



Designing Quality Philosophies Into Systems Based Programs

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Learning Objectives

- **Learn the five action steps and the nine sub-steps for designing quality philosophy into a systems based program**
- **Learn the guiding principles for designing quality philosophies**
- **Review the quality philosophies of America's most admired companies**
- **Review examples of quality philosophies designed into systems based programs.**
- **Learn six opportunities for designing quality philosophies into FDA regulated systems based programs.**

Presenter Disclosure

or, Truth In Presenting



Mitch Manning is

- **The “Forrest Gump” Of This Conference**
- **Willing To Share His Opinions, And Experience**
- **Enjoying Watching From the Sidelines**
- **Gifted at Using Your Watch To Tell You The Time**

Four of the Most Vague Words of the 21st Century

- **Quality**
- **Philosophies**
- **Systems**
- **Program**

Quality Philosophy Origins

- Invention
- Borrowing

Why Design Quality Philosophy Into A Systems Based Program?

- **Attitude**
- **Expectations**
- **Approach**
- **Deployment**
- **Results**
- **Compliance**
- **Progress**
- **Work/Life Balance**

Quality Philosophies of America's Most Admired Companies

- **Wal-Mart** **“Always low prices. Always.”**

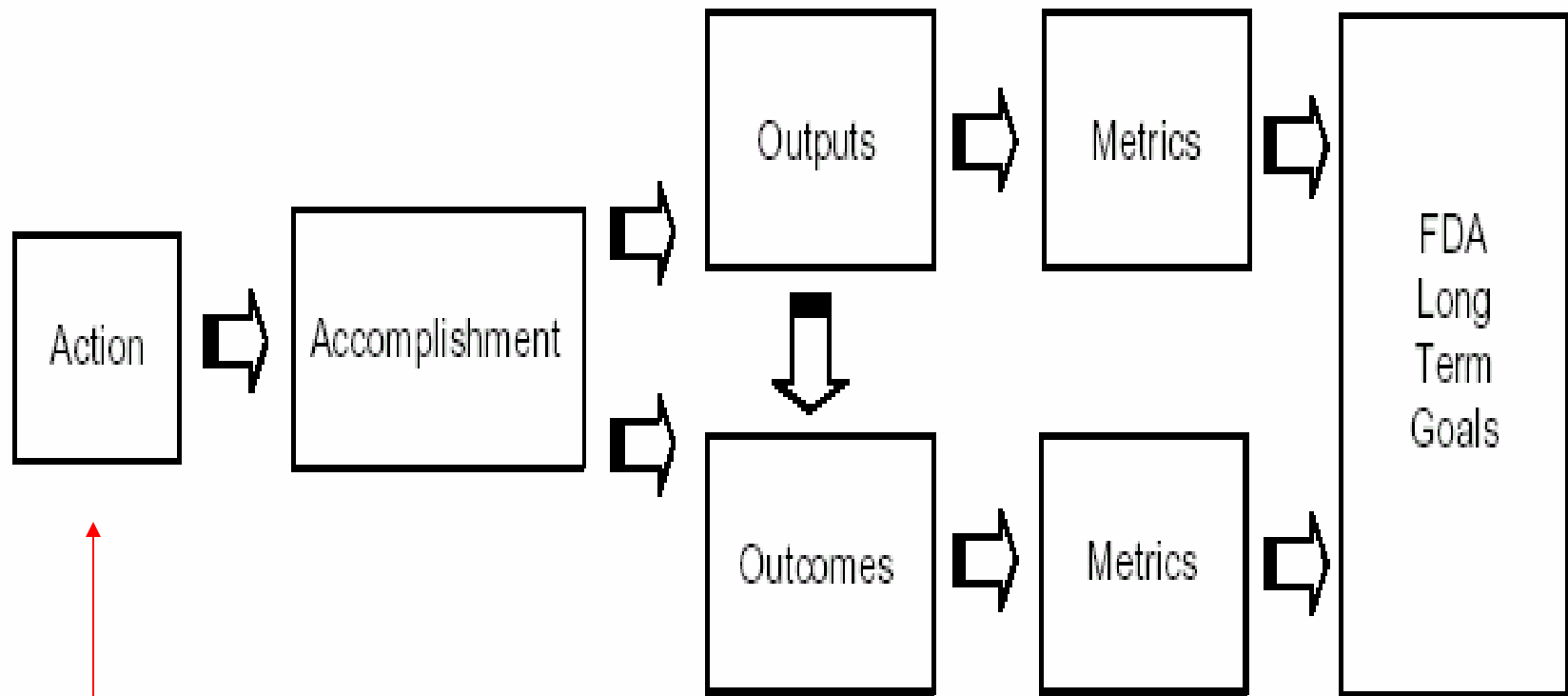
- **Berkshire Hathaway**
“Phenomenal, hardworking dealmaker”

