

How to Measure Quality Culture

A Xavier University/PwC Initiative

Using SchellingPoint Software and Methods

Industry White Paper

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Background

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law, expanding FDA’s ability to safeguard and advance public health.¹ The Act provides FDA with the ability to collect data and information from pharmaceutical companies prior to or in lieu of an inspection (FDASIA Title VII, Sections 704, 705 and 706). These provisions remove the mandatory requirement for biennial inspections, and allow FDA to justify inspectional frequency based on risk analyses. In February 2013, FDA announced its Quality Metrics Initiative², in which it engaged the pharmaceutical industry to develop a list of data FDA should request from pharmaceutical manufacturers to assess product quality risk and, therefore, aid in its risk-based resource allocation decisions. Additionally, the data requested could provide an indication to FDA of risks to drug supply disruption and can assist investigators in defining where to focus inspectional time spent in the manufacturing plants for more efficient and effective inspections.

In support of FDA’s intent to allocate its resources based on risk, Xavier University and PricewaterhouseCoopers (“PwC”) launched a Metrics Initiative in August 2014 to identify product quality risk metrics linked to patient safety that could be viewed during an inspection. Xavier University and PwC led a team of 31 industry professionals that developed a framework of 11 metrics across the Total Product Life Cycle (TPLC).³ The proposed metrics framework was designed to help offer a tool that stakeholders across the industry could use to inform decisions and trigger action. It is built upon driving a mindset of continual improvement that includes feedback loops across the entire enterprise to design quality into the product proactively at the source, instead of reactively catching inadequate quality after manufacture.

In July 2015, CDER issued its “Request for Quality Metrics” draft guidance for industry, which contained its proposal for which metrics to use to compare company-to-company risk. Within this draft guidance, CDER acknowledged “the importance of quality culture to the overall state of quality of the product, process, and commitment to quality.” CDER also indicated that a “corporate commitment to quality has been identified in multiple public forums as a strong

¹ FDA Safety and Innovation Act: <http://www.gpo.gov/fdsys/pkg/BILLS-112s3187enr/pdf/BILLS-112s3187enr.pdf>

² The 2015 FDA “Request for Metrics” draft guidance and the intent of its use are described on the following FDA Voice Blog page: <http://blogs.fda.gov/fdavoices/index.php/2015/07/quality-metrics-fdas-plan-for-a-key-set-of-measurements-to-help-ensure-manufacturers-are-producing-quality-medications/>

³ Xavier University/PwC “Pharmaceutical Quality Metrics” white paper. January 31, 2016.



indicator of a robust [Pharmaceutical Quality System].” As a result, CDER proposed an optional cultural metric to identify whether senior management is engaged in the assessment of product quality, as well as whether there is shared knowledge of this assessment with the quality and manufacturing organizations.

Contrary to the authority given to CDER, FDASIA did not remove the mandatory requirement for FDA to conduct biennial inspections of medical device firms. Therefore, in its 2016-2017 Strategic Priorities⁴, CDRH identified the need to establish a *voluntary* program to recognize the independent evaluation of product and manufacturing quality. Additionally, CDRH continues to lead its Case for Quality initiative under the Medical Device Innovation Consortium⁵, in which it is working “to identify those practices that can promote a culture of quality and the implementation of a quality management approach that fosters continuous product quality.” Xavier University and FDA led a team of industry professionals and FDA officials from September 2014 – July 2016 to identify metrics across the Total Product Lifecycle that could inform decisions and trigger actions in a way that shifts the Right-First-Time mentality as close to the initial days of development as possible.⁶ The importance of Senior Management involvement and the commitment to a culture of quality was identified through this work, which informed the final metrics proposed to industry.

