



Aberdeen *Group*

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## Compliance and Traceability in Regulated Industries Benchmark Report

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December 2006



## Executive Summary

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With recent watershed events, like the adoption of Title 21 CFR part 11, effecting change in entire industries, compliance and traceability has become top of mind for many manufacturing executives. Compliance and traceability has traditionally been viewed as a “cost of business” but this perception is changing as automation and integration gains traction across industries. This report will benchmark the ways manufacturers are utilizing compliance and traceability programs as a competitive advantage in the market place.

### Key Business Value Findings

Lacking metrics to measure success and focusing on document rather than process management are two of the most common pitfalls manufacturers face when implementing compliance and traceability initiatives. Successfully responding to these challenges is central to transitioning compliance and traceability initiatives from the typical cost of business to a competitive advantage.

### Implications & Analysis

In responding to these challenges manufacturers are “building in” compliance and traceability to production processes and measuring the success of such initiatives with operational metrics. After implementing these business capabilities and gaining visibility into production processes manufacturers are able to implement many best practices, which are central to achieving a competitive advantage, namely effective root cause analysis and real-time closed loop CAPA capabilities.

### Recommendations for Action

- 93% of manufacturers still relying on manual processes to manage compliance and traceability programs were unable to achieve Best in Class status. To become Best in Class manufacturers should utilize automated solutions to “build in” compliance and traceability to production processes.
- 73% of Best in Class manufacturers have integrated compliance and traceability solutions with other enterprise applications. Ideally, manufacturers should create a single source of data facilitating process control and continuous improvement.
- Best in Class manufacturers are more than 5x’s as likely to measure performance in real-time than other manufacturers. To become Best in Class manufacturers should measure operational metrics in real time and utilize this information to gauge success.

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## Chapter One: Issue at Hand

### Key Takeaways

- Regulatory bodies and ISO customer requirements are the main drivers of compliance and traceability initiatives for manufacturers today.
- Manufacturers see more value in achieving a competitive advantage than reducing costs when implementing compliance and traceability initiatives.
- Manufacturers demand more than just document management from compliance and traceability solutions, process control is now the focus.

Compliance and traceability programs were first implemented long before any technology solutions had been developed to manage them. Not surprisingly, there subsequently exists a wide disparity in both the corporate structure and level of technology integration used to manage these programs. The corporate structures surrounding compliance and traceability programs range from distributed sources of knowledge and authority with little focus across the organization, to centrally managed programs, driving a strong focus at every level of the organization. Similarly, technology integration ranges from pen, paper, and spreadsheet solutions, to automated software that “builds in” compliance and traceability to the production process itself.

Disregarding how any one manufacturer aligns with the corporate structure and technology integration spectrum. There are a variety of market pressures driving the strategies surrounding compliance and traceability programs. At the top of the list are regulatory bodies and customer requirements, such as FDA, DOT, EU, and ISO compliance respectively. This finding indicates that manufacturers still view compliance and traceability as a necessary business process, one, which by its very nature, is a prerequisite to viable operations at the most basic level.

However, digging down to the next grouping of pressures, it becomes evident that manufacturers are not content to view compliance and traceability as simply a requirement of doing business. In fact, utilizing compliance and traceability programs to create a competitive advantage is even more important to most manufacturers than reducing the traditional costs associated with compliance and traceability, such as audits, recalls, or service. This finding then begs the question, how do manufacturers leverage compliance and traceability programs as a competitive advantage?

### Competitive Framework Key

The Aberdeen Competitive Framework defines enterprises as falling into one of the three following levels of practices and performance:

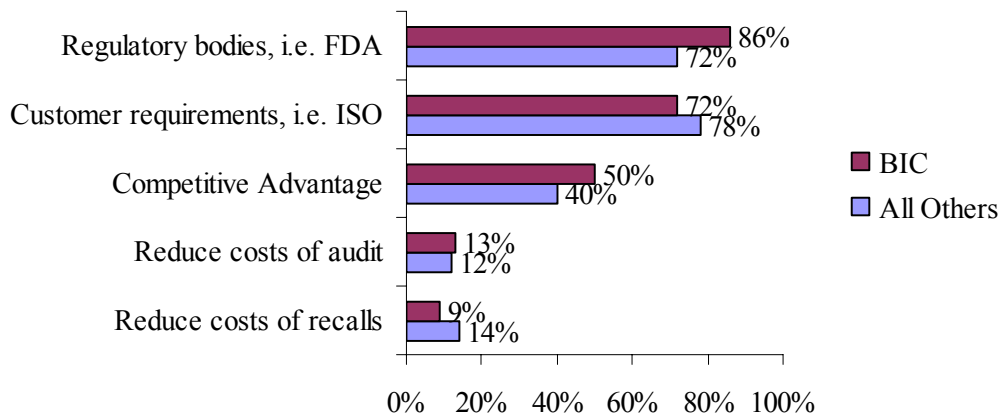
*Laggards (30%)* —practices that are significantly behind the average of the industry

