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C a m b a s h i | I n c

Risk Management: Best Practices for Medical Device Profitability

**Cambashi Reports Industry Directions
In Conjunction with**

FDANEWS

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Executive Summary

Medical device manufacturers face enormous risks – regulatory, legal, and financial – based on their products and operating processes. The risks range from minor disruptions to operations caused when auditors spot non-compliance with legislation, to the loss of public trust and brand reputation that might result from successful litigation by claimants. We would expect risk analysis to be a top priority for shareholders, owners and senior executives. The purpose of this research was to assess the extent to which risk management is routinely employed within medical device companies as part of day-to-day development, procurement and manufacturing operations. We also identify weaknesses in current approaches and identify best practices.

What this research shows is that everyone is focused on risk management and analysis, but that the processes and practices may be somewhat incomplete. Strategies for mergers and product line proliferation are common, but it's not clear that companies' approaches are adequate for the task. Further, not all companies are truly focused on what their customers care about – which inherently raises the risks that the business might meet internal metrics yet fail to gain market share.

Some of the weaknesses in risk management processes include poorly managed product development and design transfer processes, low visibility among departments, sites and partners; incomplete risk and root cause analysis, cumbersome corrective action processes, inconsistent information, and manually processed compliance paperwork. These clearly create risk to both patients and the business' success.

Companies that enjoy growth in both revenues and profits understand that their success stems from issues customers value, namely product quality, customer service, and flexibility. These growth companies also have more formal processes to foster teamwork across departments and among trading partners. They are more likely to support these processes with application software for quality, regulatory, enterprise, manufacturing, and product management. As a result of these practices, they are more likely to make gains in quality, operations, and financial metrics.



Key Findings

Innovation and product capabilities are the driving factors for success for most medical device companies. A significant portion of respondents have many product lines with many variants; over 40% provide to-order customization of their products. As a result, many respondents recognize the need to invest in R&D and design transfer. What fewer companies appear to recognize is the need to invest in root cause analysis and comprehensive feedback loops, so when issues arise in one product or area they are sure to examine the implications and risks for all other products and areas.

Nearly three-quarters of the respondents to this study report that their companies grew revenues over the past three years. However, not all of them also grew profits. In fact, volume growth and competition are the factors most commonly considered likely to cause future problem areas for medical device companies.

The 60% that have grown both revenues and profits, or “growth companies”, are different. For one, they are more focused on what their customers care about: product quality, customer service, and manufacturing flexibility. Growth companies also are much more likely to use formal business processes that ensure collaboration – within and between departments, between sites, and with their customers, suppliers and other trading partners.

Growth companies have an advantage in that they are also far more likely to use software to support key business processes: from enterprise and supply chain applications to quality, regulatory and document management, to product lifecycle management, to manufacturing execution systems. Many of these systems are designed to foster collaboration across various departments. Most respondents from companies that have moved beyond paper and spreadsheets to software applications are seeing a high level of benefits.

Yet even among the medical device growth companies, many are relatively immature in their practices, both internally and with trading partners. Some of this may be a result of feeling constrained from making needed improvements due to regulatory requirements.

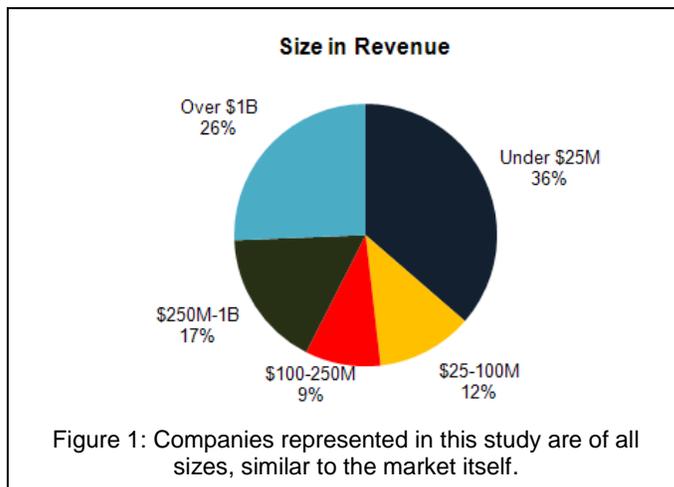
Existing isolated business structures and mindsets for quality and regulatory, product life cycle, manufacturing, and risk management are no longer adequate to ensure competitive advantage. For both companies and their regulators, a practical approach to risk management must be multi-disciplinary, holistic, and based on sound information. Leaders are gaining ground with sound practices that focus on customer concerns.



Study Methodology

Cambashi and FDAnews teamed up to develop this study of risk management issues in the medical device industry. The research for this study – a combination of an on-line questionnaire and telephone interviews – was conducted during April, May, and early June 2008. Invitations to participate were sent to medical device industry professionals, including subscribers to an FDAnews product, readers of affiliated publications, members of MassMEDIC, pre-existing contacts of the research team, and contacts of the sponsoring companies.

The data in charts and figures in this report are from the on-line survey response of 221 individuals that we verified as working for a company in the medical device market. The telephone interview results appear in quotes, sidebar text boxes, and commentary throughout the report.

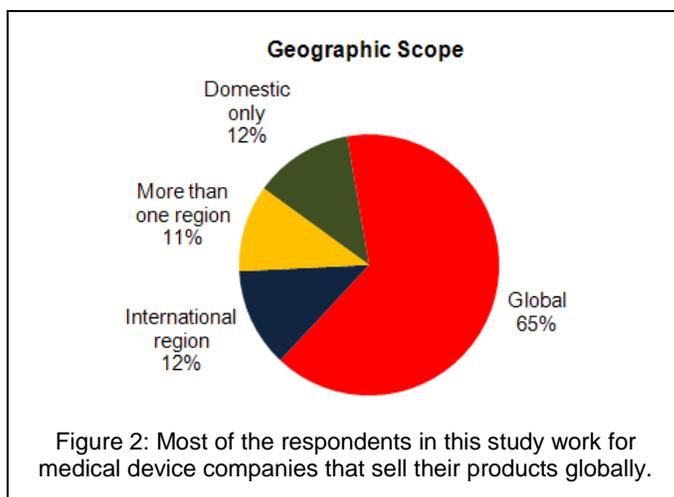


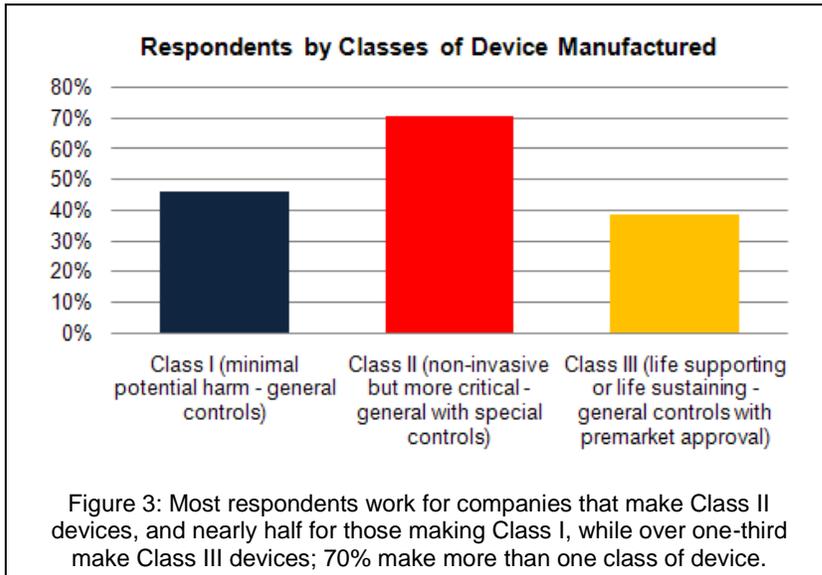
Demographics

Study respondents' companies reflect the breakdown of the industry relatively well, across several dimensions. These include size of company and class(es) of devices manufactured.

