Aberdeen Group
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The Cost of Quality: a Study on Life Sciences

In Aberdeen's July 2007 benchmark report, *The Cost of Quality*, it was shown that Best-in-Class manufacturers have distinct competitive advantages in performance metrics. In May and June 2008, Aberdeen surveyed 169 additional companies identifying themselves as Life Sciences manufacturers.

In addition to addressing performance, Life Sciences companies have the additional mandate of complying with government regulation and providing traceability in their operations. This study will investigate the different pressures that these manufacturers face and how they can improve performance while still conforming to regulating bodies so that they may take advantage of practices used by the Best-in-Class.

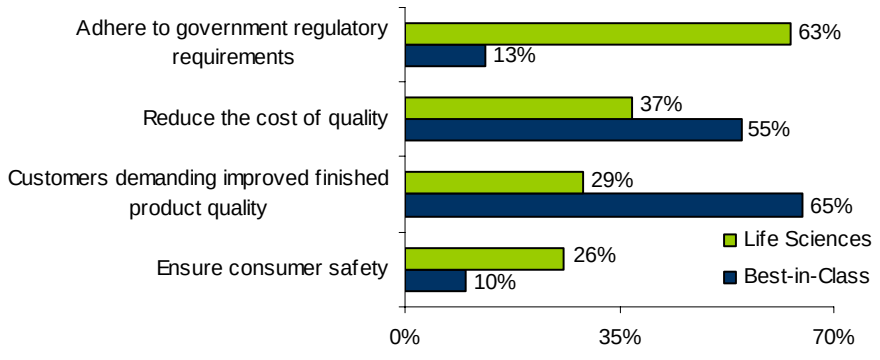
Aberdeen Analysis

To better understand the practices adopted by these manufacturers, Aberdeen analyzed the pressures driving them to focus on performance as well as the added strain of adhering to government regulation. We then analyzed the strategic actions they are taking in response to these pressures, the business capabilities they possess to support these actions, and the technology enablers being adopted to provide those capabilities.

Balancing Performance versus Government Regulation

Results from the Aberdeen July 2007 Benchmark Report, *The Cost of Quality*, show that the two top pressures which manufacturers face are their customers' demand for a higher quality product (65%), and the need to reduce the cost of quality (55%). However, Figure 1 shows that Life Sciences manufacturers have a distinctly different primary focus.

Figure 1: Market Pressures



Source: Aberdeen Group, July 2008

Sector Insight

Aberdeen's Sector Insights provide strategic perspective and analysis of primary research results by industry, market segment, or geography.

Industry Definition

Companies focusing on pharmaceuticals, biotechnology, blood/biologics and medical devices were studied in this report and grouped together as Life Sciences

Best-in-Class Criteria

The Best-in-Class, Industry Average, and Laggard classifications in this study are defined as the top 20%, middle 50%, and bottom 30% of performers respectively, where performance is based on an aggregate score of 3 KPIs: First Pass Yield, Overall Yield, and DPMO (where Defects per Million Opportunities is reflected as the number of Sigma in production processes).

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They are focused on, first and foremost, adhering to government regulatory requirements (63%), followed by reducing the cost of quality (37%). Of note, ensuring customer safety is cited one and a half times more likely than with Best-in-Class at (26%).

One trend in the benchmark study worth noting is that for adherence to government regulation, Industry Average respondents cited this pressure as 24%, and Laggards as 30%. This shows that Life Sciences companies (63%) that need to address complex regulatory environments may be in a more difficult position to perform as well as Best-in-Class.

Given this trend that focusing on regulation correlates negatively with performance, it is commendable that as a group Life Sciences can still perform at the Industry Average level for performance metrics as shown in Table 1. There is however still plenty of room to improve performance metrics as a class. The Life Sciences DPMO is comparable to the Industry Average of all manufacturers, but is significantly less than the Best-in-Class.