Research has demonstrated for many years that a strong culture of quality is the foundation for a company’s ability to consistently perform at a safe, effective and reliable level. For example:

- “The most important factor driving innovation is the internal culture of the company” *MIT Sloane Management Review. July 1, 2007. “Measuring the Culture of Innovation”*
- “Organizational culture can be a major asset or a damaging liability that hinders all efforts to grow and become more successful.” *Business Finance Magazine. October 3, 2011. “How to Measure a Company’s Most Elusive Element: Culture.”*
- “Without the proper leadership even the best people will gradually disengage and lose direction.” *The American CEO. August 27, 2013. “How can CEOs measure culture?”*

⁴ CDRH 2016-2017 Strategic Priorities.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/default.htm>

⁵ CDRH Case for Quality initiative under the Medical Device Innovation Consortium. <http://mdic.org/cfq/>

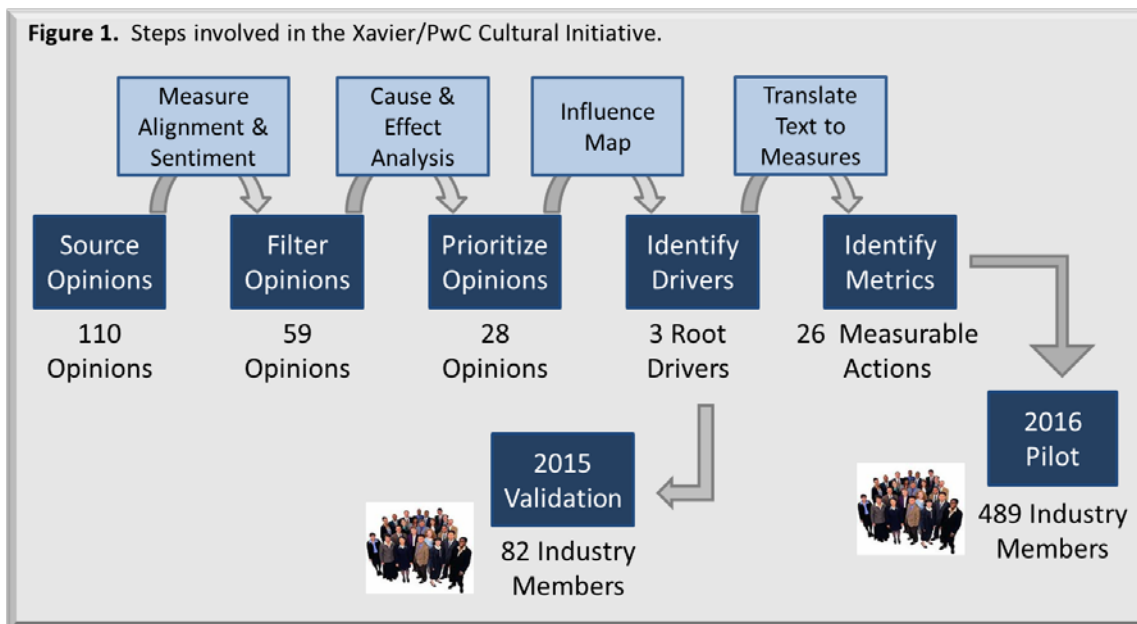
⁶ Xavier University/FDA Medical Device Metrics initiative. <http://xavierhealth.org/device-measures-initiative/>



Based on the need for the pharmaceutical and medical device industries to quantitatively and objectively measure the strength of an organization’s commitment to a culture of quality, Xavier University and PwC launched a Cultural Metrics Initiative in 2014. Xavier and PwC partnered with SchellingPoint to develop an assessment of an organization’s quality culture using sophisticated quantitative algorithms based on the Nobel Prize winning game theory research of Thomas C. Schelling.⁷ The outcome and benefit of this work is the focus of the remainder of this white paper.

Methodology and Results

The Xavier University/PwC Cultural Metrics Initiative involved a rigorous, five-step methodical process that is depicted in Figure 1. Importantly, every step in the process included orthogonal verification processes to ensure (a) the thoroughness and objectivity of the input; (b) that the information could be correlated to the intended purpose of our work, and (c) that the input was not inadvertently biased by group-think or lack of diversity. The verification processes included alignment assessments through SchellingPoint technology, pilot studies, and use of multiple analytical tools per step with a comparison of the output.



