Living a Quality Culture: Questions to Consider While Evaluating and Measuring

REGULATORY COMPLIANCE ASSOCIATES® INC.
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Impact of Quality Performance

FDA Vision

> "A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drug products without extensive regulatory oversight."
>
> Janet Woodcock, October 2005

Benefits to Industry
Opportunity to build a quality-minded company culture to drive continuous improvement and ensure stable supply of drug product. For demonstrated Quality Performers, the FDA will grant privileges such as potentially less frequent inspections and "preferred handling" of post approval changes

What Companies Need to Report

- The number of lots attempted of the product
- The number of specification-related rejected lots of the product, rejected during or after manufacturing
- The number of attempted lots pending disposition for more than 30 days
- The number of OOS results for the product, including stability testing
- The number of lot release and stability tests conducted for the product
- The number of product quality complaints received for the product
- The number of OOS results for lot release and stability tests for the product which are invalidated due to lab error
- The number of lots attempted which are released for distribution or for the next stage of manufacturing the product
- If the associated APRs or PQRs were completed within 30 days of annual due date for the product
- The number of APRs or PQRs required for the product

Plus 3 option metrics

RCA can determine if these are value-add for your company

Setting Metrics - Scenarios

Scenario 1
Company was having issues with excessive OOS's in the lab. Senior Management overreacted and set a Metric Goal of Zero (0) OOS's.

Intended Metric

1) To reduce the amount of repeat analysis and OOS investigations.
2) Improve Analyst Execution of methods to reduce errors.

Actual Outcome

1) Analyst began classifying OOS results as out-of-trend or non-conforming results to avoid counting towards OOS.
2) Some laboratory issues were not properly elevated to management, and proper root cause not determined.
3) Ultimately the goal was unrealistic and ineffective.

Scenario 2
Company wanted to reduce time to close out investigations, so set a reward structure based on meeting investigation close out goals.

Intended Metric

1) To minimize time spent on investigations which deter from more productive activities such as making and releasing product.

Actual Outcome

1) Analyst began closing out investigations on or before target date, then if needed, re-opened under new investigation.
2) The completeness of the investigations faltered, root cause was not found for many issues.
3) Resulted in repeat paperwork, and repeat issues due to lack of root cause identification.

Scenario 3
Company implemented a new Metric to track days from Manufacturing to Product Release.

Intended Metric

1) To reduce product inventory waiting for product release and improve cash flow.

Actual Outcome

1) The first month, the average days to release was 34 days.
2) When informed of the result, management initiated a cross-functional team to map timeline for product release and identify areas for improvement.
3) The team identified several functions that were currently performed in sequence that could be done in parallel, QC was included in production planning to better anticipate product testing schedule and the QA review process was streamlined resulting in a drop in average days from 34 to 18 days in just the third month.

Lessons Learned
The first two Scenarios show the outcome when established metrics were not realistic or when setting metrics when either the metrics were not realistic or when management does not properly convey the intent. The staff, either in fear of repercussions or in search of monetary rewards found a way to meet the goal.

Scenario 1 and 2 also reflect a problem with the quality culture. The management was not aware of the quality culture, and the staff felt either unsupported in their quality goal, or manipulated the reporting results for a positive outcome.

Scenario 3 is an example of a success story. The management acknowledged and took ownership of the problem once it was apparent, and initiated an investigation to resolve. The team worked collaboratively between several departments to achieve the intended goal for the company. The long term result was faster product release, reduced overhead and improved cash flow. Well worth the time invested to proper assess, identify and correct the issue.

Quality is Embedded into the Culture

Do's

- Be sure to convey the intent behind each Quality Metric. The objective isn't to hide the problems to make the numbers look good.
- Emphasize the fact that Quality Metrics are a tool to identify areas for improvement, not the result.
- Support the intent of the Quality Metric, and encourage others to do the same. Do the right thing.
- Focus on proper root cause identification of the issues, and correction of issues. If you are successful, the numbers (both metrics and financial) take care of themselves overtime.

Dont's

- Set Metrics without first determining the quality goals.
- Set goals that are not achievable.
- Make the Metrics too Complex.
- Overreact to initial data without understanding the context.
- Let Metrics replace Quality.
- Dismiss Quality over short- term gain.
- Think of Quality as someone else's responsibility, take ownership.
- Let Metrics become a surrogate for Quality.

Timeline

FDASIA Becomes Law
July 9, 2012

Federal Register
Notice 12 Feb 2013

Industry meetings, conferences, surveys between February 2013 and issuance of Guidance

Guideline Issues
July 2015

Public Meeting Held
August 24, 2015

Federal Register Notice of August 26, 2015 extends comment period to November 27, 2015

FDA Draft Guideline on Quality Metrics

FDA Goals

- Help FDA develop Compliance and Inspection Policies and Practices
- Help FDA Predict and Mitigate Future Drug Shortages
- Encourage Implementation of State-of-the-art, Innovative Quality Management Systems within the Pharma Industry
- Encourage Improvement of Pharma Quality Culture

In this Guidance Document, FDA "acknowledges the importance of quality culture to the overall state of quality of the product, process, and commitment to quality".

