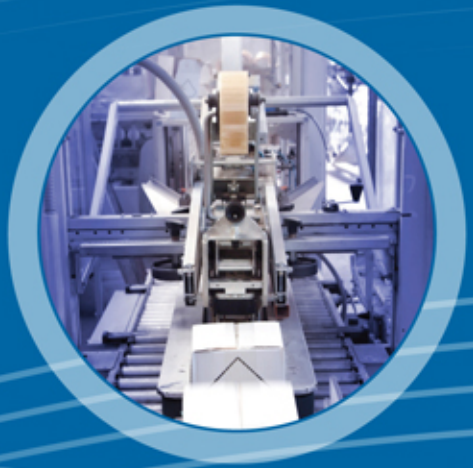
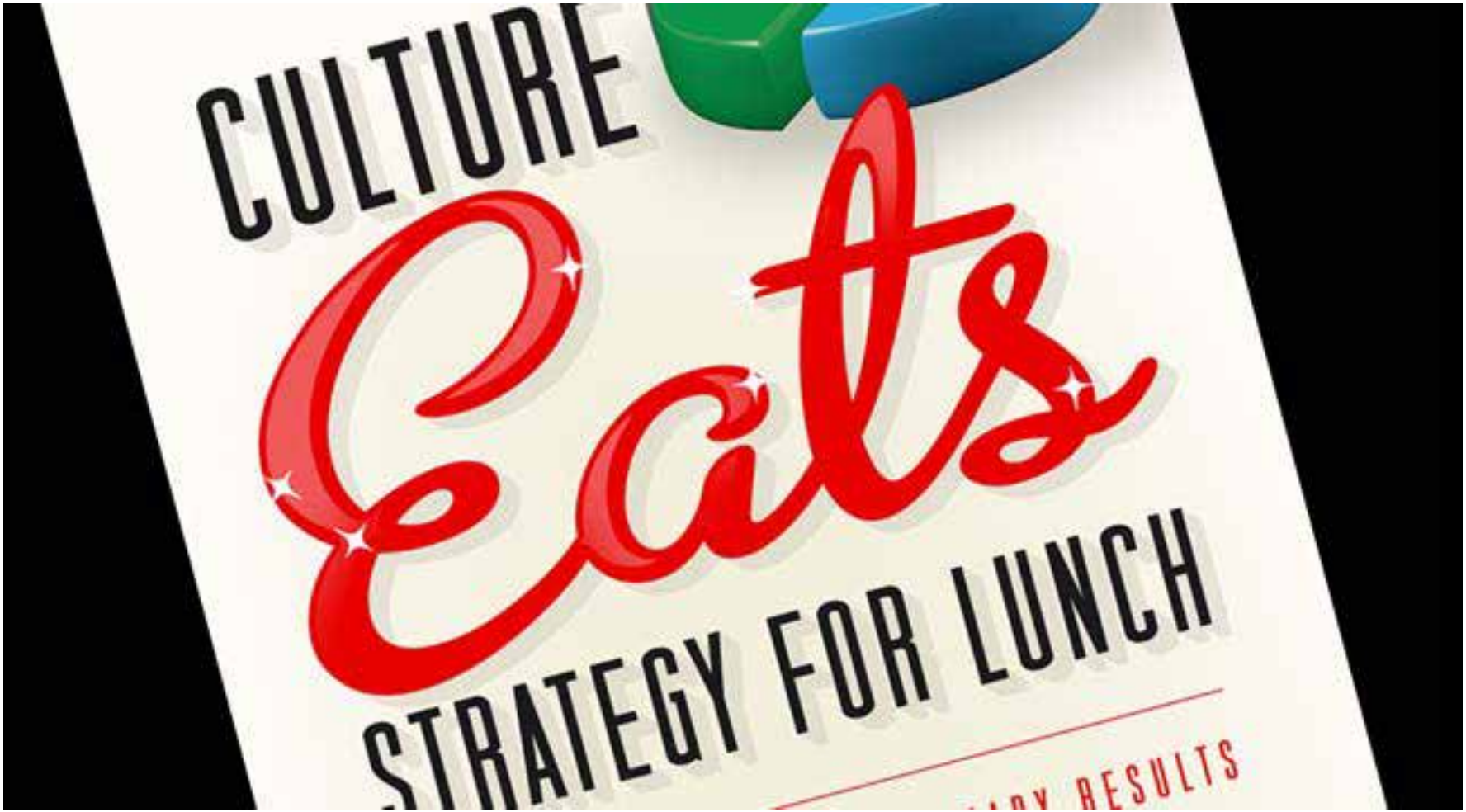
Connecting People, Science and Regulation

