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# Product Compliance: Protecting the Value of Innovation

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*Business Value Research Series*

December 2005



## Executive Summary

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Corporate strategies today are focused on growth. More specifically, manufacturers today are focused on *profitable* growth, targeting increased revenue while keeping product costs in control. Many firms are achieving this goal by focusing on product innovation and product lifecycle management (PLM). Aberdeen's [Product Innovation Agenda Benchmark](#) study determined that improving product innovation, product development, and engineering allows manufacturers to increase product revenue by 19%, decrease product cost by 15%, and reduce product development cost by 16%. Growth and innovation are hot topics, and are getting a lot of attention in corporate boardrooms across the globe. The boardroom conversation is not complete, however, until risks are defined and discussed.

The value generated by product innovation is put at risk without regulatory compliance. This report further analyzes the results of two Aberdeen studies, [The Product Innovation Agenda](#) and [Design for Compliance Benchmark](#), to shed light on the benefits of innovation, the challenges that compliance presents, and the actions companies are taking to ensure compliance and protect sustainable product innovation value.

### Issue at Hand

While compliance is not nearly as engaging of a topic as growth, it is a critical part of a product innovation program. Recalls and significant noncompliance events can tarnish brands and impact corporate value. Smaller, less noticeable compliance problems eat away at profitability. The benefits of improved product innovation can be quickly overturned by compliance issues such as public perceptions of the manufacturer as unfriendly or irresponsible with regards to public safety. But often smaller, less noticeable impacts of noncompliance can greatly hamper time to market, product revenue, and product cost benefits tied to improved product innovation and product lifecycle management (PLM). These more subtle impacts are very hard to measure, and can erode profit margins throughout the product lifecycle.

### Key Business Value Findings

Compliance is strategic to protecting innovation value, and companies should include compliance objectives as a part of their product innovation strategies. Unfortunately, compliance frequently does not get its share of attention until there is a problem. Too many companies treat compliance as an afterthought or a checklist at the end of the process as opposed to a fundamental design requirement. According to Aberdeen's "[Design for Compliance Benchmark Report](#)" companies are not organized for success:

- Less than half of product companies have formal metrics, procedures, and systems for measuring and enforcing product compliance.
- Nearly 80% of companies lack a cohesive systems infrastructure to track, audit, or manage product compliance.



- Two-thirds of product companies lack insight into the regulatory, environmental, and operational rules that impact their products – let alone being positioned to measure and comply with these requirements.
- 75% of product firms have not audited product content within the past six months.

## Analysis and Implications

Companies that take best-in-class approaches to designing for product compliance are achieving tangible benefits. Aberdeen's [\*Design for Compliance Benchmark\*](#) indicates that leading companies are adopting organizational approaches that encourage compliance, measure compliance performance more frequently, and use appropriate enabling technologies to support designers in making the right compliance choices at the point of design.

Leading companies are also moving towards identifying and meeting compliance requirements early in the product design process. Companies that elevate the focus on compliance are achieving results:

- 27% product recall reduction
- 15% reduction in design failure rates.
- 31% improvement in the number of products in compliance.

## Recommendations for Action

- Include regulatory requirements early in the product design process to identify design constraints.
- Proactively monitor ongoing regulatory changes for existing products.
- Change the focus of compliance from a reactive process to a strategic program to help drive sustainable product profitability.
- Recognize compliance as a global issue and manage compliance for multiple jurisdictions and languages.
- Establish metrics (and incentives) to measure and promote product compliance.
- Reinforce compliance review checkpoints and procedures through product development, project management, and product lifecycle management systems.
- Enable compliance with a platform approach that can be applied to varied compliance needs using common approaches to data, process, and document management.

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## Chapter One: Issue at Hand

Aberdeen's [Product Innovation Agenda Benchmark](#) reported that improving product innovation, product development, and engineering performance can provide significant, bottom-line benefits to manufacturers. Manufacturers are implementing corporate strategies that place significant emphasis on increasing product revenue and decreasing product costs, with 82% and 47% (respectively), reporting these as very important to their corporate strategies. Firms improving product innovation are achieving these benefits (Table 1), resulting in profitable growth for their shareholders.