⁷ Thomas C. Schelling, Nobel Prize Winner, 2005. www.nobelprize.org/nobel_prizes/economic-sciences/laureates/2005/

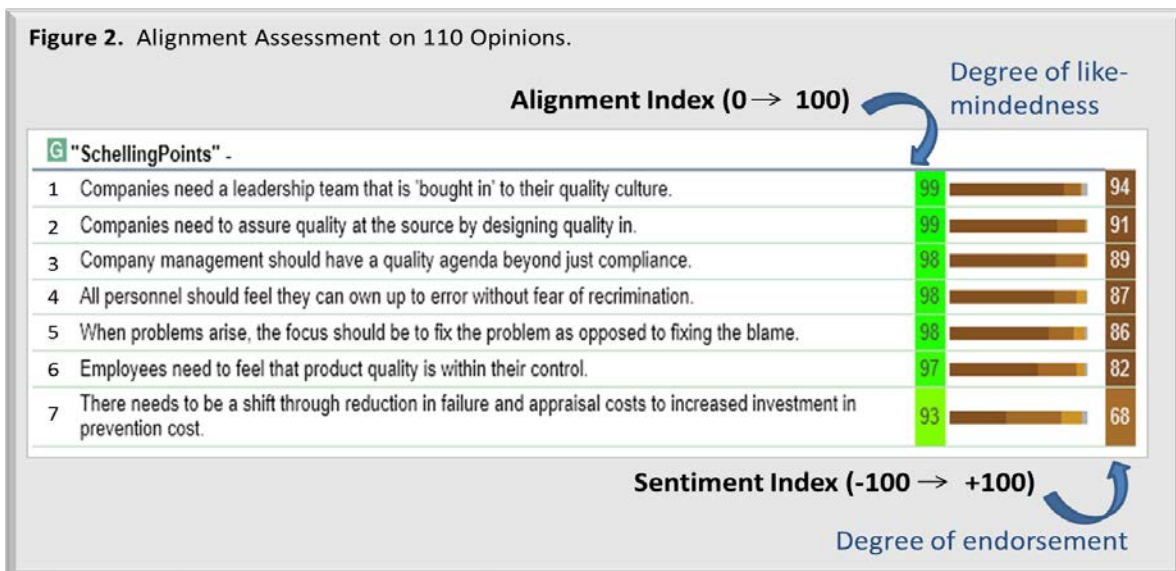


In order to quantitatively measure culture, employees need to be able to point to tangible activities they can see in action, and therefore, measure. Based on this notion, we asked a group of 8 pharmaceutical industry thought leaders the following question in the Fall of 2014 to generate and capture their opinions:

If you walked into a company today, what would you have to see in action to know that company has a strong culture of quality?

Each thought leader responded independently through the SchellingPoint virtual interview software, resulting in 110 unique and relevant opinions. As a point of reference, SchellingPoint research from over 250 firms across a wide array of industries has found that on average groups have 167 opinions driving their behavior. It is believed that our group of thought leaders generated fewer opinions collectively due to their experience on the topic, their awareness of cultural driving forces, and their experience in the pharmaceutical industry directly.

Instead of going forward blindly with all 110 opinions generated by our thought leaders, we gave each individual an opportunity to provide their input on how strongly they felt each opinion was correlated to signifying a strong culture of quality. Using the SchellingPoint virtual interview process, the degree of alignment and sentiment of each opinion was generated (refer to Figure 2).