- **Southwest**
“Dedication to the highest quality customer service ...”

Source: Respective websites

A Borrowed Process Model for Designing Quality Philosophies

Conceptual Framework of Evaluations



Added by Mitchell W. Manning, February 2, 2005

Challenge of Change

Designing Quality Philosophy Into A Systems Based Program Is Charting A Course For A Lifestyle Change

“Of those who attempt lifestyle change, 70 to 80 percent are ultimately successful, though it may take two, five, ten tries or more”

Thomas Hayden, “50 Ways To Fix Your Life”, U.S. News & World Report,

December 27, 2004 / January 3, 2005

Motivators of Change

- Fear
- Desire

Hayden's 50 Rules for Change

1 – 10	Simplify
11 – 16	Stimulate
17 – 25	Organize
26 – 46	Get Well
47 – 50	Take Stock

Identify Your Philosophy

- Hedonism – Pleasure
- Empiricism – Experience
- Naturalism – Science
- Rationalism - Procedures

The Process for Change

- Aware
- Believe
- Comprehend
- Do
- Excel

“The Christian religion teaches the path of salvation passes through acknowledging sin, confessing, begging forgiveness and repenting.”

Appreciate Human Diversity

Know the team's personalities

Personality	Strengths	Stressors	Goals	Fears
Dominance	Initiative	Loss of control	Control	Being taken advantage of
Influence	Enthusiasm	Loss of approval	Approval	Being rejected or disliked
Steadiness	Follow-through	Loss of predictability	Stability	Being asked to change
Conscientiousness	Thoroughness	Loss of personal privacy	Quality	Being criticized for poor quality

Liberate the Levels

in your organization to do what they need to do.

- **Top – vision and mission**
- **Middle – processes and operations**
- **Bottom – functions and tasks**

A photograph of the White House in Washington, D.C. The building is white with a prominent portico supported by four large columns. In the foreground, there is a fountain with water spraying upwards, surrounded by green bushes and a black metal fence. A row of red flowers is visible at the bottom of the frame. The sky is clear and blue.

Mission Planning

- **Approach**
- **Deployment**
- **Results**

What Do You Want To Do?

- Promote Opportunities
- Prevent Problems
- Enhance Decision Making
- Resolve Problems
- Know The Issues



Purpose of Quality Philosophy

- **Promoting – Vision and Mission**
- **Preventing - Problems**
- **Resolving - Issues**
- **Deciding – Next Steps**

Inventing Quality Philosophy

Action Steps – assign Who and When

- 1. Brainstorm key values and ethics.**
- 2. Conduct target area survey to obtain feedback on key values and ethics.**
- 3. Conduct focus group with employees.**
- 4. Decide encompassing quality philosophy.**
- 5. Communicate. Listen. Learn.**

