

CULTURE/VALUES

PRESENTED BY

ROBERT G. KIEFFER, Ph.D.
4100 Ravenwood Court, NW
Albuquerque, NM 87107
(505) 344-1613
Rkief81270@aol.com

Outline:

- 1. Importance of culture
 - The Pharmaceutical Quality System
- 2. Components of a quality culture
- 3. Analysis of your organization's culture
- 4. Measurement of culture
- 5. Change/improvement of culture
- 6. References for further reading
- 7. Appendices

CULTURE

The behaviors and beliefs characteristic of a particular social group.

(Webster's dictionary)

Culture/Values serve as a guide to decision-making: they indicate what is important to the enterprise.

Forbes Insights, "Culture of Quality" (ASQ)

- Only 51% say values are clearly understood throughout the organization.
- Only 50% say leaders lead by example or otherwise "live" the values.

ISPE PILOT RESULTS, April 2015

- A stronger site culture correlates with fewer action limits exceeded in sterile product production.
- Stronger culture scores are associated with high lot acceptance rates.
- Sites with higher quality culture scores have lower recurrence of deviations.
- Sites with higher quality culture scores have higher CAPA effectiveness rates.

IMPORTANCE OF CULTURE

- Integral part of Pharmaceutical Quality System (PQS)
- Essential for continuous improvement of PQS
- Root cause of many failures

THE QUALITY SYSTEM

QUALIFIED PEOPLE

SUCCESS

PROCESSES

- Core (production)
- Supporting
- Supplier
- Management

CULTURE

An organization is made up of processes and people that make those processes happen.

An organization's culture - the way it does things, the way it "lives" - has a direct impact on how well its processes and people operate.

Culture of Quality:

Yes - 75% of executives:

Yes - 47% of ASQ members

(Hankel, "Clues about Culture")

CULTURE/VALUES

- 1. Customer focused (internal and external), Patient first.
- 2. Senior Management is responsible for the PQS and compliance with it.
- 3. Quality is responsibility of every employee, of the person doing the work. Product quality is the responsibility of production.
- 4. Quality before cost.
- 5. Employee empowerment giving power, responsibility, accountability to employees in proportion to their capabilities.
- 6. Continuous improvement.

Culture/Values

- 7. System approach to management: managing interrelated processes as a system; processes are well-designed, capable and controlled; process thinking
- 8. Use good science and quality and statistical tools
- 9. Emphasis on prevention, not appraisal.
- 10. Balance between short term and long term. Excellence require years.
- 11. Teamwork
- 12. Integrity
- 13. Drive out fear (Deming's 14 points)
- 14. Mitigate patient, employee and company risk
- 15. Give priority to learning individual and organizational

Culture/Values

- 16. Quality by Design, not Quality by Inspection
- 17. Beyond compliance to Excellence
- 18. Innovation
- 19. Rigidity vs Flexibility
- 20. Reduce waste

Which are the most important characteristics of culture? (5) Why?

Deming's 14 Points

- 1. Create a constancy of purpose focused on the improvement of products and services. (Long-term quality plan)
- 2. Adopt a new philosophy that recognizes we are in a different economic era. (Quality throughout the organization)
- 3. Do not rely on mass inspection to "control" quality. (Build quality into the process)
- 4. Do not award business to suppliers on the basis of price alone, but also consider quality. (Suppliers as partners)
- 5. Focus on continuous improvement. (Reduce waste)
- 6. Practice modern training methods and invest in on-the-job training for all employees. (Workers understand their role in the big picture)
- 7. Improve leadership, and practice modern supervision methods. (*Expect supervisors to understand their workers and processes*)

Deming's 14 Points

- 8. Drive out fear. (People are not afraid to express their ideas and concerns)
- 9. Break down the barriers between functional areas of the business. (*Internal customer concept*)
- 10. Eliminate targets, slogans and numerical goals for the workforce.
- 11. Eliminate numerical quotas and work standards. (*Measure processes not people*)
- 12. Remove the barriers that discourage employees from doing their jobs. (Allow everyone to take pride in their work)
- 13. Institute an ongoing program of education for all employees.
- 14. Create a structure in top management that will vigorously advocate the first 13 points. (*The transformation/change is everyone's job*)