Table1: Key Performance Indicators

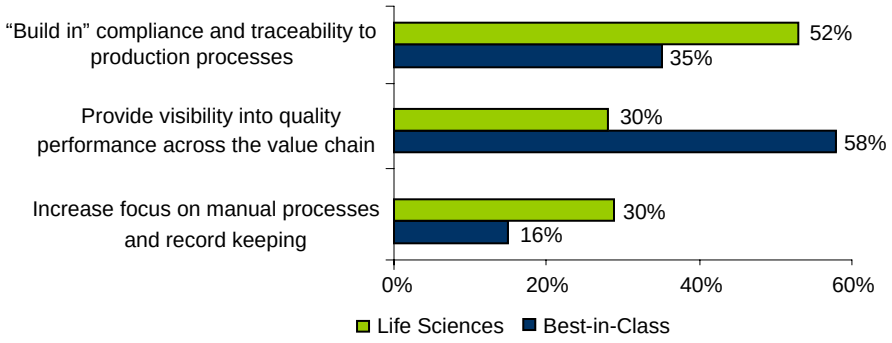
	Best-in-Class	Industry Average	Life Sciences	Laggard
First pass yield	91%	89%	86%	70%
Overall yield	95%	90%	89%	70%
DPMO	5.04 Sigma	3.68 Sigma	3.87 Sigma	1.81 Sigma

Source: Aberdeen Group, July 2008

Strategic Actions

As shown in Figure 1, since Life Sciences are less likely to cite the pressures of improving product quality or reducing the cost of quality, and almost five-times as likely to cite the pressure of adherence to regulatory requirements, one would suspect that they are adopting a significantly different set of strategic actions to address regulatory compliance. However, Life Sciences companies actually take a very similar set of strategic actions as compared to all manufacturers with the notable exceptions shown in Figure 2.

Figure 2: Differentiated Strategic Actions for Life Sciences



Source: Aberdeen Group, July 2008

Technology Acronyms

PFA: Plant Floor Automation which includes automated data collection, data historians and instrumentation

MES: Manufacturing Execution System

QMS: Quality Management System

ERP: Enterprise Resource Planning

SCM: Supply Chain Management

BOM: Bill of Material

FDA PAT Guidance

The PAT guidance was launched by the FDA in 2002 to guide pharmaceutical manufacturers to improve overall quality and reduce the cost of compliance.

The FDA's overall goal is to build-in quality by design, not test after the fact to improve quality, reduce drug shortages, and speed up regulatory approval for new drugs coming to market.

For more information see: http://www.fda.gov/cder/OPS/PAT.htm

First, Life Sciences are about 50% more likely to build in compliance and traceability into their production processes. This can partially be attributed to the fact that "building in" product and process traceability aligns very well with the FDA's Process Analytical Technology (PAT) guidance launched in 2002 and in that regard does address compliance.

Second, they are about half as likely to strive to provide visibility into quality performance across the value chain. This shows that there is more focus on local regulatory operations than a holistic approach to providing full visibility into quality performance.

Third, Life Sciences are almost twice as heavily weighted towards addressing manual processes and record keeping than other industries. Given that Life Sciences are always trying to keep up with old regulations while responding to new ones, attention and resources are persistently being drawn to this clerical function rather than addressing quality issues. We provide an analysis later in this study which will show that the automation of these manual processes is a differentiator for Best-in-Class performance.

Fast Facts

The Best-in-Class are:

- √ 12% more likely to institute quality process workflows at the departmental level but 76% more likely to drive them at the corporate level
- √ 37% more likely to have adopted PFA as compared to Life Sciences
- √ 13% more likely to have adopted QMS as compared to Life Sciences
- √ 50% more likely to adopt MES as compared to Life Sciences

Industry Capabilities

Table 2 shows that compared to the benchmark study, *The Cost of Quality*, Life Sciences performs between Laggards and Industry Average in most reported capabilities of process, organization, and technology and often less than Laggards for knowledge based capabilities. The noted differences, which might go a long way to explain why they are able to still perform comparably to Industry Average, lie more in the technologies they are choosing to implement and integrate together.

Life Sciences are 43% less likely to establish quality process workflows and alerts at the corporate level as compared to Best-in-Class, but only 10% less likely to manage them at the departmental level compared to the Best-in-Class. There is definitely recognition that quality workflows and alerts are needed, but confusion as to which level they should be applied. They would benefit from creating a corporate strategy first and then pushing workflows down to the departmental level, and then bubbling back standardized alerts so that each level in the organization will have the correct knowledge with which to make decisions.