**Table 1: Benefits of Improved Product Innovation**

Benefit	Average Improvement
Increase Product Revenue	19%
Decrease Product Cost	15%
Decrease Product Development Cost	16%

Source: [AberdeenGroup](#), September 2005

Those benefits result from better operational performance such as improved time-to-market, increased product development success rate, and increased product quality. They also result from actions companies pursued to foster innovation from organizational, process, and technology perspectives. These improvements can be significantly reduced or even reversed, however, if companies fail to comply with regulatory requirements.

The impact of noncompliance may come in the form of major fines, negative publicity, or legal actions that catch attention at the corporate level. More frequently, however, non-compliance comes in the form of smaller, less noticeable impacts. These issues can appear throughout the product lifecycle, and can cause delays and added costs that add up to big impacts. They often don't draw a lot of attention, however, because each individual occurrence might be minor. The following examples are representative of these types of issues:

- Products can't be sold in target geographic locations
- Late redesign for compliance impacts product performance
- Product changes required for compliance increase product cost
- Product launches are delayed to meet unforeseen regulatory requirements
- High recycling costs must be held as corporate liability
- Product requires special labeling for certain markets



Addressing these noncompliance issues late in the design cycle or after product launch can greatly hamper time to market, product revenue, and product cost benefits tied to improved product innovation and product lifecycle management (PLM). These smaller impacts are very hard to measure, but can erode profit margins throughout the product lifecycle. Some typical values that companies seek in product innovation can be greatly hampered by noncompliance, as seen in Table 2, below:

**Table 2: Noncompliance Impact on Innovation Value**

PLM / Innovation Value	Potential Impact of Noncompliance
Improved Time to Market	Product Introduction Delays
	Design Rework for Compliance
	Delayed Rollout to Geographies
Reduced Product Cost	Last Minute Design Changes
	Need to De-Optimize Designs
	Fines and Penalties
	Unforeseen Supply Chain Costs
	Manufacturing Process Changes
Reduced Development Cost	Unidentified Pollution and Exposure Control
	Design Rework
	Manual Creation of Documentation
	Manual Effort to Catch Flaws
Increased Value of Product Portfolio	Limited Markets for Products
	Product Value Discounted for Risk
	Company Value Discounted for Risk
	Negative Public Perception
	Criminal Prosecution
Improved Innovation	Company Not Seen as a “Green” Company
	Last Minute Design Constraints
	Product Delays or Cancellations
Increased Success Rate of New Product Development Projects	Missed Window of Opportunity
	Products Not Valid for Geographies
	Product Registration and Limitation
	Unforeseen Pollution Control Issues
Increased Product Quality	Product Performance Reduction from Changes
	Impact of Late Changes on Product Quality

Source: [Tech-Clarity](#), 2004



These risks to product innovation and PLM value may be the reason that more companies are beginning to place greater emphasis on product compliance. Another driver for companies to focus on compliance is an increasingly complex and changing compliance landscape. According to Aberdeen's *Design for Compliance Benchmark*, more than 70% of companies cite new environmental, industry, and regulatory mandates as chief drivers for their increased emphasis on product compliance. Over the past two years, manufacturers have faced an increasing array of new environmental mandates from jurisdiction such as the European Union, Japan, and some US states including California and Connecticut.

Regulatory requirements are frequently industry and geographically specific. As companies are selling into more global markets, the challenge has increased because there are multiple, overlapping requirements. Without going into detail on any particular compliance issue, it is important to understand that compliance comes in multiple forms, including regulatory compliance, environmental compliance, and operational compliance. It is also important to consider that not all requirements come from outside of the enterprise, as many companies wish to enforce corporate standards as well. Some sample compliance issues that companies face today are found in Table 3, below:

**Table 3: Representative Compliance Requirements**

Compliance Type	Compliance Requirement
Regulatory	ITAR: Defense Trade Controls: International Traffic in Arms Regulations (22 CFR 120-130)
	ANSI/ ASTM/ ISO/ UCC / OSHA standards
	Transportation Recall Enhancement, Accountability, and Documentation Act (TREAD)
	Sarbanes – Oxley
	FDA/ USDA regulations
Environmental	Restrictions on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive
	End of Life Vehicle (ELV)
Operational	Green Design (internal)
	Part Reuse Strategy

