Research Report

Walking the Global Tightrope:
Balancing the Risks and Rewards of Med-Tech Globalization
Balancing the Risks and Rewards of Med-Tech Globalization

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EXECUTIVE SUMMARY

The Medical Technology industry is experiencing a significant transformation. The globalization of design, sourcing, manufacturing, distribution and sales of Medical Technology (Med-Tech) has created opportunities and challenges for the entire Med-Tech ecosystem.

Globalization has increased demand for medical technology around the world. Today, emerging economies represent burgeoning marketplaces for the sale of Medical Devices. Nine out of 10 Industry Executives surveyed reported that they expect their business to grow in the next 3 years. Med-Tech Executives are also working to shift the Industry’s business model from selling products to providing integrated solutions that improve care and enhance population health.

While Brand Owners are poised to capitalize on these new opportunities, they need to balance the risks and rewards of Med-Tech globalization. The growth in the volume of global partners, facilities, suppliers, and regulations, as well as the increased variety and complexity of products across a large number of countries has Industry Executives on alert. The vast majority of Executives surveyed face a confidence crisis due to the lack of visibility and control over their global and outsourced operations. They are especially concerned about:

△ Complying with an increasingly complex regulatory environment
△ Ensuring the quality of products and raw materials across the globe
△ Maintaining consistent standards across an extended network of internal sites and external partners

Within this context, Industry Executives must navigate three primary macro trends:

△ Managing sustainable global growth
△ Complying with tightening global regulatory environments
△ Supporting changing healthcare delivery models globally

These opportunities and challenges call for new strategies for managing the life cycle of Med-Tech products in a global and networked environment; where Brand Owners increasingly rely on partners to perform functions traditionally done exclusively within the corporate four walls. Based on our research of current and emerging business, technology, and regulatory trends, coupled with our analysis of interactions with Industry Executives, Regulators, and other Stakeholders, we have cataloged our research findings into three broad categories. These represent important issues and concerns that should be taken into consideration when managing in the new “Normal” of a global and outsourced environment.

The categories are:

△ Holistic control over governance, risk management and compliance practices
△ Enhanced visibility across the Med-Tech extended partner network
△ Improved collaboration with all constituents in the ecosystem

We hope findings from this research study provide actionable advice to enable the Med-Tech Product ecosystem to capitalize on the benefits of Globalization while controlling or mitigating the risks.
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RESEARCH APPROACH:

This report is based on a survey of 125 individuals from 89 different companies from 16 countries. The research was guided by insight from a 12-member “Executive Advisory Council” comprised of leading Industry Executives. This Council played an advisory role throughout the research, data collection, and analysis phases of the project. We also deployed a web-based survey to gain a quantitative sample from Industry Executives across a range of products, organizational size, and geographies in the Medical Devices ecosystem. The analysis, charts, and figures presented in this report represent the data from the web-based survey respondents. In addition, we examined relevant literature on this topic and performed in-depth interviews with “Industry thought leaders” to validate, distill, and refine our analysis.

This study is co-sponsored by leading companies active in the Medical Technology sector. They are (in alphabetical order): Camstar Systems Inc. (www.camstar.com), iGATE (www.igate.com), and PwC (www.pwc.com). These companies supported this research to increase the understanding of processes and systems that enable global visibility and transparency across the Life Sciences value chain.

Axendia retained full editorial control during the execution, analysis, and compilation of this report.

ACKNOWLEDGEMENTS:

This research is the result of the insight and collaboration from many thought leaders. The research team for this project was led by Daniel R. Matlis and David J. Lennard of Axendia. The team wishes to thank the following Industry Executives for their contributions as members of the “Executive Advisory Council” for this research (in alphabetical order):

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- **Nino Pionati**
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BUSINESS OUTLOOK FOR MED-TECH COMPANIES IN THE GLOBAL MARKET

The Medical Device industry is experiencing a significant transformation. The globalization of design, sourcing, manufacturing, and distribution of medical device products has created unique opportunities and challenges for industry and regulators alike.

The Med-Tech Industry is poised to capitalize on new opportunities; however, it needs to balance the risks and rewards of globalization.

Executives are working to shift the Industry’s business model from selling products to providing integrated solutions that improve care and enhance population health.

Initially the primary driver for globalization and outsourcing was access to lower costs for labor and suppliers in emerging economies (supply drivers). Globalization has created increasing demand for medical technology around the world. The growth of an increasingly affluent middle class in emerging markets creates new opportunities for the Industry. Today, emerging economies represent burgeoning marketplaces for the sale of Medical Devices.

Within this context, Industry is navigating three primary macro trends:

△ The need to manage sustainable global growth:
  • Striking the proper balance between developed economies versus emerging markets
  • Addressing increasing labor and material costs
  • Working to minimize the impact of the US device tax
  • Navigating the macro economic impact of sovereign debt and investment

△ The tightening global regulatory environments:
  • Bringing medical devices to market takes longer and is more costly than ever before.
  • The focus on 510K reform has added uncertainty for Industry and investors.
  • Accessing innovative medical technologies has become more difficult
  • Complying with the Foreign Corrupt Practices Act (FCPA) can be challenging in a global environment.
    o What one government may consider a common place expediting fee could be construed as a bribe by another.

△ Supporting changing Healthcare delivery models globally:
  • Managing increasing price pressures and changing reimbursement strategies
  • Setting up systems to support competitive bidding
  • Defining comparative effectiveness and ROI analysis to support the provider, patient, and payer.

ACHIEVING SUSTAINABLE GLOBAL GROWTH

We asked “What trends does your company expect to see in the next three (3) years for the following for both developed and emerging economies?” Executives are extremely positive on the Industry’s growth over the next 3 years.

Over 90% of Executives reported they expect an increase in compounded annual growth rate (CAGR) in the next 3 years.
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When we asked about sales projection for both developed and emerging markets, we again see a bullish outlook.

Sales growth is expected to be very strong in both developed and emerging economies. However, the increased rate of growth in emerging markets makes dominance of the market by developed countries a lesser factor, not because of an expected drop in sales, but rather as a result of higher growth rates in emerging markets.

