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

Study Background

To assess the impact of globalization and outsourcing in the Medical Technology Industry, Axendia conducted a survey research of 125 Medical Technology Industry Executives'.

This Research Digest provides a summary of the project's comprehensive research report entitled, "Walking the Global Tightrope: Balancing the Risks and Rewards of Med-Tech Globalization."

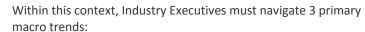
Findings and analysis in the report are based on input from 125 individuals representing 89 different companies across 16 countries. The research was guided by insight from a 12-member Executive Advisory Council.

Introduction

The globalization of design, sourcing, manufacturing, and sales of Medical Technology (Med-Tech) has created opportunities and challenges for the entire ecosystem. As Med-Tech Executives embrace this trend, they need to balance the risks and rewards of globalization. .

Med-Tech Industry Executives are also working to shift the Industry's business model from selling products to

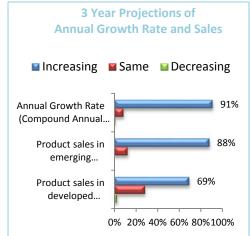
providing integrated solutions that improve care and enhance population health.



Δ Managing sustainable global growth

 \triangle Complying with tightening global regulatory environments Δ

Supporting changing healthcare delivery models globally



To mitigate globalization risks and attain its sustained benefits, Med-Tech companies will need to implement new strategies, processes, and technologies. These will allow them to proactively manage risk across 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.

Key Findings

According to our research, nine out of 10 Med-Tech Executives report that they expect their business to grow globally in the next 3 years.

While Industry Executives anticipate very strong sales growth globally, emerging economies represent burgeoning marketplaces with increased sales rates over developed markets.

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The top two reasons driving globalization are:

△ Supporting emerging markets with locally produced product (64%)

△ Improving the rate of innovation (63%)

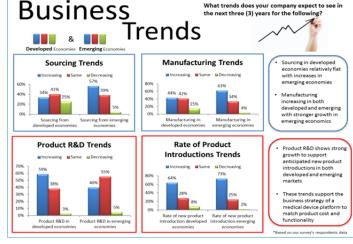


Brand Ownersⁱⁱ are poised to capitalize on these new opportunities, but they are also experiencing significant

globalization growing pains. 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 report high risk due to poor visibility and control over their global and outsourced operations.

Our research shows that the following globalization and outsourcing issues "keep Executives up at night:"

- △ The quality of products, raw materials or services provided (60%)
- △ The ability to maintain consistent quality standards across internal and external sites (59%)
- △ Protecting the company's intellectual property (49%)





Nearly 7 out of 10 executives rated their level of risk as moderate to high based on their current level of visibility into critical suppliers.

According to the research, Industry Executives are especially concerned about:

- △ The increasingly complexity and cost of compliance in a global regulatory environment
 - △ 65% see the global regulatory environment as the top business threat over the next 3 years
- The ability to ensure the quality of finished products and raw materials around the globe
 - △ 68% perceive moderate to high risk based on their current visibility into critical suppliers.
 - △ 90% would like access to real time data and on-demand data from Critical Suppliers, Contract Manufacturers, and other Tier 1 Suppliers
- The challenge of maintaining consistent standards across internal and external sites
 - △ 59% worry about maintaining consistent quality standards across internal & external sites
 - △ 68% perceive moderate to high risk based on their current visibility into critical suppliers.

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Conclusion

To attain the sustained benefits of globalization, Brand Owners should implement 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.

Governant

They include:

Holistic Control Over Governance, Risk Management and Compliance Practices

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.

Enhanced Visibility Across the Med-Tech Extended Partner Network

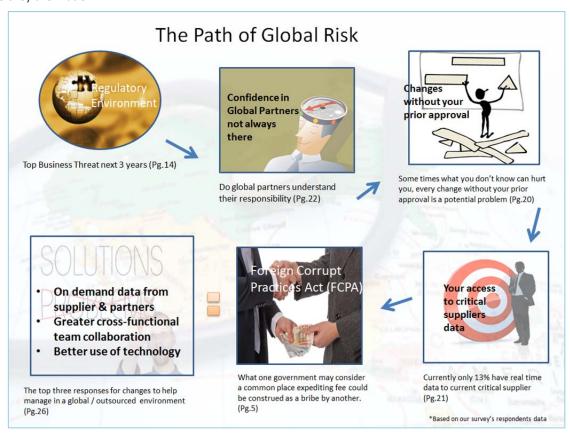
Executives report high risk due to poor visibility into global and outsourced operations. To address this issue, Med-Tech organizations should gain tighter control over their partner's ecosystem - from ingredient to patent.

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.

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 welcome 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.

The combination of these approaches will enable Med-Tech Brand Owners to get past globalization growing pains and capitalize on the opportunities. To this end, we recommend that implementation of approaches outlined in the research report. This can improve the safety, effectiveness, and quality of products around the world regardless of where they are made.



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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.

NOTE TO EDITORS

Detailed findings from this research study as well as charts and graphs of key findings, will be available for your use with proper attribution in a report entitled, "Walking the Global Tightrope: Balancing the Risks and Rewards of Med-Tech Globalization."

For additional information or to schedule an interview or briefing with the study's lead researchers, please contact Lisa George via email at Igeorge@axendia.com or by phone at +1 (267) 392-2009

To request a copy of this report, please visit www.axendia.com/Med-Tech-Report.html

About Axendia, Inc.

Axendia, Inc. is a leading analyst, and strategic advisory firm focused on the Life-Sciences, and Healthcare markets. We provide trusted advice to Industry Executives on Business, Regulatory, and Technology issues. Axendia professionals offer a unique combination of deep hands-on industry experience coupled with strategic vision. Axendia serves the complete ecosystem including Life-Science, and Healthcare Organizations, Technology & Service Providers, and the Investment community.

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i 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.

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