Source: [AberdeenGroup](#), December 2005

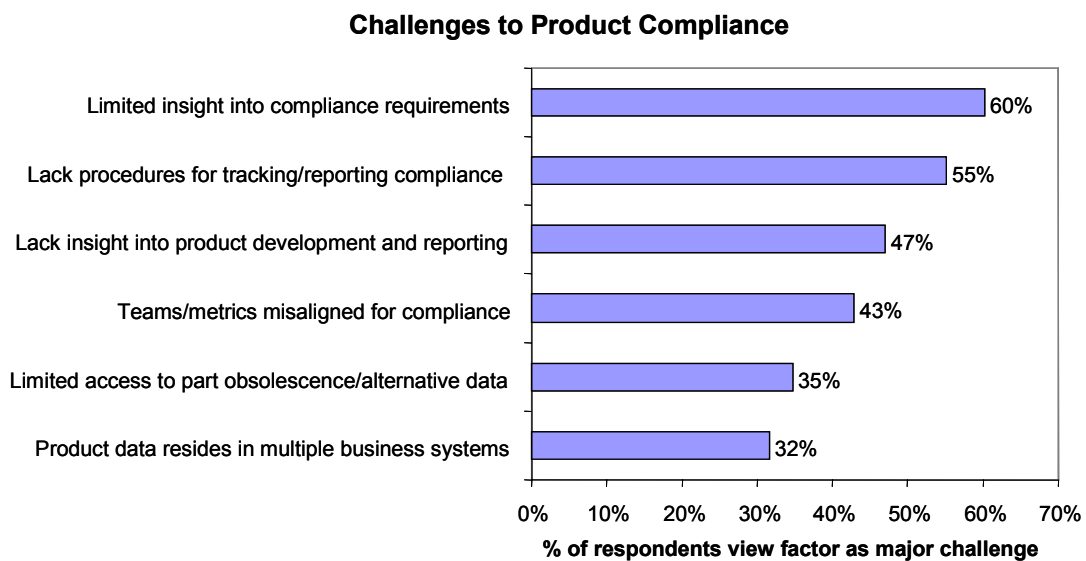
Regardless of the type or source of the compliance requirement, companies are facing pressure to comply from multiple angles. To protect innovation value, companies must reduce the risk before critical, and potentially public, problems occur. Maybe just as importantly, companies need to address compliance to prevent the smaller noncompliance events that hamper profitability and growth.



## Chapter Two: Key Business Value Findings

Meeting compliance requirements to protect innovation value is difficult. Aberdeen’s *Design for Compliance Benchmark* indicates that companies do not have the required infrastructure to address compliance in a holistic way, either from an organizational or a technical perspective (Figure 1). The major issues identified fall into two major classifications; visibility and accountability.

**Figure 1: Most Firms Lack Insight, Procedures, and Metrics for Compliance**



Source: AberdeenGroup, November 2004

### Visibility

Good decisions can not be made without access to the right information. Improving compliance performance is not possible unless the requirements are well defined and made visible to engineers and others on the product development team. Two-thirds of product companies, however, lack insight into the regulatory, environmental, and operational rules that impact their products – let alone the position to measure and comply with these requirements. Almost one-half of departments responsible for compliance have little or no visibility into product development. Even if requirements were known, over one-third of companies don’t have access to obsolescence/alternative data, making it difficult for designers to readily find solutions to meet compliance targets. Given the lack of visibility between compliance and product design, it should be no surprise that many companies miss compliance targets.

