



COMPLIANCE
INSIGHT, INC

Quality Culture Improvement Program (QCIP)

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Quality Culture Improvement Program (QCIP)

The FDA is challenging the way pharmaceutical and medical device companies are doing business. The FDA has raised the bar and made it clear; regulatory compliance is just the starting point when it comes to operational excellence and commitment to quality. The FDA is asking about **your** organization's commitment to quality. How will you demonstrate this commitment? Will you mention lagging indicators such as customer complaints? Reworks? Will you show them batch records? Do these metrics predict quality? Do FDA inspections predict quality? The FDA has already acknowledged that although lots of resources and dollars have been spent on inspections every year, they do not predict quality.

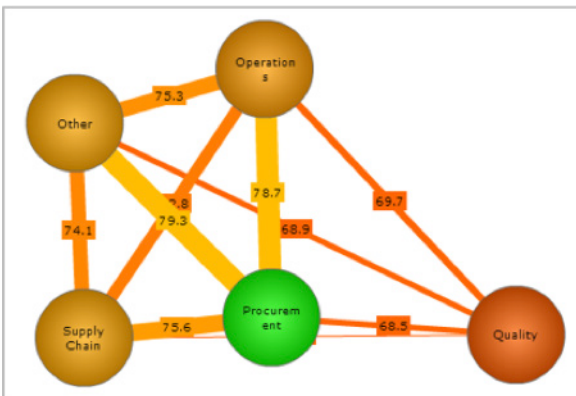
RM Project Symphony Change Roadmap

The set and sequence of activities which will ensure sponsor and user support for the implementation and their ability to realize its potential.

Process Design	Solution Design	Solution Testing	Production
Corporate *Value Proposition	*Success Criteria	*Training Calendars	
Sites *Roles and Resp	*Role-Based Training	*Training Hours *Efficiency Training	*Issue Mgmt
Change Team *Comms Processes	*Custom Enhancements	*Training Standards Compliance	*Rollout Plan
Partners *Cross-Training			
SAP *SAP Support Model	*Multi-Tasking	*Training Databases *Training Materials	

Through a collaboration between Xavier Health, Price Waterhouse Coopers, SchellingPoint and over twenty seasoned industry professionals, there is now a proven way to quantitatively measure an organization's commitment to quality and their quality culture. After successfully completing pilot studies involving 22 companies, not only did the data provide direct quantitative measurements that the FDA is seeking, but the data also revealed pre-failure knowledge and unknown risks that were simply unavailable previously.

A unique and critical deliverable of the Quality Culture Improvement Program or QCIP system is a personalized actionable roadmap, that has been established through an integrated process that will advance your culture of quality. This action roadmap contains actions that address the root cause of real evidence provided by your employees, which are verified by your team and aligned with your organization's strategies and goals. Your actions will make a difference.



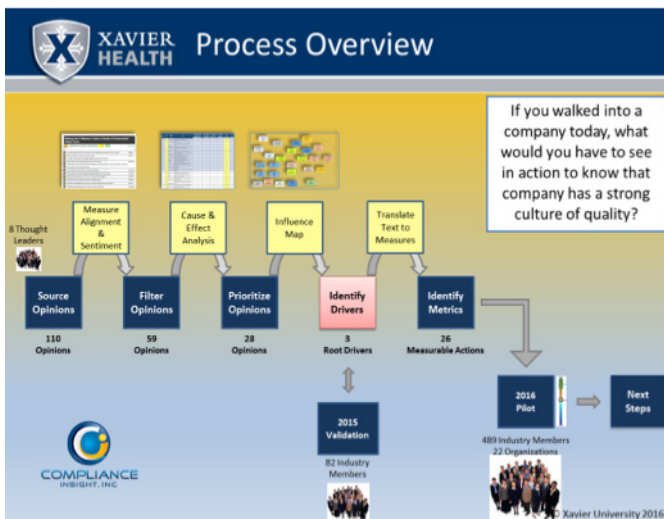
Big Data Analytics creates a color-mapped Node Diagram depicting the cross-functional alignment throughout the entire organization.

