

Developing A Proactive Quality Culture

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Johnson & Johnson

Johnson & Johnson

The world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the Consumer, Pharmaceutical, and Medical Devices & Diagnostics markets.

- More than 275 operating companies
- 128,000 employees worldwide
- Selling products in more than 175 countries
- 3 Segments: Pharmaceutical, Medical Devices & Diagnostics, and Consumer
- 2013 Sales \$71.3 Billion



We Are Comprised of Many Businesses. . .

Johnson & Johnson

Medical Device & Diagnostics

Global Surgery

Cordis  **Biosense Webster**
Johnson & Johnson FAMILY OF CARDIOVASCULAR COMPANIES

ETHICON

 **Ethicon
Endo-Surgery**

 **MENTOR**
MAKE LIFE MORE beautiful.

 **STERILMED**

Acclarent

 **ASP**

Johnson & Johnson
Vision Care, Inc.

 **LIFESCAN**  **Animas**
CORPORATION
Johnson & Johnson FAMILY OF DIABETES COMPANIES

Global Orthopedics

 **DePuy Synthes**
COMPANIES OF *Johnson & Johnson*

Why Focus on Quality Culture

Working in an environment of heightened regulatory scrutiny

- Increasing Food and Drug Administration (FDA) focus on quality and **dramatic increase in number of adverse** event reports, outpacing overall industry growth
- **Rising impact of quality errors** on share price, bottom line, and reputation as a result of **increased media and investor attention** on medical device quality
- Rising customer scrutiny and **increasing consciousness of medical device quality** increases likelihood of **exposed quality issues**
- Increasing likelihood of negative quality events due to **increasing complexity of devices** and user environments

Understanding Barriers to Medical Device Quality – FDA Oct. 31, 2011

Companies with strong cultures of Quality see real business value

Fewer mistakes seen in companies with strong culture of Quality

For every 5,000 employees, improving the Quality culture can save up to **\$67 MM**

Why is Culture Important



Affects everything we do

Will have significant impact on product quality

It's the SECRET SAUCE to world-class high performing organizations

What is Culture?

- ❖ The collective pattern of beliefs, values and expectations
- ❖ Observable Actions and Behaviors
- ❖ Unwritten rules – “the way we do things around here”
- ❖ Culture and leadership are interdependent. Senior leaders say, do and reward behaviors that create culture and allow for or derail successful implementation of change.

The Big Challenge.....!

- Can you see it?



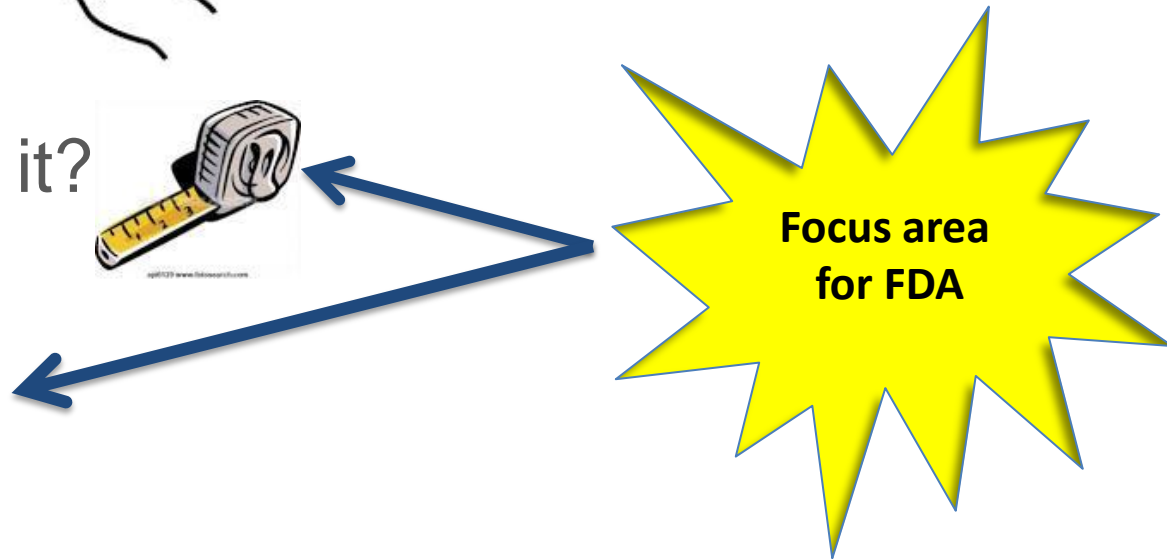
- Can you touch it?