STERLING WINTHROP VALUES

We are a winning team

We are customer driven

We are dedicated to continuous improvement

We have a sense of urgency

We act responsibly

PDA Quality Culture Metrics Survey

- Communication/transparency honesty
- Commitment and engagement leadership
- Technical excellence sharing, QbD, PAT
- Standardization of criteria and requirements
- Cross-functional vision
- Rewards and recognition
- Management and co-workers speak up for quality
- Metrics
- Prevention
- Issue escalation
- Training and personnel development
- Quality management system
- People and communication
- Continuous improvement

MALCOLM BALDRIGE CORE VALUES AND CONCEPTS

Visionary Leadership

Organizational and Personal Learning

Focus on the Future

Valuing Workforce Members and Partners

Managing for Innovation

Management by Fact

Focus on results and Creating Value

Agility

Societal Responsibility

Systems Perspective

Customer-Driven Excellence

ISO 9000 PRINCIPLES

Customer focus

Leadership

Involvement of people

Process approach

System approach to management

Continual improvement

Factual approach to decision making

Mutually beneficial supplier relationships

(See ISO 9004 for self assessment tool)

What culture should your organization have?

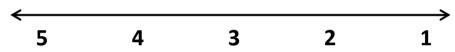
What is your organization's current culture?

What are the gaps/differences?

CULTURE/VALUES MEASUREMENT

- 1. Survey of employees, customers, suppliers (OPRA, Tigers Success Series)
- 2. Departmental Teamwork

Departmental Conflict



3. Maturity Scales: ISO-9004, Oliver Wight, etc.

Roles	10 Questions Regulatory Compliance Officer	Responses
Quality is owned by all Quality permeates the work	Does your company have a culture that quality is not just done for the sake of the job?	1
environment Staff feel safe to speak about issues because human lives are the bottom line	2 Do quality and operations personnel present operational issues to senior management together versus quality staff alone?	2
	3 Does the quality organization attract top talent?	3
	4 Are quality jobs open on average longer than other positions?	4
	Do people dread talking about issues, or are they seen as opportunities to make improvements?	5
	6 Is your turnover in quality higher than other parts of the organization?	6
	7 Do you understand what motivates people and use this information to do so?	7
	8 Is there a clear career path for quality professionals?	8
	9 Are opportunities for career advancement in quality equal to those in other parts of the organization?	9
	10 Do you have a formal strategy to increase employee engagement and do employees know about it?	10

Magnani and Vinther, PDA Letter, July/August 2013

In your opinion what is the most serious problem facing teams today?

	Agree	Disagree	No Opinion	This is not a problem
Clear communication between team members	*What is the most serious problem facing teams today? Clear communication between team members Agree	Clear communication between team members Disagree	Clear communication between team members No Opinion	Clear communication between team members This is not a problem
Conflict between team members	Conflict between team members Agree	Conflict between team members Disagree	Conflict between team members No Opinion	Conflict between team members This is not a problem
Poor team leader behavior	Poor team leader behavior Agree	Poor team leader behavior Disagree	Poor team leader behavior No Opinion	Poor team leader behavior This is not a problem
Procedural misunderstanding	Procedural misunderstanding Agree	Procedural misunderstanding Disagree	Procedural misunderstanding No Opinion	Procedural misunderstanding This is not a problem
Poor communication between leaders and team members	Poor communication between leaders and team members Agree	Poor communication between leaders and team members Disagree	Poor communication between leaders and team members No Opinion	Poor communication between leaders and team members This is not a problem
Unclear goals	Unclear goals Agree	Unclear goals Disagree	Unclear goals No Opinion	Unclear goals This is not a problem
Too many team meetings resulting in a back load of work	,	,	Too many team meetings resulting in a back load of work No Opinion	,