*Industry norm (50%)* — practices that represent the average or norm

*Best in class (20%)* — practices that are the best currently being employed and significantly superior to the industry norm



**Figure 1: Pressures Driving Compliance and Traceability Implementations**



Source: **AberdeenGroup**, December 2006

In order for compliance and traceability programs to be leveraged by manufactures as a competitive advantage the true spirit behind these regulations must be identified and embraced. Regulatory bodies view inspection and document management as a means to an end, the real goal is process control and final products that are safe for consumers. In order for programs, such as HACCP (hazard analysis and critical control points) and GAMP (good automated manufacturing principles), to become a competitive advantage production processes must be documented and analyzed, thresholds for acceptable operations must be established and finally adhered to.

In the same way, traceability can be utilized as a competitive advantage by automating and giving visibility to continuous improvement initiatives. When lot traceability and automated batch processing information is at the finger tips of those who need it, root cause analysis and real-time closed loop CAPA (corrective and preventive actions) become attainable best practices. Manufacturers with visibility into production processes and automated traceability have the wherewithal to address issues while still in process. This ability can only be viewed as a competitive advantage over those manufacturers with no visibility into production processes and no automated traceability. During continuous improvement initiatives, manufacturers without these capabilities are often relegated to recreating situations and conducting root-cause analysis days after the events have occurred.

**PACE Key — For more detailed description see Appendix A**

*Aberdeen applies a methodology to benchmark research that evaluates the business pressures, actions, capabilities, and enablers (PACE) that indicate corporate behavior in specific business processes. These terms are defined as follows:*

**Pressures** — external forces that impact an organization's market position, competitiveness, or business operations

**Actions** — the strategic approaches that an organization takes in response to industry pressures

**Capabilities** — the business process competencies required to execute corporate strategy

**Enablers** — the key functionality of technology solutions required to support the organization's enabling business practices



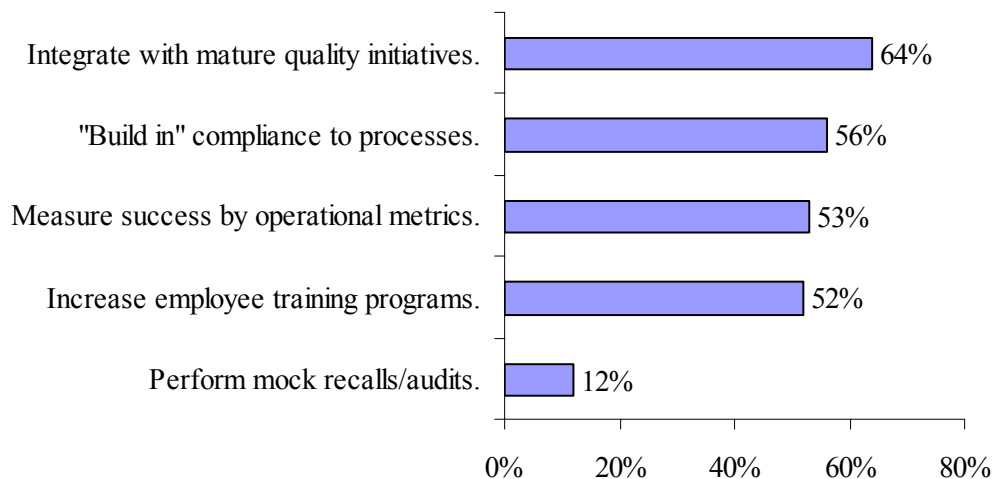
## Chapter Two: Key Business Value Findings

**Key Takeaways**

- To achieve a competitive advantage, integrate compliance and traceability initiatives with mature quality initiatives and “build in” compliance and traceability to production processes.
- Lacking the capability to measure program success is the chief challenge facing compliance and traceability initiatives today; improving a system without performance visibility and operational metrics is next to impossible.
- Utilizing technology to gain visibility into production processes is a successful strategy when manual tools are falling short.