Inventing Quality Philosophy

How

- 1. Create diagonal slice team from the target area of the systems based program.**
- 2. Brainstorm list of key values and ethics to use with survey questions.**
- 3. Consolidate list to the values and ethics essential to program success.**
- 4. Use open-ended questions and brainstormed list to develop a survey instrument.**
- 5. Test essential values and ethics with employees from the target area. Analyze responses.**

Inventing Quality Philosophy

How

- 6. Develop focus group questions. Invite employees from the target area to participate in focus group. Conduct focus group. Analyze responses. Provide program requirements, segmented by key program components to Quality Philosophy team.**
- 7. Decide clear, concise, correct quality philosophy. Share with target area.**
- 8. Post quality philosophy throughout the organization and on the intranet site.**
- 9. Hold two town meetings to communicate philosophy and test employee ownership.**

Quality Philosophy Ideals of America's Most Admired Companies

- **Innovation**
- **Employee talent**
- **Use of corporate assets**
- **Social responsibility**
- **Quality of management**
- **Financial soundness**
- **Long-term investment value**
- **Quality of products and services**

Source: Fortune, magazine

Guiding Principles

for Designing Quality Philosophy Into A Systems Based Program

- 1. Quality philosophy must be freely chosen from alternatives.**
- 2. Quality philosophy must be consistent with the purpose of the systems based program, and the sponsoring organization.**
- 3. Quality philosophy must be clear, concise and correct.**
- 4. Quality philosophy must be actionable.**

Guiding Principles

for Designing Quality Philosophy Into A Systems-Based Program

- 5. Quality philosophy must enhance performance.**
- 6. Quality philosophy must be attractive and pride-giving.**
- 7. Quality philosophy must be capable of being communicated.**
- 8. Quality philosophy must be prominently displayed.**