Manufacturing trends are also increasing in both developed and emerging economies. These trends are supported by sales projections. Manufacturing growth in emerging economies is very strong with only 2% of companies expecting a decrease.

72% of respondents are also anticipating increasing labor cost within these emerging economies as part of this growth.

CONTINUOUS INNOVATIONS

*It has been said that Innovation is the lifeblood of the Medical Device Industry.*

The key to success in a fast moving industry is the rapid development and introduction of new products that either improve existing technologies or address unmet needs.

Delivering improved Medical Technologies into the hands of patients, physicians, and other end users is a continual and complex process that begins with Research and Development (R&D).

**Our research findings support this paradigm.**

Industry Executives expect to see strong product R&D growth to support anticipated new product introductions in both developed and emerging markets. Respondents expect an increasing rate of New Product Introductions (NPI) to support continuous innovation as well as new market needs. Our survey respondents see highest product quality and most innovative technology as the primary strategies for both developed and emerging markets (see Business Trends Info-graphic next page). This data supports the need for increased R&D efforts.

The vast majority of respondents (88%) noted that they expect increased product sales in Emerging markets compared to 69% for Developed markets

Demand growth was led by strong increases in emerging markets. On the supply side, respondents reported that sourcing from developed economies is expected to be flat while sourcing from emerging economies shows positive growth.
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GLOBAL BUSINESS TRENDS

What trends does your company expect to see in the next three (3) years for the following?

- Sourcing in developed economies relatively flat with increases in emerging economies

- Manufacturing increasing in both developed and emerging with stronger growth in emerging economies

- Product R&D shows strong growth to support anticipated new product introductions in both developed and emerging markets

- These trends support the business strategy of a medical device platform to match product cost and functionality

*Based on our survey’s respondents data*
FOCUS ON EMERGING ECONOMIES

With strong economic growth facilitating a greatly expanding middle class in many emerging economies, Medical Device companies are looking at unprecedented growth in these markets. Virtually all companies surveyed are currently selling products or plan to sell in these markets.

The chart on the following page represents trends for the top 5 emerging economies according to our survey. They represent trends for planned sourcing, contract manufacturing, as well as internal manufacturing and joint ventures.
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Top 5 Emerging Economies for Sourcing, Contract Manufacturing & Internal Manufacturing / Joint Ventures

Data is from our survey respondents identifying where their companies plan to conduct business in the next three years.
WHY OUTSOURCE AND GLOBALIZE

Our survey data provides empirical evidence to support the typical top two reasons to justify outsourcing:
- Access to skills outside the company's core competency
- Reduced cost

However, when examining the rationale companies utilize when considering globalizing (establishing their own facilities in other countries) the reasons are inverted. When it comes to globalization, the following top reasons are cited as justification:
- Improve rates of innovation
- Support emerging markets with local products

It is interesting to note that both outsourcing and globalization are seen as viable approaches to improve speed to markets (53%, 57% respectively) as well as improve quality (56%, 54% respectively). Medical Technology companies are looking to participate in the global market for innovation, sales, and manufacturing. According to the survey, the top two reasons driving globalization are “supporting emerging markets with locally produced products” (64%) and “improving the rate of innovation” (63%). As one senior executive told us, many Medical Technology organizations are working to co-locate R&D capabilities close to manufacturing. This approach allows organizations to attract, develop, and retain key talent with the appropriate skill sets needed to support reduced time to market while improving product quality through the use of more consistent processes. Establishing local facilities can also ameliorate cross cultural differences as well as facilitate a thorough understanding of local requirements, business etiquette, and regulatory frameworks.

Some organizations are also building smaller plants locally (instead of global sourcing) to address trade barriers and tariffs.
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BUSINESS STRATEGY FOR GLOBAL MARKET PLACE

From our interviews with Advisory Council members and survey data, it is clear that providing the highest quality products and innovative technology will continue to be the primary strategies for most Medical Device companies in the global marketplace. Cost considerations play a more prominent role for companies selling in emerging markets. However, as one senior executive told us: “...competing on price alone is a race to the bottom.”

For both emerging and developed markets quality and innovative technology will remain the cornerstones of the vast majority of Med-Tech companies’ primary competitive strategy.

It is clear from our discussions with Industry Executives that today’s global Medical Technology companies are focusing on providing the “right feature set at the right price point for the right market.”

A deeper look at patterns for larger organizations (over $1B) reveals an interesting shift in priorities between developed and emerging markets. In developed markets, the focus continues to be on innovative technology coupled with quality. However, in emerging markets there is a marked shift to leverage quality as a competitive advantage, with cost climbing as the second closest competitive strategy.

Based on our interviews, most Med-Tech companies are pursuing a multi-tiered approach to address market needs. This may be accomplished through the introduction of a continuum of products ranging from a premium brand offering advanced functionality to a value brand with a reduced feature set at a lower price point. We refer to this strategy as a “platform approach” (See Sidebar Next Page).

When we asked: “What is your company’s priority for providing a medical device platform to meet multiple customer needs and cost constraints?” it is clear that developing a medical device platform is a high priority for Medical Technology in both developed and emerging markets (67% and 49% respectively). It is interesting to note that this level of interest is a significantly higher priority for developed markets.
Although this result may be counterintuitive, our conversations with Executive Advisor Council (EAC) members show that this correlates with significant cost pressures Medical Device organizations are facing in developed markets. In developed markets, healthcare spending takes up a large proportion of Gross Domestic Product (GDP) (9% to 16% of GDP). As a result, payers have placed a heavy emphasis in recent years on comparative effectiveness and outcome based payer reimbursement.

In emerging markets, by contrast, many of our Executive Advisor Council members report the use of a different approach to penetrating emerging markets. There is a wide diversity of needs and variety of delivery models in the emerging markets. These range from broad access to basic healthcare to highly sophisticated care for a narrow fraction of the population. This diversity calls for a distinct implementation of the platform approach to support the variety of features, functions, and cost structures.