It is clear how compliance and traceability initiatives can become a competitive advantage for manufacturers. The ability to perform root cause analysis and CAPA on a real-time basis can be viewed as nothing less; the uncertainty is in determining the strategic actions necessary to achieve such business capabilities. When asked, 64% of manufacturers surveyed are integrating compliance and traceability programs with mature quality initiatives and 54% of manufacturers surveyed are “building in” compliance and traceability to production processes. Both of these strategic actions can be categorized as increasing the process orientation of compliance and traceability programs. The other strategic action that falls into this category is measuring the success of compliance and traceability initiatives by operational metrics.

**Figure 2: Strategic Actions Addressing Market Pressures**



Source: **AberdeenGroup**, December 2006



## Aligning with Mature Quality Programs

The alignment between compliance and traceability initiatives and mature quality programs is a natural one. Six Sigma and SPC (statistical process control), which are both well penetrated quality assurance programs, both focus on variability reduction and processes control, as do HACCP and GAMP. Considering this overlap in both content area and overall goals, it only makes sense that these disparate programs perform better when managed in tandem.

With both initiatives being managed by the same individuals and the data being collected for both programs residing within the same location, manufacturers experience returns to scale on program investments. The benefits are two-fold, quality managers have the opportunity to become more process aligned, as do compliance and traceability programs. Once this jump is made, it becomes only a matter of time before manufacturers conceptually align compliance and traceability with process not just document control.

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Quality can not be tested into products; it should be built in ... PAT is a system for designing, analyzing, and controlling manufacturing through timely measurements (i.e. during process) of critical quality and performance attributes, with the goal of ensuring final product quality.

FDA: Guidance for Industry PAT - September 2004

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## “Build In” Compliance and Traceability

A great example of what it means to “build in” compliance and traceability is the FDA’s PAT (process analytic technology) framework guidance. PAT is a framework that is applicable well outside of life sciences and other FDA regulated industries. In fact, HACCP, a theoretical precursor to PAT, has its origins in NASA’s early efforts to ensure the integrity of complex systems in the space program.

No matter what the industry or product being manufactured, final product quality can not be ensured by statistical testing of the final product itself. A quality assurance framework, based on final product testing, will invariably allow the release of some out of specification product. Under such a framework, the amount of bad product being released can only be measured; it can not be eliminated.

The only way to ensure the release of 100% “in specification” final products is to operate under a quality assurance framework, like PAT, that analyzes and tests the production process itself. The first step is to identify those in process critical control points that can be measured and are predictive in regards to final product quality. Then, threshold levels for these critical control point metrics must be established, i.e. if the production process critical control point metric is within the threshold, the final product is within specification, and conversely; if the production process critical control point metric is outside of the specification, the final product will be as well.

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The auditors noticed that everything was easily traceable, documents were readily available, and electronic signatures were all there.

Gary Jerabek  
Senior Quality Engineer  
Mallinckrodt Baker Inc.  
MasterControl User

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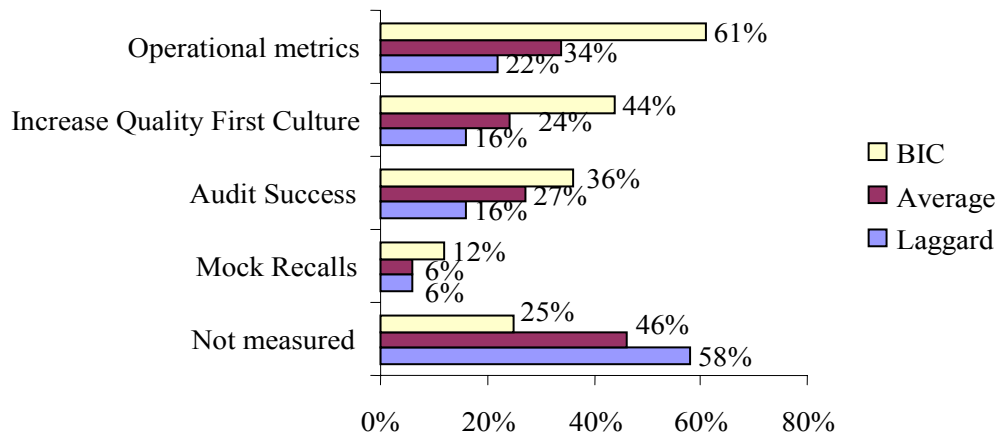
The final piece is then to measure these critical control points in real or near real-time, which will allow for in processes adjustments and “live” closed loop CAPA capabilities.