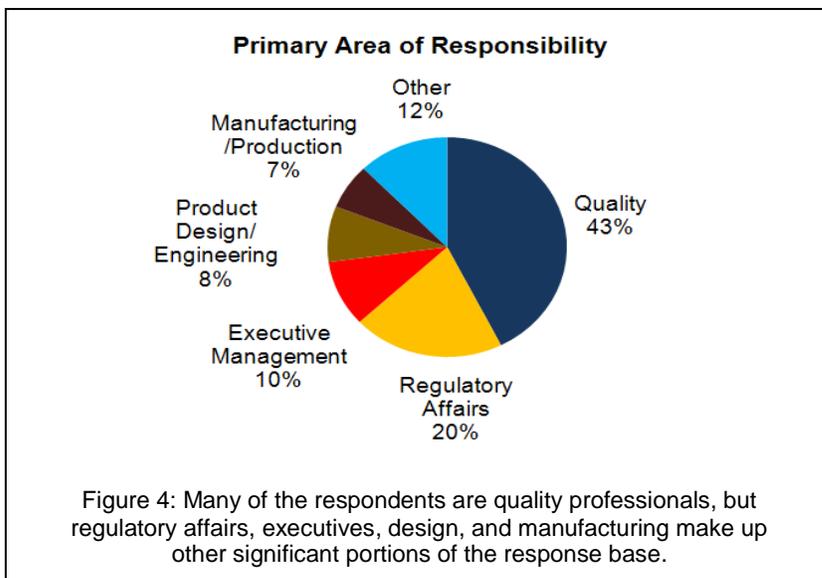
Figure 1 shows the breakdown by company size. Over one-third of respondents work for small companies with less than \$25M in annual revenues. At the other end of the spectrum, about a quarter work for large companies with over \$1B in revenues. The remaining 38% are split between three medium-revenue size ranges.

Even though a large portion of the respondents are from relatively small companies, a vast majority sell their products globally. Figure 2 shows the scope of product sales. Fully 65% of respondents work for companies that sell their product worldwide, and only 12% are producing and selling only in a single market.





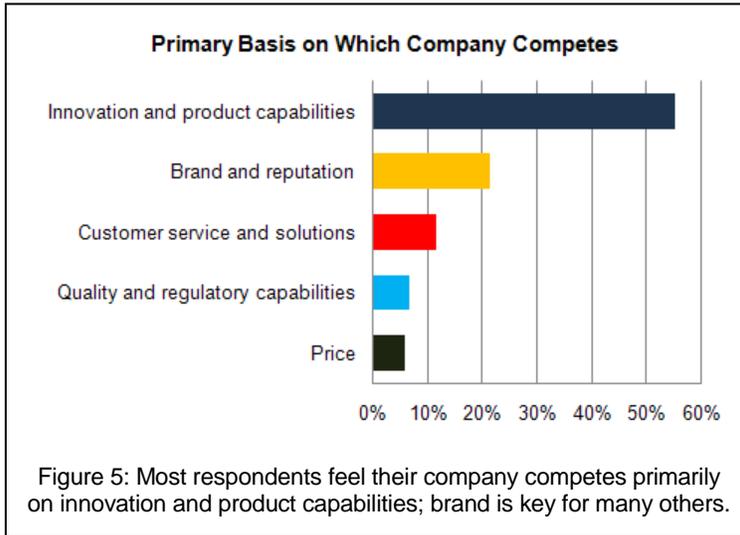
Responding companies make all classes of devices, as well. Figure 3 shows that 39% make Class III highly regulated medical devices. A full 71% make Class II devices, while 46% of respondents make Class I devices. Over half of responding companies (56%) make two classes of devices, and 14% make devices in all three classes.



The respondents themselves are largely (43%) quality professionals, as Figure 4 shows. This is a factor of the types of individuals invited to participate. We expect the adoption of risk management practices to be most relevant to quality professionals.

Regulatory affairs, executive management, design engineering and manufacturing are also well represented in this study response base. Some of the respondents represented in the 'Other'

section work in information systems or information technology (IT/IS), supply chain management, sales and marketing, and procurement.



Company Strategy

Basis of Competition

Most respondents feel their company competes primarily on the basis of product innovation, as shown in Figure 5. Brand and customer service are also important for significant portions of this respondent base. One of the interesting factors here is that all respondents in procurement feel their companies compete primarily on brand and reputation, as do a

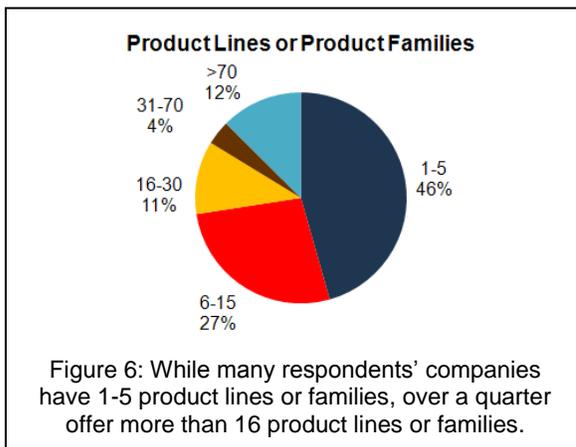
“As every new product is brought into the market, the customers’ expectations and desire for something new changes. We must find out what it is and make the new thing, whatever it is.”

large portion of respondents working in manufacturing. In contrast, half of IT/IS respondents believe their companies compete mainly on the basis of quality and regulatory capabilities. Certainly, the IT department feels the most heat from these groups as they support various aspects of validation.

When asked which processes contribute the most to the company’s market success, a similar pattern emerges. Product quality is at the top of the list, followed by product innovation. The next most important processes are relationships, customer service, and brand building.

Product Complexity & Options

If innovation is the primary basis of competition, does that drive product variety? Sometimes, but not necessarily. As Figure 6 shows, nearly half of respondents have just 1-5 product lines. One innovative product can make a market. However, over a quarter of respondents’ companies have 16 or more product lines. Every product family generally has



separate factors to consider and document from design through procurement, production, distribution, and service.

Complexity is also in the structure of the products themselves. In this response base, less than a quarter of respondents report that the bulk of their products are simple, defined as having a one to two level bill of materials (BOM) and fewer than 10 direct materials. Figure 7 shows that nearly half report a medium complexity to their products, defined as a two-to-three level BOM and 10-50 direct materials or parts. A third of respondents

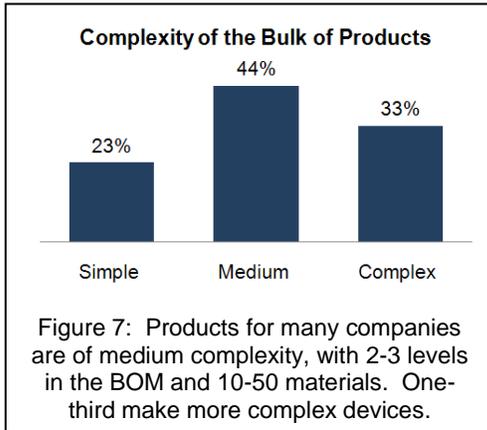


Figure 7: Products for many companies are of medium complexity, with 2-3 levels in the BOM and 10-50 materials. One-third make more complex devices.

make mostly complex products, with over 50 parts or materials and three or more levels to the bill of materials.

Another factor in product complexity for nearly half of these companies is that each product line may have many configurations or options. When asked how many variants or options each product has on average, the pie chart looks similar to Figure 6. For product configurations, only 39% report 1-5 options. So over 60% offer six or more variants for each product they sell. Fully one-third report 16 product variants or more on average.

Over 40% of respondents' companies also offer to-order

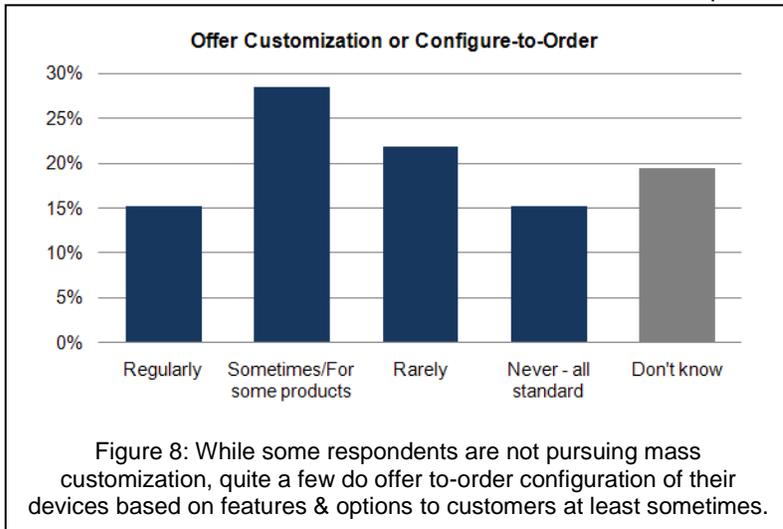


Figure 8: While some respondents are not pursuing mass customization, quite a few do offer to-order configuration of their devices based on features & options to customers at least sometimes.

customization of their products.