As indicated in Figure 2, the Alignment Index ranges from 0 to 100, and measures the degree of like-mindedness of the group. A group that is highly aligned on the opinion statement has a group level closer to 100. Conversely, levels close to 0 demonstrate that the group is not aligned on the opinion, while levels in the mid-range indicate divided levels of alignment. This technology moves a group from “Are we aligned?” to “How aligned are we?” Also shown in Figure 2 is the Sentiment Index, which ranges from -100 to +100, and measures the degree of endorsement of the group. A group might be aligned on an opinion, but the sentiment level provides an indication of their level of agreement with the opinion statement. A level of -100 would indicate that the group largely does not feel the stated opinion is one that is true, whereas a level of +100 indicates that the group agrees with the statement. A sentiment level in the 80’s or higher indicates that the group “endorses” the opinion.

The virtual alignment interview process resulted in 59 opinions that were sufficiently supported by the group of thought leaders to carry forward in the process. In order to ensure the resulting 59 opinions were relevant to the goal of the initiative, Xavier and PwC led the team through a Cause and Effect analysis which allowed each team member to vet each opinion against the following critical requirements:

1. How strongly do you feel that this behavior will provide an indication of the cultural assurance of product quality?
2. How likely do you feel this behavior can be objectively measured?
3. What is the likelihood that companies are not measuring this yet?
4. How strongly do you feel that this behavior is innovative?

After a Pareto analysis of the combined results of the Cause and Effect matrix, an inflection point was observed at opinion 28. Upon review of the opinions in relation to the inflection point, it was decided to carry forward only the top 28 opinions. These 28 opinions were discussed with the team, upon which the top 3 opinions were agreed upon. Again, these opinions were related to what these thought leaders would have to see in action to know that a company has a strong culture of quality. The top 3 opinions are referred to as the “Root Drivers”.

In order to demonstrate that the top 3 Root Drivers were objectively obtained and relevant to the goal of our work, a separate, orthogonal approach was taken to create an influence map of the 28 opinion statements. An influence map is created by demonstrating which opinions are



dependent on other opinions. The opinion statements that have the most dependent sub-opinions linked to it could then be carried forward to represent multiple other statements.

The resulting Root Drivers obtained through Pareto analysis versus those obtained through the Influence Map are shown in Table 1.

Table 1. Comparison of top Root Drivers obtained through Pareto analysis versus Influence Mapping.

Top Root Drivers from Pareto Analysis	Top Root Drivers from Influence Map
Enterprise-wide quality ownership would include the integration of quality, and collaboration across all functional areas and processes	Companies need a leadership team that is “bought in” to their quality culture
Companies need to assure quality at the source by designing quality in	Quality improvement programs/initiatives should be in place
A quality culture includes “doing the right thing when no one’s looking”	The best way to achieve quality is by prevention

Interestingly, a side-by-side comparison shows that the Root Drivers highlighted in gray cover the intent of all 6 root drivers listed in the table. As a result, the team decided that the Root Drivers highlighted in gray should be carried forward in the overall process, which represent the themes of Collaboration, Leadership and Continual Improvement. The Root Drivers obtained through our process confirm the intuition of our thought leaders, which is important. Now the challenge was to determine how to measure whether a company has enterprise-wide quality ownership, and that the leadership team is “bought-in” to the quality culture, and the company is designing quality in at the source. This posed an interesting question since most people would agree that the root drivers are important, but are not able to articulate how any of them are actually measured.

In order to establish how to measure the 3 Root Drivers identified in gray in Table 1, a face-to-face meeting was held in August 2015 whereby a facilitated SchellingPoint process was used to convert the logical and rational statements in the 3 Root Drivers into identifiable practices. This involved defining every word in each of the three statements to ensure a common understanding of what was to be measured. This challenging exercise was crucial to the



success of this work and involved several surprising revelations in how differently each team member was interpreting the statements. One such example was in defining the word “source” related to designing quality in at the source. One team member envisioned the start of the product development cycle in choosing the right incoming materials, process, design of experiments, and formulation. Another team member envisioned the Human Resource process of ensuring the right people were in place to do the job right from the beginning. Again, these discussions proved critical to successful identification of measures, and also triggered ideas of what could be measured. At the conclusion of this exercise, the group finalized 26 actions that could be observed and measured to assess the strength of an organization’s culture of quality.