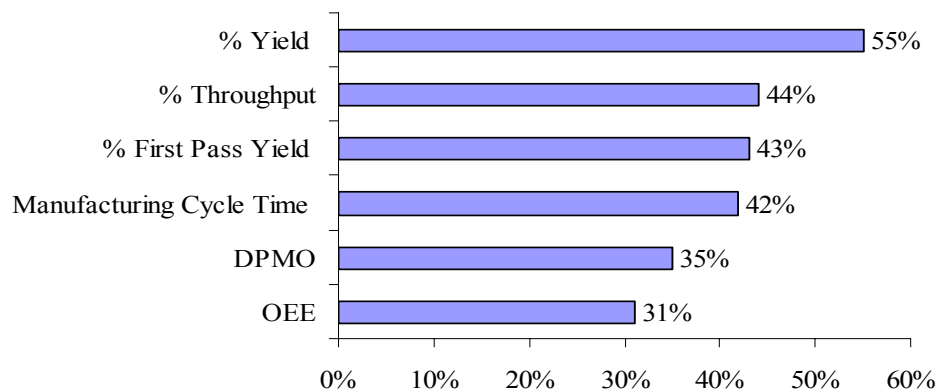
### Measuring Success with Operational Metrics

The third strategic action that a manufacturer can take when implementing a compliance and traceability program is to measure the success of the program by operational metrics. Clearly this strategy aligns with the two previous strategies in that it continues to put the focus of compliance and traceability programs on process not document control. When those individuals with ownership of compliance and traceability programs within an organization are given a yard stick by which to measure success and can subsequently attribute the success of “their” compliance and traceability program to the success of the overall firm, employee buy-in becomes a reality.

**Figure 3: How Manufacturers Measure Success of Compliance and Traceability**



**Figure 4: Specific Metrics Used to Measure Success**



Source: AberdeenGroup, December 2006



## Challenges and Responses

Not surprisingly, the challenges manufacturers face in implementing compliance and traceability programs are almost a one to one mapping from the strategic actions manufacturers are attempting to implement. Obviously, manufacturers find it a challenge to focus compliance and traceability programs on process not document management. Luckily, there is a logical flow of ideas that can be used to categorize both the challenges and responses that manufacturers have.

Manufacturers have realized that the easiest way to transition compliance and traceability programs from a “cost of business” to a “competitive advantage” is to align compliance and traceability initiatives with mature quality initiatives and “build in” compliance and traceability to the production processes themselves. The challenges manufacturers are experiencing when aligning compliance and traceability programs with either mature quality programs or production processes themselves includes a lack of measured success, which is result of lacking process visibility. The way in which manufacturers are responding to these challenge is by implementing technology solutions that automates document management, unifies quality and compliance and traceability data, and gives real or near real-time visibility into process performance.

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Utilizing SAP and Sparta Systems’ TrackWise we have automated complaint tracking, product traceability, and raw material traceability. We can now both track and view, in real-time, the critical control points, equipment, raw material lots, and customer complaints attributed to any product shipped. Compliance is critical to our business but at the same time we have utilized technology to streamline our processes and create a competitive advantage.

Tim Culbreth  
 Director of Quality  
 Roche Carolina Inc.

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**Table 1: Compliance and Traceability Challenges and Responses**

Challenges	% Selected	Responses to Challenges	% Selected
Focus is document not process management.	69%	Integrate document and process management.	59%
The success of compliance and traceability initiatives are not measured.	59%	Utilize technology to measure operational metrics.	49%
Quality and compliance and traceability initiatives are not aligned.	49%	Align mature quality initiatives with compliance and traceability initiatives.	46%
Limited visibility into production processes, no automated traceability.	37%	Manage quality, compliance, and traceability data with an integrated solution.	45%
No corporate focus on compliance and traceability.	30%	Utilize integrated technology in order to gain visibility into production processes	35%