	Agree	Disagree	No Opinion	This is not an issue for our team
I have no understanding or experience in core value behaviors	*How familiar are you on the importance collaborative core values play in your daily operations? I have no understanding or experience in core value behaviors Agree	I have no understanding or experience in core value behaviors Disagree	I have no understanding or experience in core value behaviors No Opinion	I have no understanding or experience in core value behaviors This is not an issue for our team
I am not sure what core values are	I am not sure what core values are Agree	I am not sure what core values are Disagree	I am not sure what core values are No Opinion	I am not sure what core values are This is not an issue for our team
Our company values are well defined and we see demonstrations of our values daily in how we treat one another and our customers	Our company values are well defined and we see demonstrations of our values daily in how we treat one another and our customers Agree	Our company values are well defined and we see demonstrations of our values daily in how we treat one another and our customers Disagree	Our company values are well defined and we see demonstrations of our values daily in how we treat one another and our customers No Opinion	Our company values are well defined and we see demonstrations of our values daily in how we treat one another and our customers This is not an issue for our team
Our company has never considered values in the strategic planning process	Our company has never considered values in the strategic planning process Agree	Our company has never considered values in the strategic planning process Disagree	Our company has never considered values in the strategic planning process No Opinion	Our company has never considered values in the strategic planning process This is not an issue for our team
Our workplace is unpredictable at best	Our workplace is unpredictable at best Agree	Our workplace is unpredictable at best Disagree	Our workplace is unpredictable at best No Opinion	Our workplace is unpredictable at best This is not an issue for our team
Our leaders understand what we experience every day and this is evidence that our value system is working	we experience every day and	Our leaders understand what we experience every day and this is evidence that our value system is working Disagree	Our leaders understand what we experience every day and this is evidence that our value system is working No Opinion	Our leaders understand what we experience every day and this is evidence that our value system is working This is not an issue for our team

Oliver Wight

		LEXCEL MERCE RIP ROOF POLICE
2-2e	A process is in place to help workers expand their roles to become team players; (highly skilled, knowledge resources, customer advocates, trainers, problem solvers, and decision makers). This process includes training and follow-up support.	
2-2f	A process is in place to help supervisors, managers, and technical support professionals modify and expand their roles to become coaches, facilitators, customer advocates, barrier busters, motivators, and leaders. This process includes training and follow-up support.	
2-2g	Major achievements stemming from the continuous improvement and empowerment efforts are formally recognized and rewarded.	
2-2h	Major improvements and lessons learned are documented and integrated into daily management processes and future organizational development plans.	

Oliver	Wight
--------	-------

A comp	LTURE rehensive culture exists to support and e effective people and team processes.	
2-2a	Employees are empowered to take direct action whenever they encounter a problem that is likely to impact customer satisfaction, product or service quality, cost, and/or schedule.	
2-2b	Operating decisions are made at the lowest possible level, flowing logically and expeditiously throughout the organization.	
2-2c	There are few "status" distinctions be- tween managers and workers. There is a clear intention to minimize artificial barri- ers that would be detrimental to creating an open, highly empowered work environ- ment.	
2-2d	Information-passing processes, such as team meetings and "state-of-the-business" assemblies, are a regular part of work.	

CULTURE OF QUALITY: SELF-ASSESSMENT TOOL (cultureofquality.org)

- 1. Overall approach
- 2. What drives your organization's pursuit of quality?
- 3. To what degree are the following statements applicable to your organization's actions relating to customers?
- 4. Is the need to manage business risks a key driver of my organization's quality programs?
- 5. Which of the following are unquestionably key elements of your organization's quality vision?

Self-Assessment

- 6. Which of the following are unquestionably key elements of your organization's values?
- 7. Which of the following are unquestionably key elements of the leadership at your organization?
- 8. To what extent are investments in technology at your organization being used to improve performance against quality objectives?
- 9. To what degree are the following statements applicable to the key performance metrics used by your organization to measure and ensure quality?
- 10. Which of the following incentives does your organization rely on to ensure or reward quality?

Self-Assessment

- 11. Does your organization use explicit customer input, such as direct ratings or broader customer satisfaction surveys, in evaluating performance against quality metrics?
- 12. How effective is the use of customer input in evaluating performance against quality metrics?
- 13. What should your organization be doing in terms of involving customers in evaluating performance against quality objectives?
- 14. How effective is your organization in the following areas? (Customers)
- 15. What are the challenges faced by your organization in adapting quality programs such as training, metrics and supervision to meet the needs of an international workforce?

Self-Assessment

16. Which of the following best describes your organization's spending on quality over the next 18 months?

At the end of the self-assessment you receive an overall score and a report comparing your results with all the other organizations that took the self-assessment.

CULTURAL CHANGE

- 1. Assessment of the current culture
- 2. Vision of the desired state
- 3. Culture measures
- 4. Action Plan

Cultural Change

Responsibility of senior management

• Need to model desired behavior by their actions.