The Life Sciences industries have a somewhat lower adoption to Plant Floor Automation (PFA) as compared to Industry Average and Best-in-Class, but about two thirds higher an adoption rate as compared to Laggards. This clearly shows that while they may be focusing on regulatory requirements, they recognize more so than Laggards that the beginning of quality lies with understanding what is happening at the plant floor level. Still, once they have this information they are not applying it as well as the Best-in-Class to turn this into actionable intelligence.

Similarly they have 55% better adoption of QMS than Laggards and are just 11% less likely to have adopted a QMS system as Best-in-Class. In addition they have more than double the adoption rate of MES than Laggards, but

"We found it very important to demonstrate to senior management what benefits we would get by automating our record keeping. We had a particular problem when it came to locating documents for audit preparation. After giving management a feel for what the software could do, we showed that we would get a strong ROI for the project and we would also reduce our risk during any audits. It was a winning situation when we showed what the consequences could be if we didn't go forward. Since we completed the project we reduced the time it takes for audit preparation from 15-30 days to just 3-5 days."

~ Tom Golden, Quality Manager, BioMimetics Therapeutics

still only about two thirds that of Best-in-Class. Here, there is a burgeoning competitive advantage waiting to be exploited across all Life Sciences sub-vertical industries.

There is clearly a connection between these systems and their performance, but this picture is incomplete until we recognize how these systems work together to deliver on performance.

Table 2: Competitive Framework

	Best-in-Class	Industry Average	Life Sciences	Laggards
Process	Quality process workflows and alerts are established and standardized at the corporate level			
	74%	55%	42%	37%
	Process workflows and escalations are managed at the departmental level			
	87%	74%	78%	60%
Organization	Executive ownership of quality initiatives across the enterprise			
	74%	81%	60%	54%
Knowledge	Quality data is collected automatically			
	43%	38%	24%	26%
	Supplier quality data is used as actionable intelligence			
	67%	58%	48%	56%
	Factory floor quality data is used as actionable intelligence			
	70%	69%	60%	57%
	Customer quality data is used as actionable intelligence			
	73%	70%	60%	65%
Technology	Share of manufacturers currently using technology:			
	▪ PFA: 30% ▪ MES: 30% ▪ QMS: 70% ▪ ERP: 71% ▪ SCM: 70%	▪ PFA: 29% ▪ MES: 29% ▪ QMS: 63% ▪ ERP: 61% ▪ SCM 43%	▪ PFA: 22% ▪ MES: 20% ▪ QMS: 62% ▪ ERP: 48% ▪ SCM 35%	▪ PFA: 13% ▪ MES: 8% ▪ QMS: 40% ▪ ERP: 44% ▪ SCM: 31%

Source: Aberdeen Group, July 2008

Interoperability

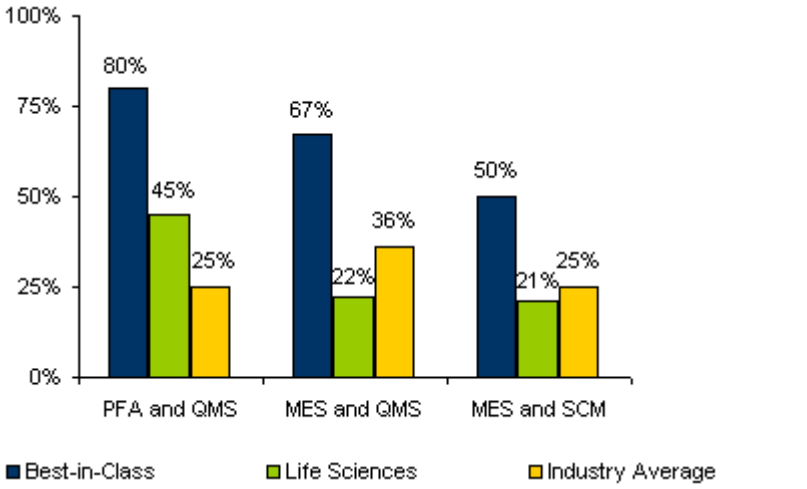
Findings from *The Cost of Quality* report show that when certain technology solutions are linked together in real-time, they prove to be enablers for improving performance. The data from this study support those earlier findings and stresses the connection for the Life Sciences industries.