2015 and 2016 Pilot Study Results

The SchellingPoint virtual interview process can be utilized by any organization to measure its performance against the finalized action items. This methodology goes beyond calculating average, mean, median and standard deviation results of typical surveys, and moves to more powerful analytics of alignment and sentiment that can be cut in numerous ways and combined into true Big Data (including Cluster Analysis) to identify meaningful patterns and gaps. The result of this process is an immediate identification of strengths and gaps specific to the organization, which results in focused remediation efforts tied directly to measurable improvements.

A. 2015 Pilot Study Results

Prior to the FDA/Xavier University PharmaLink Conference in March of 2015, an alignment assessment was conducted on a diverse range of 82 of the conference attendees to determine how strongly they felt each of the 26 actions under the 3 Root Drivers could measure the strength of an organization’s culture of quality. The diversity of the participants is shown in Figure 3.



Figure 3. Demographics of 2015 Pilot Participants

Branded Pharma (45)	Executive Management (9)	Operations (7)
Generic Pharma (15)	Vice President (8)	Procurement (2)
Contract Organization (7)	Director (34)	Quality (60)
Supplier (6)	Manager (14)	Regulatory Affairs (3)
Other Service Provider (9)	Supervisor (2)	Supply Chain (5)
	Individual Specialist (11)	Other (5)
	Consultant (4)	

Collectively, the group of volunteer pilot participants endorsed the 26 actions under the 3 Root Drivers, with Sentiment Levels of 83 for Collaboration, 82 for Leadership, and 76 for Continuous Improvement (100 being the highest possible level).

B. 2016 Pilot Study Results

Prior to the FDA/Xavier University PharmaLink Conference in March of 2016, 489 industry professionals participated in an alignment assessment around the following question:

How strongly do you believe the 26 actions are in place and are functional in your company?

The demographics of the 489 participants were as follows:

- 17 Senior Leadership
- 94 Directors and Managers
- 32 Supervisors
- 101 Operators
- 245 Non-Supervisory and Others

The 489 participants came from 22 organizations varying in organizational type as follows:

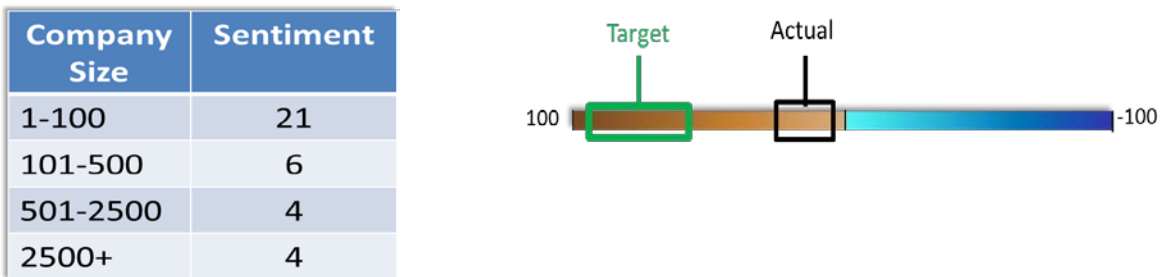
- 12 Pharmaceutical Manufacturers
- 6 Medical Device Manufacturers
- 2 Contract Manufacturing Organizations
- 2 Suppliers



The results of the Pilot Study are provided below along with demographic information. Additionally, next to each demographic breakdown is a sliding scale to demonstrate the level of endorsement versus the endorsement range that is targeted for any group around any topic.

