrics Strategies Drive Improvement

This research rests on an assumption that companies measure improvement both at a business and at a production plant level. Previous Cambashi research with the Manufacturing Enterprise Solutions Association International (MESA) has consistently shown that companies with better business results have stronger linkage between their business metrics and operational metrics. Hall Cristman, Quality Assurance Manager for Amendia points out the discipline involved: *"We are developing a cohesive organized metrics approach for the company – not just a shotgun approach. No weird assortment of data as in many companies. This was no small feat. We started with a small set of metrics for the top financial level and then pushed that down through the company to see what we need to collect to support that. We asked each manager what else they need to manage their department. However, we do not collect information for the sake of doing it."* Beyond linkage, the metrics data collected must be reliable. This is a behavior issue that Amendia has also tackled from the executive office, according to Cristman. *"The President of our company asks for people to report everything. He says he won't be upset at anything reported, only if problems are not reported."* So consider whether your performance management strategy is driving the outcomes you want, and prepare to do some work if not.

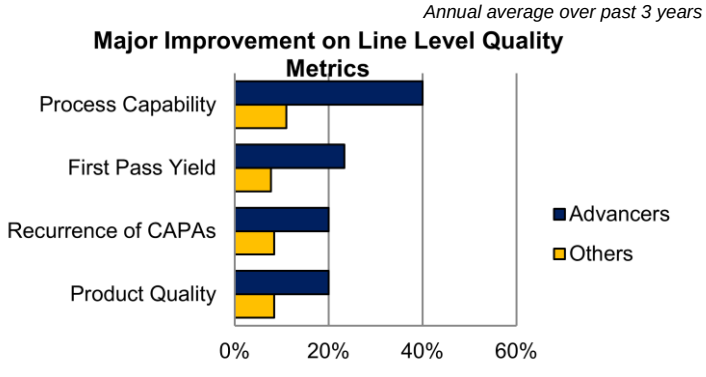

Figure 13: Advancers' business improvement may be driven by quality capability improvements in the plant.

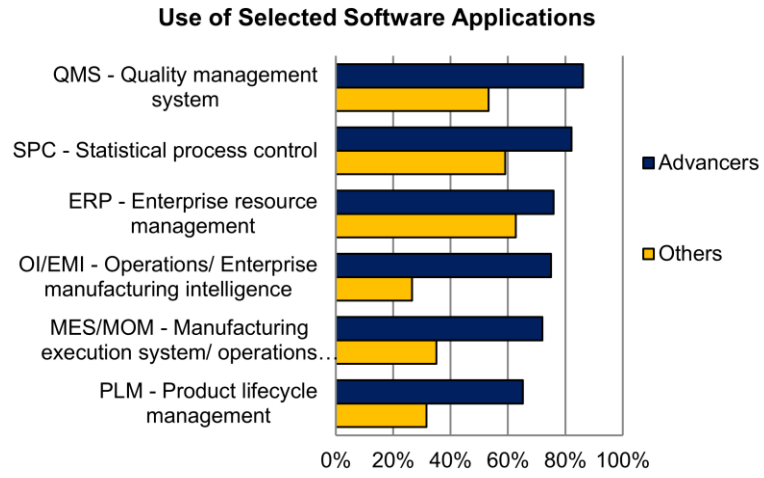

Figure 14: Far more of the Advancers than Others use software. This shows just a selection of the 14 applications in the survey.

Beyond QbD, some companies are also focused on Compliance by Design. This helps ensure their materials choices meet customer, environmental and possibly even trade regulations.

The Advancers illustrate that the QbD concept can work in practice. They have a focus on product innovation and have made the process improvements needed to reap the full rewards in better business performance. Remember that two of the business metrics that companies had to improve in order to be included in the Advancers group are cost of quality and cost of compliance.

"We have used handheld mobile devices with our ERP and document management systems to meet regulatory requirements in a way that reduces manual steps. We needed an auditable workflow and a controlled set of processes, and we got that. These mobile apps also reduce costs in validation."

- Andrew Dancan, Director of Enterprise Resource Planning, CSI

"We haven't been focused on cost of quality and cost of compliance and have not had enough means of measuring that. It's a manual process – we don't have good dashboards. We are looking forward to better data analysis and dashboards out of our new QMS, and an ability to pull data out of our ERP system."

