



Medicines & Healthcare products  
Regulatory Agency



# Driving Sustainable Cultural Transformation

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IPA Annual Conference, Mumbai 23<sup>rd</sup> February 2018



Making it  
stick!

Quality

Culture







# Cultural Excellence Report

Cultural Excellence  
Report

April 2017



## Be Transformed!!

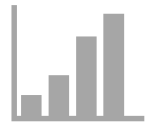
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**Define**



Sustain



Measure

The Quality  
Culture  
Journey



Improve



Analyse



**Follow quality guidelines**

**See others taking quality focused actions**

## **What is quality culture?**

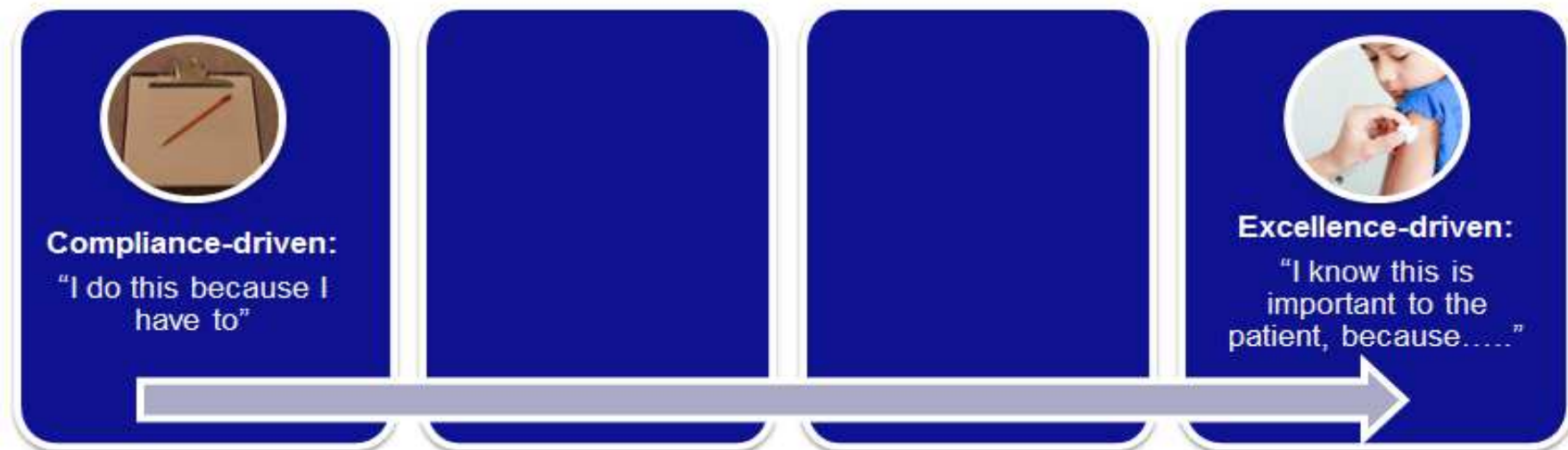
**Hear others talking about quality**

**Feel quality all around them**



# Quality Culture: what MHRA looks for

- Confidence that the company is (and will remain) in control
- Understanding of how quality attributes impact the patient
- Confidence in quality-related decision making
- Maturity of organisational mind set:



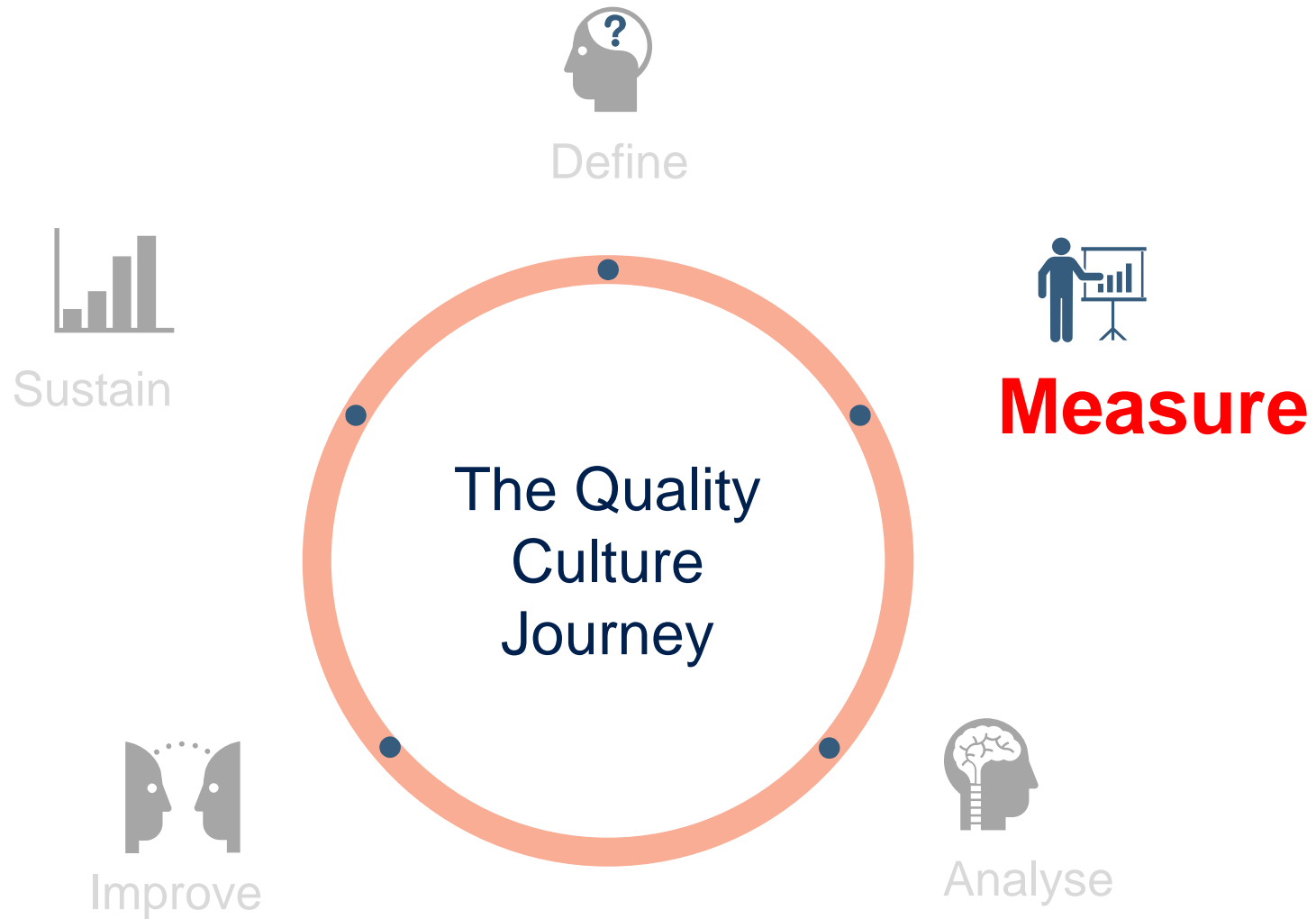
# What Do We Mean by Cultural Excellence?

Culture determines quality outcomes, because it affects the organization's ability to identify and act upon near-miss shortages, assure transparent problem escalation, and strive for operational excellence.