The interoperability between PFA and QMS for Best-in-Class manufacturers is 80%, whereas for Life Sciences it is only 45%. However, interoperability

for Life Sciences is higher than the Industry Average which is only 25%. This shows that when teamed together, real-time data from the plant can be used as actionable intelligence to aid in making quality related decisions. This helps to explain that even though Life Sciences had implemented many capabilities at the level of Laggards, they did partially overcome this by integrating what they did have to drive performance.

Other noteworthy combinations are that the Best-in-Class, which had both MES integrated with QMS systems and/or MES and SCM, also have a competitive advantage. All of these point towards a tighter relationship between information and driving quality.

Figure 3: Interoperability Enables Best-in-Class Performance



Source: Aberdeen Group, July 2008

Technology Enablers

Above and beyond the actual technology group which is enabled, we find that within QMS, certain modules are being used by more Best-in-Class companies, and that the Life Sciences industries have much to gain from following their lead. Figure 4 shows that most Best-in-Class companies tend to implement more quality modules, which implies more maturity towards solving quality problems and moving towards prevention. Of these, Life Sciences met the Industry Average in only genealogy and traceability and audit documentation, which is consistent with their need for compliance.

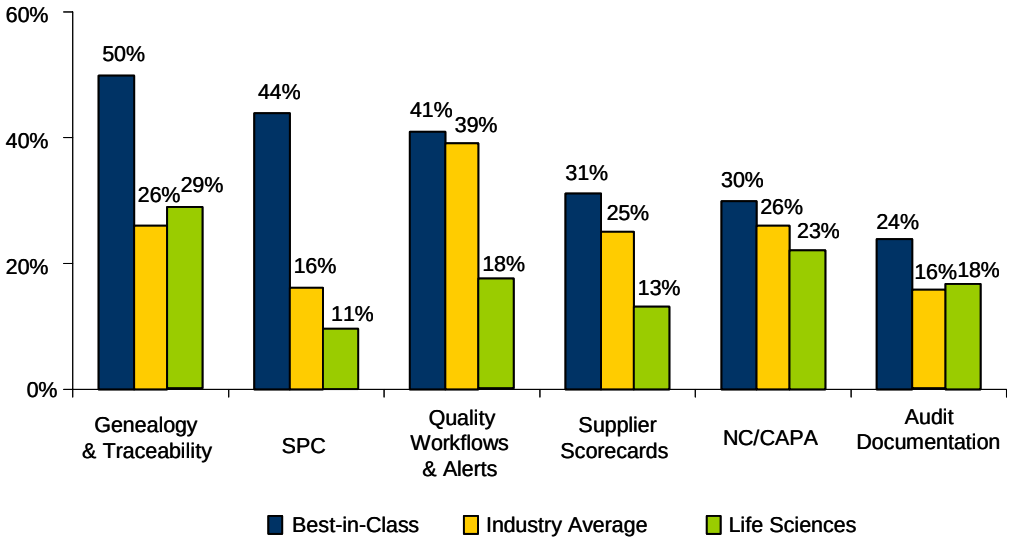
When we focus on the technology enablers that address the reduction of the manual process of compliance shown in Figure 4, it is evident that there are many things which the Best-in-Class are doing which could be adopted by Life Sciences. Automating SPC allows a real-time view of the various processes in place and acts as the front line source of intelligence for understanding the health of the manufacturing process.

Tying this into the quality workflows enables action on this information, and when a common language is designed into these workflows, alerts can be

established so that any part of the business can know immediately what is needed to either more closely monitor or correct a potential situation from ever occurring. This can further enable your NC/CAPA programs so that actions are taken quickly and succinctly so they can be tracked to the extent which regulations require. This can be extended to suppliers as well by instituting supplier scorecards so that you ensure quality as early in the manufacturing cycle as possible.