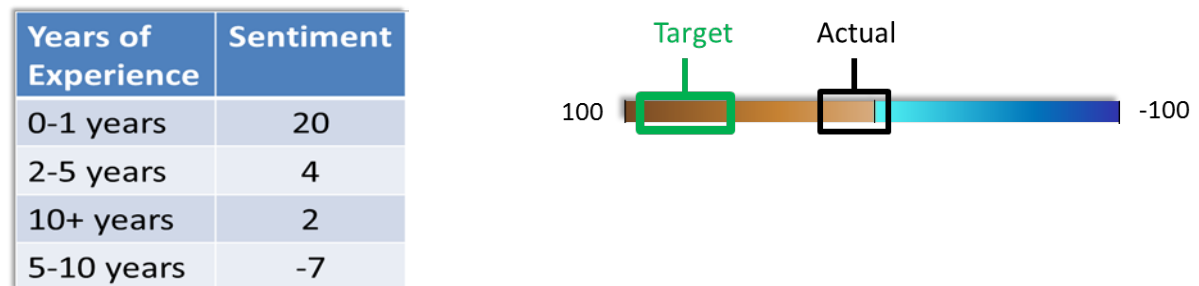
The first set of results can be seen upon comparing the sentiment across participants at varying company sizes (refer to Figure 4). The smallest companies felt most strongly that the actions are in place and are functional within their company; although a sentiment level of 21 is still well below the target range of greater than 80.

Figure 4: Sentiment across company size.



In Figure 5, sentiment generally decreases with years of experience. This could be related to assumptions made regarding company operations by new employees, or it could reflect a jaded impression by those who have worked in industry longer. In either case, however, the sentiment level is well below the target range, and would reflect a need to improve company actions around the identified 26 specific actions within all 3 Root Drivers.

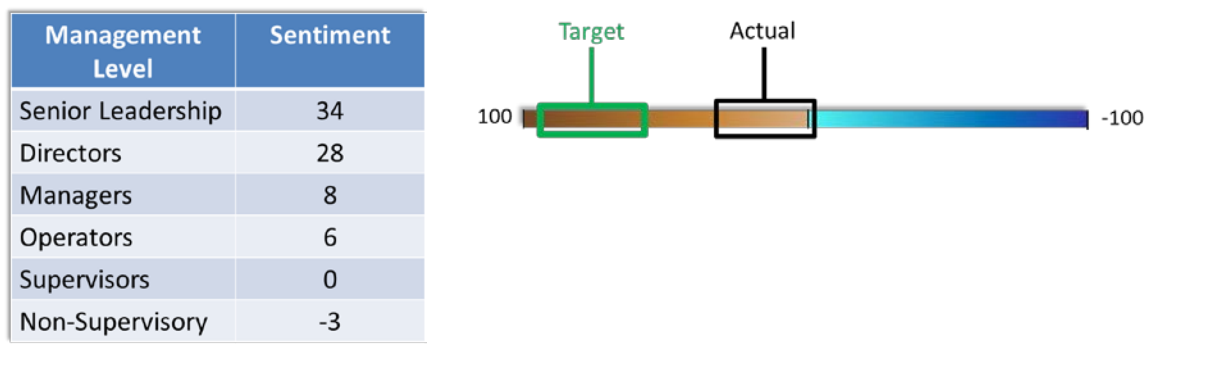
Figure 5: Sentiment across years of employee experience.





Upon review of the sentiment levels expressed by various levels of management in Figure 6, it is apparent that Senior Management feels most strongly that it has the actions in place and that those actions are functional. It is interesting that the level of sentiment decrease linearly with the level of management. The closer the employee is to the operation, the less the employee feels the company has a strong culture of quality around the themes of Collaboration, Leadership and Continuous Improvement. Again, all respondents support the need for mitigation and improvement around the 26 action items.

Figure 6: Sentiment across levels of management.



The sentiment response across management levels is provided in Figure 7 versus categories of some common processes. The data reveals a continuation of the pattern described above whereby senior management has the highest opinion of its organization.

Figure 7: Sentiment across levels of management per category.