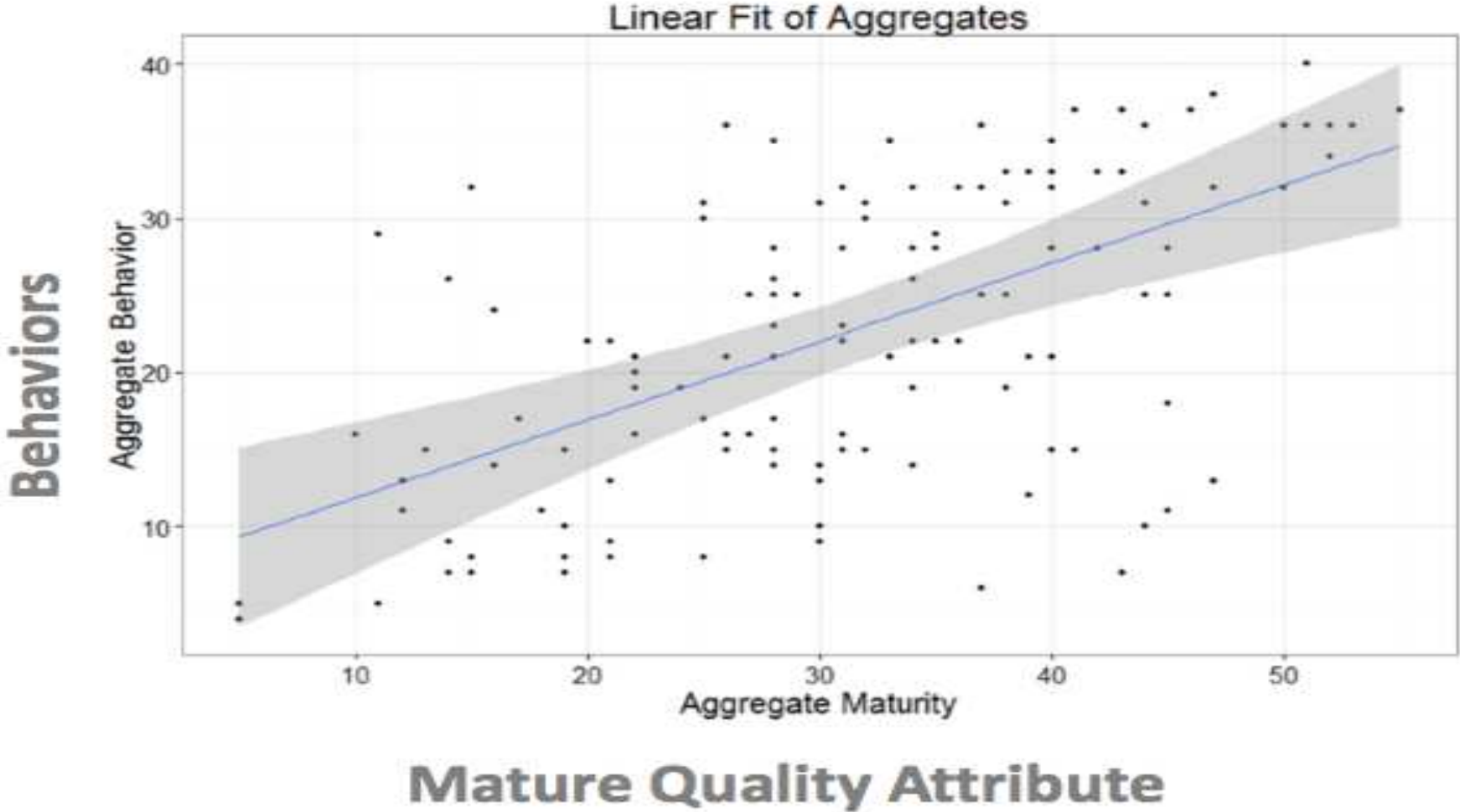


ISPE Cultural Excellence Report, April 2017

<https://www.ispe.org/products/cultural-excellence-report-six-key-dimensions>



# Can Quality Culture be measured?



# There are several existing quality maturity models

| FOUNDATIONAL ELEMENT          | SUB-ELEMENT  |
|-------------------------------|--|
| 1. Employee Empowerment       | 1.1 Enabling Performance<br>1.2 Knowledge, Skills and Ability        |
| 2. Teamwork and Collaboration | 2.1 Team Performance<br>2.2 Learning Communities                     |
| 3. Leadership                 | 3.1 Understanding and Structuring the Customer                       |
| 4. Customer Understanding     | 4.2 Satisfying the Customer<br>4.3 Reprioritizing and Creating Value |
| 5. Quality Improvement        | 5.1 Strategic Planning   |

NACCHO

DuPont

ISO

### Leadership

Safety-oriented leaders demonstrate a visible commitment, embrace clear, meaningful policies and principles, challenge all goals and plans from a safety perspective, and demand high standards of performance. The survey's Leadership questions relate to:

- the priority individuals give to safety
- the priority respondents think others give to safety
- the extent that safety is built in
- the presence and influence of safety values
- the extent line management is held accountable for safety
- involvement in safety activities
- the extent safety rules are enforced
- recognition for safety activities

### Structure

The structure element supports safety staff, an infrastructure, and progressive accountability, and progressive

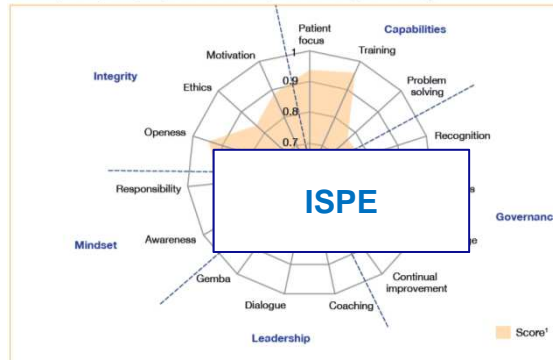
- the belief that injuries can be prevented
- the effect of a drive for safety on business performance
- the level of safety where the cost-benefit break-point occurs
- the quality of safety rules and extent obeyed
- knowledge of safety performance
- rating of the safety organization
- rating of the safety department
- satisfaction with the safety performance of the organization