Many Medical Device companies are initially targeting the “top of the Pyramid” as a strategy to enter emerging markets.

We refer to this strategy as a “platform approach” - taking a cue from the automotive industry. Auto makers have been utilizing a platform approach to build cars appealing to a different consumer and price point as well as regional models based on the same powertrain/platform.

Using this approach, Medical Device companies can offer a continuum of products based on a single platform designed to meet various healthcare delivery models, levels of sophistication, customer needs and market cost constraints. This platform approach allows companies to build on earlier successes with previous generation products and apply continuous improvement using their own device as a predicate.

This strategy focuses on offering sophisticated medical products to the growing and affluent middle class, who perceive "western" brands as possessing the most innovative technology and highest quality.

The growth of the middle class in emerging markets has the ability to pay for more sophisticated
healthcare out of pocket or through the use of private insurance plans.

To meet multiple customer needs, cost constraints, and the different requirements and cost structure of each segment of the market, Medical Device manufacturers are clearly pursuing this platform approach. Utilizing a Medical Device platform enables companies to offer the appropriate set of features and capabilities to meet the market needs and price points.

One senior executive told us that they enter some markets using this tiered approach with a full featured Premium product commanding higher pricing and a Secondary tier product - under a value brand.

These value brands would be based on the same “core product” and meet the same stringent safety and effectiveness profiles. However, they would be offered at a lower cost through the use of a platform approach as well as regionally sourced materials and components; manufactured and packaged locally.
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WHAT KEEPS YOU UP AT NIGHT

We asked Industry Executives: “Looking forward over the next three (3) years, what do you see as the biggest business threats?”

The changing regulatory environment is the top business threat (65%) cited by Industry Executives for both developed and emerging markets.

Based on our conversations with Executives in our Advisory Council, the concern centers on the increasing number of regulatory regimes Medical Device companies must address and comply with as a result of selling their products globally. The lack of regulatory harmonization was a key issue raised by Executives. Despite many initiatives by governments to “harmonize regulations” (e.g. Global Harmonization Task Force, International Medical Device Regulators’ Forum) the complexity of current regulatory frameworks represents an increasing burden on the Industry.

Also significant are concerns stemming from risks associated with geopolitical unrest and natural disasters due to single sourcing (43%). Recent world events such as the earthquake and tsunami in Japan, flooding in Thailand, and tensions in the Middle East, have heightened the awareness of these potential disasters.

When we asked: “What globalization and outsourcing issues keep you up at night? (Or you worry about the most?)”, the majority of respondents cited product quality and the ability to maintain consistent quality standards across internal and external sites as the top sources of insomnia.

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A deeper analysis of the data across functional areas of responsibility reveals an interesting pattern regarding sources of concerns relating to globalization and outsourcing. Executive management and R&D are primarily concerned with protecting intellectual property, while QA and Regulatory’s top issue relates to quality and Manufacturing’s focus is on-time delivery and cost.

1. Protecting your intellectual property
   - Quality of the product, raw material or service that is provided
   - Maintaining consistent quality standards across internal & external sites

2. Ability to deliver product, raw material or service as promised (on-time and on budget)
   - Changes without our approval
   - *Quality of the product, raw material or service that is provided

3. Maintaining consistent quality standards across internal & external sites
   - Ability to deliver product, raw material or service as promised (on-time and on budget)
   - *Inadequate visibility into in-process parametric quality information

4. Changes without our approval
   - Product theft, diversion or counterfeiting
   - *Outsourcing partners becoming competitors

5. *Tie

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HOW DOES COMPANY SIZE EFFECT THEIR VIEW ON GLOBALIZATION AND OUTSOURCING?

The following graphic provides a snapshot that compares and contrasts small vs. large company’s view of key globalization and outsourcing issues.
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REPORT TRENDS AND ANALYSIS

Based on the macro business trends, we have broadly characterized our findings into one of these three categories representing important issues or concerns that should be taken into consideration when managing in the new “Normal” of a global and outsourced environment.

Governance, Risk Management & Compliance cover a wide gamut of issues ranging from obtaining initial regulatory approvals to market the products to maintaining consistent quality standards across the value chain to ensure device safety and effectiveness. It also includes control over commercial, environmental, and fair labor practices.

Collaboration.....Knowledge work requires working effectively in groups (Internal and External) as peers with mutually shared accountability. Command and control approaches are virtually impossible in a global and outsourced environment.

Visibility.... Axendia defines “On-Demand-Visibility” as the ability to obtain relevant information about the product at the appropriate time to enable decisions with a high degree of confidence based on the analysis of contemporary data.
Managing a Medical Device business was tough enough when it was contained within four walls. When Med-Tech companies begin working with partners half a world away, that don’t share the same culture or language and in many cases have a completely different set of goals, the potential risk and opportunity for misunderstandings multiples. The following diagram looks at some of the elements that contribute to this risk but is meant to illustrate the complexity and the connectedness of the chain of factors that need to be managed effectively to not only produce a safe and effective Medical Device but to maintain a profitable business as well.
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GOVERNANCE, RISK MANAGEMENT & COMPLIANCE

Traditionally, Medical Device manufacturers relied significantly on the skill and experience of their employees to ensure that only the highest quality products reached consumers. This typically involved relying on “Tribal Knowledge” for developing and improving products, setting up, and fine tuning processes. A progression of “incoming”, “in-process”, and “finished goods” inspections was a key tool to remove defective products.

In the 1990s, Industry and Regulators began cooperating to change the paradigm for product development and manufacturing; shifting from “testing quality out” to “building quality in”. This collaboration resulted in initiatives such as Quality by Design (QbD), Total Product Lifecycle (TPLC), and more recently, Idea Development Exploration, Assessment, and Long-Term Study (IDEAL).