Hire for values, train for skills.

Office Kaizen II

"Every process improvement must be guided by the defined structure of an overarching cultural change initiative."

"If leadership is to be successful in changing its corporate culture, if the organization is to succeed at doing something different, a continuing, intense firestorm of matches must rain down on every cognitive map on a daily basis for years."

"The grooming and maintenance of a corporate culture that fosters improved performance is a leader's most critical and most difficult challenge. It can't be done with speeches, "programs", and tools; it demands active, daily leadership from every leader at every level."

"What genuinely assures compliance and then takes an organization to levels of quality way beyond the minimum is the organization's quality culture that is embedded in the values of the people that make any site function."

"A firm can have all the SOPs, systems, controls required but, without a quality culture, product quality and business continuity are not assured." "Henry Ford said 'Quality means doing it right when no one is looking'."

(Guy Villax, reference 5)

Develop a strategy and plan for improving your organization's culture

High quality standards and cultures cannot be achieved overnight by reading some books, manuals or FDA Guidance Documents or employing consultants. (P. Basu et al.)

"A system can not understand itself. The transformation requires a view from outside." (Deming)

References:

- 1. R. Kieffer, "The Quality Culture and its Measurement", PDA Letter, Feb. 2015
- 2. Deming's 14 points
- 3. Oliver Wight, "ABCD Check List for Operational Excellence", John Wiley and Sons
- 4. ISO 9004-2009 and ISO 9000
- 5. Guy Villax, "Culture of Quality", Pharmamanugacturing.com, 4/22/14
- 6. OPRA Group, "culture surveys", www.opragroup.com/survey/culture-surveys
- 7. Tigers Success Series, surveys", www.corevalues.com/tiger_survey/
- 8. Forbes Insights, "Culture of Quality", ASQ
- 9. W. Lareau, "Office Kaizen II", ASQ
- **10. PDA Quality Culture Metrics Survey**
- 11. A. Hankel, "Clues About Culture". Quality Progress, August 2014, ASQ
- 12. Friedli et al., "Leading Pharmaceutical Operational Excellence", Springer, 2013

Appendix 1: Maturity Models

Maturity Models

ISO 9004-2009, ANNEX A, Self Assessment Tool

4. Managing for the sustained success of an organization 9. Improvement, innovation and learning 5. Strategy and policy 6. Resource 8. Monitoring, measurement, analysis management and review 7. Process management



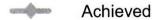




Table A.1 — Self-assessment of key elements — Correlation between key elements and maturity levels

Key element	Maturity level						
	Level 1	Level 2	Level 3	Level 4	Level 5		
What is the management focus? (Managing)	The focus is on products, shareholders and some customers, with ad hoc reactions to changes, problems and opportunities.	The focus is on customers and statutory/regulatory requirements, with some structured reaction to problems and opportunities.	The focus is on people and some additional interested parties. Processes are defined and implemented for reacting to problems and opportunities.	The focus is on balancing the needs of identified interested parties. Continual improvement is emphasized as a part of the organization's focus.	The focus is on balancing the needs of emerging interested parties. Best in class performance is set as a primary objective.		
What is the leadership approach? (Managing)	The approach is reactive, and is based on top-down instructions.	The approach is reactive, and is based on decisions by managers at different levels.	The approach is proactive, and the authority to take decisions is delegated.	The approach is proactive, with high involvement of the organization's people in its decision making.	The approach is proactive and learning-oriented, with the empowerment of people at all levels.		
How is it decided what is important? (Strategy & policy)	Decisions are based on informal inputs from the market and other sources.	Decisions are based on customer needs and expectations.	Decisions are based on the strategy and linked to needs and expectations of interested parties.	Decisions are based on the deployment of the strategy into operational needs and processes.	Decisions are based on the need for flexibility, agility and sustained performance.		
What is needed to get results? (Resources)	Resources are managed in an ad hoc manner.	Resources are managed effectively.	Resources are managed efficiently.	Resources are managed efficiently and in a way that takes into account their individual scarcity.	The management and use of resources is planned, efficiently deployed, and satisfies the interested parties.		
How are the activities organized? (Processes)	There is a non-systematic approach to the organization of activities, with only some basic working procedures or instructions in place.	Activities are organized by function, with a basic quality management system in place.		There is a quality management system that is effective and efficient, with good interactions between its processes, and which supports agility and improvement. The processes address the needs of identified interested parties.	There is a quality management system that supports innovation and benchmarking, and which addresses the needs and expectations of emerging, as well as identified, interested parties.		