PDA's Quality Culture & Industry Activities



Steven Mendivil
PDA Quality Metric Task Force Leader

Everyone Agrees Culture is Critical



Pharma Industry is re-focusing on Quality Culture

- Utilization of Quality Metrics

- Widespread Data Integrity issues

- Cost of Quality / Right First Time approach and prevention of re-works

Other industries have benefited from strong Quality Culture programs

Quality Culture is Hard to Define

- "*An environment where each and every person understands and embraces their responsibility for protecting product quality and patient safety*" (Mary Oates)
- *"True Quality Culture – 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." "A culture in which employees "live" quality ….. as a personal value rather than simply obeying an edict from on high" (HBR 4//14)*

"Quality means doing the right thing when no one is looking" Henry Ford

2014 Quality Metric Conference

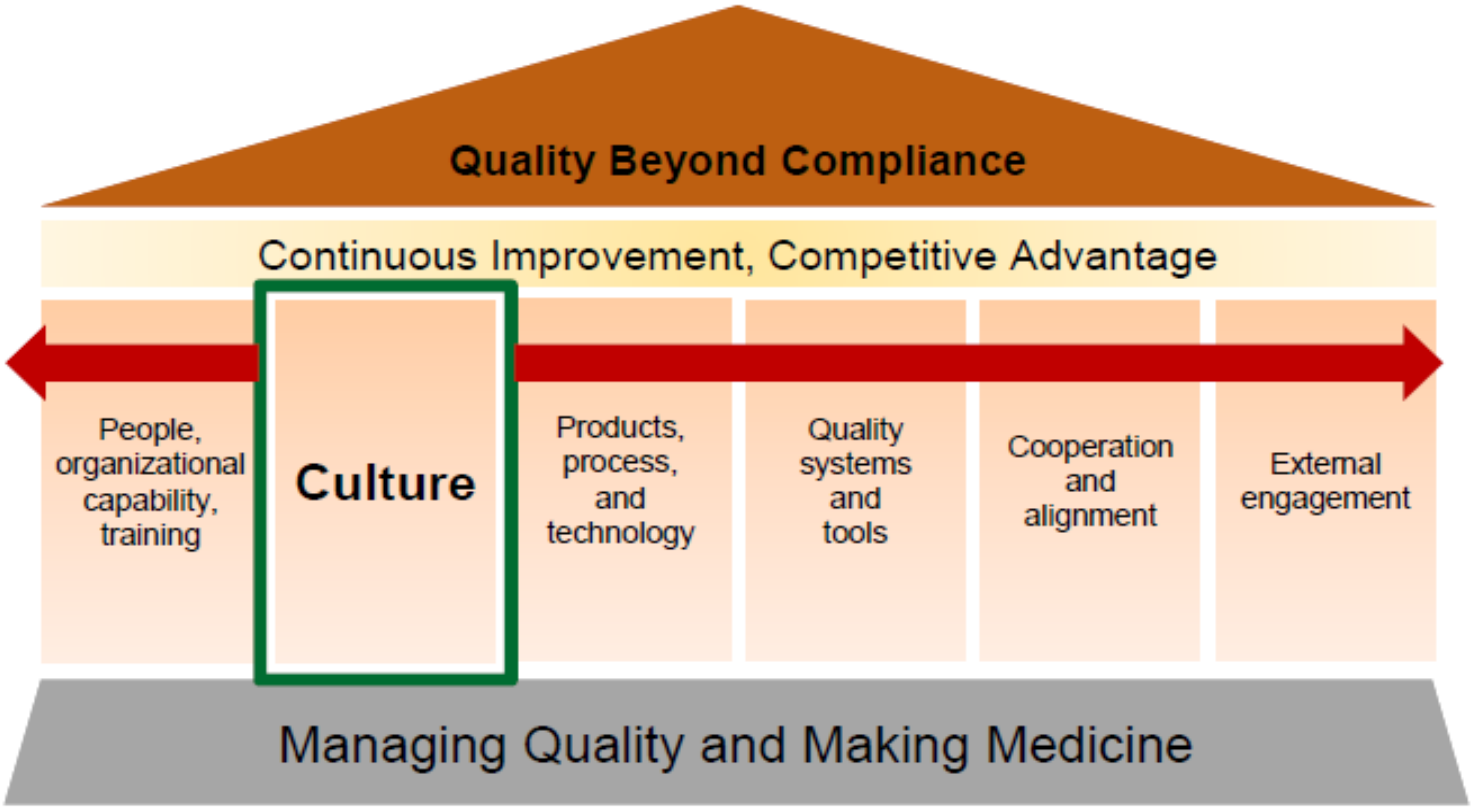
- 2013 focused on Quality System metrics
- 2014 focused on best practices and measuring Quality Culture.
  - Heads of Quality speaking on their Quality Culture journey and program.
  - Regulators (FDA and EMA) speaking on their approach to assessing quality metrics and quality culture.