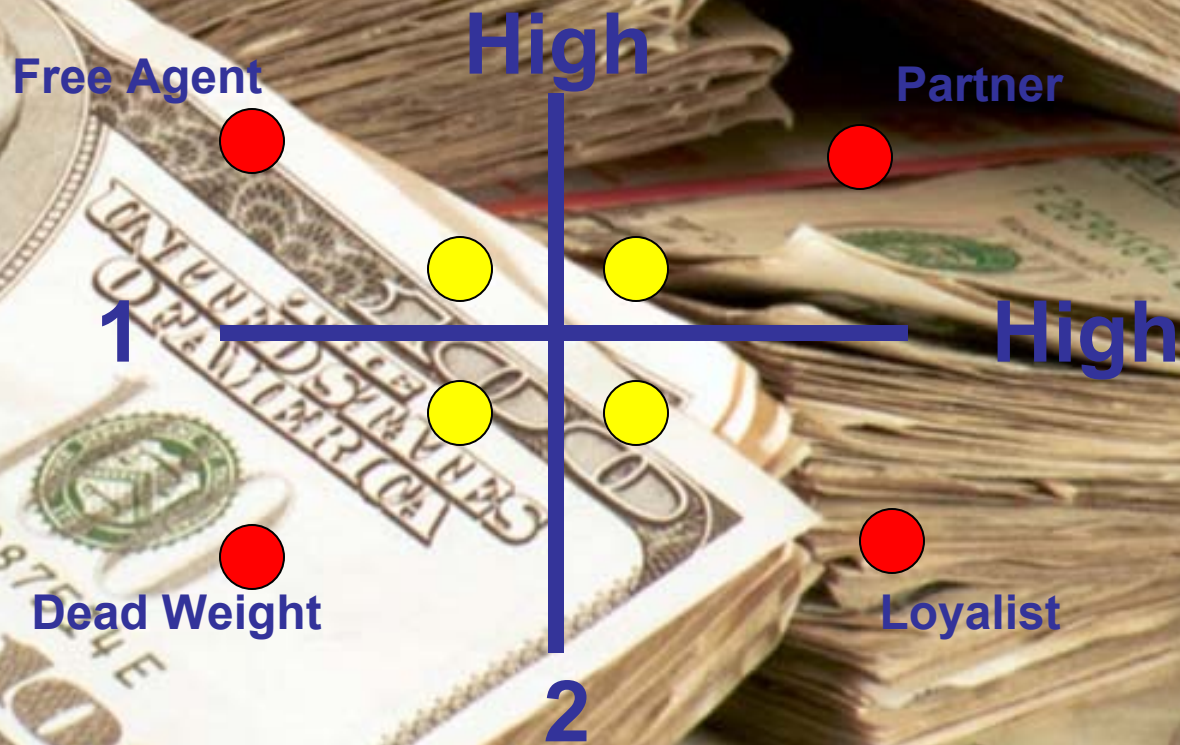
Clear, Concise and Correct

Quality Philosophy

- Guides people, procedures, and programs
- Provides the context for ethical behavior
- Is the grounding point for program values
- Helps clarify and separate right from wrong
- Shelters people in challenging times
- Motivates and inspires people in all situations

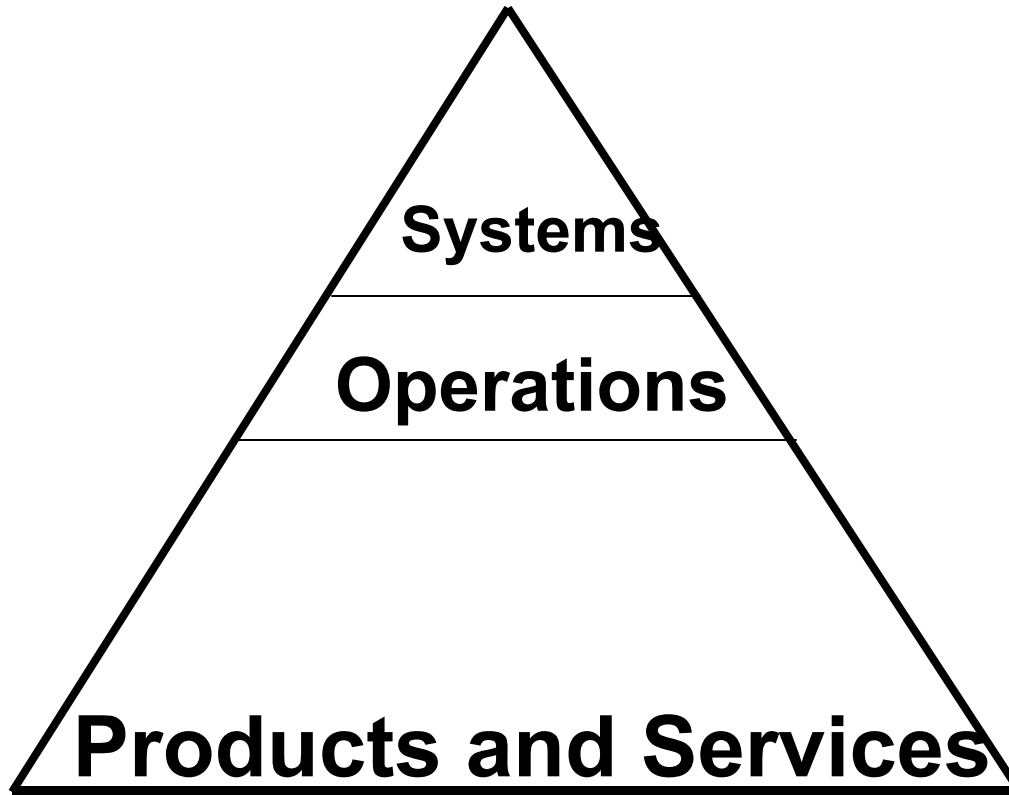
Who Is On Your Team?