- Dave Empey, Director, Regulatory and Compliance

Making Information Flow

Another area where Advancers differ is in investing in information systems. A significantly larger portion of Advancers than Others have every one of the 14 applications listed in the survey. Figure 14 shows the use of just a few of these applications.

Strategy for profit: use software

Of the 14 application types in the survey, the majority of Advancers use all of these, while a majority of the Others use only six applications: ERP, Statistical process control (SPC), electronic document management (EDMS), quality management (QWS), supply chain management (SCM), and warehouse management (WMS).

Typically, larger companies do use more software. Advancers are more likely to be large companies (37% are over $1B compared with 18% of others). However, this means that over 60% of the advancers are small or medium size businesses. With the advent of cloud-hosted solutions, and systems tailored specifically for smaller businesses, there is less reason for smaller companies not to invest in information technology. Note that use could be wide use, some use, or piloting.

Since plant floor manufacturing improvements are the number one strategy to cope with growth (shown in Figure 4), we reviewed a few issues based on the status of implementation. Apparently, significant challenges to quality based on regulatory compliance changes are a driver for using or piloting MES/MOM. There is a strong business case for making this investment to solve this problem. In addition to gathering and

tracking the data for compliance reporting, MES/MOM can enforce processes and prevent quality challenges from creeping in as a result of operator error. Naturally, they are also designed to help with 21 CFR Part 11 electronic signature compliance. They are particularly useful in dynamic environments to ensure only up-to-date SOPs are viewed.

Clearly, making information flow is easier with systems in place. However, even among those with systems, there are differences. Traditionally, one area that has been challenging is data flow between enterprise and plant floor systems, such as MES/MOM. So we asked about interoperability between these plant systems and others. Figure 15 shows that Advancers are far more likely to have interoperability than others.

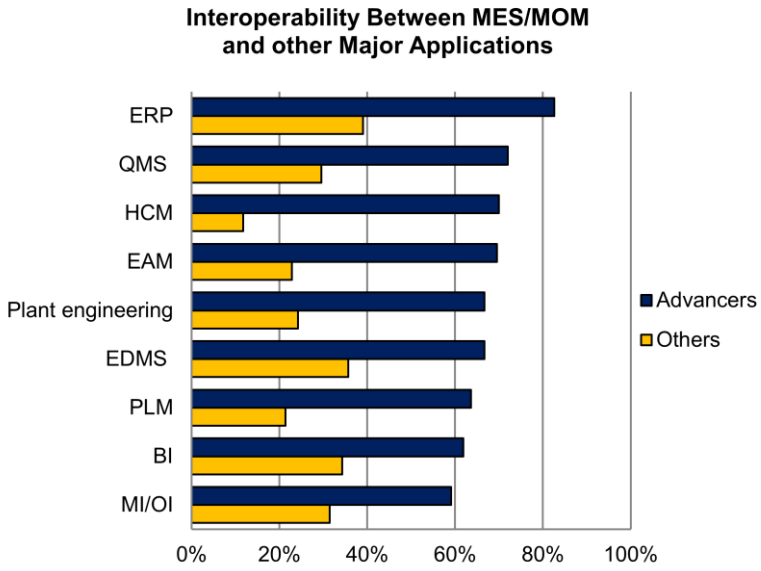

Figure 15: The majority of Advancers have other applications integrated to their plant floor system, but only a few of the Others do.

Information flow between plants and enterprise is critical for every aspect of the business – this is a strategic advantage where Advancers benefit. For example, plant floor information exchange is critical for:

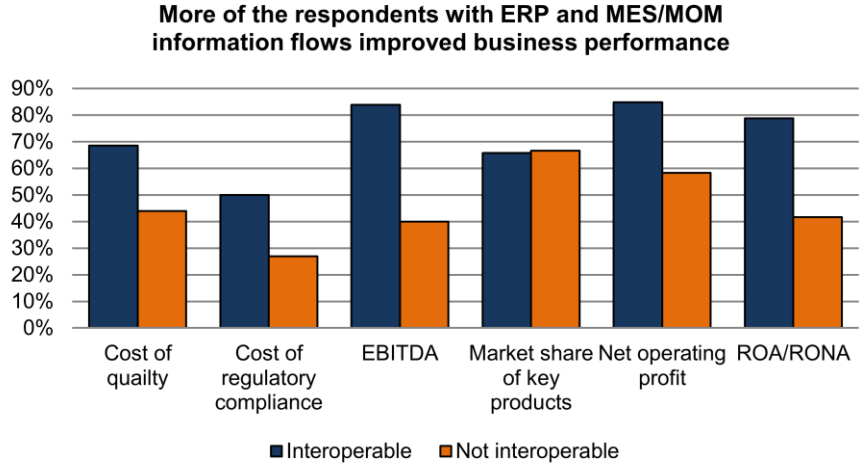

Figure 16: Allowing information to flow from plant MES/MOM to enterprise ERP and back is important on financial goals; market share can be gained without the benefit of lower costs or higher returns for shareholders.

- Understanding the ramp up during new product introduction
- Managing materials wisely, from ordering to staging to Work-in-Process (WIP), planning sales and distribution based on availability, and engaging transportation providers
- Triggering business transactions based on materials consumption or products shipped
- Initiating and executing on engineering changes to the product

"As we are ramping up – we are on a pretty good growth curve. Managing rapid growth is tougher in a slow economy. You can crash and burn fast. So we must capitalize on all of the information in the system to get real-time reporting out of the operations and get away from the plethora of Excel."

- Dave Empey, Director, Regulatory and Compliance, Zynex Medical, Inc.

"By using a materials compliance module from our CAD and PLM provider, we have one fully integrated platform to manage environmental compliance. In addition to the platform, by using outside data sources and contractors, we now get environmental compliance data into the system for $5-10 per component, not the $25-100 I hear some companies are paying."

- George Valaitis, RoHS Program Manager, AB SCIEX

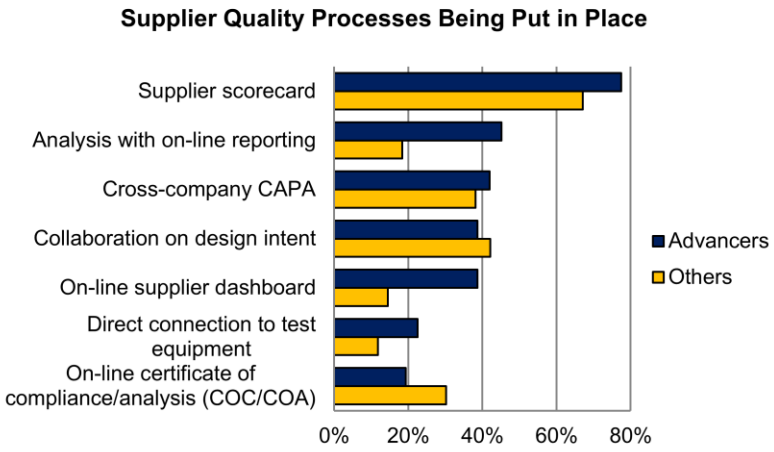

Figure 17: Processes for supplier quality vary widely, but advancers are far more likely to use on-line reporting, COC/COA and connection to test equipment at supplier sites.

Which is more accurate: people or automation?

While research shows that automated processes are far less likely to produce errors than human processes, people often have a hard time believing it and altering how they work.

"Automating a process can be challenging because ink on paper, hand on the desk is still very powerful and has powerful feelings to it. People may not have a realistic view of the risks of that. For example, I wanted to introduce bar coding to collect data. The quality folks said that to validate that the bar code reader reads correctly they would want to do multiple tests. Their approach to this is that human checking is completely without error – so any mechanical check has to come close to that standard of performance. However, with the people who check and cross-check numbers and data, we don't have that level of rigor. We don't sit with them once a year and test them on a sample of numbers as a proof. We never have a validation of the inspectors' visual acuity – never check that they are reading properly. Yet for an instrument or programming, we go to extremes to be sure it's correct."

- Carl Heeder, Director ERP Systems, IDEV Technologies

- Gauging supplier performance to feed into procurement

Taking just one example of that, those who have interoperable MES/MOM and ERP are far more likely to have improved on every business metric in the study except market share, as Figure 16 shows. Market share can be gained with rapid and effective new product development plus sound sales and marketing. However, improving on costs, earnings, operating margins, and return on assets requires efficient operations. This is where having information flow smoothly between the enterprise system and the plant floor is so critical, and where the results are so clear. Information flows support improvement in costs, profits, and return on assets.