Figure 8 shows that this mass customization approach is one that 15% of companies in the study use regularly, and over a quarter report that they sometimes customize for certain product offerings. This leads to a very complex environment, with more products and documentation to track in every department and through every process. Some of the variants may require separate failure mode and

effects analysis (FMEA), standard operating procedures (SOPs), unique tests, as well as qualifying different suppliers and materials.

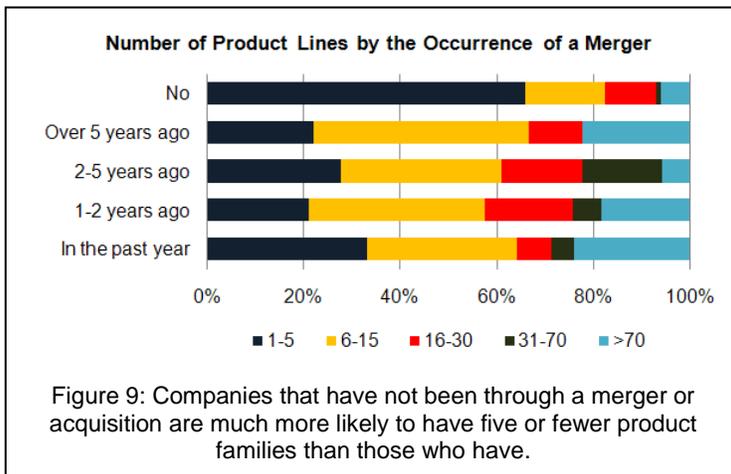
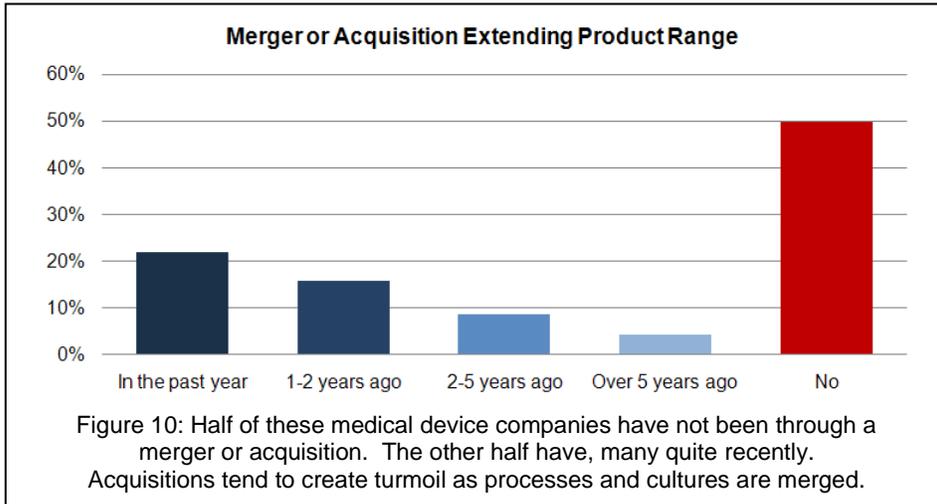


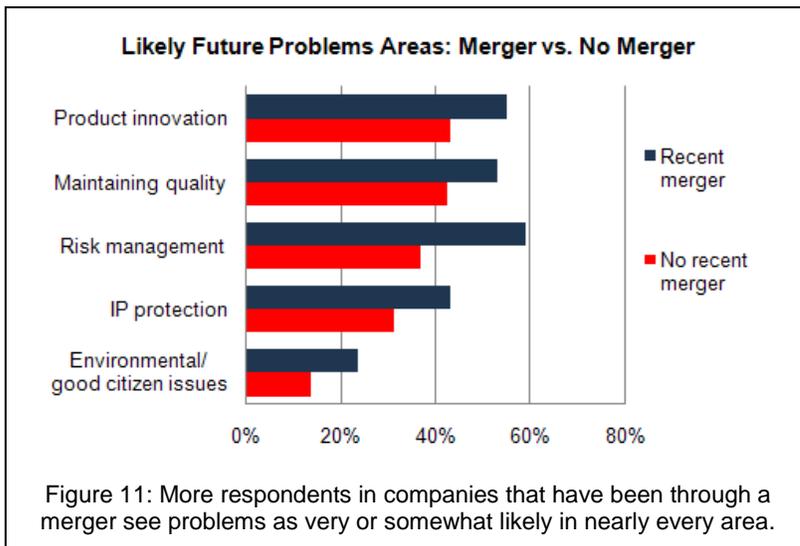
Figure 9: Companies that have not been through a merger or acquisition are much more likely to have five or fewer product families than those who have.

Mergers & Acquisitions

One of the ways that companies end up with many product lines is through acquisition. As Figure 9 shows, at least two-thirds of respondents who have been through an acquisition have more than five product lines. In contrast, two-thirds of those who have not been through an acquisition have five or fewer product lines.



About half of the respondents to this study have not been through an acquisition or merger that expanded their product line. Figure 10 shows that of the other half, more recent mergers within the past year or two are most common.



Companies use mergers and acquisitions as a strategy, along with product line expansions, to better serve customers with a more complete offering. They may also use acquisitions to get into faster-growing or higher margin businesses.

However, mergers also increase complexity, and thus the likelihood of problems and risk. In examining those who had been through a merger versus those who had not, a

“Globalization has a huge impact. A few years ago, it was headed toward harmonization. Now it’s spread out more again. That means you need more people to manage that, taking away resources from new product introduction (NPI).”

larger percentage of respondents from the merged companies perceive a high likelihood of problems in every area except regulatory compliance. A few examples of this difference are shown in Figure 11.

Companies in some other industries deal with complexity in products, speed-to-market and global markets by outsourcing operations. In this medical device response base, only a slight majority of respondents outsource some part of manufacturing (55%) and distribution (51%). Forty-seven percent outsource IT, and 37% outsource product engineering. No other function is outsourced by even one-third of respondents.



Views on Risks & Critical Investments

Risk vs. Profit or Risk Drives Profit

Risk management takes multiple forms. The most obvious view of risk management involves risk to the patients using the device, but the risk to the business itself is also a critical consideration. In theory, risk management for patient safety should also reduce the overall risk for the company and lead to a higher probability of profits. This is the foundation of the name of this report: *Risk Management: Best Practices for Medical Device Profitability*.

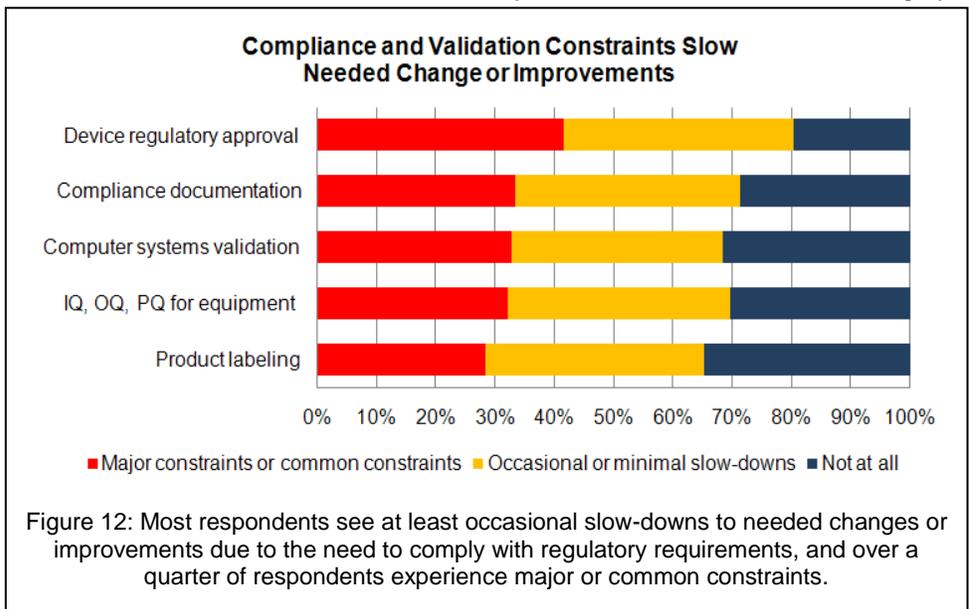
“Mitigating risk and containing costs should be what drives innovation. If it does not do that, it’s a mistake. Most companies increase risks and costs because they are not willing to make risks and costs constraints to designs.”