1. Shared Goals and Values
2. Sense of Control and Accountability

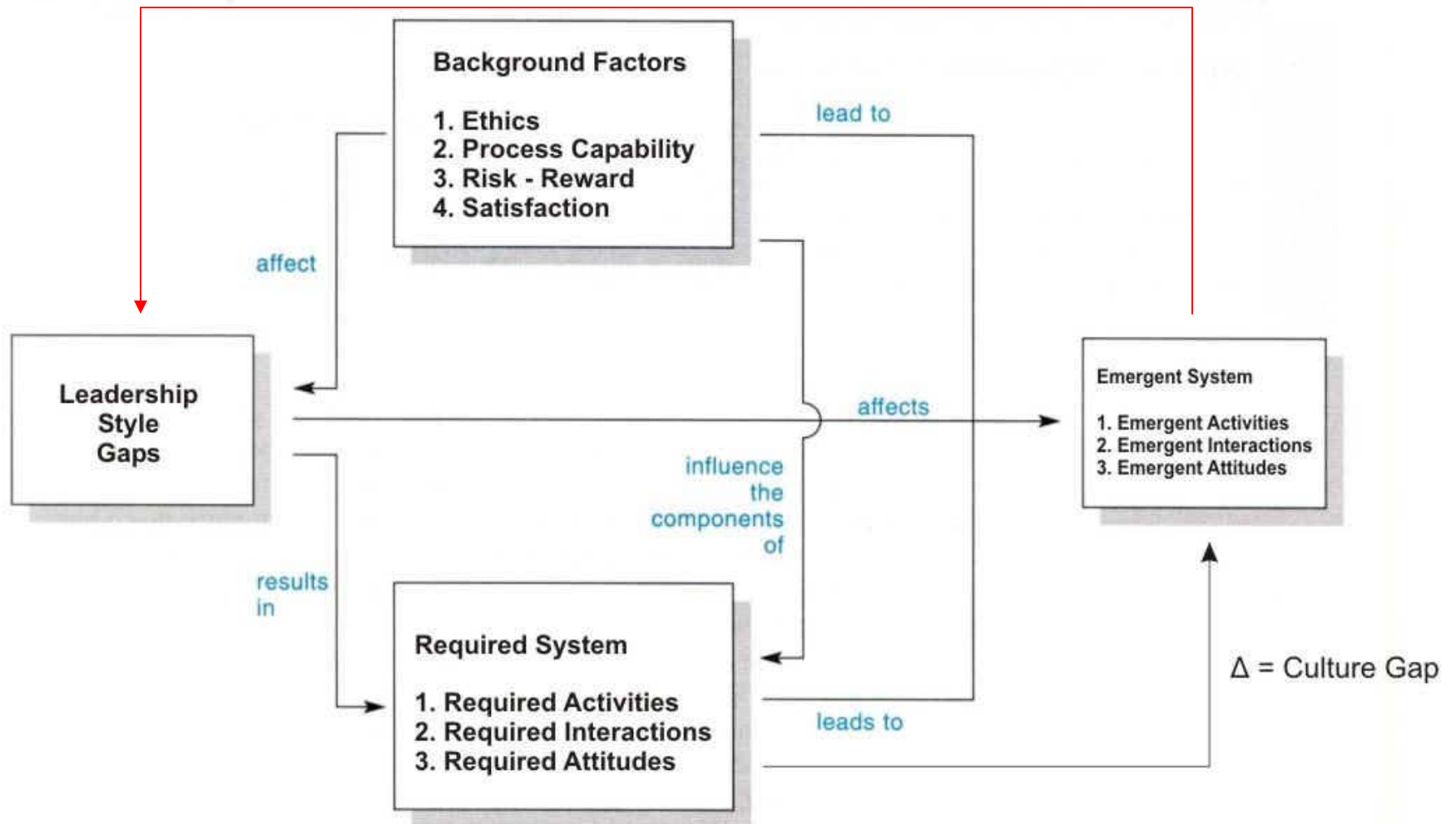


Communicate to the Hierarchy

Designing Quality Philosophy Into a Systems Based Program



The Orgculture Management Model





Ethics Quality, Inc.