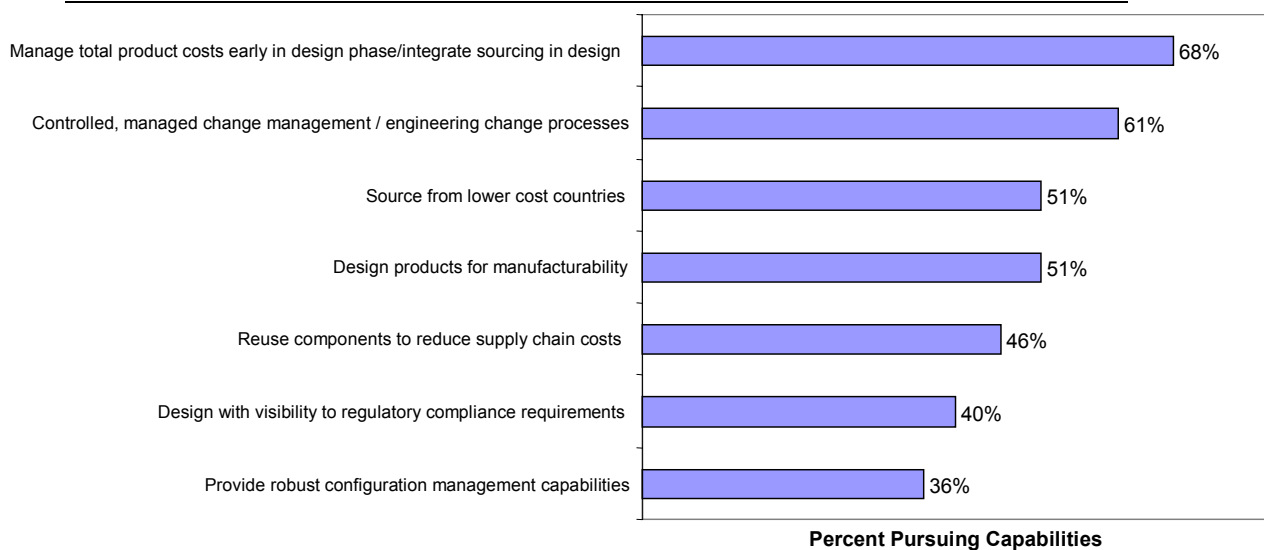
## Accountability

In addition to lack of visibility, the other classification of issues identified related to accountability. Over one-half of companies lack formal procedures for tracking and reporting on compliance. The same is true for performance measurement, where over one-half of companies lack formal metrics. Key performance indicators are not tracked consistently across product lines and divisions, and frequently not measured consistently. With misaligned organizational structures and a lack of formal compliance performance measurements, improving product compliance and protecting the value of innovation stands little chance.

## Design for Compliance

There was some positive news reported in the [Product Innovation Agenda Benchmark](#). Forty percent of manufacturers indicate that they are pursuing the ability to design with visibility to regulatory compliance requirements (Figure 2). This action is being taken in efforts to reduce product costs, recognizing that issues found in early design phases can be addressed much more effectively, and with significantly less cost.

**Figure 2: Product Innovation Capabilities That Reduce Product Cost**



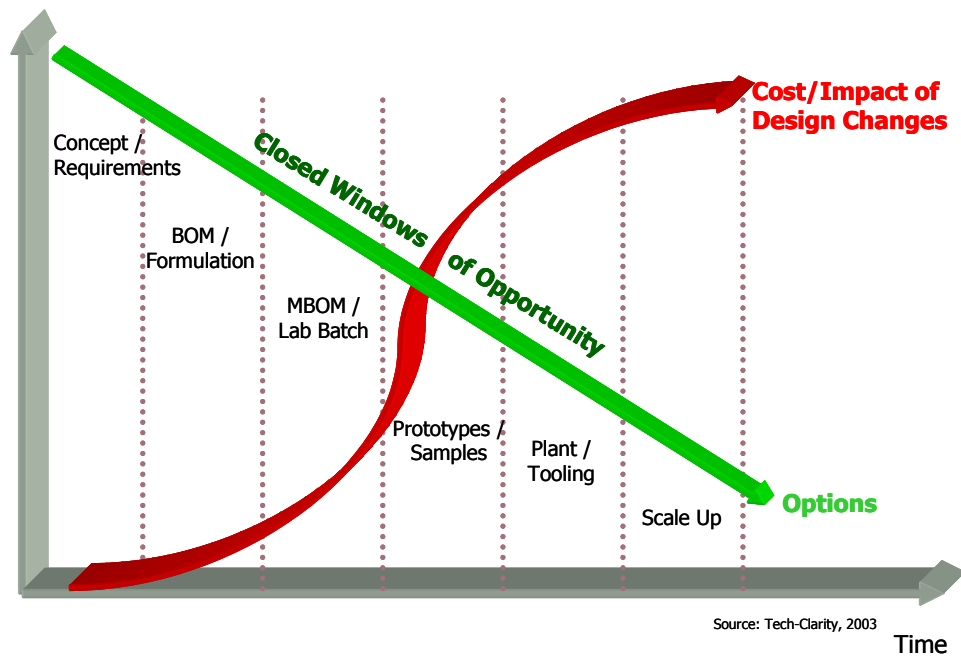
Source: [AberdeenGroup](#), September 2005