“We constantly have to educate regulators on what’s state of the art. They are not focused on manufacturers’ risk management. We see it as a practical, good science approach, but the FDA wants to just be the police. That makes it more important for us to document why we do and don’t do things – or they win the argument.”

As we formed the industry council to guide this research, one of the first considerations was selecting an appropriate title for the study. At that time, the proposed title was *Minimize Risk and Maximize Profit in Medical Devices*. One of the industry council members, Robert Dicheck, VP of Quality and Regulatory Affairs at Osmetech Molecular Diagnostics, pointed out that the title might be controversial. His view is that many regulatory professionals would see a conflict between risk and profit.

Unfortunately, many medical device companies find that regulatory compliance and validation processes constrain the business from making needed changes or improvements (Figure 12). In fact, many feel a threat from regulatory bodies under pressure to increase oversight. The continuous improvement approach driving many quality activities can be seen as in conflict with the validation of processes and systems that regulatory agencies require.

Of respondents who don’t see any impediment to improvement, some may have never worked outside a highly-regulated industry.



Others may have found a practical approach to making risk trade-offs.

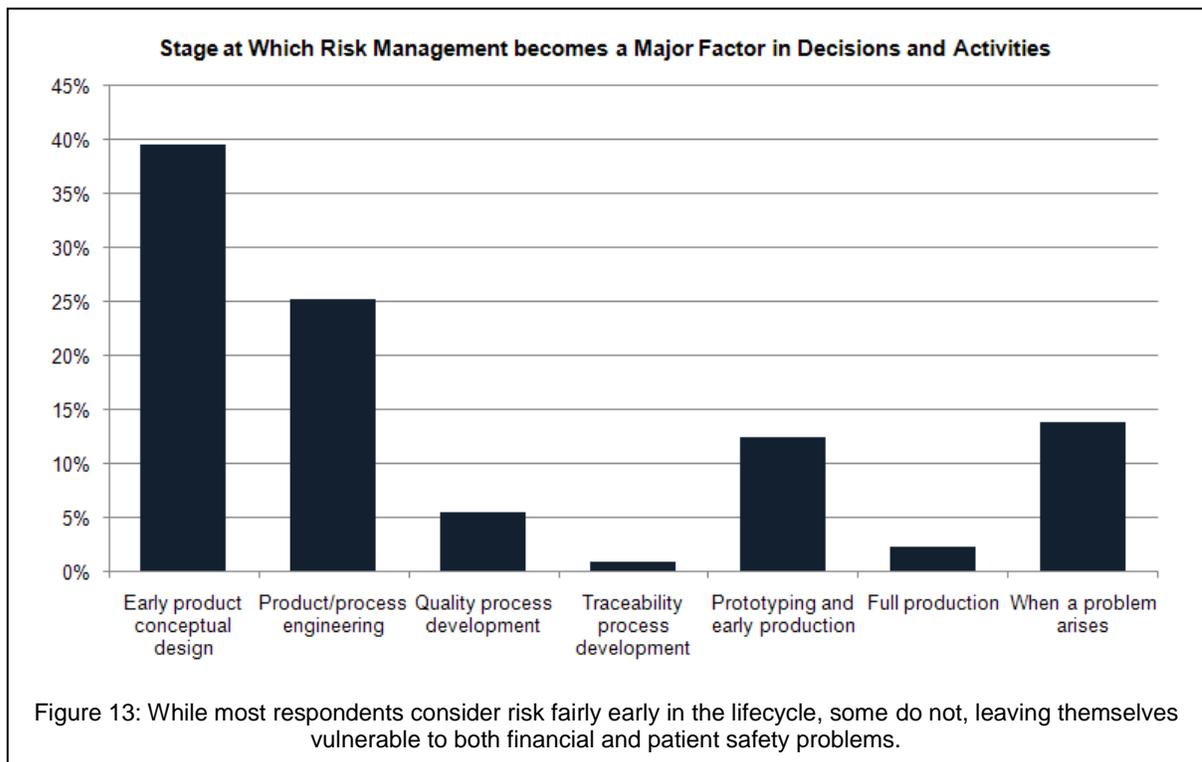
One example comes from Michael Checketts, VP of Technology at Technical Services for Electronics, Inc., a custom cable and interconnect solutions



manufacturer. "A good common sense factor is important. For example, we might partner with the customer to cut two weeks out of the prototyping process by making and testing only five instead of 30 samples. The cost and time factor will go down, but risk will go up. In some cases, that will be an acceptable risk and the customer will agree to the five. In others, it won't be. The fact that we understand their needs and are willing to offer alternatives is probably the biggest competitive edge that our company has."

Risk Management Processes

We asked respondents at what stage they believe risk factors heavily into decisions and activities in their companies. As hoped, most companies do consider risk early in the cycle during conceptual design and product/process engineering, as shown in Figure 13.



However, a sizeable portion still wait until later in the lifecycle. The most troubling are those who believe the company considers risk mainly after a problem arises. This approach can

"A good system for evaluating both [business and patient] risks involves getting a very thorough understanding of what the market needs. In short, being confident of what is safe and effective and what the market will buy. That sounds trivial, but few do it. It requires an extraordinary amount of voice of the customer (VOC) studies, quality function deployment (QFD) analysis, and prototypes. Combine that with a rapid development method and you mitigate risk to both patient and company."

truly hurt profitability as well as patient outcomes.

Risk management clearly involves formal processes of good governance to identify and quantify potential risks, the scale of their impact should they occur,



Strengths	Weaknesses
Consistent and aligned risk-based analysis for all areas with lifecycle approach	Isolated departments working with piecemeal software that does not foster teamwork
Constantly improve standards	Can't justify Six Sigma
Sound process & mindset at early concept phase to stop or push projects by analysis	Post-market surveillance does not feed prevention at concept stage
Root cause analysis & trending for re-occurrence	Incomplete FMEA focused on process, not on design
Sit on standards committees to stay in front of practices	Regulatory affairs views all change as risk
Clinician staff & QMS software for complaints	Design validation often compliant but inadequate

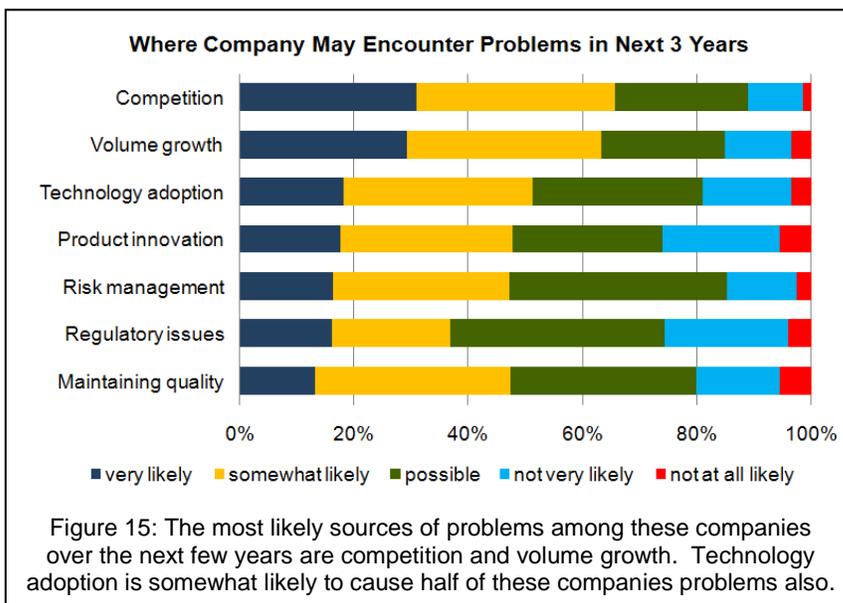
Figure 14: Areas of risk management strengths & weaknesses among telephone respondents indicate some issues to consider in evaluating the process.

and their likelihood. It also comes from the mindset and culture of the company. At some level, every process in every department can contribute to the risk level of the business. From this research data, it appears that one of the challenges most respondents have is getting the full picture and connecting all of the factors across products, departments, and facilities to truly have a strong picture of risk and mitigate both patient and business risk effectively.