Why do
we go
from
individual
saints...



... to groups of
scoundrels?



Its the culture! It makes us do
things we would not do alone.



Ethics Quality, Inc.

Order of
Importance



Organizational Policies and Requirements

4.

Good
Process

Refine with Higher Forms

Poor
Process

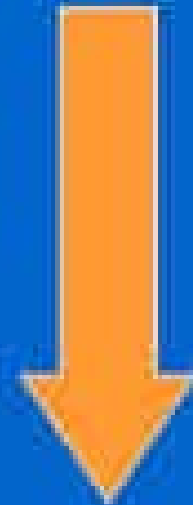
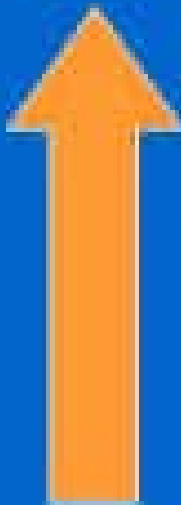
3.

ID and Resolve Dilemma

2.

Eliminate Lower Forms

1.



Quality Philosophy Examples

- **Merck** “Committed to bringing out the best in medicine.”
- **Eli Lilly** “Eli Lilly and Company is a leading, innovation-driven corporation committed to developing a growing portfolio of best-in-class and first-in-class pharmaceutical products that help people live longer, healthier and more active lives.”

Quality Philosophy Examples

- Pfizer “We dedicate ourselves to humanity’s quest for longer, healthier, happier lives through pharmaceutical, consumer, and animal health products.”
- GlaxoSmithKline “Our global quest is to improve the quality of human life by enabling people to do more, feel better, and live longer.”

Quality Philosophy Examples

- Food and Drug Administration

“Protecting Consumers, Protecting Public Health”, “Protecting and Advancing America’s Health”

- American Society for Quality

“Quality is there for you 24/7. Acknowledge it. Embrace it. Champion it.”

Dominant Global Values

- Fast
- Cheap
- Perfect
- Personalized
- Unique



Systems Based Program Examples

- **Balanced Scorecard**
- **Knowledge Management**
- **Six Sigma**
- **Total Quality Management**
- **Activity Based Costing**
- **Core Competencies**
- **Re-Engineering**
- **Customer Focus**
- **Work Simplification**
- **Waste Elimination**
- **Process Analytical Technology**

When In Rome...

The following remain our guiding principles:

- . Risk-based orientation**
- . Science-based policies and standards**
- . Integrated quality systems orientation**
- . International cooperation**
- . Strong public health protection**