- Can you measure it?



- Can you feel it?



Culture Studies

Corporate Executive Board (CEB)

Large scale study of over 850 employees across multiple levels of seniority, and industries to understand the nature and drivers of quality in a company's culture. Culture database has since been expanded to over 64,000 employees across a variety of large global companies.

Measure culture of Quality, quantify its impact and identify actions that drive it. Created model for evaluating Culture of Quality

Identified four core elements that determine the strength of quality in a company culture – Hear, Feel, See, and Transfer Quality.

Forbes Insights/ASQ

2,291 Executives and Managers at large and small companies, both U.S and international

Factors that drive a Quality Culture

CEB Study

1. Create a Model for Evaluating Culture of Quality

CEB identified four core elements that determine the strength of quality in company culture.

Hear it
Feel it
See it
Transfer it

2. Quantify the business value of Culture of Quality

CEB analysis focused on a reportable outcome-mistakes in work-to establish the costs companies face from not having a strong culture of quality.

\$350 million in
employee productivity
gain by high Quality
Culture

3. Identify Actions that Drive a Culture of Quality

Through regression analysis. CEB isolated activities with the greatest impact on quality's presence in company culture.

Employee ownership
Peer involvement
Message credibility
Leadership emphasis

CEB Study – Key Findings

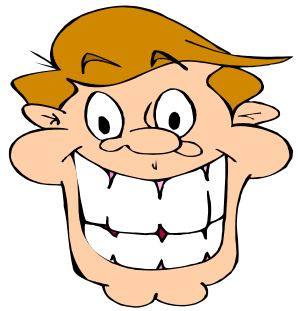
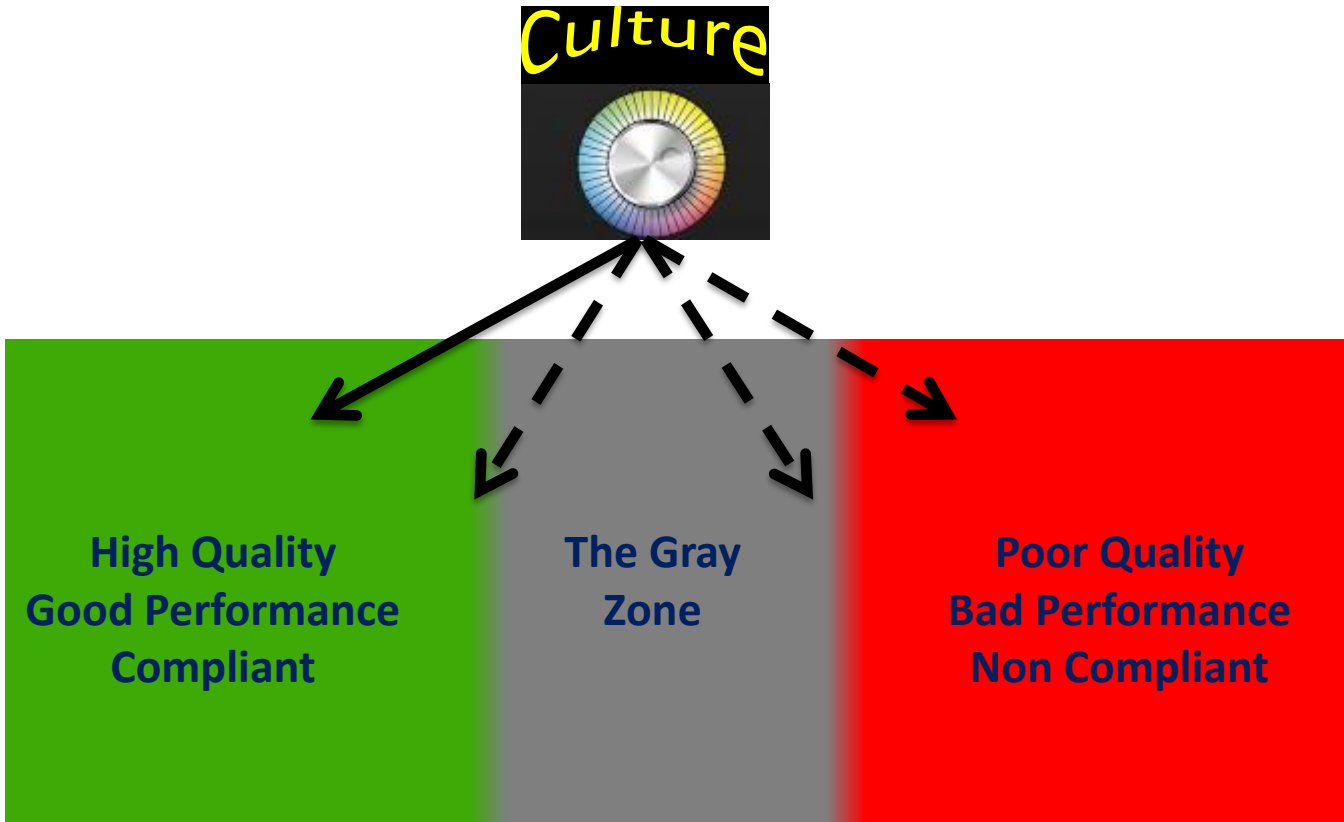
- Strong Culture of Quality is rare
 - 60% of respondents are in environments where culture of Quality is less than half of overall potential
- Extent to which employees “*transfer*” quality is weak
- Culture of Quality pays
 - Where Quality plays an important role in Culture, employees make fewer significant mistakes