The thrust of these initiatives focused on gaining deep product and process understanding to ensure tight controls over critical-to-quality parameters. As a result, the product resulting from these well-characterized products and highly controlled processes would meet quality standards while minimizing the need for testing at the completion of each manufacturing operation. The new approaches enabled forward-thinking organizations to implement innovative strategies to speed innovation, improve quality, and lower costs while facilitating compliance to Regulatory requirements. This model has shifted with the proliferation of outsourcing.

As companies began to outsource they are experiencing a significant loss of visibility and control.

According to our survey, the primary reasons Medical Device organizations are pursuing outsourcing strategies are to gain access to skills outside the company’s core competency, reduce cost, and improve speed to market.

The increased complexities associated with global and outsourced realities have led to the significant decrease of control over many of the gains Industry has sought through initiatives such as QbD Initiative and TPLC.

The lack of control, along with the sluggishness of systems used to support Global Supply Chains, contributes to a high level of concern over outsourced products and processes. According to the research these trends are expected to grow.

In some cases, Industry has reverted to “testing quality out” approaches where incoming ingredients and components undergo incoming inspections. Gone is the visibility into critical-to-quality attributes tightly controlled during internal manufacturing.

Today, control over the Supply Chain extends well past ingredients and components coming though the Brand Owner’s receiving dock. Brand Owners are also faced with the necessity to maintain control over the product once it leaves their facilities. Counterfeiting, product diversion, and thefts are on the rise. Brand Owners need to deploy systems and technologies to provide visibility and control not only in the Supply Chain, but also in the entire Value Chain, from ingredients to the consumer.

Brand Owners are responsible for the safety, efficacy, and quality of their product in a court of law and the court of public opinion.

In a Risk-Based regulatory environment, lack of visibility translates to higher risk:

- Brand Owners cannot outsource liability, compliance nor safety
- If Brand Owner’s name is on the box, the Brand Owner responsible
- Brand Owners should address issues when they are a trend, not a recall
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The global and outsourced reality calls for a new approach to Governance, Risk Management & Compliance

GLOBAL REGULATORY REQUIREMENTS

Our respondents indicated that the U.S. FDA is still the leading regulatory body that companies comply with, followed by the European Union and other developed economies. The two leading regulatory bodies that remain as a benchmark are United States Food and Drug Administration (USFDA) and European Union Regulators.

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<th>Regulators We Comply With</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>U.S. FDA</td>
<td>89%</td>
</tr>
<tr>
<td>European Union</td>
<td>76%</td>
</tr>
<tr>
<td>Canada</td>
<td>63%</td>
</tr>
<tr>
<td>Australia</td>
<td>54%</td>
</tr>
<tr>
<td>Japan</td>
<td>47%</td>
</tr>
<tr>
<td>China SFDA</td>
<td>43%</td>
</tr>
<tr>
<td>India IMDRA</td>
<td>28%</td>
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A major change that companies are now facing in the expanding world markets is the need to comply with individual country’s regulatory bodies. In interviews with our Advisory Council, and reflected in our survey data, regulatory submissions and approvals are becoming one of the most challenging issues confronting companies moving into new markets. Regulatory cost and compliance is viewed as the number one business threat that companies will face over the next 3 years (66% of respondents). Virtually all functional segments see this as the number one issue.

We believe that this is an important area that companies will need to strengthen and address more proactively so that time getting into new markets is minimized.

When we asked “Where do you see your risk with regulatory compliance activities?” The number one reason (75% of respondents) said that “maintaining quality systems through the supply chain” was a significant to moderate concern. Six out of 10 executives said they are concerned about related regulatory issues and 59% are concerned about getting materials through ports of entry.

WHAT YOU DON’T KNOW CAN HURT

Do you want any changes without your prior knowledge? The fact is that almost no process ever runs without changes. Variability across many parameters contributes to the need for change. The challenge arises when changes are made without the Brand Owner’s prior knowledge. When we asked "In
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general, how often do your suppliers make “changes without your prior knowledge?”, our respondents indicated the following as areas where changes occurred most frequently.

<table>
<thead>
<tr>
<th>Changes without Prior Knowledge</th>
<th>Occasionally</th>
<th>Frequently</th>
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<tbody>
<tr>
<td>Process Changes</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Testing/Inspection Practices</td>
<td>59%</td>
<td>55%</td>
</tr>
<tr>
<td>Raw Materials</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Critical Components</td>
<td>37%</td>
<td>33%</td>
</tr>
<tr>
<td>Design Changes</td>
<td>2%</td>
<td>3%</td>
</tr>
</tbody>
</table>

All the above changes have the potential to impact device performance and therefore safety. For Brand Owners, our survey data provides a hierarchy of where additional controls and scrutiny might be needed in your systems.

Of some concern to our respondents are frequent changes without prior knowledge, with raw materials being the most frequent, occurring over 5%. While overall the numbers are low, any change could potentially affect how the product functions, its reliability, and safety.

Only 13% of respondents indicated they had current visibility to critical suppliers with real time data. 68% of respondents felt their perceived risk was high to moderate based on their current visibility into critical suppliers. Almost half would like to have on-demand data and 43% would like real time data.

When we asked “What function in your company do you believe should never be outsourced?” the top three were: Quality Assurance, Product R&D / Design, and Regulatory Affairs. We believe this is a direct reflection of the significant concerns raised by our respondents in many functional areas about maintaining quality throughout the supply chain.

<table>
<thead>
<tr>
<th>Functional Area that should not be Outsourced</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Quality Assurance</td>
<td>65%</td>
</tr>
<tr>
<td>Product R&amp;D / Design</td>
<td>51%</td>
</tr>
<tr>
<td>Regulatory (Submissions)</td>
<td>45%</td>
</tr>
<tr>
<td>Finance</td>
<td>26%</td>
</tr>
<tr>
<td>Marketing</td>
<td>21%</td>
</tr>
<tr>
<td>Sales</td>
<td>21%</td>
</tr>
<tr>
<td>Legal</td>
<td>18%</td>
</tr>
<tr>
<td>Auditing</td>
<td>14%</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>10%</td>
</tr>
<tr>
<td>Any function can be...</td>
<td>8%</td>
</tr>
<tr>
<td>IT</td>
<td>7%</td>
</tr>
</tbody>
</table>

These three functions generally serve as the company’s guardians of quality, safety, and compliance. To balance the needs of working with external partners in order to expand and increase innovation, companies should look for mechanisms that provide strong assurance that product quality is maintained through the products’ lifecycle and distribution chain. Real time data, on-demand data, and greater cross functional collaboration are ways to increase the level of quality and reduce risk as indicated by our survey data.