Most companies must rely on their suppliers to ensure consistently high quality, so we asked about how companies manage that process. Advancers are more likely to use on-line technology to monitor or improve supplier quality. Figure 17 shows that the most significant difference is within "analysis with on-line reporting," "on-line supplier dashboard," and "direct connection to test equipment." These high tech methods can begin to speed the flow of information between medical device makers and their suppliers in ways that can improve outcomes for both the supplier and the brand owner. These types of systems can also alleviate misunderstandings and differing views of performance. The anomaly in the data is that "on-line COC/COA" are more likely to be in an "on-line system" for Others – but it could be that respondents consider accessing PDF files an on-line

system. However, the advanced method would be to have them in a software system, linked to other data about that material.

Of course, some of the most challenging cultural changes have to do with moving to automated systems. Not only must people learn to use the systems, but they must sometimes change their mind set. (See the sidebar "Which is more accurate: people or automation?") Sometimes, the ideas of previous generations die with new ones; we suspect that the younger generation of workers will not have this set of fallacies about automation and software.

Trade-off	Sample Strategy
Innovation vs. quality & compliance	QbD of products and processes
Regulatory changes vs. quality	Incorporate regulations in software so it replicates automatically
Growth vs. compliance, manufacturing, supply chain	Create streamlined processes with high reliability and capability
Product changes vs. quality	Make information flow from R&D to quality to manufacturing and supply
Supply chain complexity vs. quality	Use software with suppliers
Checks and balances vs. innovation	Minimize quality process and innovate process with product
Growth vs. financial performance improvement	Production efficiency, reliability and improvement on operations metrics
Product variants vs. operational efficiency in plant and enterprise	Put requirements and tests per variant in PLM & distribute with MOM

Figure 18: Key trade-offs in medical device manufacturing and sample approaches that allow improvement on both factors.

Moving Beyond Trade-offs

This report has pointed out many trade-offs. Such is the nature of a manufacturing enterprise. Companies must constantly prioritize and make decisions about what to do to achieve the best outcomes. Advancers have learned to move beyond and actually improve aspects that historically have been viewed as mutually exclusive. Advancers are showing that they can, in fact, innovate rapidly and perform well in operations and as a result, improve their business performance.

Figure 18 lists some of these trade-offs, plus offers a view of strategies to consider to help achieve balance to move both aspects forward simultaneously. Some of the key elements to improving profit while growing are:

"We try to do the minimum we can to be in compliance with regulations. That enables us to streamline the process and stay competitive."

- Andrew Dancan, Director of Enterprise Resource Planning, CSI

"With modern software, the biggest benefit and the biggest problem is it's highly configurable. Everything depends on how you set it up, and the best way to do it is not always obvious."

- Hall Cristman, Quality Assurance Manager, Amendia

Streamline quality processes

Keeping the quality processes at a level that ensures compliance yet does not unduly slow down the business is a genuine challenge. Yet some of the processes used in lean manufacturing such as value stream mapping may help. Review the regulators' guidance and create a posture on what is truly required. Then work to streamline processes and eliminate steps that do not either add value or provide minimum regulatory compliance.

One good way to do that is to use information systems to not only create SOPs, but to enforce those processes. The key is to find systems that are flexible enough to keep up with this constant change. Many current systems qualify and are easy to configure. Another factor is that the system should be easy enough

to administer that the process of change is still significantly simpler and more reliable than with a manual system.

Lower costs at the source

To effectively avoid excess checks and balances, companies clearly must have sound processes that are not likely to result in problems. Those who eliminate checks and balances before they have improved process capability are liable to face fines from regulators. Thinking about quality at the source must go beyond manufacturing process capability in equipment. The people are a critical factor as well, and since most companies cannot automate everything, people must be educated, equipped, and empowered to make sound decisions and take appropriate action. Beyond even that, lower cost at the source comes back to product and process design. It also rests heavily on supplier quality.

"If anything, I would have liked to have seen us make some of these changes and move in this direction a year ago. The benefits coming from this software project mean we would be a year further along than we are right now."

- Dave Empey, Director, Regulatory and Compliance, Zynex Medical, Inc.

"With updateable and mobile dashboards that work in sales and in manufacturing, our executives now spend 90% less time looking for data. The entire process is simplified."