### Processes and Actions

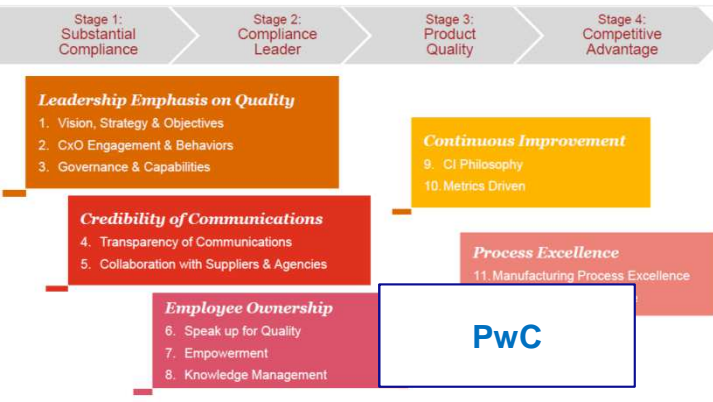
The element of safety management requires through investigations and evaluation, effective communication processes, and safety management and actions questions relate to:

- empowered to take action in safety
- safety meetings
- n of injuries and incidents
- safety audits
- and return-to-work systems
- safety programs
- is and equipment

| Element                 | Maturity level  |   |   |   |   |
|-------------------------|---|---|---|---|---|
|                         | Level 1   | Level 2   | Level 3   | Level 4   | Level 5   |
| Results                 | Results are achieved in a random manner.                                      | Some predicted results are achieved.  | Predicted results are achieved, especially for identified interested parties.   | There are consistent, positive, predicted results, with sustainable trends.   | The achieved results are above the sector average for the organization, and are maintained in the long term.  |
| Corrective & Preventive | Corrective actions are ad hoc.  | Corrective and preventive actions are performed in a systematic way.                                  | There is consistent use of monitoring, measurement and improvement.   | Improvements and innovations are performed in a systematic way.   | There is implementation of improvement and innovation throughout the organization.  |
| Financial & Commercial  | Financial, commercial and productivity indicators are in place.               |   | 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. |
| Improvement             | 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.  |
| 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.   |



## 12 Quality Culture Attributes (& Maturity Matrix)



## Crosby Maturity Grid

| Measurement Categories                | Stage 1: Uncertainty   | Stage 2: Awakening   | Stage 3: Enlightenment  | Stage 4: Wisdom  | Stage 5: Certainty  |
|---------------------------------------|--|--|---|--|---|
| Management Understanding and Attitude | No comprehension of quality as a management goal. Tend to blame quality department for quality problems. | Recognizing that quality management may be of value but not willing to provide money or time to make it happen | While going through quality improvement program learn more about quality management, becoming supportive and helpful. | Participating, understand absolutes of quality management. Recognize their role in continuing emphasis   | Consider quality management as an essential part of company system                                |
| Quality Organization                  |  |  |   | Quality manager is an officer of company, effective status reporting and preventive action. Involved with customer affairs and special assignments | Quality manager on board of directors. Prevention is a main concern. Quality is a thought leader. |
| Problem Handling                      | Problems are fought as they occur, no resolution, inadequate definitions, yelling and accusations        | Teams are set up to attack major problems. Long range solutions are not solicited                              | Corrective action established. Problems are faced openly and resolved in an orderly way                               | Problems are identified early in their development. All functions are open to suggestion and improvement   | except in the most unusual cases, problems are prevented  |
| Quality Improvement Actions           | No organized activities. No understanding of such activities   | "Trying obvious" "motivational" short range efforts  | Implementation of multi-step program. With a thorough understanding and establishment of each step                    | Continuing the multi-step program and starting other proactive/preventative product quality initiatives  | Quality improvement is a normal and continued activity  |
| Company Quality Posture               | "We don't know why we have quality problems"   | "It's absolutely necessary to always have problems with quality"   | "Through management commitment and quality improvement we are identifying and resolving our problems"                 | "Defect prevention is a routine part of our operation"   | "We know why we do not have problems with quality"  |

Crosby

PwC

### Employee Ownership

- Clearly understand quality fit with job
- Empowered to make quality decisions
- Comfortable raising concerns over violation
- Comfortable with directives for quality