Compliance Insight has been chosen to be a key distributor for this model known as QCIP. It is a seven-step action-determination system that will save you time and money, and quantify your quality-culture. It will assign an indexed score that can be used to compare your organization to the rest of the industry.



TWENTY-SIX (26) KEY INDICATORS OF QUALITY

Seasoned industry professionals from the top Medical Device and Pharmaceutical companies in the world were asked to identify key indicators of quality. They were asked what would they have to see in an organization to determine that they were committed to quality. Over time through facilitated collaboration and utilizing cause and effect analysis and influence mapping, it was determined that these twenty-six (26) key indicators should be present and practiced in organizations that are committed to quality. The initial phase of QCIP asks the question: "How strongly do you believe these twenty-six (26) practices are in place and are functional in your company." The data captures sentiment and alignment of senior leadership, directors, managers, operators, supervisors and non-supervisors and compares functional groups and sub-groups within each of these functional groups. Sophisticated algorithms, developed by Thomas P. Schelling, create BIG data that is used as the foundation for initial baseline understanding. After completing all seven (7) steps, you will have an action roadmap, a clear path to mitigation, so that you know exactly where to spend time and resources that will have the greatest impact on quality culture.



Process Overview to Determine Leading Indicators

A key aspect of the QCIP model is the systematic approach used to determine the true leading indicators that should be present and practiced in an organization that is committed to quality; a direct reflection of the quality culture. Utilizing influence mapping and cause and effect analysis, the key leading indicators were edited down from 110 to 26.

This picture represents the seven-step action determination system that leads to the Action Roadmap. The steps are:

- 1) Interview Process: Provide Level of Agree/ Disagree (sentiment)
- 2) Provide initial reasoning for sentiment.
- 3) Leadership learns alignment and sentiment across organization.
- 4) Confirmation of Key endorsed assumptions.
- 5) Pinpoint inadequate indicators.
- 6) Action Determination: Review surface reasoning and diagnose issues.
- 7) Action Determination: Sequence actions and assign owners.

Quality Culture Improvement Program model



OUR CODE OF COMMITMENT TO YOU

All of the members of Compliance Insight appreciate your commitment to use our services to meet your compliance goals. We, therefore, commit the following actions to you – our partner:

ETHICAL EXECUTION OF WORK

- Trustworthy – We will:
 - § Not deceive, cheat or “milk” a client for time or services performed
 - § Be honest and reliable
 - § Be loyal, reliable and maintain integrity
- Respectful – We will:
 - § Abide by the Golden Rule — do unto others as you would have them do unto you
 - § Be respectful of the clients’ money – be a good steward

EXPERTISE AND SKILLS

- Colleagues assigned to the project will have the skillsets to perform the task
- Being accountable. Ethical people show responsibility by being accountable and pursuing excellence by being diligent and persevering
- Have the ability to respond to expectations
- Own the task assigned

CUSTOMIZATION OF EXECUTION

- Fitting project actions into the client’s unique circumstances and operations
- Learn the specific processes at the site to understand how best to effectively and efficiently implement compliance

TIMELINESS

- Rapid response to effectively execute the tasks assigned
- Have skilled colleagues on site and/or actively working to resolve issues quickly

ACCESSIBILITY

- Easy availability to discuss the project execution with key decision makers

Our mission:

Go beyond the regulations to compliance that makes sense

Our vision:

Your first and best choice for decisive insight into GxP compliance!

2018 Pharma Tech Outlook: Company of the Year

Compliance Insight has been selected for Company of the Year! They have demonstrated a commitment to excellence and gained strong industry credibility,” Said Stacy Smith, Managing Editor, Pharma Tech Outlook. “I congratulate Compliance Insight and look forward to its continued success.”



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