- Andrew Dancan, Director of Enterprise Resource Planning, CSI

"Supplier data collection was the biggest challenge we had to overcome. We have already loaded about 6000 components into our materials environmental compliance system. Now, we get about a 75%-80% hit rate on full material disclosure. We are doing this without building an empire. It is just me and a very good materials compliance engineer, with good partners and systems."

- George Valaitis
  RoHS Program Manager, AB SCIEX

"Everyone says they want to engage their people, but many of the systems we put in place are idiot-proofing systems. What is the purpose of educating and training your people if you don't really trust them? What is the purpose of having tools like ERP and shop floor tools to empower decisions if you won't let them make the decisions? At some point, human intervention is there – someone must make a decision."

- Larry Dube, VP of Operations
  Medical device supplier

Focus on innovation and value

A major difference between Advancers and Others is the degree to which they both focus and improve on areas that matter to their customers. Clearly most medical device companies are very innovative, bringing out new products, product line extensions, and product improvements regularly. However, many companies lose track of their fundamental value proposition, and these may be at either end of the spectrum. Some R&D-driven companies are simply looking at how to advance their product line. Some data-driven companies may end up focusing more on cost reduction or core operational metrics than on indicators of customer value. These tend to revolve around quality and speed.

Automate information flows

One great way to achieve both quality and speed for customers while reducing costs is to automate information flows. The Advancers in this study have done that – they not only use more software applications, but they are much more likely to have the information integrated between the plant and an array of other applications. Interoperability of systems delivers an ability to see cost of quality or regulatory compliance (pulling from MES/MOM and ERP), or to measure the NPI time from concept to stable production (pulling from PLM and MES/MOM) as the process is occurring. People at all levels in the organization can see what they need to make timely decisions if the information from multiple systems is available in a useful context for them.

Holistic approaches

More mature views of performance use holistic metrics rather than only the simple ones. For example, cost of quality is far more predictive of company success than simply product quality; NPI time is more important than simply development efficiency. Some of this is taking it from a customer value viewpoint, and some is putting operational metrics into the larger scope of the business. Another example of a holistic approach is TPLC, where each group at each stage of the product lifecycle leverages information from other disciplines and stages to succeed.

Boost manufacturing capabilities

The most common strategy to cope with growth is to improve manufacturing operations (shown in Figure 4). However, the approach to doing so can vary. Among the smallest manufactures, the number one strategy for growth is to outsource manufacturing, as Figure 19 shows. Given that many small companies do not have an expertise in production and that manufacturing facilities can be very capital-intensive, this is probably a wise approach. It will create a need for stringent oversight of those outsourced partners.

Priority	Small <$25M	Medium	Large >$1B
#1	Outsourcing Manufacturing / Improving our planning (tie)	Improving our plant operations	Improving our plant operations
#2	Improving training	Improving our planning	Improving our planning
#3	Improving our plant operations	Improving logistics	Improving logistics
#4	Improving logistics	Improving training / Implementing new software systems (tie)	Improving training

Figure 19: Top strategies to cope with growth vary somewhat by company size.

"The biggest challenges are likely to be cultural for us. This is change management – getting people to adopt to new ways of doing things, and adapting to electronic systems vs. carrying paper around and talking to people. There are a few people who are technology-averse who are going to have to figure out how to make it work for them or how they are going to change. Someone will have to lead the charge."

- Dave Empey, Director, Regulatory and Compliance, Zynex Medical, Inc.

Beware the Advancers!

Clearly, the Advancers have all of the pieces in place to dominate their markets. They are innovating more rapidly than others. It appears they will be able to cope with that innovation and growth effectively. By improving operational performance they create a stable environment built to accommodate change. Their continued improvement in their business performance will also allow them to invest in education, information systems, and better approaches throughout their business and with their suppliers.

While cultural change is usually the biggest issue for every company, success is a strong driver. Since the Advancers have financial success to show from their operational improvements, there is a natural momentum that can build. This is a never-ending process, since the changes to regulations, products, and information technology will continue. Those who master change and improvement to business outcomes by focusing on customer value will continue to win. Fortunately, there are steps any company can take to move into the Advancers category. It has to do with seeing not just the trade-offs, but approaches that allow improvements on all fronts simultaneously.