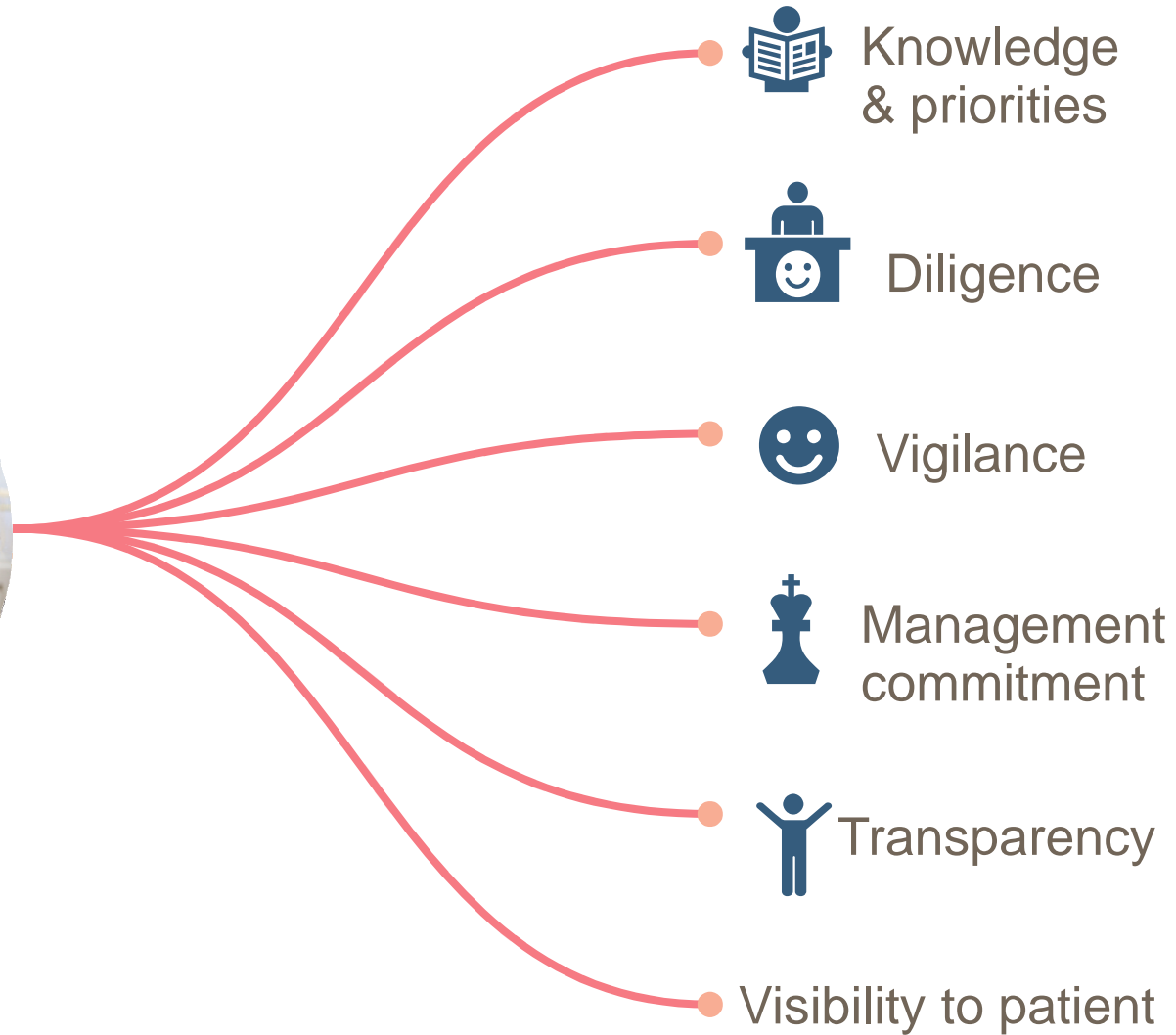
### Leadership Emphasis

- Told that quality is a leadership priority
- Manager "walks the talk" on quality
- Manager emphasizes importance