- Four activities differentiate a high Quality Culture
 - Employee Ownership
 - Peer Involvement
 - Message Credibility
 - Leadership Emphasis
- Few employees report their companies are effective at the activities most likely to drive Quality into Culture

Forbes/ASQ Study – Key Findings

- 59% of study participants stated that their companies exhibit a Culture of Quality
 - Executives 75%
 - Mid Level Managers 47%
- 60% agree that Quality Vision is clearly stated but only 50% agree that it is well understood
- 61% agree Values are clearly stated but only 50% agree that Values are clearly understood
- 47% stated that their leaders lead by example

The Culture Continuum...



Beware of De-railers

- ***The Slippery Slope*** – Shaped by conditions that are subtle

- Knew it was wrong and did it anyways
- Felt uncomfortable and justified
- Didn't know what you didn't know



- *“The road to hell is paved with good intentions”*

Avoid the Pitfalls!...These are Indicators

- Are there Quality Metrics? Where and by whom are they reviewed? Is there accountability? Do they drive the right behaviors and actions?
- Repeated timeliness issues (CAPA, Audit responses, training, etc.)
- Internal audits not conducted according to schedule
- Quality issues only addressed by the Quality organization
- The Justification/Rationale machine!
- Speed to market at any cost

Quality System and Culture

- Its not either/or!
- The Quality Policy is the starting point and yet often not given enough emphasis
- Culture has as much if not more impact on product quality than your Quality System...and yet remediation efforts often only focus on Quality System

Developing the Culture

➤ Culture is a RESULT of many influencing factors

➤ A Culture is defined by the following factors:

- Direction that we set
- Decisions that we make
- Actions that we take
- Priorities that we set
- Behaviors that we reward
- Things that we value



Leadership

Developing the Culture *cont'd*

Key Components of Culture



- **Quality Foundation:** Embedding the core quality values and beliefs into how work gets done across the organization
- **Leadership:** Aligning leaders on the quality vision and providing them with tangible action steps to begin living quality and helping others do the same; ensuring leaders develop the appropriate capabilities and exhibit the behaviors needed to drive quality within their respective organizations
- **Infrastructure:** Ensuring that the appropriate organizational structure and processes (e.g., performance management, rewards and recognition) are in place to drive the behavior needed to achieve the desired future state
- **Processes:** Continuing to proactively identify opportunities to enhance and strengthen quality within the organization

Developing the Culture *cont'd*

- Do not assume Quality
- Establish Quality metrics and hold people accountable
- Ensure employee engagement at all levels
- Keep the customer at the center of decisions

- Define Leadership Behaviors
- Ensure risk management is understood
- Communicate Effectively
- Create a Centerpiece and a Brand – Not just a slogan

“It is not only what we do, but also what we do not do, for which we are accountable.”

Moliere

Quality Culture at J&J – The Centerpiece

Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services.

In meeting their needs everything we do must be of high quality.

We must constantly strive to reduce our costs

in order to maintain reasonable prices.

Customers' orders must be serviced promptly and accurately.

Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world.

Everyone must be considered as an individual.

We must respect their dignity and recognize their merit.

They must have a sense of security in their jobs.

Compensation must be fair and adequate,

and working conditions clean, orderly and safe.

We must be mindful of ways to help our employees fulfill

their family responsibilities.