	Level of Role							
	Executive Management	Vice President	Director	Manager	Supervisor	Operator	Individual Specialist	Other
Strategy & Governance	83	73	76	65	49	56	54	53
Processes & Procedures	67	75	75	64	51	57	59	56
Culture and Organization	78	58	71	59	53	54	53	50
Tools and Infrastructure	81	84	75	62	53	56	56	54

Figure 8 provides an analysis of the sentiment of all 3 Root Drivers across all 489 participants. This data demonstrates that the participants largely felt that none of the 3 Root Drivers are in place and effectively implemented within their organization.



Figure 8: Overall Sentiment of the 3 Root Drivers.

3 Root Drivers	Sentiment
Designed in at Source	17
Enterprise-Wide Collaboration	6
Leadership Buy-in	1

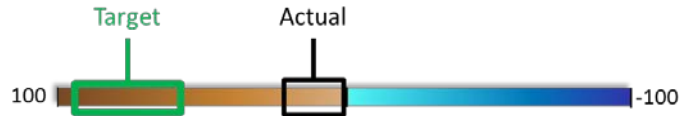
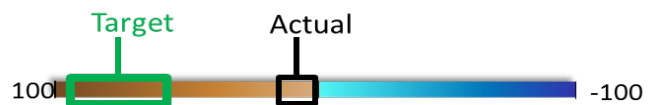


Figure 9 shows the sentiment data per functional area. Perhaps the most telling information is the way in which the Quality Organization responded in regards to the Culture of Quality within its own organization. Again, certainly the sentiment levels of all functional areas were well below the target endorsement range.

Figure 9: Sentiment level per functional area.

Functional Area	Sentiment
Regulatory Affairs	13
Procurement	11
Supply chain	9
Other	9
Operations	4
Quality	0

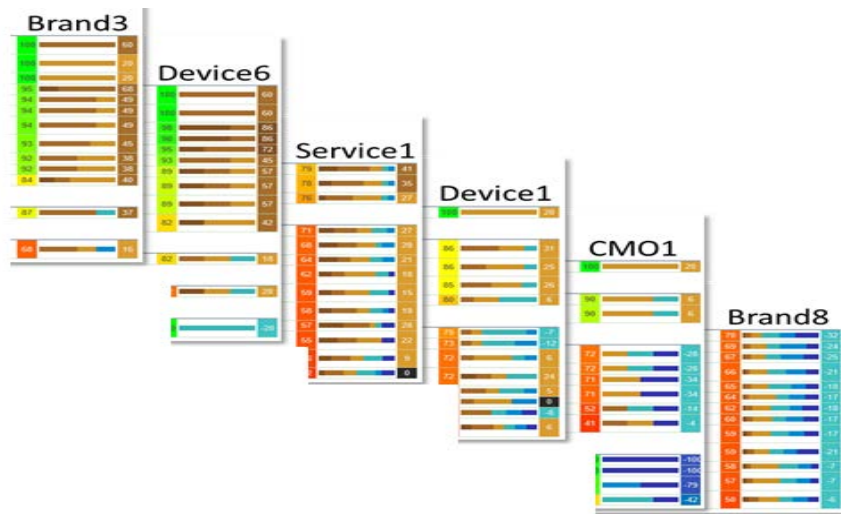


A deeper assessment of the responses made by Quality professionals was conducted by looking at only the data from Quality professionals, but across all types of organizations involved in the Pilot Study. Figure 10 shows that there is no bias toward any type of organization. A Branded pharmaceutical company is at the top, however, a different Branded pharmaceutical company is at the bottom. These charts are read as follows: The alignment level is given in the left column, while sentiment is given in the right. The greater amount of brown seen on the gradient bar between the two indicators corresponds to a



higher level of endorsement. Therefore, these organizations become progressively lower in endorsement level as you move from left to right.