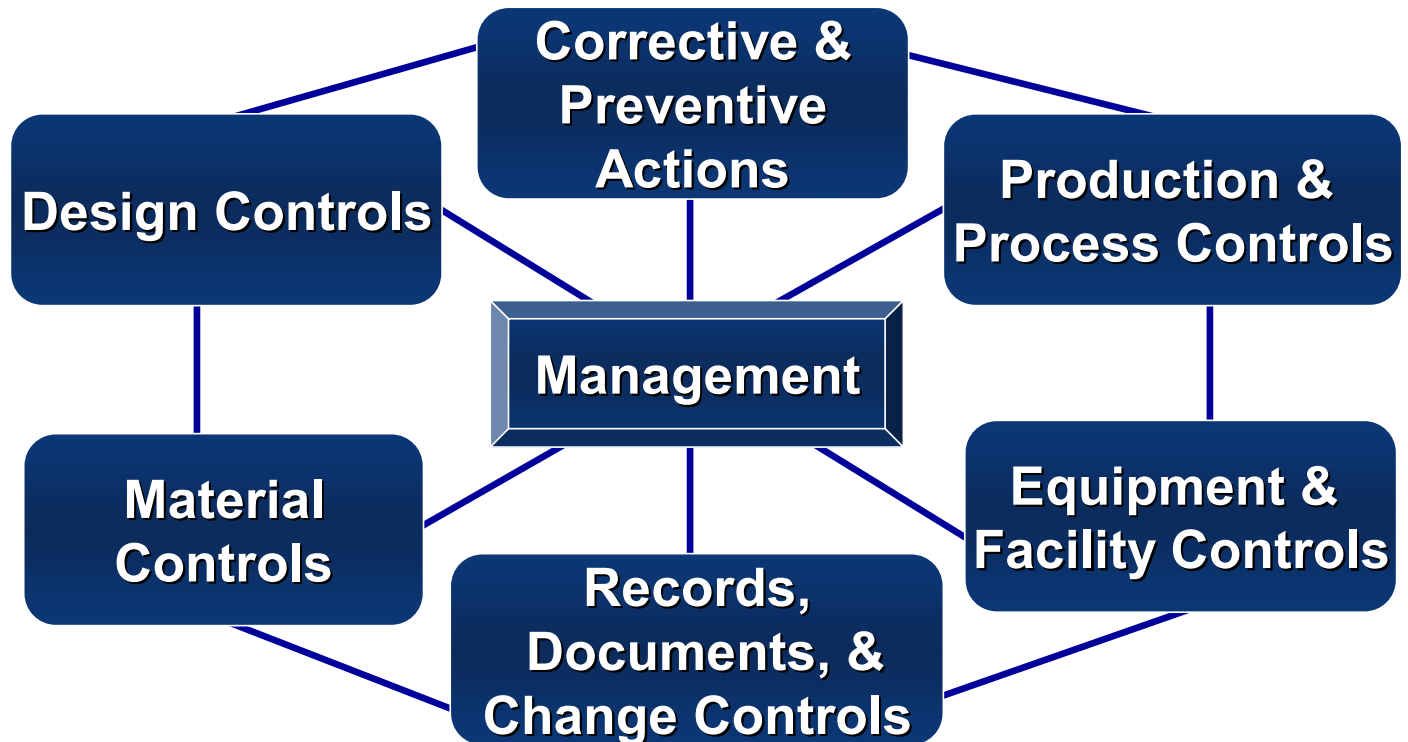
Source: Final Report – Pharmaceutical cGMPs for the 21st Century, September 2004.

Our findings have put the Agency on a path to restructure its oversight of pharmaceutical quality regulation, thereby developing the product quality regulatory system of the future. The following remain our guiding principles:

Website: <http://www.fda.gov/cder/gmp/gmp2004/CGMP%20report%20final04.pdf>

cGMP Quality Systems

Quality System's Sub-systems



Opportunities

for Designing Quality Philosophies Into FDA Regulated Systems-Based Programs

- **Enabling Technology Development and Innovation**
- **Patient and Consumer Protection**
- **Protecting the Homeland – Counter terrorism**
- **Using Risk-Based Management Practices**
- **Empowering Consumers for Better Health**
- **Improving FDA's Business Practices**

Source: Food and Drug Administration Progress and Priorities 2004,
September 2004

“Handle The Truth”

“The Future Evolves In
An Orderly Manner,
Out Of The Realities
Of The Past, Filtered
And Shaped By The
Decisions Of The
Present.”

David Pearce Snyder
www.davidpearcesnyder.com



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Designing Core Quality Philosophies Into a Systems-Based Program

Conclusion

- **Know what you want.**
- **Know when you have to have it.**
- **Know what you are willing to pay.**

Parting Advice

Do the right thing.

Do your very best.

Do good for others.

A magnifying glass with a black handle is positioned over a financial document, likely a stock market report. The lens of the magnifying glass is focused on a section of the document, which is illuminated with a red light. The document contains various columns of numbers and text, including the words "NET ASSET" and "LINK". The word "Questions?" is written in large, white, bold letters across the center of the image, partially overlapping the magnifying glass and the document. The background is dark, and the overall lighting is dramatic, with a mix of red and green hues.

Questions?