If compliance is not designed into the product from the beginning, decisions are made that will cost the manufacturer time, additional development cost, higher products costs, and missed product revenue targets. As time passes and more decisions are made, the impact of change increases significantly. As illustrated by Figure 3 below, the cost of addressing noncompliance increases through the life of the product. As purchasing, equipment, and tooling decisions are made, the windows of opportunity close and the choices to correct become fewer, less appealing, and more costly. Late redesigns are often not only costly, but impact the performance of the product as a whole as product



changes are made that can sub-optimize the overall product effectiveness. The time to act is before non-compliant materials, formulas, content, or labeling are locked down.

**Figure 3: Cost/Impact of Design Changes over Time**



Source: Tech-Clarity, 2003

The critical importance of the design and development function in product compliance is evidenced by the fact that more than 80% of manufacturers surveyed in the [Design for Compliance Benchmark](#) identified these functions as the most integral to driving product compliance. While catching noncompliance in design stages is ideal, regulatory issues can come up at any stage of the product lifecycle. Regulations change, enforcement policies shift, products are introduced to new geographies, or customers may use the product in new ways. As these changes occur, compliance requirements might change. Continued compliance requires proactively monitoring products and product designs.

### Documenting Compliance

Frequently, it is not enough to just follow the rules. For the most part, compliance must be proven by documentation and reporting. Compliance audits that focus on the compliance process itself (as opposed to the end results) require a sure handle on current product designs and configurations. Audits are more likely to focus on product compliance documentation, making records management critical. Even corporate compliance issues such as Sarbanes-Oxley depend highly on documentation. There are regulatory requirements for records management as well, including DoD 5015.2-STD, "Design Criteria Standard for Electronic Records Management Software Applications" and FDA 21 CFR Part 11 for electronic signatures. These standards are beginning to create standards of



compliance themselves, making ready search and retrieval of documented compliance information more critical. Emergence of standards such as COBIT (Control Objectives for Information and related Technology), whose fourth addition was issued by the IT Governance Institute, is becoming internationally accepted as good practice for control over information, IT, and related risks.

Beyond compliance information, base product information must be under control and readily searchable. As compliance requirements change, assessing the subsequent impact of the change can be a significant challenge. Frequently, such as with RoHS regulations, the manufacturer needs to understand more than just the identity of the parts and components used, but their composition. Ideally, visibility and documentation of product contents can be manipulated to develop summary reporting at a product, product line, or enterprise level. For this information to be trusted, of course, it must not only be captured but it must be accurate. Proven change management and periodic data audits can help to ensure that what is reflected in the systems is really what is happening in the plants.



## Chapter Three: Implications and Analysis

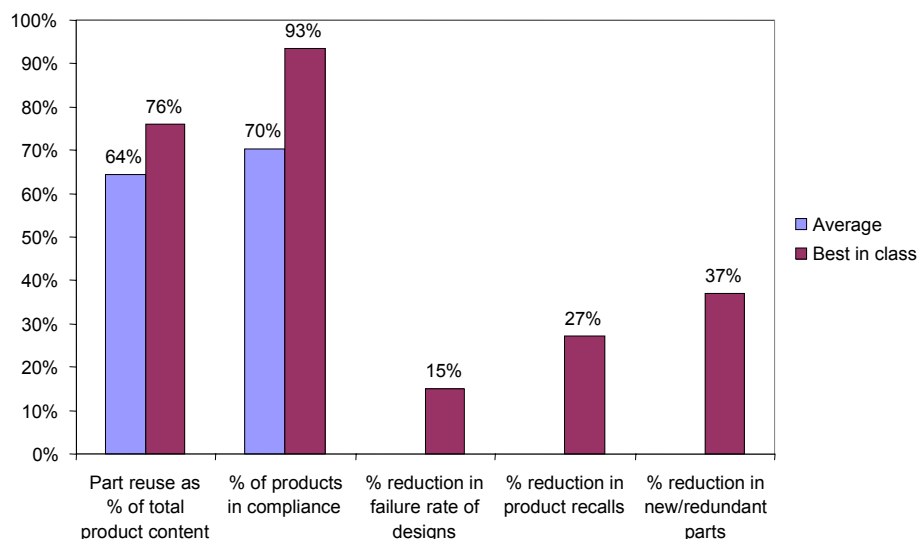
**A**berdeen research shows that companies that take best-in-class approaches to designing for product compliance are achieving tangible benefits. Companies with a proactive approach to compliance issues are adopting organizational approaches that encourage compliance, measuring compliance performance more frequently, and using appropriate enabling technologies to support designers in making the right compliance choices at the point of design.