Source: **AberdeenGroup**, December 2006



## Chapter Three: Implications & Analysis

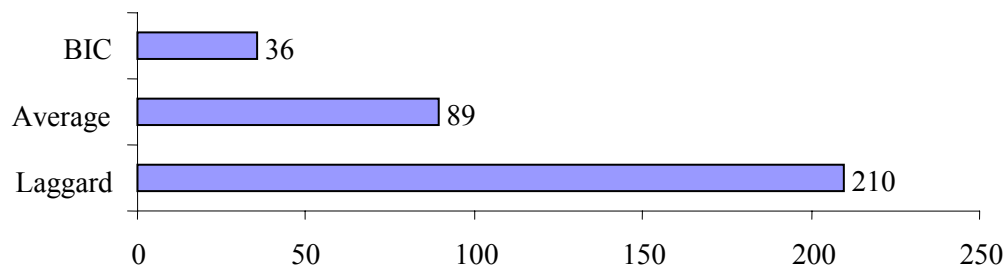
**Key Takeaways**

- Best in class manufacturers are more than twice as likely as other manufacturers to integrate disparate software solutions.
- Best in class manufacturers are 75% more likely to have process visibility and automated traceability than other manufacturers.
- Best in class manufacturers are more than five times as likely as other manufacturers to measure compliance and traceability performance in real or near real-time.
- Best in class manufacturers are more than twice as likely as other manufacturers to have compliance and traceability centrally managed at the corporate level.

Aberdeen, for the purpose of this report, has categorized manufacturers as Best in Class, Industry Average, or Laggard based on a weighted average of results in three key performance indicators: audit preparation time, percent of product produced in compliance, and average number of CAPA completed per week. As stated in the previous description, Laggards are the bottom 30% of performers, Industry Average are the middle 50% of performers, and Best in Class are the top 20% of performers. These key performance indicators were chosen because they are representative of a manufacturer’s ability to comply with regulatory documentation demands, to operate within the parameters of governing regulations, and to improve processes based upon the underlying principles and motivations of many regulations.

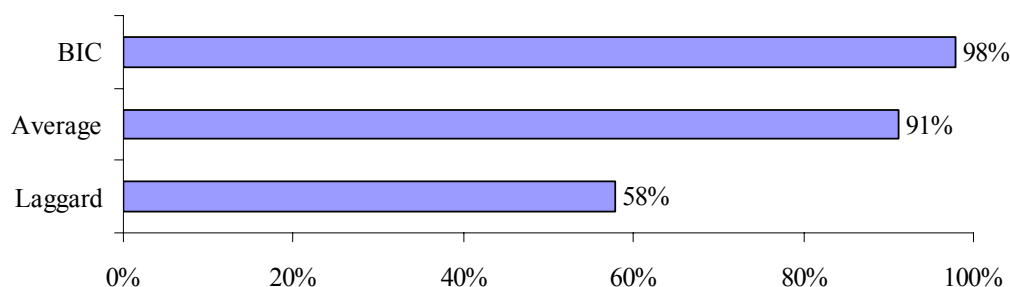
CAPA (Corrective and Preventive Actions) is a best practice that falls under the broad umbrella of continuous improvement initiatives. A completed CAPA has identified an area of improvement in the production process, implemented a corrective action, and closed the loop by integrating the solution throughout the enterprise, preventing future occurrences

**Figure 5: Average Number of Hours Spent in Audit Preparation**

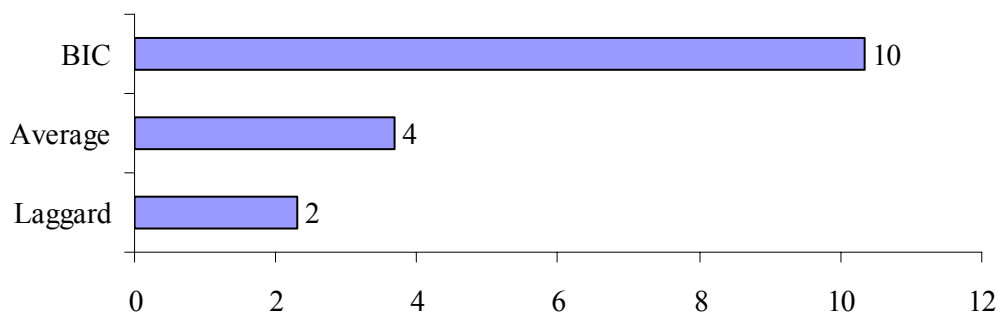




**Figure 6: Average Percentage of Product Produced in Compliance**



**Figure 7: Average Number of CAPA Completed per Week**



Source: **AberdeenGroup**, December 2006

### How are Best in Class Manufacturers Different

By definition, Best in Class manufacturers are performing better than Industry Average or Laggard manufacturers, but how else do these manufacturers differ from their competition? To answer this question, the technology choices Best in Class manufacturers are making will be analyzed. By doing so, correlations can be drawn between the superior operational performance that Best in Class manufacturers enjoy and the areas where Best in Class manufacturers differentiate in regards to technology implementation.