“Risk management has formal and non-formal avenues,” according to Adam Prime, President of contract manufacturer Phase II Medical. *“Some controls we use are FMEAs*

at design, production, and where required, application; control plans; qualification and release of components; process validations; execution of in-process and final inspections during assembly and verify that CAPA are universally applied. On an informal level, communication is the single most effective tool we utilize. People need to understand the big picture.”

The industry leaders who participated in the telephone interviews report a range of strengths and weaknesses in their risk management approaches. Figure 14 shows some of those in a summary form. Consistency and alignment of risk management processes throughout the product lifecycle is one that clearly matters here. Having a mindset and processes that are risk oriented is less formal, but clearly also important.



High-Risk Areas

Most of the respondents to this study believe that competition and volume growth are areas where their company is very likely to encounter problems over the next few years (Figure 15). All of these potentially raise risk levels. Clearly, competition can drive a situation where a product becomes more of a commodity and price pressures increase. Competition can also



Adam Prime, President at Phase II, a contract manufacturer, remarked, *“As we grow we need to be innovative and expand capabilities, services, and capacity while maintaining the responsiveness of a small company.”*

introduce new technology that can render current products obsolete. Volume growth strains every aspect of a medical device company, making documentation and process requirements grow dramatically.

Technology adoption, product innovation, and risk management are also somewhat likely problem areas for many respondents. Based on these companies’ relatively limited use of technology today, the technology adoption issue is understandable (see subsequent section, Software Use and Value). Since product innovation is the

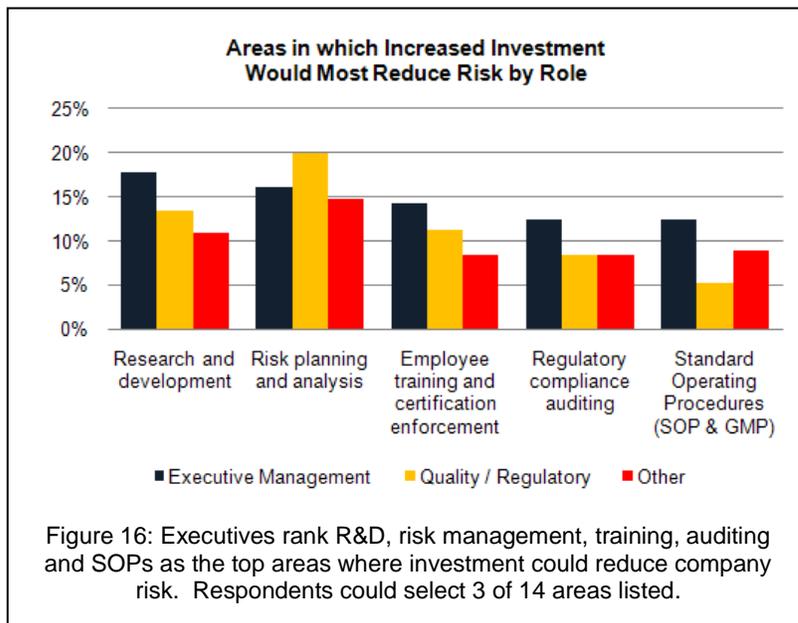
basis of competition for most of these companies, development missteps can be costly. Indications that these companies work in a somewhat disjointed manner raises the likelihood of challenges for risk management, regulatory, and quality issues. Even maintaining quality, which is an area most respondents do not believe is very likely to encounter problems, is somewhat likely to be an issue for nearly half of respondents.

Another area that came up in interviews with industry leaders is a concern about supplier quality, and particularly about the reliability of products sourced from the Far East. A major

“Many medical devices companies are looking to China as a great market to sell into and to manufacture in. However, we need reliable people and suppliers or it will create hard challenges.”

distributor who participated in a phone interview indicated that their system, which is thorough in general, did not adequately allow them to see original sources from China, despite high volumes coming from that country today. This raises not only risk to the patient from faulty products that cannot be easily traced and isolated for recall, but also corporate risk of losing control of the intellectual property that can lead to counterfeiting.

Areas for Investment



So where would the respondents make investments to mitigate their business risk? As Figure 16 shows, that depends in part on where the respondent sits in the company. Executives believe the number one area is in research and development. This is consistent with an innovation-based approach to competing in the market. In the total study population, which is heavily weighted to quality and regulatory professionals, risk



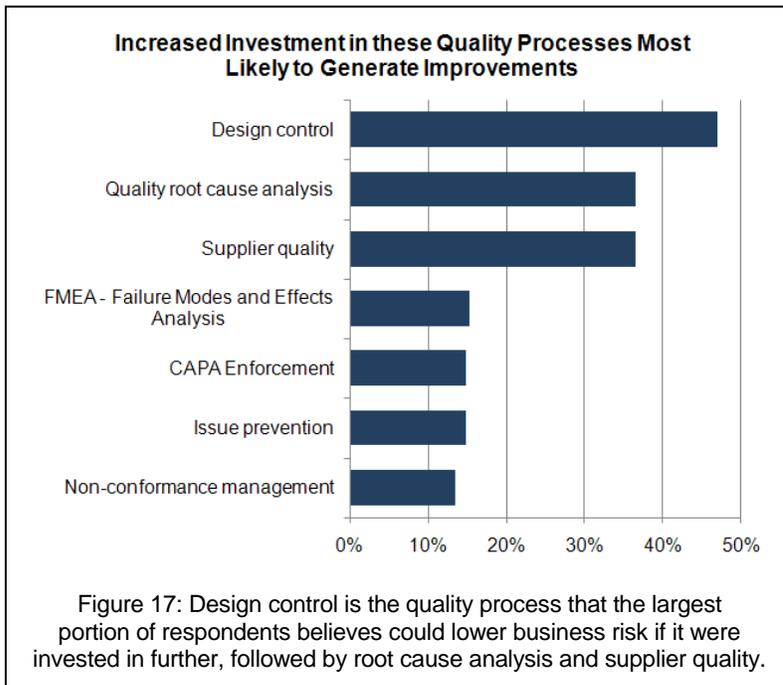
“We do trending of non-conformances to see recurrences. This becomes a KPI for the process.”

management and analysis ranks higher than R&D.

We suspect that some of the emphasis executives put on training and standard operating procedures (SOPs) is due to the fact that many corrective and preventive actions (CAPAs) are closed

through employee training and revising SOPs. However, the executives seem less concerned about investing in design transfers and new product introductions, which ranked 4th and 6th among the total response base.

The good news is that many respondents recognize that up-front planning, design, and similar efforts have a greater ability to reduce risk than activities that take place as a result of problems that have occurred. The lowest ranked areas for investment were medical device records (MDRs) for adverse events, recalls and return materials authorizations (RMAs).



Quality Process Investments

Respondents also indicated which specific quality processes might lower business risk through increased investment (see Figure 17). Here, design control is clearly a top issue for nearly half of the respondents. Other top-ranking processes where investment might reduce risk are root cause analysis and supplier quality.

A broader view and purview for quality are coming into play in some companies. On root cause analysis, the key is to measure results. So if the true

root cause is not discovered and a problem recurs, this company’s performance metrics should indicate that.

Given how interested the executives are in training and enforcing SOPs, it’s somewhat surprising that CAPA enforcement, issue prevention and non-conformance management do

“Often Quality moves in only as we’re moving into design controls. We are pushing Quality to be part of the process from early research and design.”

not rank higher. One possible explanation is that the quality and regulatory professionals making up the bulk of respondents will not have those areas under their control in organizations that suffer from the traditional “silos” where each department acts independently.



Correction & Prevention

One of the most important processes in our discussions with medical device industry leaders was CAPAs. While everyone recognizes their importance, it is also apparent that

CAPA: Big Stick or Engineering Carrot?

“All modern CAPA processes are similar to what you threaten little children with if they don’t behave. If you don’t solve that, I’ll open a CAPA!”

Another company has addressed that by tying continuous improvement (CI) and Six Sigma training to CAPAs.