These approaches are paying off. Companies that elevate the focus on compliance are achieving results (Figure 4):

- 27% product recall reduction.
- 15% reduction in design failure rates.
- 31% improvement in the number of products in compliance

These operational improvements remove the barriers that prevent companies from achieving profitable growth. Addressing compliance early and in a structured approach enables product lifecycle values such as improved time to market to help achieve revenue goals, and decreased product cost to improve product margins. Innovation value is not achievable – nor sustainable – without compliance.

**Figure 4: Focus on Compliance Yields Big Returns**

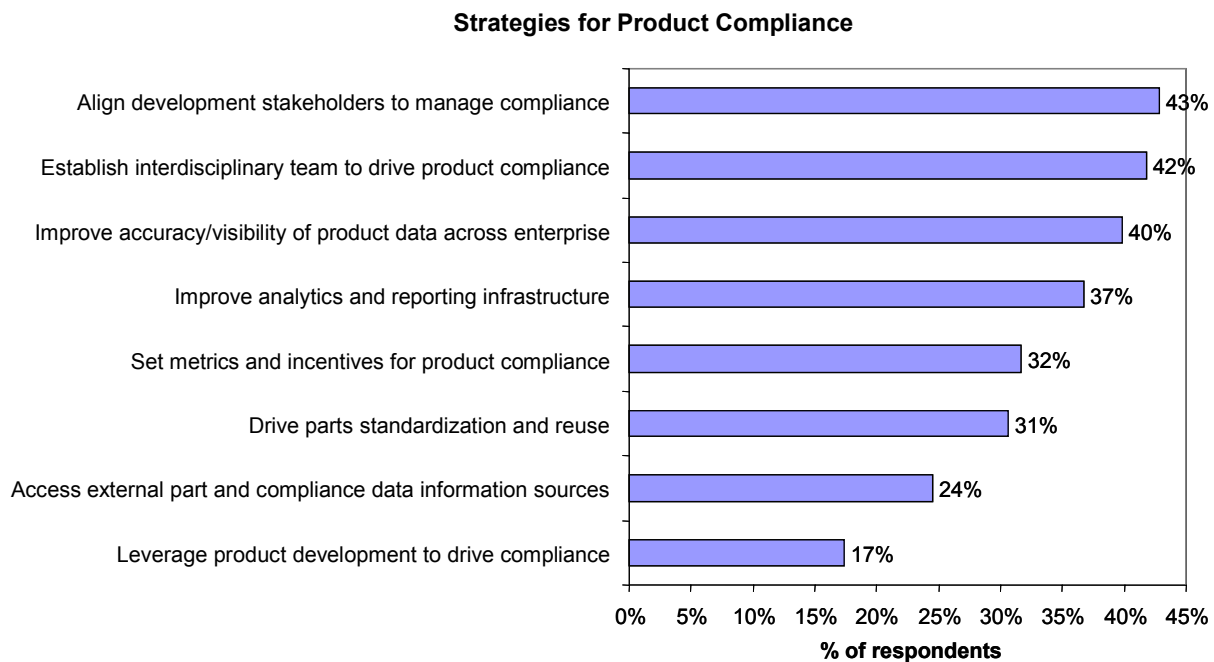


Source: AberdeenGroup, November 2004



With mounting requirements and rising expectations for compliance, companies need to respond. Best-in-class companies, according to Aberdeen's [Design for Compliance Benchmark](#), have developed approaches to improve compliance performance across the product lifecycle. Compliance is not just a systems issue, although enabling technology can help. The top two approaches that companies are adopting to improve compliance, in fact, are aligning stakeholders and developing interdisciplinary teams to focus on compliance (Figure 5). Without proper alignment of resources and stakeholders, improving processes and implementing enabling technology would provide little value. The next highest tactic that survey respondents are pursuing is improving the accuracy and visibility of product data across the enterprise. Without a solid grasp of product content and configurations readily available, product compliance can be limited to new products, at best. Aberdeen research discovered that best-in-class companies take a balanced approach that addresses both the organization and infrastructure need for compliance.