#### ***The Value of Real-Time***

One very telling aspect of any technology implementation is the frequency with which success is measured. It is often the case, and it is no different here, that the degree to which manufacturers are able to measure success is the same degree to which manufacturers are actually successful.

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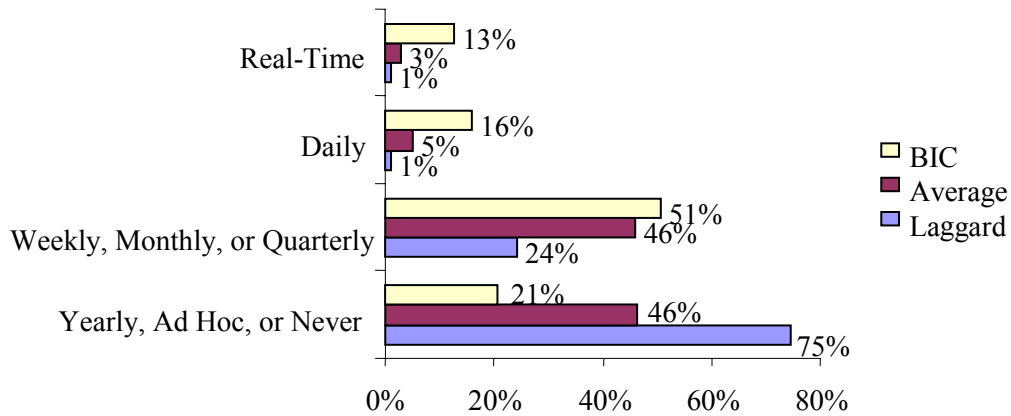
Utilizing AssurX's CATSweb we now monitor % on time delivery and our CAPA program in real-time. Subsequently, we have improved the approval cycle time on one of our key business processes from 4 hours to 45 minutes

Tom Perkins  
Audit Program Manager  
Mercury Computer Systems, Inc.  
AssurX and Oracle Customer

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**Figure 8: Frequency of Compliance and Traceability Measurement**



Source: **AberdeenGroup**, December 2006

Not surprisingly, those manufacturers achieving Best in Class status measure the success of compliance and traceability initiatives at a considerable higher rate than Industry Average or Laggard manufacturers. Measuring compliance and traceability on either a real or near real-time basis quickly becomes cost prohibitive without the benefit of integrated document and process solutions.

In addition, many of the best practices that were mentioned previously are only possible if performance is measured in real-time. It becomes nearly impossible to implement an in-production closed loop CAPA program without the ability to measure performance in real or near real-time.

***Technology Integration, Performance Visibility, and Manual Processes***

There still remain several aspects of a compliance and traceability technology implementation where Best in Class manufacturers differentiate themselves. First, is in how well integrated the technology solution is with other enterprise applications. Second, is in how well the technology implementation provides process visibility and automated traceability. The final way Best in Class manufacturers differentiate themselves is in the degree to which manual processes have been eliminated from the compliance and traceability program.

Again, a correlation is seen between Best in Class operational performance and the degree to which a manufacturer incorporates the above listed technology capabilities. The takeaway from these findings is that such technology capabilities are best practices and should be utilized in compliance and traceability initiatives.

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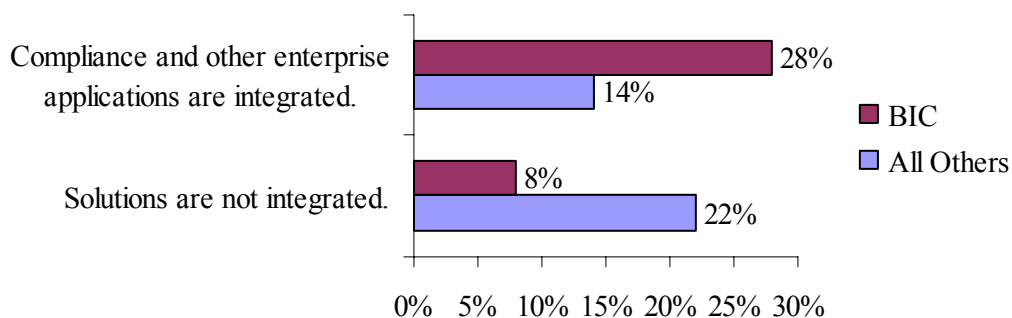
We have utilized Pilgrim’s Smart-Complaints solution to eliminate re-keying and paper forms from our complaint management program. The entire program is now audit ready 100% of the time and all of our complaint data is now available for CAPA initiatives in real-time.