Figure 10: Level of sentiment amongst Quality professionals across varying organizational type (dark brown signifies strong sentiment, whereas dark blue signifies lack of sentiment)



Interestingly, despite research published in the Harvard Business Review that “A company with a highly developed culture of quality spends, on average, \$350 million less annually fixing mistakes than a company with a poorly developed one” and “Companies ranked in the top 20% in terms of quality culture reported 75% fewer “significant mistakes” in their daily work,”⁸ we found the following results from our 2016 Pilot Study participants:

2016 Xavier/PwC Pilot Study revealed that:

- 50% of the employees surveyed reported insufficient leadership emphasis on quality
- 10% found their company’s quality messages credible
- 38% reported high levels of peer involvement
- 20% said that their company has created a sense of employee empowerment and ownership for quality outcomes

⁸ *Harvard Business Review*. April 2014. “Creating a Culture of Quality.”



Implementation and Industry Benefits

It is widely understood that company culture could impact the performance of the organization in a way that could induce risk to product quality, and therefore ultimately, increase risk to the patients served. Through the Xavier/PwC Cultural Metrics Initiative, industry is now able to pinpoint gap identification around 26 succinct action items that thought leaders identified as necessary actions to establish a strong culture of quality. Importantly, these 26 action items were orthogonally verified and assessed by larger groups of participants through pilot studies in 2015 and 2016.

The “28” Action Items:

The following list of actions that can be measured includes 2 additional actions that have been identified since the time of the original research. Therefore, the “26 Action Items” are actually “28 Action Items”.

Enterprise-Wide Quality Ownership:

1. {Company's} personnel have shared, cross-functional objectives to improve quality
2. {Company's} personnel possess sufficient incentives to collaborate cross-functionally on quality improvement
3. {Company's} personnel effectively collaborate across functions to improve quality
4. The {Company} performance management process includes 360-degree cross-functional input on performance against quality-related objectives
5. {Company} is responsive to assessments of itself from external partners through vehicles such as 2-way scorecards, partner contract complaints, or other mechanisms
6. There is sufficient bi-directional involvement from cross-functional groups on quality-related objectives
7. Quality objectives are cascaded throughout {Company's} entire organization (top to bottom and across functional areas); and performance is rolled all the way up
8. There is strong alignment of expectations between {Company} and their partners (including alignment between the supplier agreement and the quality agreement)
9. {Company's} non-quality leaders report their own quality numbers, assess trends, and resolve issues



10. {Company} personnel are self-reporting issues through self-audit

Leadership Buy-in Practices:

{Company} is making sufficient investments in:

11. IT systems that reduce quality risk
12. Employees needed in the quality function
13. Equipment maintenance necessary to reduce product quality risk
14. Facility maintenance necessary to reduce quality risk
15. Improvement projects designed to reduce quality-related risk
16. {Company's} quality projects are sufficiently proactive rather than just reactive
17. {Company} is actually spending the budget it allocates to quality improvement
18. {Company's} leadership are familiar enough with the everyday operations in my area to know the challenges, needs that have been expressed, and areas of opportunity for improvement
19. {Company's} leadership listen, without retribution, to employees who bring them quality ideas/suggestions/ concerns
20. {Company's} leadership is sufficiently acting on quality ideas/suggestions /concerns
21. {Company's} executives attend quality meetings and/or participate in an effective escalation process
22. {Company's} most recent employee survey illustrates strong corporate buy-in to quality improvement
23. {Company's} most recent employee survey illustrates strong enterprise (not corporate) buy-in to quality improvement
24. {Company's} leadership satisfactorily addresses poor performance.

Designing Quality in at the Source:

25. {Company} strives for Right-First-Time in all operations; including activities such as product development, supplier selection, Standard Operating Procedure development, etc.
26. There are sufficient policies, procedures, models and leadership support to enable {Company} employees to strive for Right-First-Time in all operations
27. There is a feedback loop/change management process in place that leads to continuous quality improvement (when needed)



28. {Company's} tolerance of risk appropriately protects product quality and safety.