Table A.1 (continued)

Key element	Maturity level						
	Level 1	Level 2	Level 3	Level 4	Level 5		
How are results achieved? (Monitoring & measurement)	Results are achieved in a random manner. Corrective actions are ad hoc.	Some predicted results are achieved. Corrective and preventive actions are performed in a systematic way.	Predicted results are achieved, especially for identified interested parties. There is consistent use of monitoring, measurement and improvement.	There are consistent, positive, predicted results, with sustainable trends. Improvements and innovations are performed in a systematic way.	The achieved results are above the sector average for the organization, and are maintained in the long term. There is implementation of improvement and innovation throughout the organization.		
How are results monitored? (Monitoring & measurement)	Financial, commercial and productivity indicators are in place.	Customer satisfaction, key realization processes and the performance of suppliers are monitored.	The satisfaction of the organization's people and its interested parties is monitored.	Key performance indicators are aligned with the organization's strategy and are used for monitoring.	Key performance indicators are integrated into the real-time monitoring of all processes, and performance is efficiently communicated to relevant interested parties.		
How are improvement priorities decided? (Improvement, innovation & learning)	Improvement priorities are based on errors, complaints or financial criteria.	Improvement priorities are based on customer satisfaction data, or corrective and preventive actions.	Improvement priorities are based on the needs and expectations of some interested parties, as well as those of suppliers and the organization's people.	Improvement priorities are based on trends and inputs from other interested parties, as well as analysis of social, environmental and economic changes.	Improvement priorities are based on inputs from emerging interested parties.		
How does learning occur? (Improvement, innovation & learning)	Learning occurs randomly, at an individual level.	There is systematic learning from the organization's successes and failures.	A systematic and shared learning process is implemented in the organization.	There is a culture of learning and sharing in the organization that is harnessed for continual improvement.	The organization's processes for learning are shared with relevant interested parties, and support creativity and innovation.		

Table A.5 — Self-assessment of the detailed elements of Clause 7 — Process management

Subclause	Maturity level						
	Level 1	Level 2	Level 3	Level 4	Level 5		
7.1 (Process management) General 7.2 Process planning and control	Processes are planned and managed in an informal, ad hoc manner.	Key processes, such as those relating to customer satisfaction and product realization, are defined and managed. Interactions between processes are defined and managed. The effectiveness of the processes is systematically measured and acted upon.	Process planning is integrated with strategy deployment. The needs and expectations of identified interested parties are used as inputs into process planning. Improvements in process efficiency can be demonstrated. Processes are delivering predictable results. The efficiency and effectiveness of the	Improvements in agility, flexibility and process innovation can be demonstrated. All relevant interested parties are considered in process planning. Interaction conflicts between processes are identified and resolved in an effective way.	Process performance is compared to leading organizations and the results are used in process planning. The outcomes of key processes are above the organization's sector average.		
			organization's processes is reviewed.				
7.3 Process responsibility and authority	Process responsibilities are defined on an <i>ad hoc</i> basis.	Clear responsibility and authority for the management of processes is assigned (e.g. to "process owners").	A policy to avoid and resolve potential disputes in process management exists.	Process owners' competences are continually improved.	Learning is shared between process owners and interested parties.		

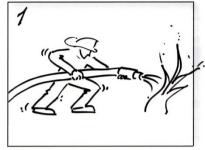
Maturity Models

Malcolm Baldrige Quality Award

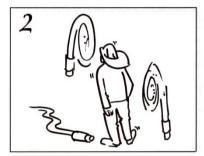
An Analogy for Learning: From Fighting Fires to Innovation

Learning is an essential attribute of high-performing organizations and, therefore, a critical concept in performance excellence. It is a key term used throughout the Criteria booklet and is one of the four scoring factors used to assess the maturity of an organization's processes (pages 66 and 68, scoring system and scoring guidelines).