CONFIDENCE IN CRITICAL OUTSOURCING PARTNERS
Balancing the Risks and Rewards of Med-Tech Globalization

When we asked, "(On average) When dealing with critical outsourcing partners, how confident are you that they really understand their role and responsibilities in complying with applicable regulations, and requirements?" almost one in four Executives said they had low or no confidence in their critical suppliers in understanding regulations, and requirements.

To contrast, only 7% of companies report having complete confidence. It may be difficult to ever have complete confidence in a critical supplier; it should certainly be a goal that is strived for and systems set up to support increasing that confidence which translates into reduced risk.

While many companies report having low confidence in critical outsourcing partners, less than 1 in 5 are doing any comprehensive training to increase the level of confidence that their partner understands their role and responsibilities. Almost half the respondents report that they do no training whatsoever in helping a critical supplier understand their product, regulatory requirements, and most important, quality requirements.

VISIBILITY INTO YOUR GLOBAL OPERATION

Historically, the major drivers for visibility and analytics in the Life Science Industry has been processes understanding and control as well as post-facto crisis management and root-cause analysis to support Corrective and Preventive Actions (CAPAs), adverse events, recalls, etc.

The value of visibility was often measured by "how quickly can you get the data to fix the problem." Historical data, although valuable when "fixing problems", does not support the proactive and predictive approaches needed to support today's agile and fluid Life Science environments. In a global and complex supply chain environment, simply having post-facto visibility is not a viable option.

Medical Device companies strive to continuously improve their manufacturing processes by monitoring raw material, component, production, and other external data, to feed that information to close the loop on quality.

This global reality calls for the implementation of an "On-Demand-Visibility" approach across every stakeholder in the value chain.

LOW SUPPLIER VISIBILITY INCREASES RISK

The timely access to information is vital to the decision making process.
Balancing the Risks and Rewards of Med-Tech Globalization

Yet, the vast majority of Executives surveyed face a confidence crisis due to the lack of visibility into their supply chain.

We asked “What is your perception on the level of risk based on visibility to current information in your supply chain?”

Executives report high risk due to poor visibility into global and outsourced operations.

According to the survey, the vast majority of Executives expressed concern about the risk associated with their suppliers based on their lack of visibility into the supply chain. Respondents report that their highest perceived risks (73%) are associated with suppliers to their critical suppliers.

Nearly 3 out of 4 respondents rated their level of risk moderate to high based on their current level of visibility into Tier 2 suppliers to critical suppliers. As one Executive put it “we feel that the level of visibility goes down exponentially with every link in the supply chain.”

Even more of a concern is that the comfort level with "critical suppliers" is not much better, with a full 68% reporting their level of risk as moderate to high based on current levels of visibility.

This level of unease seems to be justified, given that more than half of the respondents report that their suppliers have made changes to raw materials, processes, and testing and inspection practices without their prior approval. Nearly 70% reported that suppliers have made process changes (frequently or occasionally) without their prior knowledge.

Based on the current lack of visibility, suppliers to critical suppliers represent the highest perceived risk.

When most organizations, including regulators, are shifting to a risk based approach to decision making and compliance, lack of visibility is a key barrier to its implementation. Limited visibility translates to greater risk.

To improve supplier management, and mitigate risk associated with complex supply chains, many organizations are working diligently to reduce their supplier base.

However, as one Executive commented, “the more rare/scarc/sole source a supplier is, the higher the level of visibility and control that are required from the Brand Owner.”

The Fog of Outsourcing

As a result of outsourcing, many Brand Owners have lost the ability to collect, analyze, and act on critical-to-quality indicators and parameters. Visibility into the Supply Chain is primarily based on “snapshots in
time” with little sharing of common practices and information. When we asked Industry Executives about the approach used to achieve visibility into external partners’ practices, "Periodic Audits" was the top tool response. Half of the respondents reported that they have little visibility into Tier 2 suppliers.

The challenge with audits is that they provide a snapshot in time. Companies perform an audit and often have little interaction with suppliers until they receive a shipment of product along with some form of a Quality Certificate or a Certificate of Analysis.

The lack of visibility is further illustrated by the Industry’s overwhelming interest in gaining access to relevant information across the value chain.

In every category, the vast majority of respondents report the need to improve their visibility of data from partners (real time or on-demand). Nine out of 10 respondents would like to achieve improved visibility from contract manufacturers, critical suppliers, and other Tier 1 suppliers.

Access to data from suppliers (real-time or on-demand) would provide Brand Owners the opportunity to improve quality while managing costs by enabling process optimization and adjustment of critical-to-quality in-process parameters within a design space.

Maintaining “On-Demand-Visibility” of upstream processes (whether internal or outsourced, local or global) allows downstream control strategies to take into account the actual characteristics of raw materials, sub-assemblies, and components to support TPLC, and Quality by Design (QbD) approaches.

By connecting the dots across the value chain, Brand Owners can attain on-demand-visibility to manage risks and improve quality while managing costs. Access to product data also plays a key role in reducing risk and supply disruption by enabling stakeholders to use business intelligence tools to gain value from data across the complete chain. It allows stakeholders to analyze data and begin “connecting the dots” to identify trends before they become problems. Lack of visibility leads to lost opportunities and increased costs. Increased visibility allows for a more complete picture—more accurately measuring risk associated with longer supply chains.