**Figure 5: Process Alignment, Product Data Management among Top Tactics**



Source: [AberdeenGroup](#), November 2004

## Organization

Best-in-class companies are aligning organizational structures to promote compliance. Aberdeen research indicates that only a third of companies have a formal compliance management role in the product development process. Best-in-class companies, however, have a formal compliance organization aligned with product development and product management organizations. Integration and coordination of product development and compliance resources leads to strong compliance performance.



## Metrics

- Surprisingly, 40% of manufacturers lack any type of formal metrics for measuring and ensuring product compliance. For those companies that do measure key performance indicators (KPI) for compliance, few measure compliance consistently at a divisional level, let alone the enterprise level. Best-in-class companies, on the contrary, measure product compliance on a monthly or real-time basis. Over 90% of these top performers have established formal metrics to drive product compliance. These leaders are much more likely to have standard metrics and measures for product compliance on a company-wide basis, and often extended to external design and supply partners.

## Process

- Best-in-class companies have adopted compliance processes, incorporating product compliance checks, audits, and reporting into product development procedures and systems. Leading companies have taken the approach of addressing compliance in the design phase, and then ensuring continued compliance throughout the product lifecycle as regulations, standards, and products change. Best-in-class firms have adopted, integrated, and aligned product development, data management, and project management activities and information systems to perform automated compliance checks against new designs and existing product designs.

## Technology

Nearly 80% of companies lack a cohesive systems infrastructure to track, audit, or manage product compliance. Best-in-class companies, on the contrary, have product data, designs, schematics and project data managed on a common and integrated platform across the enterprise. Common data and processes allow companies to develop a compliance platform, allowing them to address various compliance needs in a standardized, managed process. By automating the compliance process on common data, ongoing compliance can be monitored and maintained. Without common data, simply understanding the impact of a regulatory change on existing products can be a large, manual effort.

- In addition to improving product data management and developing a compliance infrastructure, companies must have visibility to new and changing compliance requirements. Best-in-class companies maintain a repository of regulatory, environmental, and operational compliance requirements, often relying on external information services firms to maintain currency. By contrast, average and lagging firms maintain compliance requirements in fragmented systems, if at all.



## Chapter Four: Recommendations for Action

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Companies must place the right level of emphasis on compliance, or risk building product portfolios on unstable foundations. Profitable growth that is achieved at the expense of compliance is not sustainable, and is an approach that carries significant business risk. Companies must remain proactive by adopting organizational approaches to elevate the visibility to compliance issues, adopting processes that encourage compliance to be designed into the product at a fundamental level, and enabling designers with technology to assist in design decisions early in the lifecycle to prevent profit degradation from late compliance retrofits.

To improve product compliance performance and reduce the compliance risk in product portfolios, manufacturers should:

- Include regulatory requirements early in the product design process to identify design constraints.
- Proactively monitor ongoing regulatory changes for existing products.
- Change the focus of compliance from a reactive process to a strategic program to help drive sustainable product profitability.
- Recognize compliance as a global issue and manage compliance for multiple jurisdictions and languages.
- Establish metrics (and incentives) to measure and promote product compliance.
- Reinforce compliance review checkpoints and procedures through product development, project management, and product lifecycle management systems.
- Enable compliance with a platform approach that can be applied to varied compliance needs using common approaches to data, process, and document management.



## Author Profile

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**Jim Brown**  
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Jim Brown leads Aberdeen Group's Global Product Innovation and Engineering research. Its goal is to provide fact-based research and experienced analysis that advises executives on how to achieve maximum product profitability and corporate value by using the right approaches and enabling technology to identify, specify, engineer, develop, and continuously improve innovative, high-value products.

Jim founded research and consulting firm Tech-Clarity, acquired by Aberdeen in May 2005. Tech-Clarity focused on making the value of PLM and enterprise software solutions clear to manufacturing business leaders. Jim began his professional experience with roles in manufacturing engineering and software systems at General Electric before joining Andersen Consulting (Accenture), where he focused on enterprise software applications. He has also served as an executive at several software companies and as the PLM analyst for Technology Evaluation Centers and The PLM Evaluation Center. Jim is a frequent author and speaker on applying software technology to achieve tangible business benefits.