CEB



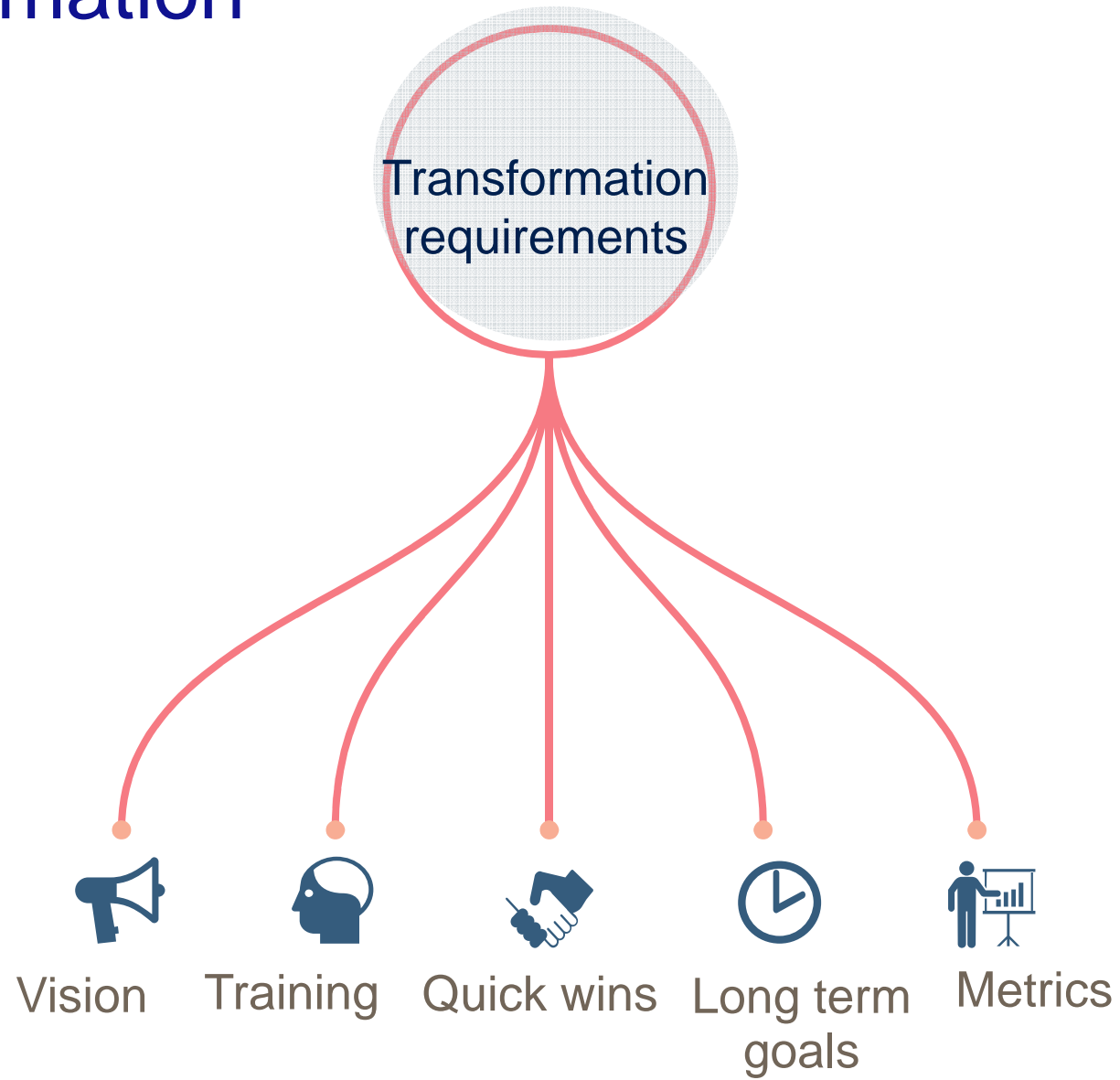
# Analysis outcomes – what is required?