“Every CI project is CAPA or PACA. This is one way that works for many people. Getting the training and solving a problem that is measured brings in more of the recognition – and less of the big stick.”

many companies’ approach to CAPA is either cumbersome or ineffective or both. A respondent from one of the most respected companies in medical devices reports *“We have a CAPA system that is so complex that it’s impossible to do correctly or effectively – and it’s not linked to FMEA, nor the process control system we have.”*

In many companies, the focus once a CAPA is open is on how quickly it is closed. More fruitful metrics might be whether there were

Michael Checketts, VP of Technology at Technical Services for Electronics, Inc., says, *“In our new product introduction (NPI), the process failure modes and effects analysis (PFMEA) process is alive and well. ... We are now introducing a newer more user friendly NPI process utilizing team development, so the engineers spend more time up front to help ensure that the tooling, molding and process de-bug all take less time.”*

recurrences or whether problems occur at a higher or lower rate than expected based on the risk analysis or FMEA.

“Most companies are not good at prevention, but only at hindsight,” according to one respondent. Another says, *“Cost pumped into prevention is often seen as a cost vs. something that saves money. Prevention had a mystique to it – but we are past that now. All of our quality processes help us fix problems before we go to the market.”* An important element of prevention is closing the loop between problem products and other products, including those in the concept and planning stages.

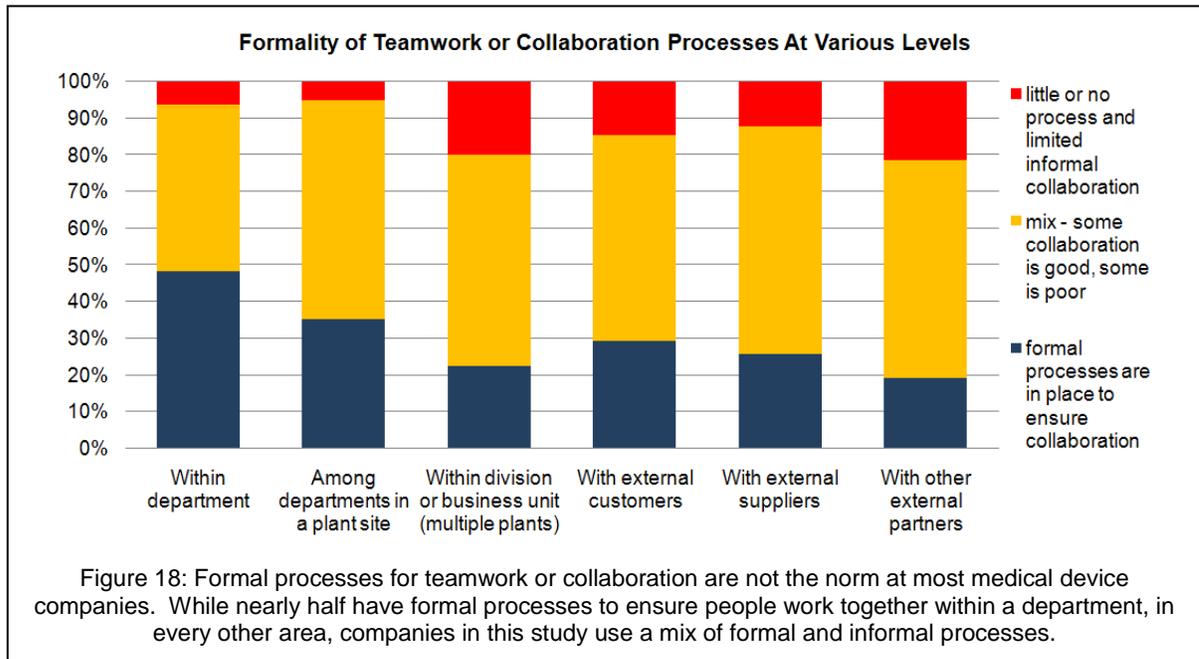
“Design review has quality assurance, manufacturing, clinical, marketing and design all involved and part of the sign-off. The multi-disciplinary approach helps us have constant communication.”

Collaboration and Information Exchange

Is the silo environment really the norm in medical device companies? Apparently it’s fairly common for groups to work either independently or if working across departmental borders, on a somewhat informal or ad hoc basis. As a result, most study respondents report that some processes are formalized and effective at fostering collaboration, while others are not. Not surprising, formal collaboration processes are only prevalent within individual departments (see Figure 18).

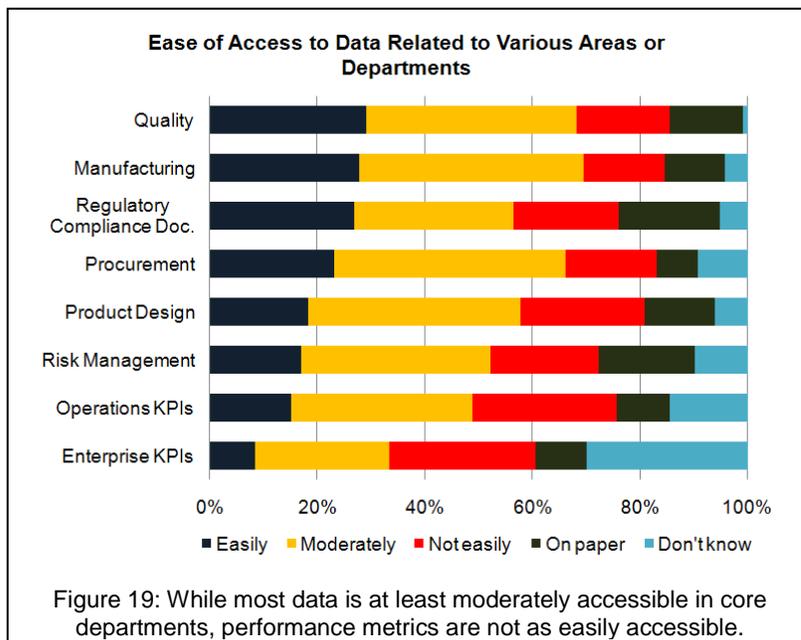
“We leverage complaints as feedback from the market. We take that information into improvement forums for each product. We give feedback to R&D – and we do such a good job that we don’t have recalls.”

While many companies are still learning to collaborate across facilities and between their company and its trading partners, the lack of formal collaboration processes between departments could lead to significantly increased risk overall. As one quality

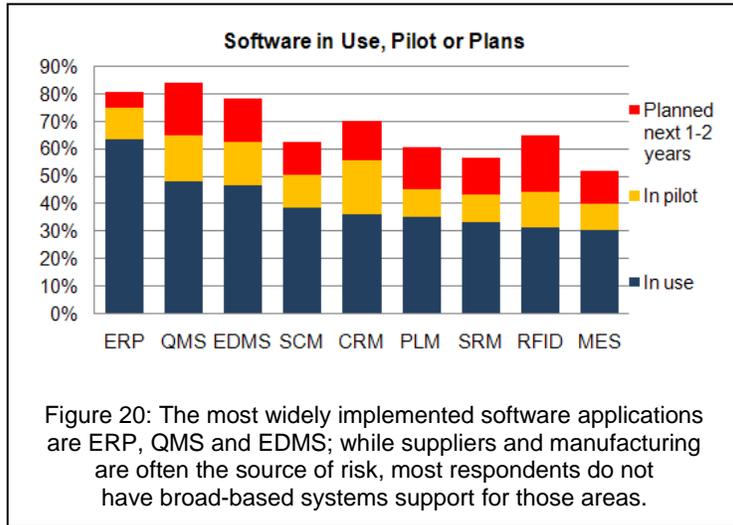


respondent reported, his experience in the electronics industry along with some others has led them to create multi-disciplinary product teams.

“In real estate, there are three most important things: location, location, location. In enforcement, those three are communications, communications, communications. You can’t over-communicate. If there is a problem on the back end of a project, and if the team does not communicate to the design engineers working on the next project, we’ll just re-live that same problem.”



Many respondents also indicate that information from various departments is not easily accessible. Even within quality and manufacturing, where information is typically at least moderately available, a quarter of respondents cannot easily access that data or it must be accessed on paper, as shown in Figure 19. Regulatory data and risk management data are stored on paper for 19% and 18% of these respondents, respectively. That opens up new levels of challenges and



risk in that the data may be incorrect and accessing data may slow down processes that depend on it. It also minimizes the opportunity for true preventive action, which is where profitability lies.