**IS TECHNOLOGY HINDERING VISIBILITY?**

The availability of interconnected systems should facilitate On-Demand-Visibility across the organization and ideally throughout the value chain. For example, in the event of a regulatory investigation the value of On-Demand-Visibility would be critical to demonstrate a state of control. It would also enable Brand Owners to have an early warning to identify trends before they evolve into non-conformances, CAPAs or recalls.
Balancing the Risks and Rewards of Med-Tech Globalization

Remarkably, “poor visibility” is not always due to a lack of technology systems. In fact, it can be due to the proliferation of ineffective systems. When asked “Which of the following systems does your company use to support global visibility?”

The lack of system integration across the global organization makes it difficult to attain the required level of visibility.

As expected, technology adoption is higher in larger organizations (over $1B); with 100% reporting that they use or plan to use ERP to support global visibility, 97% for QMS, and 88% for PLM.

However, less than 3 out of 10 Executives reported that their current IT systems are effective in helping gain visibility across internal and external locations for a global view.

The ineffectiveness of systems may be due to the way IT organizations in Medical Device companies manage and prioritize their IT portfolios. This is especially apparent for IT systems implemented in support of regulatory compliance mandates. In most organizations, technology sensitive and resource intensive projects are often tied to revenue generating activities or regulatory requirements. In the latter case, the success of the project is measured by its ability to meet the regulatory requirement. At that stage, it is not unusual for resources to be pulled before the full integration can be completed and the true value of the technology realized.

As a result, the majority of these large organizations still rely on paper and homegrown systems to achieve global visibility.

More than half report that they use QMS, ERP, and CRM to support global visibility. The challenge is that these systems are ineffective for this purpose.

The proliferation of these disconnected systems has actually created data islands. Our research shows that many of these stand-alone electronic point solutions proliferate the use of a variety of manual and paper processes needed to aggregate data to glean business information. All these individual solutions blur global visibility and create "the fog of outsourcing".

According to our survey, seven out of ten respondents report the use of homegrown systems (spreadsheet/DB/custom) and 63% report that they rely on paper system to support global visibility across their organizations.

Executives report high risk due to poor visibility into global and outsourced operations. Like driving in the...
Balancing the Risks and Rewards of Med-Tech Globalization

fog, low levels of visibility results in slow response, increased opportunity for poor decisions, errors, and potential accidents.

The ineffectiveness of current IT systems may blind decision making. The lack of visibility and ineffectiveness of systems is an issue across the range of company sizes, for larger and smaller companies alike.

When we asked, “Which of the following would help you improve managing in a global / outsourced environment?” We see the following:

<table>
<thead>
<tr>
<th>Improve Managing in Global Environment</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>On demand data from supplier and partners</td>
<td>61%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greater cross-functional team collaboration</td>
<td>61%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Better use of technology</td>
<td>57%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organizational structure changes to support...</td>
<td>37%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organizational culture changes to manage in...</td>
<td>35%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stronger support from Executive Management</td>
<td>33%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cloud based technology</td>
<td>21%</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Our results strongly support the mix of improved information and technology (in the blue bars) from global partners and greater collaboration (in the orange bars) achieved through cross functional participation, organization culture, and structure to support this new model of how companies operate effectively.

On-demand data and better use of technology supports the creation of a common framework that is required to achieve enhanced collaboration. This environment is no longer about just placing orders as a Med-Tech company. One Executive told us “If we make a decision strictly as a business and not a Medical Device business, then we are making a mistake.” Decisions need to be evaluated first for impact to human safety and then as they impact the business. The news is full of stories about companies that continually make this mistake and risk the trust consumers place on their brands. Often this is due to the fact that companies only evaluate and decide strictly on the business impact of the decision.

COLLABORATION

Effective collaboration remains the cornerstone of successful companies. When operations were contained within the corporate four walls, it was much easier to “direct” people to work together to accomplish goals and execute tasks. In a global and increasingly networked environment, the ability to “direct” a company associate 12,000 miles (19,000 kilometers) and 12 time zones away is virtually impossible.

Accountability is critical to success whether with a company employee on site or supplier half way around the world. If all constituents recognize the benefits of working together in a joint effort, then they can all achieve a greater commitment for their shared success.
Balancing the Risks and Rewards of Med-Tech Globalization

Inherent in being a Medical Device company is the trust and integrity that people expect from the Industry.

When asked, “(On average) When dealing with critical outsourcing partners, how confident are you that they really understand their role, and responsibilities in complying with applicable regulations, and requirements?” (See page 22) only 1/3 of respondents reported complete confidence or are mostly confident.

To further evaluate how Medical Technology companies are trying to increase that confidence level, we asked, “Do you provide training (about your products, regulatory requirements, quality requirements) to your critical suppliers?”

Almost 8 out of 10 Executives responded that they provide no training or basic GMP/Product training.

Only 22% of our respondents indicated that they provide comprehensive regulatory, product, and ethical/business training with their critical partners.

The comprehensive training represents a commitment to a shared understanding and accountability. If companies want a knowledgeable committed partner then it is this type of training that begins the process of true collaboration with shared goals.

When asked, “Do you feel your company has the right internal skill sets and structure to effectively manage in an outsourced environment?” 1 in 3 respondents responded that their company did not.

Companies whose primary business model is executed through outsourcing or global operations need to operate beyond traditional command and control organizational structures and need to think about roles and responsibilities that emphasize collaborative processes.

BENCHMARK: LEARN FROM SUCCESS

Our discussions with FDA officials confirm that the Agency clearly supports the need for benchmarking outside the Life Science industry.

According to Kim Trautman, FDA’s Medical Device International Quality Systems Expert:

“the Medical Device industry should look at some best practices followed by automotive, telecommunications, and aerospace sectors for risk management and supplier controls and adapt these for consistent, better quality results.”

We asked executives: “Has your company benchmarked any of the following industries in terms of outsourcing practices?” The vast majority of
respondents reported that they have not benchmarked outside of their own industry.

“Our sector can learn from these other industries, and it would likely provide quality and financial benefits that are worth exploring,” Trautman told us. She recommended the following practices:

1. Pay attention to internal suppliers: "a supplier is a supplier even if they are part of the same corporate structure, you still need soundproof terms of agreement under QSR."