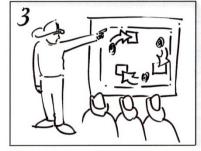
Effective, well-deployed organizational learning can help an organization improve from the early stages of reacting to problems (0–5% in the scoring guidelines) to the highest levels of organization-wide improvement, refinement, and innovation (70–100%). The firefighting analogy illustrated here depicts a progression through the levels of maturity for this scoring dimension.



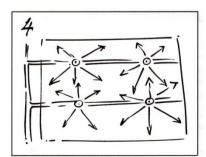
Reacting to the problem: Run with the hose and put out the fire. (0–5%)



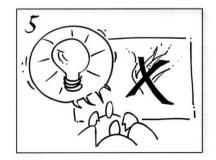
General improvement orientation: Install more fire hoses to get to the fires quickly and reduce their impact. (10–25%)



Systematic evaluation and improvement: Evaluate which locations are most susceptible to fire. Install heat sensors and sprinklers in those locations. (30–45%)



Learning and strategic improvement:Install systemwide heat sensors and a sprinkler system that is activated by the heat preceding fires.
(50–65%)



Organizational analysis and innovation:

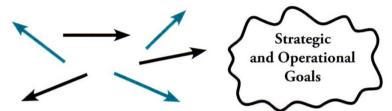
Use fireproof and fire-retardant materials.
Replace combustible liquids with water-based liquids.
Sensors and sprinklers become the secondary line of protection, with prevention the primary approach for protection.

(70–100%)

Steps Toward Mature Processes

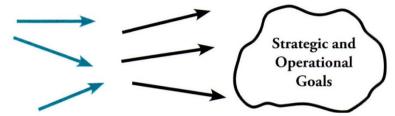
An Aid for Assessing and Scoring Process Items

(1) Reacting to Problems (0-25%)



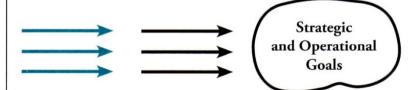
Operations are characterized by activities rather than by processes, and they are largely responsive to immediate needs or problems. Goals are poorly defined.

(2) Early Systematic Approaches (30–45%)



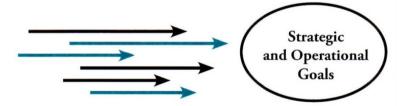
The organization is at the beginning stages of conducting operations by processes with repeatability, evaluation and improvement, and some early coordination among organizational units. Strategy and quantitative goals are being defined.

(3) Aligned Approaches (50-65%)



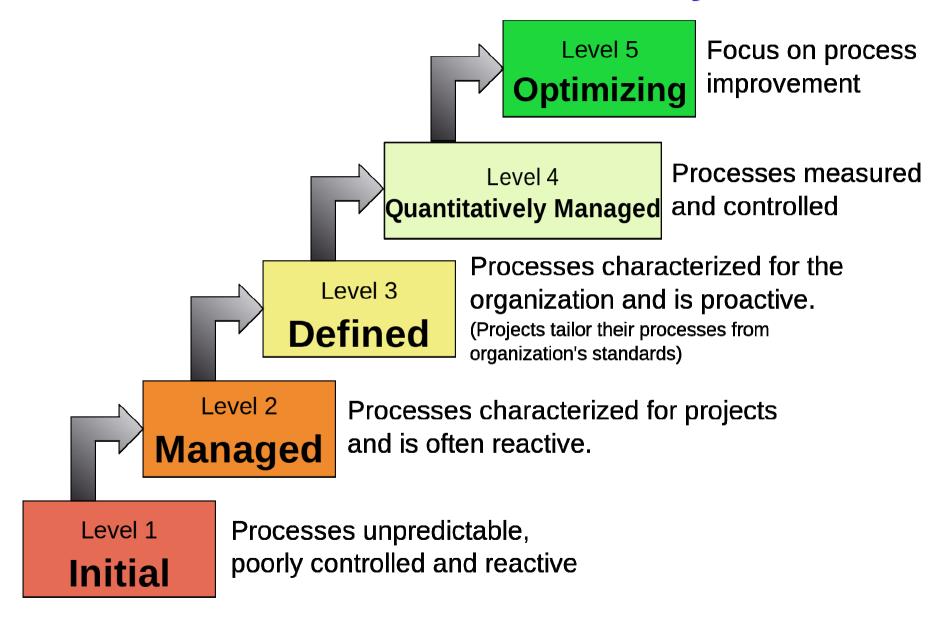
Operations are characterized by processes that are repeatable and regularly evaluated for improvement, with learnings shared and with coordination among organizational units. Processes address key strategies and goals of the organization.