Software Use & Value

Applications in Use

Part of the challenge with collaboration and information access for many medical device companies

lies in the fact that they don't have commercial software systems implemented. Among the 14 software application types in the survey, enterprise resource planning (ERP) is the only one that over half of the respondents have implemented (Figure 20). Still, over one-third of respondents do not yet have ERP in production use.

Nearly half of respondents also have a quality management system (QMS) and/or an electronic document management system (EDMS) in production use. No other application is in use by more than 40% of respondents.

Many medical device companies see risks in their supply base, particularly as it becomes more global. However, supply chain management (SCM) and supplier relationship management (SRM) are not even in the plans for well over a third of respondents.

Similarly, the manufacturing environment is an area where executives believe investments in training and SOP enforcement could significantly reduce risk. Yet manufacturing execution systems (MES) are not in the plans for nearly half of respondents. In some other industries, such as semiconductor and electronics manufacturing, companies would never consider running manufacturing without an MES to automatically record data in context, guide the overall process flow, and help enforce good practices.

Having said that, many of today's MES and SRM systems are aimed at larger customers. Since nearly half of the respondents are from companies under \$100M in revenues, they may also have challenges finding applications that fit into their budget and IT capabilities.

"Another problem with risk management is that all the programs out there are piecemeal. ...There ought to be a single database for all your CAPAs, FMEAs, etc. However, today, CAPA is not connected to the risk documents, which are modified Excel spreadsheets."

Integration between Applications

To gain maximum value from software, companies will also integrate applications to facilitate information flow and ensure alignment. Among the sub-set of respondents that have two of the applications in use today, the only applications that are commonly

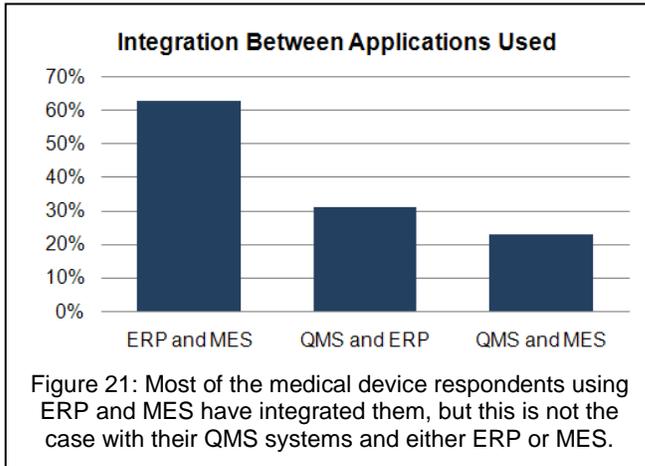


Figure 21: Most of the medical device respondents using ERP and MES have integrated them, but this is not the case with their QMS systems and either ERP or MES.

integrated are MES and ERP, as shown in Figure 21. This is likely because the MES relies on receiving orders from ERP, and because MES data adds valuable real-time data to improve ERP functions. QMS is not commonly integrated with ERP or with MES.

This standalone application situation is a problem many respondents would like to change. Integration of information between functions being so rare in medical devices makes risk management far more difficult. Since the foundation of risk-based decisions is to analyze all relevant information, having

“At best you need to use four or five interfaces to pull data from different places [for a recall]. This is very time consuming, and then we wait for multiple plants to get back to us with information from their legacy ERP systems. By the time we put it together, it takes weeks. Once a recall took us a few months.”

data both accessible and integrated across departments can be the critical difference-maker in companies’ ability to confidently determine root-cause of issues and minimize risks.

Benefits from Software

Those respondents using the applications listed for the most part feel these investments have generated improvements for them, even if they are not the main users of the system. Figure 22 shows that the largest portion of respondents using any of the selected software systems feel they have received benefits from that investment.

Some of the less widely implemented systems such as MES and product lifecycle management (PLM) are the most widely perceived as beneficial by those who have invested in them. These types of integrated systems that provide specialized support for either production information or product information can greatly reduce risk through their core functionality.

PLM is designed to foster multi-departmental teamwork during product conceptualization, design and design transfer, as well as acting as a common store for product information through the entire lifecycle. MES ensures that manufacturing operations are performed as specified, and provides early warning of quality or logistics issues.

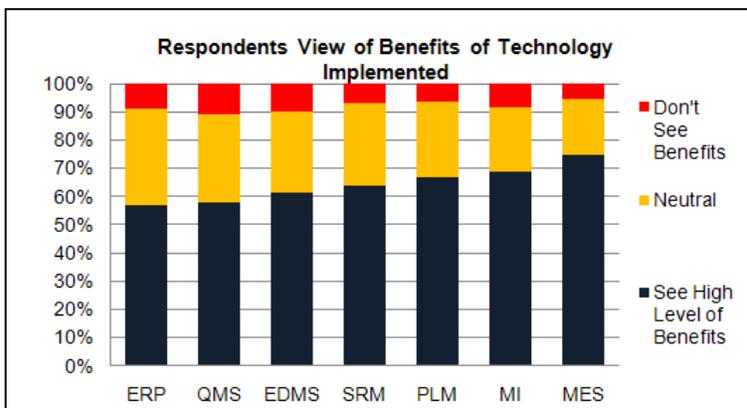


Figure 22: Most of the respondents agree with the statement “I have received a high level of benefit from the technology we have implemented.”

Given the high levels of software benefit and the low levels of



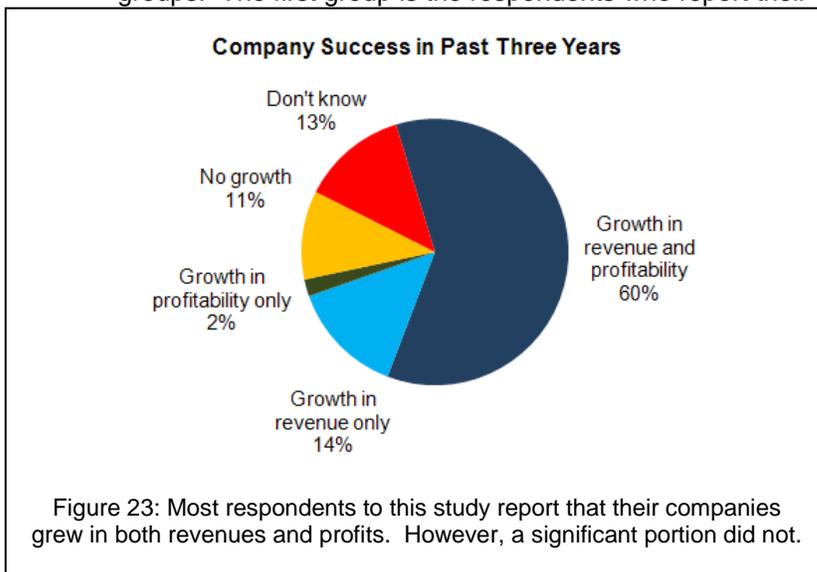
“We have a plant floor system that disallows incorrect processes. It provides error-proofing for the SOPs.”

software in production use at medical device companies today, those using software may be gaining a competitive advantage. As product proliferation and complexity continues, along with the plethora of regulatory requirements in various countries for those

selling globally, the explosion of information will become harder and harder to manage without software. Clearly, there is quite a bit of progress yet available to companies who have not yet implemented key types of software to support minimizing risk to both patients and the business.

