Moving Beyond Compliance Towards a Quality Culture

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Which comes first….Compliance or Culture?
Compliance vs Culture

Compliance:
- Driven by regulations and guidance
- Demonstrated through procedures and documentation
- Purpose of inspections

Culture:
- Driven by people, mindsets, values, beliefs
- Demonstrated through behaviors, actions and decisions
- Indicative of future state of organization
“A company with a highly developed culture of quality spends, on average, $350 million less annually fixing mistakes than a company with a poorly developed one.”

Putting a Spotlight on Pharma Quality Culture

**External**
- Changing regulations/guidance
- Evaluation of culture during inspections
- Economic pressures

**Internal**
- Increasingly complex and global supply chains
- Desire to avoid regulatory action
- Organizational changes
"We define a “true culture of quality” as an environment in which employees not only follow quality guidelines but also consistently see others taking quality-focused actions, hear others talking about quality, and feel quality all around them."

Quality Culture Formation

01 Founding Leaders
- Beliefs and values
- Model behaviors

02 Shared Experiences
- Both good and bad
- Shape and reinforce

03 New Leaders
- Different experiences
- “Fresh eyes”

04 External Influences
- Societal
- Economic
- Regulatory
“Lasting success lies in changing individuals first; then the organization follows. An organization changes only as far or as fast as its collective individuals change.”

~ Black & Gregersen (2003)
Our Roadmap through Culture Change

Creating a Climate for Change

1. Recognize need for change
2. Understand current state
3. Develop a vision and strategy
4. Communicate the vision

Engaging & Enabling the Whole Organization

5. Empower action and model behaviors
6. Get quick wins

Implementing and Sustaining

7. Leverage wins to reinforce change
8. Embed culture

Adapted from Dr. John Kotter’s Change Model
So where were we

“All I do is fight fires”

“I don’t want to get blamed”

“I was only doing what I was told”

“That’s not my job; it’s QA’s”

“We’ve always done it that way”

“Our existing quality culture

“Pound out the pounds”

“I’m drowning”

“throw it over the wall to….”
Where did we want to go

Proactive

Root cause focused

Focused

Right the first time

Our NEW quality culture

Continuous Improvement

Collaborative

Empowered

Quality is my job
How we helped others see....

....created an analogy to The Bradley Curve™

External Motivation Compliance

Internal Motivation Commitment

Felt Leadership, Role Modelling, Influencing > Engagement

Injury Rotate

NATURAL INSTINCTS

Reactive
• Safety by natural instinct
• Compliance is the goal
• Delegated to safety manager
• Lack of management involvement

SUPERVISION

Dependent
• Management commitment
• Condition of employment
• Fear / Discipline
• Rules / Procedures
• Supervisor control, emphasis and goal
• Value all people
• Training

SELF

Independent
• Personal knowledge, commitment & standards
• Internalization
• Personal Value
• Care for Self
• Practice & Habits
• Individual Recognition

TEAMS

Independent
• Help others conform
• Being other’s keeper
• Network contributor
• Care for others
• Organizational Pride

“I follow the rules because I have to”

“I follow the rules because I want to”
Other Support Measures

- Implemented skip level meetings
- Visible commitment from management
- Frequent “check-ins” with new employees
- Right people; right roles
- Fostered a speak up environment
- Changed what we were measuring
- Defined Vital Few Priorities
- Changed our hiring practices
- Upskilled front line leaders
- Rewarded desired behaviors
So where did we end up?
Thank you for your time!

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