Employees must feel free to make suggestions and complaints.

There must be equal opportunity for employment, development

and advancement for those qualified.

We must provide competent management,

and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well.

We must be good citizens -- support good works and charities

and bear our fair share of taxes.

We must encourage civic improvements and better health and education.

We must maintain in good order

the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders.

Business must make a sound profit.

We must experiment with new ideas.

Research must be carried on, innovative programs developed

and mistakes paid for.

New equipment must be purchased, new facilities provided

and new products launched.

Reserves must be created to provide for adverse times.

When we operate according to these principles,

the stockholders should realize a fair return.

Johnson & Johnson

Our Credo |
Established 1943

Johnson & Johnson

“...everything we do must be of high quality...”

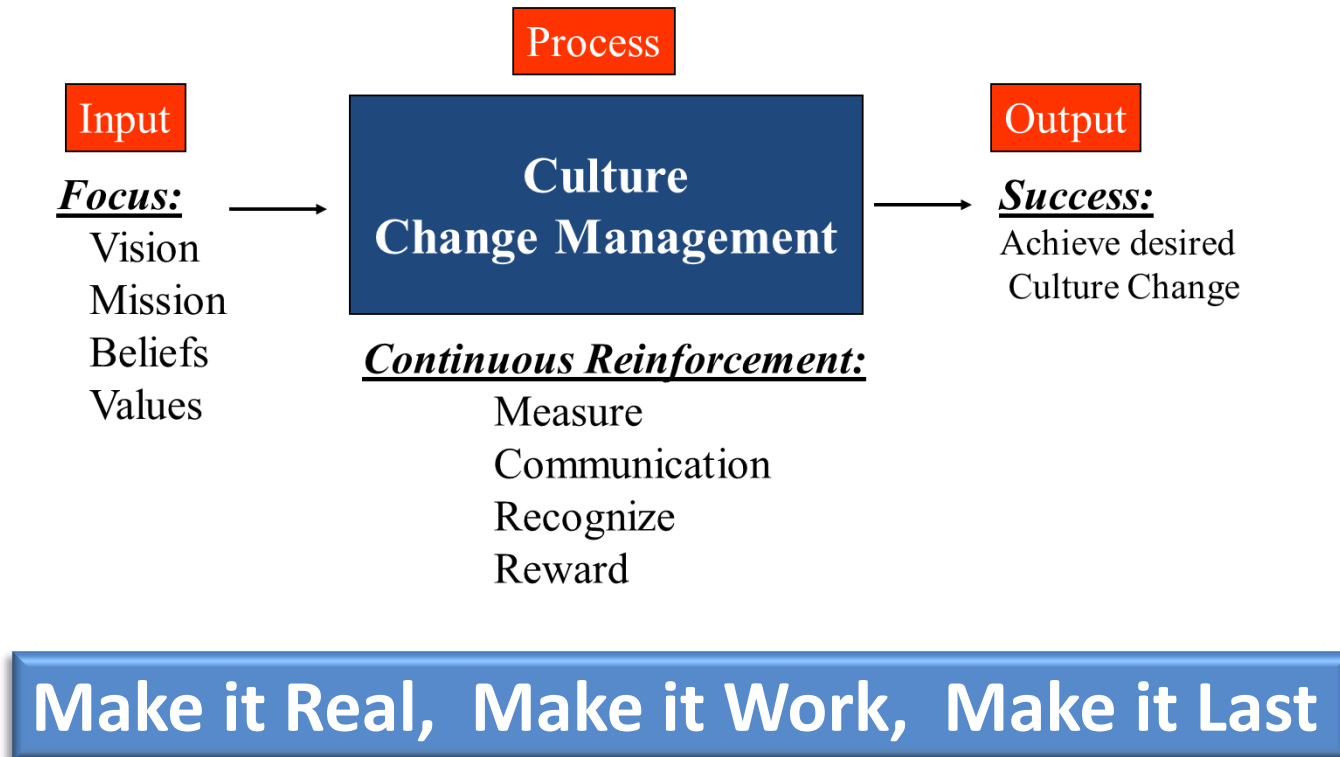


Quality Culture at J&J – Another Centerpiece



Culture Change Management

- A culture change is achieved over a period of time with continual reinforcement of the factors that define our culture



Questions to Consider

- What is your Culture?
- Are there visible signs of a Quality Culture?
- What do you want your Culture to be?
- Would the organization be more effective if the Culture was enhanced?

Thank You