



PATHWAYS TO IMPROVE YOUR COMPANY'S QUALITY CULTURE

PRESENTED BY

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

OUTLINE

1. Quality does not equal compliance.

- **Problems with the regulatory culture**
- **Changes in the philosophy of the quality unit**

2. Role of Senior Management

- **Responsible for QS**
- **Action – “Walk the Talk”**

References

- R. Kieffer, “Problems with the Regulatory Culture”, GMPs Online, GMP Publishing, April 2016
- R. Kieffer, “The Changing Role of Quality Assurance in the Pharmaceutical Industry”, PDA Journal, 2014, 68 313-319
- Carolyn Taylor, “Walking the Talk”, Random House, 2005

REGULATORY CULTURE

**Strongly influences a company's quality culture,
especially the culture of the quality unit.**

Problems with Regulatory Culture

1. Confusion

“To my knowledge, there’s no detailed common understanding within the United States about what GMP compliance exactly means.” (Janet Woodcock)

She further bemoans the unnecessary complexity in the regulatory system.

Problems with Regulatory Culture

2. **cGMP's are not current.**

- **They reflect the philosophy of quality of the 1950s. Inspection and control.**
- **Today: capable production processes based on design; well-trained personnel who take responsibility for the quality of their work; production responsible for product quality.**

Problems with Regulatory Culture

3. Role of the Quality Unit

- **Frequently takes responsibility for tasks that they do not have the capability to perform and which rightly should be performed by other departments. (investigations of failures, writing of SOPs, validation.....)**
- **“Functions that are properly those of the engineering department or other specialized units because of their unique training and expertise should not be duplicated or usurped by the quality control unit.... The responsibility of the quality control unit is to assure that such expertise has been utilized.”**
- **Modern Role of QU**
 - **Process improver - design of effective and efficient processes**
 - **Quality promotor – recognize superior performance**
 - **Quality expert – look outside of the pharmaceutical industry for best practices**

Process Improver:

- **Production**
- **Validation**
- **Training**
- **Materials Management/Supply Chain**
- *Failures/Deviations, Change Control*

Quality Promotor:

- **Disseminate best quality practices, benchmarking**
- **Recognize good performance,**
 - **Audits**
 - **Quality Day**
 - **Publish**

Problems with Regulatory Culture

4. Continuous Improvement

- Lack of world-wide harmonization
- Regulations make it difficult to make changes
- Will ICH Q12 eliminate these obstacles?



Problems with Regulatory Culture

Given a less than perfect regulatory culture what can industry do?

Role of Senior Management

Senior Management is responsible for the development, implementation, control and improvement of the Quality System. (ICHQ10)

The Plant Manager must be the **champion of quality.**

These responsibilities cannot be delegated to the quality department.

Role of Senior Management

Requirements:

- Training
- Plan
- Time
- **Action**

Role of Senior Management – Walking the Talk

Critical role of the behavior of the leader

- **Humility – ability to accept honest feedback**

“Have those individuals in key leadership positions shown an openness to the possibility of learning and changing themselves?” (page 39)

“Significant culture change can only occur when the behavior and mind-set of the top team changes.” (page 97)

Role of Senior Management – Walking the Talk

The culture improvement process:

Assess – the culture today

Define – the culture you want

Commit – the business case for change, top team has signed on, some committed advocates

Plan – at least three years to see measurable shift

Implementation

Role of Senior Management – Walking the Talk

Time Investment:

- **every employee 2-3 days/year**
- **managers 6-8 days/year**

The business case for culture change – at least 20% reduction in costs.



**FOR THINGS TO CHANGE,
I MUST CHANGE**

R. Kieffer