Audits are an absolute reality for Life Sciences and these companies need to be prepared for them, but this shouldn't be a manual process. As most can attest, if you have everything at your fingertips during an audit, you are demonstrating control of your plant and quality. Only 18% of Life Sciences are currently doing this, which means there is a large opportunity to redirect resources away from preparing for the audit and more time in other initiatives to improve quality.

Figure 4: Quality Modules to Reduce Manual Processes



Source: Aberdeen Group, July 2008

Case in Point

Headquartered in San Clemente California, eVent Medical, Inc. designs and manufactures clinician focused respiratory products for neonatal through adult patient care. Their ventilators are designed to be easy to use for the hospital clinician in intensive and critical care units. Features include having a patented high performance breath delivery system with a five hour battery life and a built in mini web server so that settings and readings can be monitored remotely on any windows based computer with internet service giving hospital staff more flexibility to provide care.

"We found that the best way to ensure quality in our products was to have a quality management system which covered our business end to end," said Bob Lundberg, VP Regulatory Affairs and Quality Assurance. "We needed to

Recommendations for Action

- √ Automate PFA to provide compliance and traceability and shift away from manual processes
- √ Adopt PFA, QMS, and MES as enabling technologies
- √ Integrate PFA with QMS and MES with QMS to develop competitive advantages
- √ Deploy multiple Quality modules

have quality workflows with document control and information integration throughout our entire process. We linked alerts and notifications within our assembly process to provide qualification checks, but also went further to link any inline changes in the process or bill of materials back to our business systems. We also set up automatic alerts and notifications to suppliers when design changes or software updates were made they could be sure to use the most up to date information possible.

Communication to the right role and with the right information for anything which might affect the quality of a product is critical. He continued, "Whenever there is a design or approved materials change, we can tailor who is notified and how much information we send them so that only the right people are informed and with as much detail as they need. Our system only notifies a user when there is an action to be taken which requires their attention. During final assembly we can configure alerts to detect early trends in quality and automatically notify suppliers if we start to see a problem. By doing this we get in front of potential problem as soon as possible before it becomes a problem."

"The key to our approach is we are managing information in a controlled way. This paves the way for early non conformance detection in assembly and simplifies audit preparation because all of our users whether in-house or external are working from the same documents and information."

He concluded, "We reduced the time people spent doing non-value added work from 15-20% down to less than 2%, greatly improved supplier coordination and we got a payback on our system in only 5 months."

Required Actions

The Life Sciences industries are performing in line with the Industry Average with respect to performance metrics. Although they still trail Best-in-Class, they are making strides towards recognizing that quality must be addressed in addition to fulfilling their regulatory compliance mandates. This study uncovers several areas by which Life Sciences can improve and thereby move towards Best-in-Class performance while still addressing all of their compliance objectives.

- **With plant floor automation, continue to automate the collection of real-time quality data so that it can be leveraged to drive quality management decisions as well as be an aid towards regulatory compliance.** Instituting PFA will drive down the variability of manual processes and allow a focus on other aspects of improvement. Where possible drive these principles through the entire supply chain so that you can gain visibility into quality performance before it becomes an issue in your plant. This will also help your suppliers be better prepared strengthening your relationship with them.
- **Institute QMS and MES as enabling technologies.** Within QMS, quality process workflows and alerts should be standardized

at the enterprise level, but driven down to the departmental level; in effect think globally, and act locally. QMS and MES should focus on genealogy and traceability, SPC data, supplier scorecards, in addition to the audit capabilities you will need for compliance.

- **Leverage your PFA and MES data to feed your Quality Management System (QMS), implementing multiple QMS modules.** Use PFA to work with your suppliers and establish supplier scorecards so that quality can be benchmarked with all inputs. Within MES, enable at least the portions which will give you a window into quality metrics such as SPC, quality workflows, and alerts.

The Best-in-Class are more likely to have seen synergy from the offerings within QMS and their integration with other technologies. It is time for Life Sciences to use these synergies as opportunities to gain a competitive advantage.

For more information on this or other research topics, please visit www.aberdeen.com.

Related Research	
The Cost of Quality; July 2007	*Compliance and Traceability: Insight into Pharmaceutical Manufacturing*; Jan 2008

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