2. Look at some best practices followed by automotive, telecommunications, and aerospace sectors for risk management and supplier controls and adapt these for consistent, better quality results.

3. Work with the FDA, which has a number of initiatives for managing global supply chain integrity and quality, and have the assurances in place to understand your suppliers, manage risk, and ensure a good quality product.

**IS OUTSOURCING REDUCING PROFITABILITY?**

Brand Owners often limit their outsourcing decision on unit cost (after auditing to ensure that quality requirements can be met). In fact, this approach can actually lead to reduced profitability and increased risk. Nearly two out of three executives surveyed rated their company’s performance or track record for evaluating the total cost of outsourcing as average, poor or very poor. Only 11% rated their track record as excellent.

Today’s audit-driven approach to visibility and control should be reevaluated to support the realities of globalization and outsourcing. Before evaluating outsourcing partners, Brand owners should develop thorough performance and product characterization for every aspect of their product, including process, equipment, raw materials, and packaging.

As an Executive told us, in some cases, “not enough work is done up front before outsourcing, and as the saying goes, there is never enough time to do it right, but there is always time to do it over. Companies should take into account the risk, cost of potential recalls, rework, travel expenses, etc. when calculating the total cost of outsourcing.”
Balancing the Risks and Rewards of Med-Tech Globalization

OUTSOURCE, OFFSHORE OR SMART-SOURCE?

Before outsourcing or offshoring a process or product, companies should consider “Smart-Sourcing” strategy. That is, looking at the total cost and implications of their decision, not just the initial per part cost.

Variables to be considered include:

- Labor costs
- Energy costs
- Cost of quality
- Reliability (built to last)
- Risk (regulatory, geopolitical, etc.)
- Travel expenses and time
- Shipping cost

As one Executive told us, “we are in the business of making Medical Devices, so "lowest cost" is usually not the best approach to evaluating suppliers. If you only look at cost, you may get a product that only meets the specification (spec).” The challenge is that suppliers often work diligently to meet the spec provided by the Brand Owner. However, without the benefit of “Tribal Knowledge” and experience the product spec is only one dimension.

“The product may look the same, and smell the same, but doesn’t perform the same.”

Adequate evaluation of suppliers and partners often requires a deep understanding of process and product. Brand Owners should encourage their supply network to collaborate on gaining understanding of:

- Critical-to-quality parameters
- Process capability
- Product characterization
- Sourcing strategy (multiple tiers suppliers)

These, along with improved visibility would support product and process control based on actual parametric attributes, rather than incoming inspection testing.

To support collaboration in a global and networked environment, Medical Device manufacturers should put into practice approaches to improve “On-Demand-Visibility” across their supply networks. This would enable them to shift from reactive to predictive approaches to support Governance, Risk Management, and Compliance initiatives.

Additionally they should implement technological, commercial, and legal frameworks that promote the exchange of information to enable the supplier and value networks to become an extension of the Brand Owner’s own quality and information systems.
EXECUTIVE SOUND BITES

Much of our research involved talking with Industry Executives about the impact of globalization and outsourcing on their organizations and the industry as a whole. Their perspective helped shape our research approach and survey questions. The following “sound bites” are intended to provide a small sampling of some these Executives’ experiences and insights. Although most in the Industry intuitively knows and understands these viewpoints, sometimes a single thought can help reconnect and reinforce them in a new and powerful way.

Observations from our Executive Advisory Council about Outsourcing and Globalization

“People focus on the honeymoon period of a vendor relationship, but forget it’s more like a marriage”
(Picking outsourcing partners)

“If we decide as a business and not a medical device business, then we make a mistake”
(Manufacturing a medical device)

“We think they understand but they don’t. We just get the polite nod”
(Dealing across cultures)

“If you want to spend less on labor, you must address high turnover and training issues upfront”
(Outsourcing labor costs)

“Cross cultural differences are a problem – We need to know what do they value”
(Dealing across cultures)

“Not enough work done up front before outsourcing”
(Picking outsourcing partner)

“Lots of bad guys who are always a trying to stay a step ahead of the good guys”
(Product counterfeiting, thief or diversion)

“Hidden costs tend to be ignored until an issue arises”
(Picking outsourcing partner)
CONCLUSION

The Med-Tech industry is experiencing a significant transformation as a result of the globalization of product design, sourcing, manufacturing, distribution, and sales. The new global reality has created opportunities and challenges for the entire Med-Tech ecosystem.

Globalization and outsourcing dynamics are driving the Med-Tech ecosystem to seek innovative approaches, which improve product safety, effectiveness, and quality for enhanced clinical outcomes. At the same time Industry is pursuing approaches to reduce costs and risks all while managing compliance with a growing number of global regulatory requirements.

While Brand Owners are poised to capitalize on these new opportunities, they need to balance the risks and rewards of Med-Tech globalization.

To attain the sustained benefits of globalization, Brand Owners should utilize consistent strategies which capitalize on the opportunities set forth by globalization and outsourcing while proactively reducing and controlling risks. This calls for changing the business, technology, and regulatory models traditionally used in the industry.

Med-Tech organizations should implement appropriate organizational structures, processes, and technology systems designed to address the confidence crisis they face due to the lack of visibility and control over their global and increasingly networked operations.

Industry Executives are especially concerned about compliance with an increasingly complex global regulatory structure. However, compliance should be the natural outcome of well-designed, executed, and documented processes, not a means in and of itself.

Med-Tech Executives are also concerned about the quality of products, raw materials across the globe and the challenge to maintain consistent standards across internal and external sites.

To support these initiatives, we recommend that Med-Tech companies implement solutions to address issues and concerns that should be taken into consideration when managing in this global and outsourced environment.

Brand Owners are responsible for the safety, effectiveness, and quality of their product in a court of law and the court of public opinion.