Michelle Donatich  
 Director of Quality & Professional Services, Cardinal Health  
 Pilgrim Software User

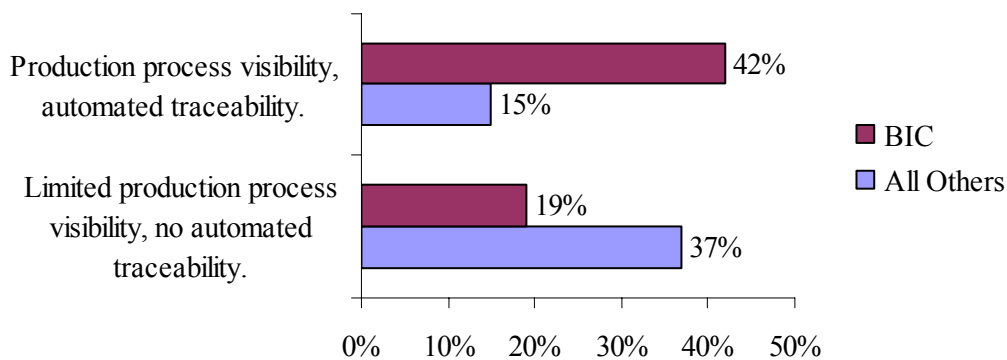
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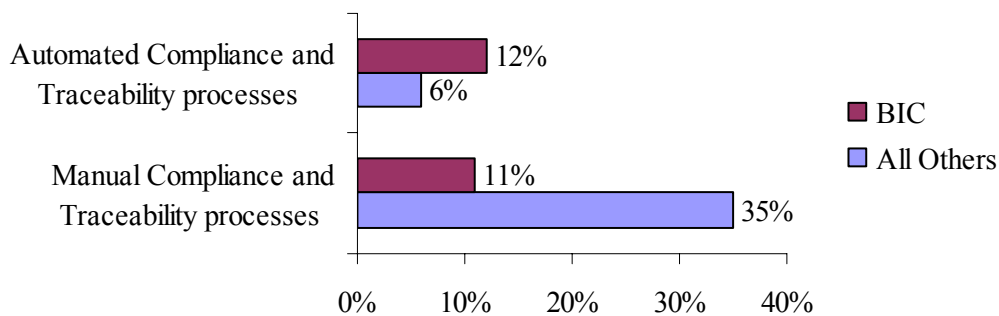
**Figure 9: Integration of Compliance and Other Enterprise Applications**



**Figure 10: Process Visibility and Automated Traceability**



**Figure 11: Manual Processes in Compliance and Traceability Programs**



Source: [AberdeenGroup](#), December 2006



## Which to Choose: MES, QMS, or ERP?

Among survey participants there was no single software solution that was an overwhelming preference. However, a trend can be seen in what technology is being used to manage compliance and traceability programs if multiple software solutions within the same implementation are considered.

**Table 2: Software Solutions Used**

Software Solutions Used to Manage Compliance and Traceability	% Used
QMS (Quality Management Solution) used either independently or in conjunction with other enterprise applications.	82%
ERP (Enterprise Resource Planning) used either independently or in conjunction with other enterprise applications.	50%
MES (Manufacturing Execution System) used either independently or in conjunction with other enterprise applications.	16%

Unfortunately, there is no correlation between the above software solution classifications and Best in Class performance; rather Best in Class performance is correlated with how well manufacturers utilize technology to manage compliance and traceability programs. Manufacturers must evaluate the present state of their MES, QMS, and/or ERP implementations and then determine how best to achieve the integration and functionality necessary to implement the best practices identified above.

### **MES**

Best practices, such as achieving processes visibility and measuring success by operational metrics maybe best accomplished with the use of an MES system. MES solutions excel at plant floor integration and process control. These solutions should be leveraged while implementing those best practices which attempt to “build in” compliance and traceability to production processes.

### **QMS**

Aligning mature quality initiatives with compliance and traceability programs, eliminating manual processes, and implementing CAPA programs maybe best accomplished through the use of QMS solutions. QMS products leverage a single source of quality, compliance, and traceability data and often have specific CAPA and change management capabilities, making these solutions a logical choice for such best practices.