Best Practices from Growth Companies

To ascertain some of the best practices, we divided the on-line response base into two groups. The first group is the respondents who report their companies have experienced



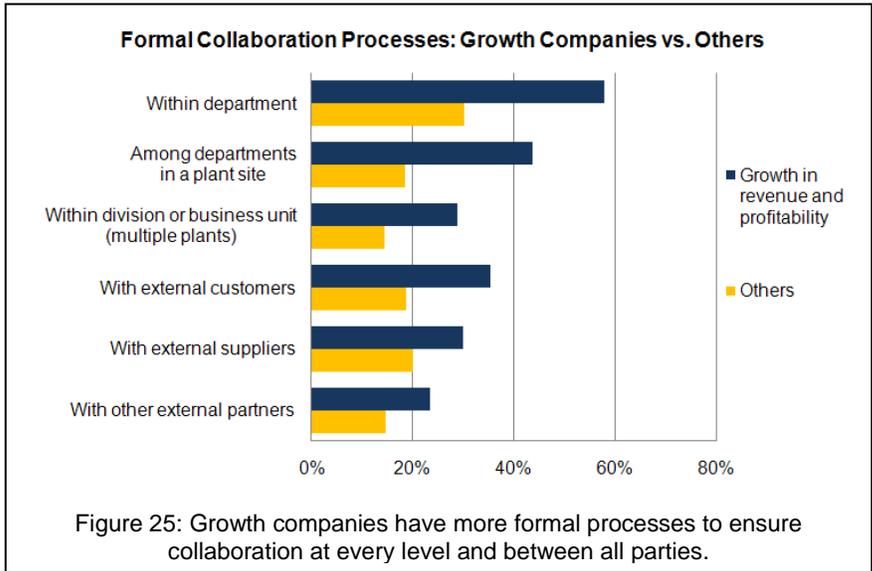
growth in both revenues and profits over the past three years. The others report one or the other, or no growth – or they don't know. As might be expected in the rapidly expanding medical device market, most of the companies did enjoy growth in both revenue and profitability, as shown in Figure 23.

In this section, the group of respondents who indicate that their companies have



grown in both revenues and profits are called growth companies. The remaining respondents are in the other category. Growth companies display some differences from the others, and we suspect some of these reflect best practices.

One of high-level areas where there are some significant differences is in the business



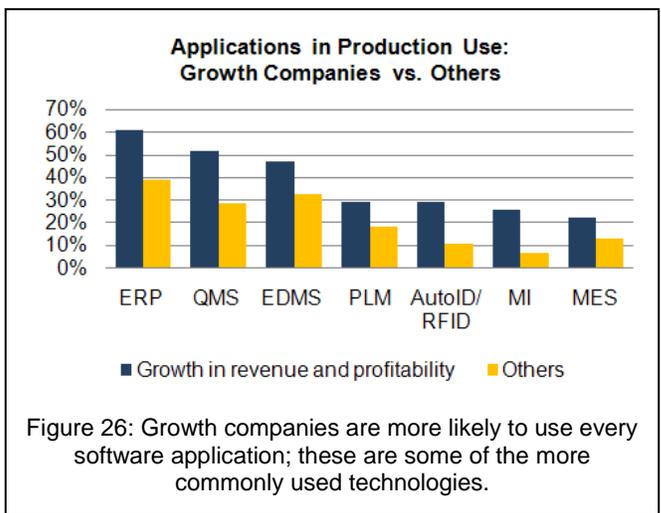
processes respondents consider key to their companies' market success. Figure 24 shows that the growth companies are more likely to be focused on the issues their customers notice – namely product quality, customer service, and flexibility. In fact, growth companies are much more likely to find that their primary basis of competition is either

brand and reputation or customer service and solutions.

The others are more likely to be focused on internal challenges such as regulatory approval and intellectual property (IP) protection. In areas such as product innovation, brand building and relationships with professionals, the two groups had a more similar view.

Growth companies are also far more likely to have formal processes to ensure teamwork. Figure 25 shows this dramatic difference between the growth companies and others. The growth companies are twice as likely to have processes that enforce collaboration across departments, sites, and with customers.

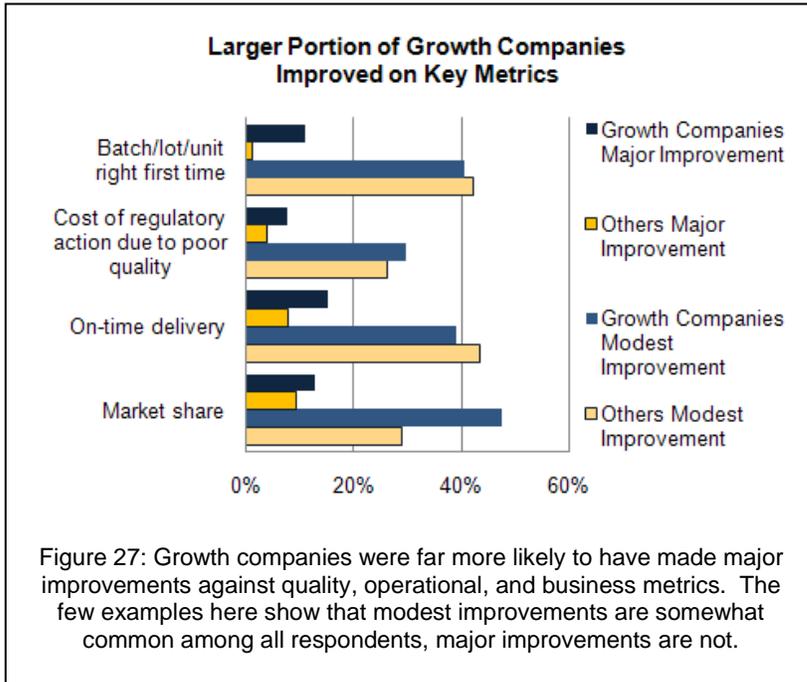
Not surprisingly, the growth companies accomplish these collaborative processes in part by using software. Growth companies use every category of software more commonly than their counterparts that have not experienced growth in both revenues and profits. Figure 26 shows just a selection of the software applications – this pattern holds true for every



software type we listed, and is particularly noticeable for newer applications such as governance, risk and compliance.

All respondents in this study tend to buy software to increase quality, reduce internal effort and cost, and adhere to regulations. However, the growth companies are more likely to buy software to gain speed to market, help control resource needs, and to manage their growth and increased volumes.

Not surprisingly, growth companies were far more likely to make major



improvements against a wide array of quality, operational, and business performance metrics as well. Figure 27 shows just a few examples. Notice that while both groups were likely to make some modest improvements across selected metrics, the growth companies were nearly twice as likely to make major improvements in on-time delivery as others. This once again reflects their customer-centric focus. The result is much more common gains in market share, to accompany growth in revenues and profits.

We expect that to continue to compete, a larger portion of medical device companies will need to begin learning the best practices that are more common in growth companies already. A focus on customers is what drives market success. In order to accomplish that, teamwork between departments, facilities, and trading partners is essential. These leaders have learned to use the technology that's available to support those processes.



Conclusions

Many medical device companies appear to lack the sophistication of practices and systems they need to succeed in a rapid-innovation global business. Efforts are somewhat disjointed, information may be hard to retrieve, and feedback is not always arriving where it's most needed – whether from sustaining engineers to concept engineers, quality to production, or manufacturing back to suppliers. If companies are achieving prevention, it's at a high cost through inefficient processes that don't make effective use of IT.

As growth continues and capacity is stretched for many companies, solving these problems will become more critical. With volume growth and competition as the top threats, companies can no longer continue to operate in an environment of disconnected departmental silos and inaccessible data. Innovation and acquisitions will continue to increase the variability of operations and the amount of information to analyze and manage.

Success comes to those who consistently employ thorough analysis, collaborative business practices, and up-to-date technology. This is the path to sustainable quality improvements. Leaders truly view quality as an all-encompassing process that starts with early concept

“Because we have no integrated system of anticipating difficulties that may or may not be problems, efforts are disjointed. We are good at prevention, but we're not cost-effective – and not as good as we could be.”

and is driven through every stage of the lifecycle of every product and variant. Risk analysis needs to be conducted at every stage and leveraged throughout the company and its supply chain. Risk analysis should also be connected to the corrective and preventive action process, and to performance measures. It's important to measure how effective CAPAs and other changes are, not just how quickly they can be implemented.

Risk management is a critical topic for medical device manufacturers, and the industry is moving to an understanding that lowering patient risk can also lower business risk. The trick is to move past a view that every change requires a cumbersome compliance process and on to the view that every issue or change must be viewed in a holistic manner. Some high risk areas need extra time and care to prevent problems; other low risk changes may need minimal regulatory documentation. New mindsets must also move from a major focus on the back end processes for MDRs, recalls, and even corrective actions to preventive action that begins in early concept stages through multi-disciplinary product teams.

Medical device companies have a nearly unmatched opportunity for growth and high profitability. However, this growth brings with it complexity and risk. Managing risk should mean lowering risk to both patients and the company. Growth companies got there by focusing on the customer, using sound practices, supporting processes with software, and understanding the true balance of risk management. These leaders will leave competitors who do not adopt modern practices and systems far behind.



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