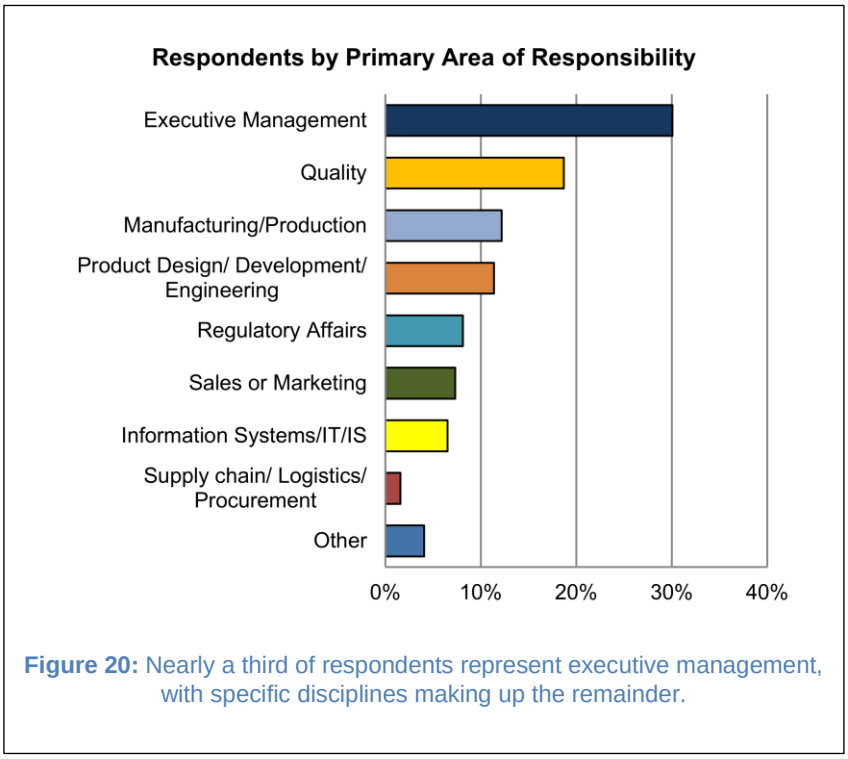

Figure 20: Nearly a third of respondents represent executive management, with specific disciplines making up the remainder.

Methodology and Response Demographics

The research for this study was conducted during the first half of 2012. An on-line survey generated the quantitative data in the charts and graphs throughout this report, based on 123 responses. That on-line survey was complemented by a small set of telephone interviews with those whose responses put them in the Advancers category or who we believed had interesting insights to share. The results from those interviews are in the blue-shaded boxes scattered throughout the report with their quotes.

Responding individuals

The respondents are overwhelmingly in a management position, with 33% at a senior executive, C-level or VP scope and 42% at the director, manager of managers or head of department scope. A further 15% were managers or project managers. Only 10% were supervisory or staff level.

Figure 20 shows the respondents by discipline or area of responsibility. The executives are the largest single group, and we have good representation from quality, manufacturing, product engineering and development. Given the topics in this survey and the focus for these companies, these are the departments perhaps most on the hot seat to make improvements in profitability and company success. A number of respondents are also from regulatory affairs, sales and marketing, and IT. All of these have a major stake in creating solid outcomes and helping to move beyond trade-offs.

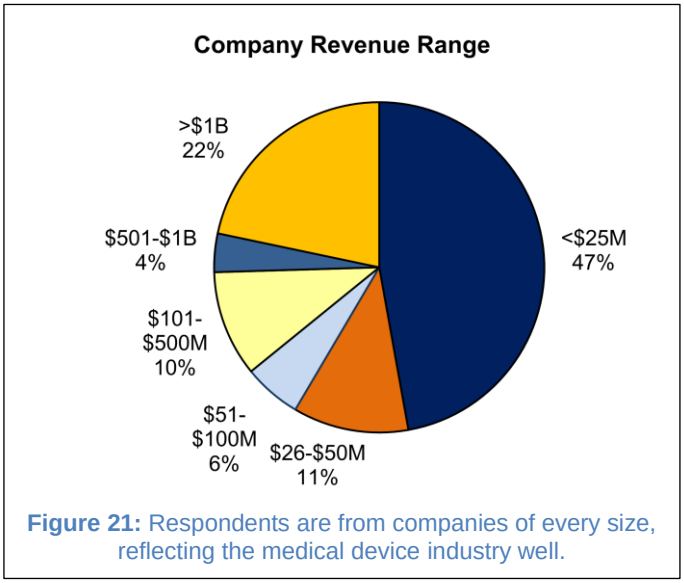

Figure 21: Respondents are from companies of every size, reflecting the medical device industry well.

