





# Quality Culture- The What

- Quality culture starts with leadership that understands that human behavior and motivations are critical to meeting ongoing quality requirements, and naturally emphasizes continuous improvement of processes.
- Defined as the shared beliefs, values, attitudes, and behavior patterns that characterize the members of an organization.

# Pharmaceutical Industry Built on a Foundation of Data

- **Attributable**
- **Legible**
- **Contemporaneous**
- **Original**
- **Accurate**



**Relying on incomplete, misleading or unreliable data in the pharmaceutical arena isn't humorous, and things rarely turn out well in the end.**

# For This Reason We Have an Abundance of Regulations and Controls in Place

Guidance Documents to Outline Product Requirements and Expectations  
for Commercialization

21CFR and Federal Register

Quality Systems

Auditing and Inspections

Electronic Audit Trails and controls

Policies

483 and Warning Letters

# What Does Quality Culture Mean for Regulatory?



# Trust and Accountability

**Regulatory Affairs Job Requires a Healthy Dose of Trust to Be Successful. We rely on Completeness and Integrity of the Data Supplied to Regulatory from Multiple Sources**

- **Product Development**
- **Validation**
- **Manufacturing**
- **Clinical**
- **Analytical/QC**
- **Quality Unit**

**We in Regulatory may not have generated the data but we do sign our name to it each and every time we submit to FDA.**

# Take Ownership

- **Stay Knowledgeable in your Field**
- **Stay Current in Guidelines and Regulations**
- **Be Prepared to Reference or Cite Guidance or Regulations in support of your Regulatory Strategy**
- **Broaden Your Knowledge Base Past your Immediate Responsibilities**
- **Network, Find out What Others are Doing.**
- **Elevate to Management for awareness**
- **In Short, Own the Role**

# Trust is a 2-Way Street

**Product Teams Trust that We, as Regulatory SME's, will also Prove to be Trustworthy:**

- **Provide a Complete and Thorough Regulatory Strategy**
- **Accurate Interpretation of Guidance**
- **Be Responsive, Deliver on Time**
- **Maintain an Open Dialog and Provide Clear Expectations**
- **Manage Workloads to Meet Deadlines**
- **Represent the Company's Best Interest**
- **Present and Defend the Data Effectively**
- **Be a Fully Engaged Member of the Team, Be part of the Solution**



# Trust But Verify

Ever Heard the Term “Throwing it Over the Fence”?

- Understand the Quality Culture for the Groups Providing Data
- Do Not Let Others Shift to the Responsibility and Risks Associated with an Incomplete or Chaotic Deliverable to Regulatory just to “Get it Off Their Plate”
- Always Provide a Thorough Review
- Make Sure All the Pieces Fit
- Look for Gaps
- Ask Questions

# Collaboration

- Internally
  - Fully Participate Early and Often
  - Act as Liaison Between Drug Development, Manufacturing, Marketing and Clinical
  - Seek to Understand, Encourage Open Communication
  - Provide Clear Expectations
- Externally
  - Key Interface Between you and Company
  - Know Your FDA Contacts
  - Initiate Dialog
  - Encourage Synergies between Regulatory Agencies and company departments

# Focus On Improvement

- **Continuous Improvement:** It's not just for Manufacturing or Quality, it's a mindset
- **Focus On Personal Performance**
- **Elevate issues** when needed. Management can't fix what they don't know isn't working.
- On the Flip Side, **Delegate!** Developing staff and delegating work is one of the best ways to improve your productivity.
- **Look to find the root cause**, especially if issues keep repeating themselves. Don't settle for a band-aid to a problem, work for a solution.
- **Don't Settle for Status Quo**, In today's business world if you keep doing what you've always done, you'll be obsolete in no time.
- **Keep an Open Mind to Change**

# Keep the Right Perspective

- The essence of quality culture is knowing your priorities, what is most important.
- For the Pharmaceutical industry, the key focus is the patient.
- We still manage tight timelines, limited resources, risk management, and there is always the concern with the bottom line financially.
- Be a role model for a Quality Centric Culture
- If we keep our primary priority the patient, this provides us with the right perspective from which to make our decisions

# Quality Culture in Regulatory It's All About the Data... And the Relationships

# Questions?