(4) Integrated Approaches (70-100%)



Operations are characterized by processes that are repeatable and regularly evaluated for change and improvement in collaboration with other affected units. Efficiencies across units are sought and achieved through analysis, innovation, and the sharing of information and knowledge. Processes and measures track progress on key strategic and operational goals.

Characteristics of the Maturity levels



Level 4 IT Management Process Maturity Model Level 3 Value IT as a strategic Service business partner IT as a service. Level 2 IT and husiness. provider **Proactive** • Define services, metric linkage Level 1 classes, pricing IT/husiness. Analyze trends. collaboration. Understand costs **Reactive** Set thresholds. LevelO improves business Guarantee SLAs. Fight fires. Predict problems process Measure and Chaotic: Inventory Measure applica- Beaktime. report service * Ad hoc. tion availability Desktop. infrastructure availability. software Automate. Undocumented. Business planning distribution. Integrate processes. Mature problem, Unpredictable Initiate problem. Capacity. configuration, Manage IT as a Business management management change, asset Multiple help process and performance desks Alert and event. Service and Account Management mgmt, processes management Minimal IT. Measure component operations Service Delivery Process Engineering availability (up/down) Usercall. notification. Operational Process Engineering Tool Leverage

Source: Gartner (November 2005)

Quality Managemen	nt Maturity Grid (Crosb	y) Assesso	or:	Department:	
Measurement Categories	Stage 1: Uncertainty	Stage 2: Awakening	Stage 3: Enlightenment	Stage 4: Wisdom	Stage 5: Certainty
Management	No comprehension of	Recognising that quality	While going through	Participating. Understand	Consider quality
understanding and	quality as a management	management may be of	quality improvement	absolutes of quality	management as an
attitude	tool. Tend to blame quality	value but not willing to	programme learn more	management. Recognise	essential part of company
	department for "quality	provide money or time to	about quality management;	their personal role in	system.
	problems".	make it all happen.	becoming supportive and	continuing emphasis.	
	_		helpful.		_
Quality organisation	Quality is hidden in	A stronger quality leader	is Quality department reports	Quality manager is an	Quality manager on board
status	manufacturing or	appointed but main	to top management, all	officer of company;	of directors. Prevention is
	engineering departments.	emphasis is still on	appraisal is incorporated	effective status reporting	main concern. Quality is a
	Inspection probably not	appraisal and moving the	and manager has role in	and preventive action.	thought leader.
	part of organisation.	product. Still part of	management of company.	Involved with customer	
	Emphasis on appraisal an	d manufacturing or other.	100	affairs and special	
	sorting.	_		assignments.	_
Problem handling	Problems are fought as	Teams are set up to attac	k Corrective action	Problems are identified	Except in the most usual
	they occur; no resolution;	major problems. Long-	communication	early in their development.	cases, problems are
	inadequate definition; lots	range solutions are not	established. Problems are	All functions are open to	prevented.
	of yelling and accusations	s. solicited.	faced openly and resolved	suggestion and	
		_	in an orderly way.	improvement.	-
Cost of quality as % of	Reported: Unknown	Reported: 3%	Reported: 8%	Reported: 6.5%	Reported: 2.5%
sales	Actual: 20%	Actual: 18%	Actual: 12%	Actual: 8%	Actual: 2.5%
Quality improvement	No organised activities. N	Trying obvious	Implementation of a multi-	Continuing the multi-step	Quality improvement is a
actions	understanding of such	"motivational" short-range	step programme (e.g.	programme and starting	normal and continued
	activities	efforts.	Crosby's 14-step) with	other pro-active /	activity.
			thorough understanding	preventive product quality	100
	_		and establishment of each	initiatives.	_
			step.		
Summary of company	"We don't know why we	"Is it absolutely necessar		"Defect prevention is a	"We know why we do not
quality posture	have problems with	to always have problems	commitment and quality	routine part of our	have problems with
	quality".	with quality?"	improvement we are	operation."	quality."
			identifying and resolving		
	_	_	our problems."	_	_

CULTURE OF QUALITY (Forbes Insights)

Continuum:

Set of slogans

Every employee from entry level to the chief executive embraces the company's quality vision, values and goals as a way of life.