Responding companies

The companies represent the medical device industry reasonably well. Figure 21 shows that nearly half are small companies under $25M in annual revenues. Over 20% are from large companies over $1B. The remaining 31% of respondents are from mid-size companies, distributed across three size groups.

This response base also represents the industry well in terms of what classes of device they make, as Figure 22 shows. Naturally, quite a few companies make more than one class of device. By the FDA's three major classes, most make Class II devices, and significant portions also make Class I and Class III devices.

Product line complexity

Product innovation is a key to success in this industry, and it often appears as a wide array of product families, and in products with many variants or configurations. Figure 23 shows that in this response base, nearly half (similar to the proportion of companies under $25M) of the companies have five or fewer product lines. However, about two-thirds of the companies typically offer more than five versions of a product.

Product and process complexity

Respondents also categorized their products as simple, medium or complex based on the BOM levels and number of materials. Just under half selected medium for this: two to three level bill of materials and 10-50 parts. The manufacturing process similarly was typically of medium complexity with four to 10 process steps and some outsourced processes. A larger portion of the respondents have complex processes with more than 10 steps and complex products with more than three levels in the bill of materials and over 50 materials.

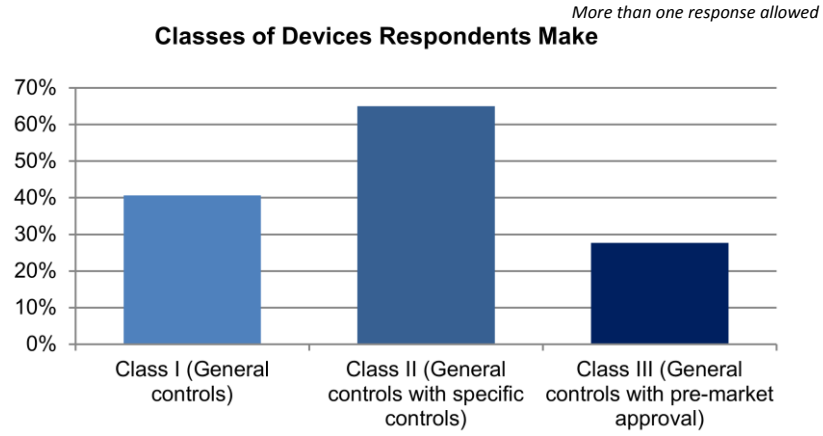

Figure 22: Nearly a third of respondents represent executive management, with specific disciplines making up the remainder.

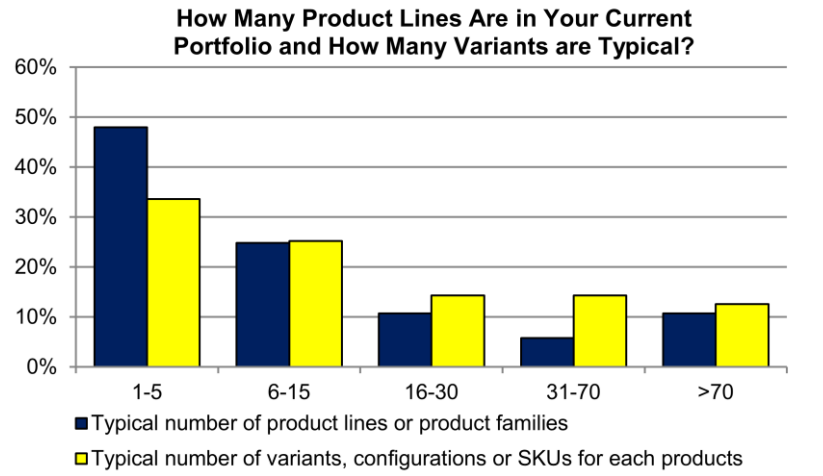

Figure 23: Most respondents have quite a few product families, and an even larger portion have many variants for those products.

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