In a Risk-Based regulatory environment lack of visibility translates to higher risk⁹:

- ▲ Brand Owners cannot outsource Liability, Compliance or Safety
- ▲ If the Brand Owners name is on the box, the Brand Owner is responsible
- ▲ Brand Owners should address issues when they are a trend, not a recall

Control Over Governance, Risk Management, and Compliance Practices

Our research shows that the primary reasons Med-Tech companies seek outsourcing are access to skills outside the company’s core competency and reduced cost. On the other hand, the rationale companies utilize when establishing their own facilities in other countries are to improve rates of innovation and support emerging markets with local products. It is important to note that both outsourcing and globalization are seen as viable approaches to improve speed to markets as well as improving quality.
Balancing the Risks and Rewards of Med-Tech Globalization

The ability to maintain consistent quality standards across internal and external sites is a top source of insomnia for industry executives. Med-Tech organizations should focus on achieving product, process, and systems excellence rather than simply ensuring “compliance”.

To address these concerns, Brand Owners should implement commercial, legal, technical, and IT frameworks that support visibility and control across the ecosystem.

To this end we recommend that

- Consider a “Smart-Sourcing” strategy; evaluating the total cost and potential risks, not just initial cost.
- Implement commercial, legal, and technological frameworks that promote the exchange of information
- Enable partners to become an extension of the Brand Owner’s own quality and information systems
- Foster collaboration to support continuous improvement
- Define a clear change control and notification framework to avoid surprises
- Don’t focus on price alone, consider overall value
- Move beyond audits to On-Demand-Visibility

Enhanced visibility across the Med-Tech extended partner network

Executives report high risk due to poor visibility into global and outsourced operations. To address this issue, Med-Tech organizations should gain tighter control over their partner’s ecosystem, from ingredient to patent.

Brand Owners should deploy systems and technologies to provide visibility and control not only in the Supply Chain, but also in the entire Value Chain, from product design, sourcing, manufacturing, and distribution to the consumer.

Remarkably, “poor visibility” is not always due to a lack of technology systems. In fact, it can be due to the proliferation of ineffective systems. To enhanced visibility across the Med-Tech extended partner network, Brand Owners should:

- Employ risk-based supplier management strategies
- Require partners to document their complete supply network
- Integrate data islands and point solutions to aggregate data needed to glean business information.
- Implement global, standards based, and interoperable systems to support visibility outside the corporate four walls
- Collect, analyze, and act on critical-to-quality indicators and parameters.
- Implement IT solutions to achieve business results, not simply meet regulatory requirements.

Improve Collaboration with all constituents in the ecosystem

Effective collaboration remains the cornerstone of successful companies. In today’s global and outsourced environment, success requires collaboration. Med-Tech stakeholders should embrace this changing environment and embrace partnership, transparency, and harmonization initiatives. It means changing the relationships where interactions begin earlier in the process to support mutually beneficial outcomes. It also means engaging suppliers who are willing to share information about the product on-demand, to support efficiencies and effectiveness across the product lifecycle.
Balancing the Risks and Rewards of Med-Tech Globalization

To improve collaboration with all constituents in the ecosystem:

△ Strive for reduction of redundant costly audits
△ Define cross functional teams to support each initiative
△ Identify partners who share your approach and philosophy to quality and compliance
△ Educate your colleagues, employees, and partners on your standards, policies, and methodologies toward compliance.
   ○ Provide a clear understanding of the letter, spirit, and interpretation of regulation (compliance or beyond compliance)
   ○ Even if it is legal in their country, you may still be legally responsible in yours.
△ Create transparency and accountability to support product safety, effectiveness, and quality
△ Create and publish standard measurable incentives to drive collaboration, improved performance, and mitigate risks.
△ Create clear lines of communication to support transparency and continuous improvement.
△ Establish an honest dialogue with partners to enhance the value and impact of the relationship.
△ Collaborate on continuous improvement to drive lower costs through improved yields, fewer returns, and less rework.

The combination of these approaches will help Med-Tech Brand Owners to get past globalization growing pains and capitalize on the opportunities. To this end, we recommend that implementation of approaches that support the transition to holistic control over Governance, Risk Management, and Compliance practices; Enhanced Visibility across the Med-Tech partner network; and Improved Collaboration with all constituents in the ecosystem. This can improve the safety, effectiveness, and quality of products around the world regardless of where they are made.

We hope the findings from this research provide actionable advice that will enable the Med-Tech ecosystem to capitalize on the benefits.
Balancing the Risks and Rewards of Med-Tech Globalization

STUDY DEMOGRAPHICS

Our interviews and survey represents:

- 125 individual participants
- 12 Executive Advisory Council members
- Over 89 companies
- 16 countries

We had a very balanced mix of organizational responsibilities with almost 50% senior decision makers.

And a balanced cross section of company size and revenue

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Published June 2012

Endnotes

1 Medical technology encompasses a wide range of health care products and, in one form or another, is used to diagnose, monitor or treat every disease or condition that affects humans. These innovative technologies are improving the quality of health care delivered and patient outcomes through earlier diagnosis, less invasive treatment options and reductions in hospital stays and rehabilitation times. Source: Advamed http://www.advamed.org/MemberPortal/About/NewsRoom/MediaKits/whatismedtechnology.htm

2 Med-Tech ecosystem encompasses all Stakeholders, including Brand Owners, Regulators, Suppliers, Distributors, Contract Manufacturers, Healthcare providers and consumers.

3 Industry Executives: For ease of readability, we refer to respondents to the quantitative survey component of this research study as Industry Executives. Please refer to Study Demographics for a complete breakdown of research respondents.

4 Brand Owner is the company authorized to market the Medical product. Simply put: the company whose name appears on the product package.

5 Industry Executives: For ease of readability, we refer to respondents to the quantitative survey component of this research study as Industry Executives. Please refer to Study Demographics for a complete breakdown of research respondents.

6 Axendia Global Supply Chain Research - 2010

7 Axendia Global Supply Chain Research - 2010

8 Interview with Kim Trautman, FDA’s Medical Device International Quality Systems Expert; Medical Device Summit, http://youtu.be/-Hqe-axsx28

9 Axendia Global Supply Chain Research - 2010