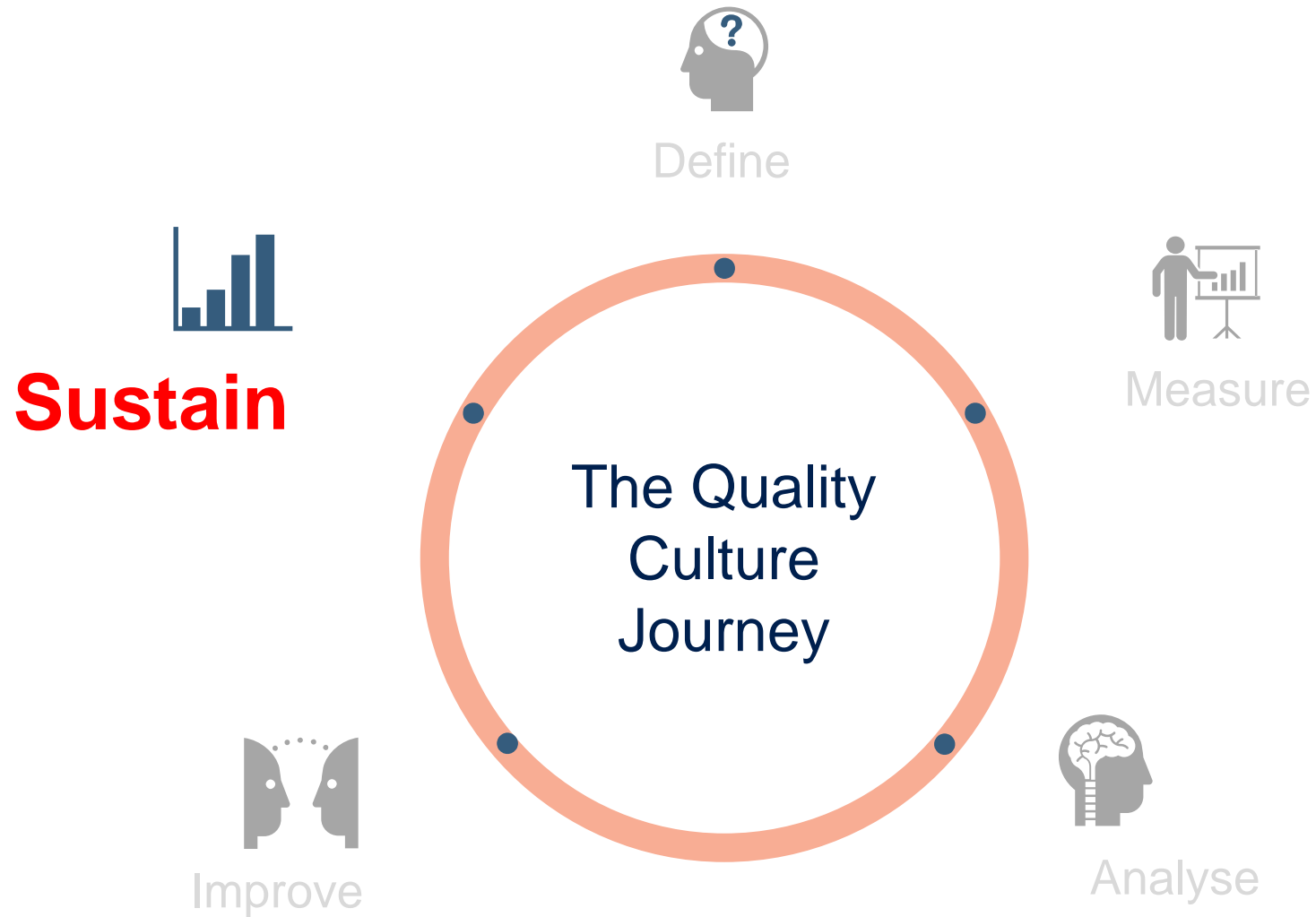






# Transformation





# Sustainability

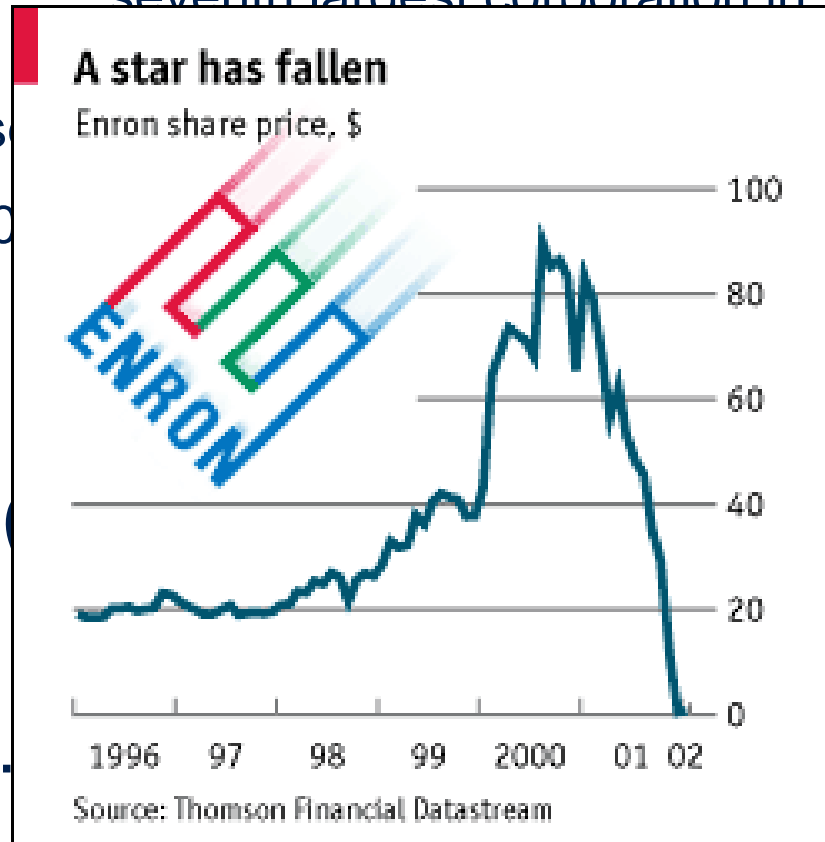


# and when it goes wrong....

seventh largest corporation in the US ( year 2000)