Where is your company on this continuum?

Findings:

- 1. Different perceptions between senior executives and quality professionals on company's culture of quality.
- 2. Only 1/3 view quality vision as compelling.
- 3. Only 61% state company values are clearly stated.
- 4. Only 60% say their management supports the quality vision and values unequivocally.
- 5. 64% say that all KPIs can be tracked directly to an overall business vision.
- 6. Only 16% strongly agree that they use big data to gauge customer sentiment.
- 7. Great variation in the use of incentives, rewards and recognition.

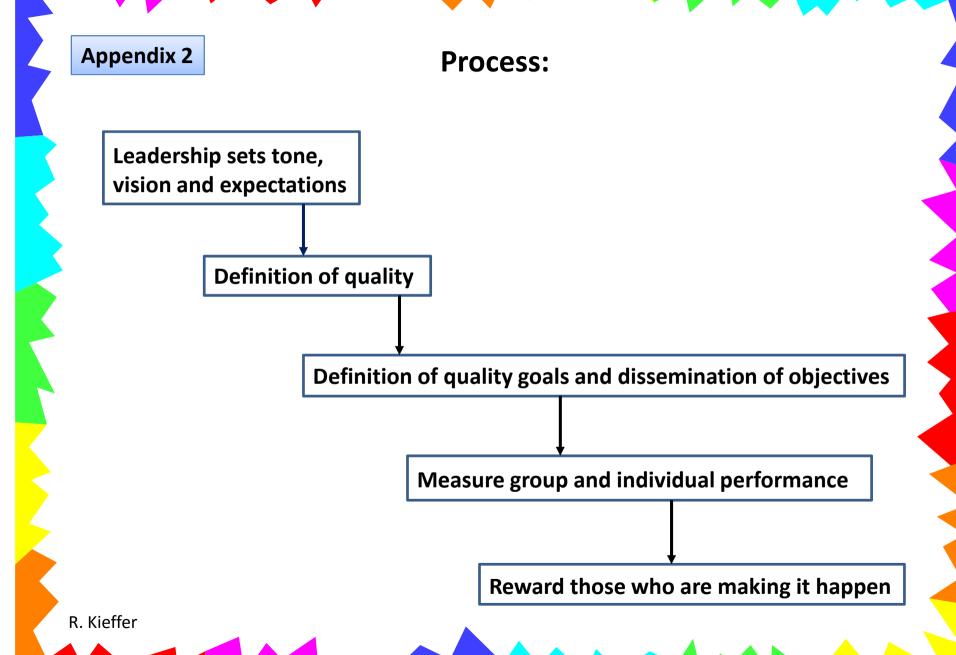
Cultural Elements:

- Leadership
- Compelling Vision
- Shared Values
- Pervasive Behaviors
- Complementary performance metrics and incentives

All employees:

- Know their product or deliverable
- Know their customer
- Know their customer's quality expectations
- Have a metric to measure that quality

There is a constant quest for problem prevention.



Trouble:

The real trouble, where a culture of quality meets its greatest resistance, is the middle layers of the organization.

INCENTIVES???

WARNING SIGNS

- The CEO and other senior executives rarely discuss quality let alone performance against quality objectives.
- The company's quality vision is either non-existent or has minimal linkage to business strategy.
- Managers throughout the organization either fail to consistently emphasize quality or are resistant to quality initiatives.
- The organization has few if any feedback loops for continuous improvement of processes.
- The company lacks formal mechanisms for collecting and analyzing customer feedback.
- Metrics used for performance evaluation feature little-to-no mention of quality goals.
- Employees are not familiar with the company's quality vision and values—or perhaps worse, view them as mere slogans.
- Training and development do not emphasize quality.
- New hires are not formally introduced to the organization's quality vision and values.
- The organization experiences frequent, though often minor, setbacks owing to inconsistent quality.



Conclusions: Desirable Components

- 1. Clearly visible, engaged and unwavering senior management support.
- 2. Active and ongoing engagement with customers.
- 3. Clearly stated quality goals.
- 4. Performance expectations for all that clearly link to quality goals.
- 5. Appropriate incentives.