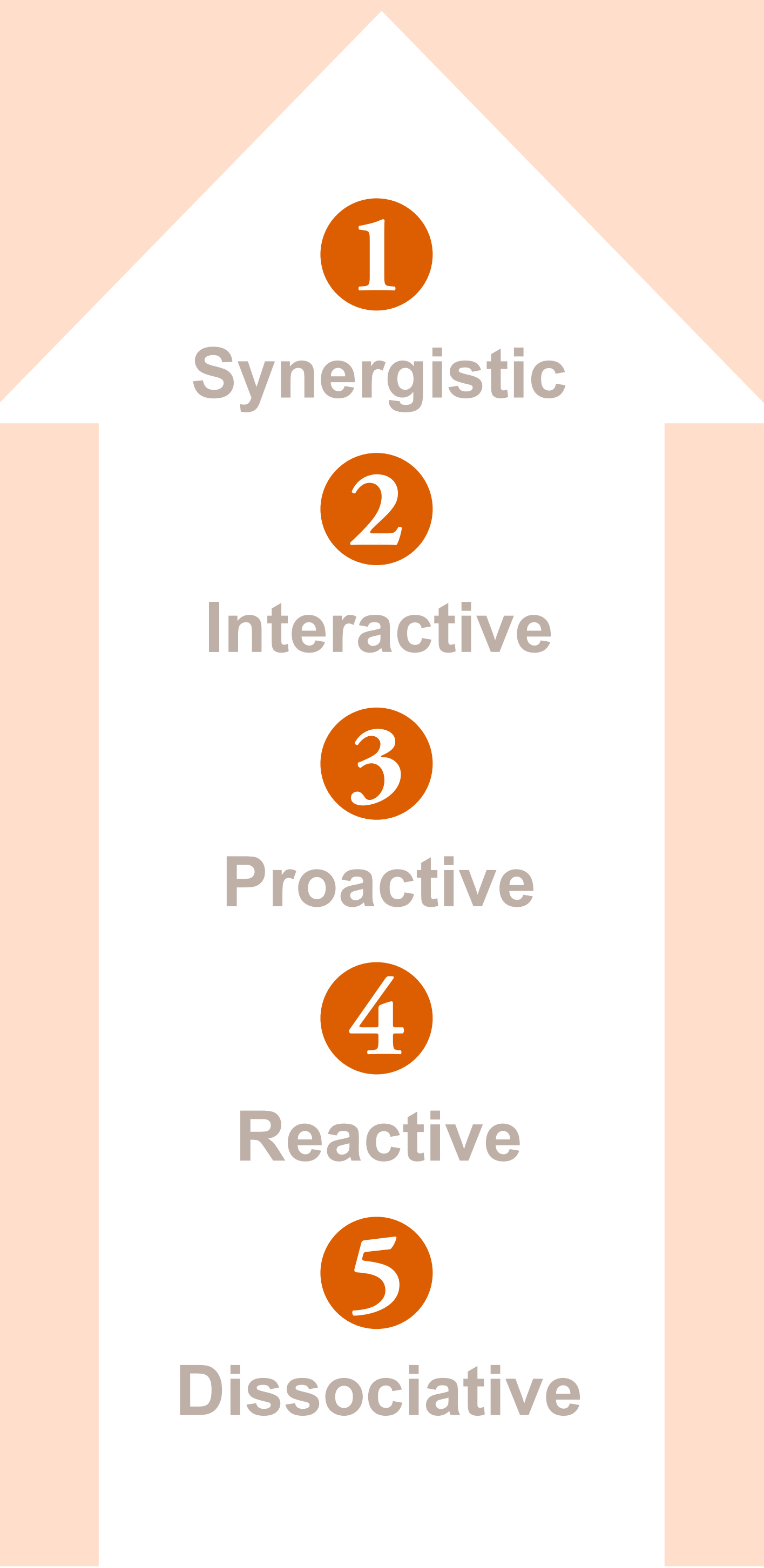
Using Metrics as a Tool to Improved Quality Culture

Objectives
Quality Metrics should start with the end goal in mind. These generally reflect the end goals the company and senior management need to achieve long term. For example, the objective could be long term success of the company which is based on producing high quality product and a competitive price.

Criteria/Functions
Define specific areas of accomplishment that satisfy major divisions of responsibility within a function. For example, Quality, QC, Management, Production and Supply Chain all have different functions. What are the critical functions from each division?

Measures
Metrics are designed to drive improvement and characterize progress made under each criteria. These are specific quantifiable goals based on individual expected work outputs. Each performance metric should lead to a quantitative assessment of gains in a particular area.

Assessing Your Quality Culture



1 Synergistic

2 Interactive

3 Proactive

4 Reactive

5 Dissociative

Conclusion

- When establishing a metrics program, companies should assess the current quality culture and determine their long term goals.
- Management should encourage interactive and synergistic cultures, and provide direction and support to achieve problem resolution.
- Employees should strive to improve current work flow, and properly track metrics and elevate issues.
- For product-Quality Metrics, companies should consider and convey the intent of the metrics in order to reduce manipulation and misrepresentation of the quality metric numbers.
- Quality Culture is a top down and bottom up goal. Each employee at each level must take ownership of quality within their area.
- There is no set requirement on which metrics a company should track to measure their overall performance. Focus on areas for improvement, be collaborative, and strive to keep staff focused on areas most meaningful for long term success.
- The Metrics chosen must be meaningful, realistic and written to provide a clear analysis of ongoing activities. It is important for operations and quality to agree on the metrics and how to report them to management to avoid overreaction to the data. It is not sufficient to simply report the data.

Remember, nothing ever improves without effort and attention.

So, where is your company spending their time?

Manage

Crises and Problems

- Daily fire fighting
- Delegate properly
- Rework
- Forced decisions

Focus

On Strategies and Value

- Opportunities
- Planning
- Continuous improvement

Avoid

Interruptions and Busy Work

- Manage time and resources needed
- Feels important but low value

Limit

Trivial and Wasteful

- Entertainment only
- Relieves stress
- Takes away from constructive work

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