### **ERP**

The final piece of the puzzle is automating traceability, technology integration, centralizing the corporate structure and focus, and managing the entire spectrum of regulatory compliance, such as OSHA, SOX, consumer safety, brand integrity, and environmental stewardship, in conjunction with operational based manufacturing compliance. ERP suites are often the best choice when implementing these best practices due to their functionality and penetration into all of the firms activities.



## Chapter Four: Recommendations for Action

### Key Takeaways

- Utilize technology solutions to achieve automated traceability and real or near real-time visibility into production processes.
- Utilize operational metrics to measure the success of compliance and traceability programs.
- Best practices should be implemented to achieve a competitive advantage, align mature quality programs, integrate document and process management, and institute a run time root-cause closed loop CAPA program.

The compliance and traceability end game, when it comes to implementing technology solutions, is in achieving a competitive advantage. Manufacturers are much less concerned with simply satisfying auditor demands, or even in reducing costs, than in facilitating the ability to outperform the competition. There are specific technological challenges that must first be addressed when implementing the best practices necessary to achieve a competitive advantage. Specifically, these challenges are timely visibility into production processes and automated traceability, which should both be considered technological requirements of any compliance and traceability solution.

### Laggard Steps to Success

1. Perform a self-assessment, begin measuring operational metrics and use these results to gauge progress.
2. Increase the focus on both quality and compliance and traceability programs. Begin to align the two programs by a coordination of ownership within the organization and an integration of technology used to manage the programs.
3. Begin “building in” compliance and traceability to production processes; accomplish this by utilizing software solutions that are integrated with the shop floor and provide automated traceability and timely visibility into production processes.

### Industry Average Steps to Success

1. Institutionalize best practices, i.e. align mature quality and compliance and traceability programs, integrate document management and process management, and measure success with operational metrics. Utilize an integrated software solution that operates with a single source of data to accomplish this end.
2. Evaluate current technological capabilities and eliminate manual processes from the compliance and traceability program, ensure that technology solutions contain both timely process visibility and automated traceability capabilities.



3. Utilize software solutions that are integrated with both the shop floor and other enterprise applications to close the loop on real-time continuous improvement efforts, concentrate on root-cause analysis and CAPA frameworks.

### **Best in Class Next Steps**

1. Evaluate technology implementations, ensure that timely process visibility and automated traceability capabilities are being utilized
2. Continue to utilize best practices, i.e. align mature quality and compliance and traceability programs, integrate document management and process management, and measure success with operational metrics, to extend the competitive advantage already achieved, continue to improve processes and maintain closed loop real time corrective action capabilities.
3. Examine the corporate structure surrounding compliance and traceability programs. Ensure that there exists a centrally backed initiative that focuses all levels of the organization on compliance and traceability initiatives.
4. The final step for Best in Class manufacturers, after mastering the best practices and implementing the technological capabilities required to create a competitive advantage, is to integrate operational based compliance initiatives with the other risk management and compliance initiatives of the firm. Integrating operational compliance with OSHA, SOX, consumer safety, brand integrity, and environmental stewardship will only further extend the competitive advantage Best in Class manufacturers have already achieved.

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## Appendix A: Research Methodology

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**B**etween November and December 2006, the Aberdeen Group surveyed more than 340 enterprises in the pharmaceutical, medical device, food and beverage, chemicals, aerospace and defense, automotive, and other industries. This online survey effort was supplemented by telephone interviews with select survey respondents; providing additional information on individual strategies, experiences, and results.

Responding enterprises include the following:

- **Job title/function:** The research sample has the following breakdown by job titles: 20% Staff, 34% Manager, 18% Director, 7% Vice President, 8% CxO, 6% Consultant, 7% Other.
- **Industry:** The research sample has the following breakdown by industry: 27% Medical Devices, 14% Pharmaceuticals, 9% Chemicals, 8% Food and Beverage, 7% Hi-Tech, 6% Industrial Equipment, 5% Automotive, and 24% Other
- **Geography:** The research sample has the following breakdown by geography: 77% NAFTA, 10% Asia/Pacific, and 13% EMEA
- **Company size:** The research sample has the following breakdown by company size: 36% small (less than 50 million), 41% medium (between 50 million and 1 billion), and 23% large (greater than 1 billion).

## *Appendix B:* **Related Aberdeen Research & Tools**

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

- [The Lean Six Sigma Benchmark Report](#)
- [The Product Quality Benchmark Report: Achieving Quality Across the Global Manufacturing Network](#)

Information on these and any other Aberdeen publications can be found at [www.Aberdeen.com](http://www.Aberdeen.com).

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