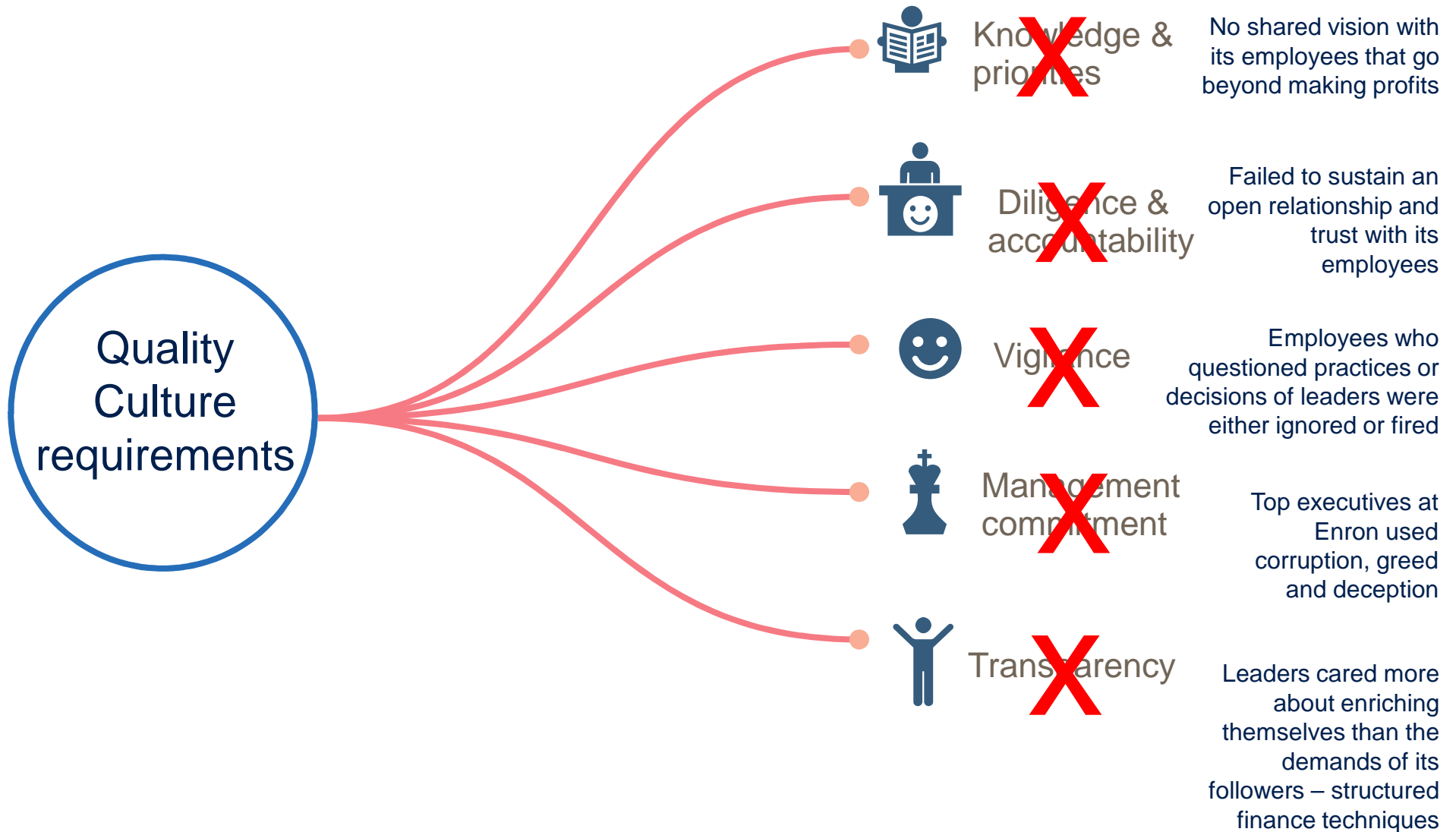
revenues close  
\$101 billion in (year 2000)

December 21, 2001.



“America’s Most Innovative Company” for six successive years (by Fortune magazine)

# Toxic culture



# Summary



- Clear vision and priorities



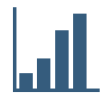
- Engage employees



- Strong processes



- Continuous improvement & reflection



- Sustainable growth





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# THANK YOU FOR YOUR ATTENTION

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