## Appendix A: Research Methodology

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### The Product Innovation Agenda Benchmark

Between July and August 2005, Aberdeen examined the product innovation, product development, and innovation processes, experiences, and intentions of more than 125 enterprises in various manufacturing industries.

Responding companies completed an online survey that included questions designed to determine the following:

- The link between the company's corporate strategy and its product innovation goals;
- The importance of specific operational improvements that could be employed to reach companies' strategic product objectives;
- The business capabilities companies are pursuing to achieve operational improvement and strategic, financial goals;
- Current and planned use of automation and technology enablers to foster innovation capabilities and activities; and
- The benefits, if any, that have been derived from improving product innovation, product development, and engineering processes.

Aberdeen supplemented this online survey effort with telephone interviews with select survey respondents, gathering additional information on specific actions, capabilities, and enablers.

### The Design for Compliance Benchmark

Between July and September 2004, Aberdeen Group examined the product compliance procedures, experiences, and objectives across a wide range of industries and size of companies. Through a *Control Engineering* magazine's respondent base, product design, development, procurement, manufacturing, sales, and supply chain operations executives completed an online survey to determine the following:

- The degree to which product compliance impacts corporate strategies, operations, and financial results
- The structure and effectiveness of existing product compliance operations and systems infrastructures
- Current and planned use of automation to aid these activities
- The characteristics and attributes of best-in-class companies and related benefits

Aberdeen supplemented this online survey effort with telephone interviews with select survey respondents, gathering additional information on product compliance strategies, experiences, and results.



The study aimed to identify emerging best practices for product compliance and provide a framework by which readers could assess their own capabilities.

### **Further Analysis**

In December of 2005, the data from these two benchmark reports was further analyzed to determine how companies could protect product innovation value by focusing on product compliance issues. Additional content was included from the [\*Regulatory Compliance across the Product Lifecycle\*](#), a Tech-Clarity report from 2004.



## Appendix B: Related Aberdeen Research & Tools

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Related Aberdeen research that forms a companion or reference to this report include:

- [\*The Product Innovation Agenda Benchmark\*](#) (September 2005)
- [\*The Design for Compliance Benchmark Report\*](#) (November 2004)
- [\*Global Product Design Benchmark\*](#) (December 2005)
- [\*New Product Development: Profiting from Innovation\*](#) (December 2005)
- [\*Enabling Product Innovation: Roles of ERP and PLM\*](#) (November 2005)
- [\*Product Development in Consumer Industries Benchmark\*](#) (June 2004)
- [\*Formula-Based Product Development\*](#) (November 2004)
- [\*Computer Aided Design for Formula-Based Industries\*](#) (Tech-Clarity 2005)

Information on these and any other Aberdeen publications can be found at <http://www.aberdeen.com>.



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### Our Mission

To be the trusted advisor and business value research destination of choice for the Global Business Executive.

### Our Approach

Aberdeen delivers unbiased, primary research that helps enterprises derive tangible business value from technology-enabled solutions. Through continuous benchmarking and analysis of value chain practices, Aberdeen offers a unique mix of research, tools, and services to help Global Business Executives accomplish the following:

- IMPROVE the financial and competitive position of their business now
- PRIORITIZE operational improvement areas to drive immediate, tangible value to their business
- LEVERAGE information technology for tangible business value.

Aberdeen also offers selected solution providers fact-based tools and services to empower and equip them to accomplish the following:

- CREATE DEMAND, by reaching the right level of executives in companies where their solutions can deliver differentiated results
- ACCELERATE SALES, by accessing executive decision-makers who need a solution and arming the sales team with fact-based differentiation around business impact
- EXPAND CUSTOMERS, by fortifying their value proposition with independent fact-based research and demonstrating installed base proof points

### Our History of Integrity

Aberdeen was founded in 1988 to conduct fact-based, unbiased research that delivers tangible value to executives trying to advance their businesses with technology-enabled solutions.

Aberdeen's integrity has always been and always will be beyond reproach. We provide independent research and analysis of the dynamics underlying specific technology-enabled business strategies, market trends, and technology solutions. While some reports or portions of reports may be underwritten by corporate sponsors, Aberdeen's research findings are never influenced by any of these sponsors.



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