Breakout Session to identify important behaviors and attributes

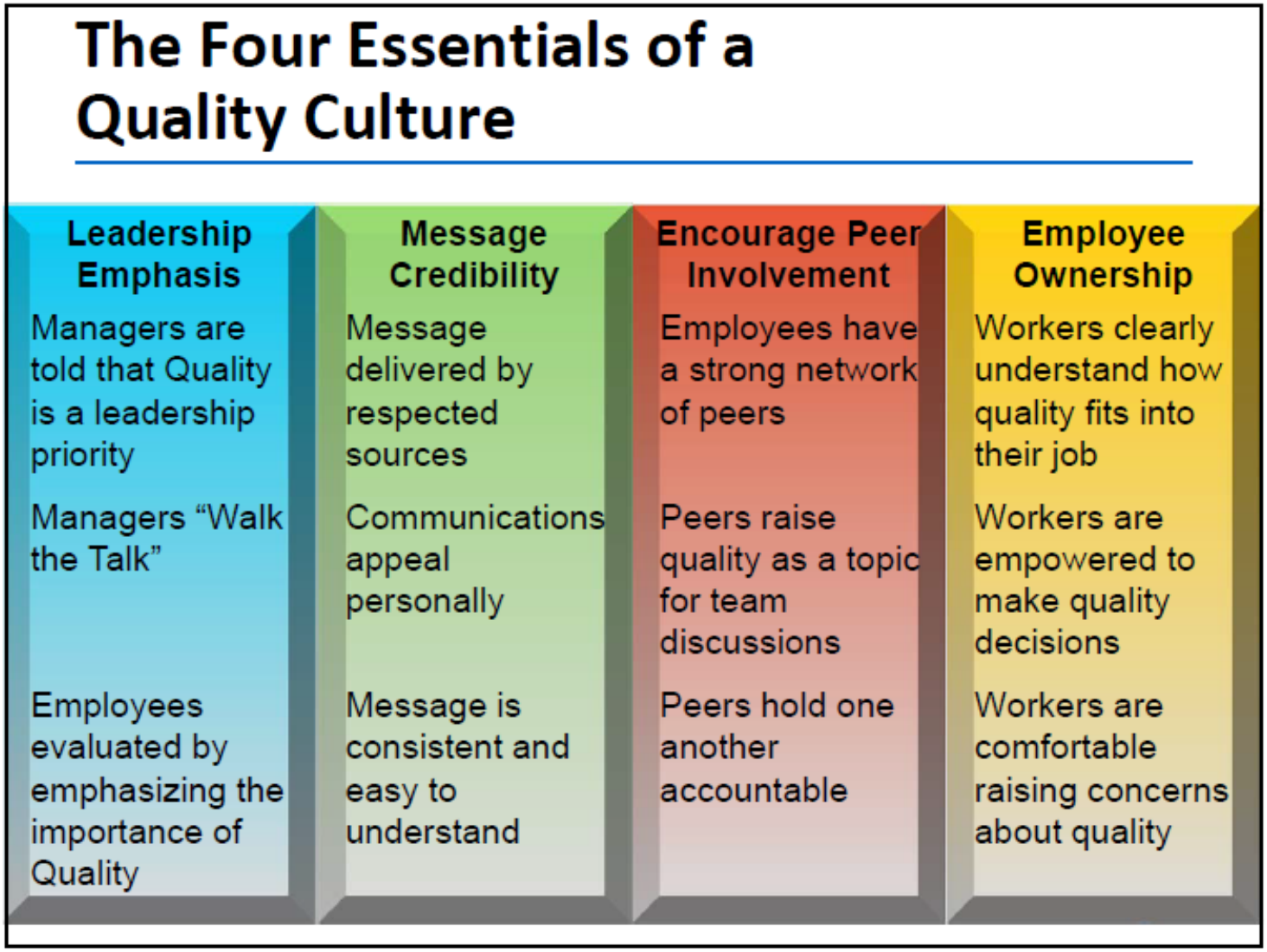
Erwin Vanhaecke: Novartis

The Novartis Quality Strategy

Anticipating long-term needs with a strong focus on the quality culture



Martin VanTrieste: Amgen



Eric Drape: Teva

Critical to Developing a Quality Culture

LEADERSHIP	Creates a shared vision	Establishes an environment of accountability	Is informed and engaged	Demonstrates genuine interest and promotes visibility
COMMUNICATIONS	Relevant and easy to understand	Customized for audience vs. one size fits all	Delivered regularly and with sincerity	Embraced by leadership from all parts of the organization
EMPLOYEE ENGAGEMENT	Engage at all levels	Celebrate success and recognize people	Tap into pride in ownership	Make it a way of life and not a program

Tools, slogans, KPIs and even rewards are secondary to building a Quality Culture.
Leadership that makes a difference!

Anders Vinther: Sanofi Pasteur

2014 PDA Pharmaceutical Quality Metrics Conference
Exploring Quality Culture and Quality Systems Maturity
December 2-4, 2014, Omni Shoreham Hotel, Washington DC
www.pda.org/metrics2014

Setting the basic expectations

Made by the IO Teams
Input by 1,300 employees

Our QMPs

Quality Mindset Principles

- Sanofi Pasteur quality vaccines should always be available to our customers
- Each of us knows how we contribute to public health through quality performance
- We all understand and own quality; we integrate quality into everything we do
- We comply with procedures and licenses, and strive for doing things right first time
- We anticipate risks, escalate and handle issues timely & solve them effectively
- I hold myself and my colleagues accountable to these quality mindset principles

Deb Autor: Mylan

Culture as a Measure of Quality System Maturity

- People
  - Quality culture engagement surveys
  - "Speak-up" indicators (reporting lines, red-button authority)
  - Can people articulate quality culture in terms of what they do and why
  - Quality culture recognition and rewards
- Senior Management Engagement in Quality
  - Executive leadership emphasis of quality & quality culture (role modeling, communication)
  - Quality reports on board agenda
  - Attendance and participation in quality-related meetings
  - Frequency of leadership walkthroughs and resulting action completion rate
  - Senior management production access and GMP training completion
- Product, Process and Equipment Practices
  - Organization understanding of product failure and improvement plans
  - Critical process and equipment ownership (accountability for state of compliance)
  - Shop-floor engagement in quality events and CAPA selection affecting their areas
- Governance and Visualization of Quality Metrics
  - Use of quality indicators to drive shop floor decision making / actions
  - Total Cost of Quality tracking
  - Proactive quality continuous improvement based on trends

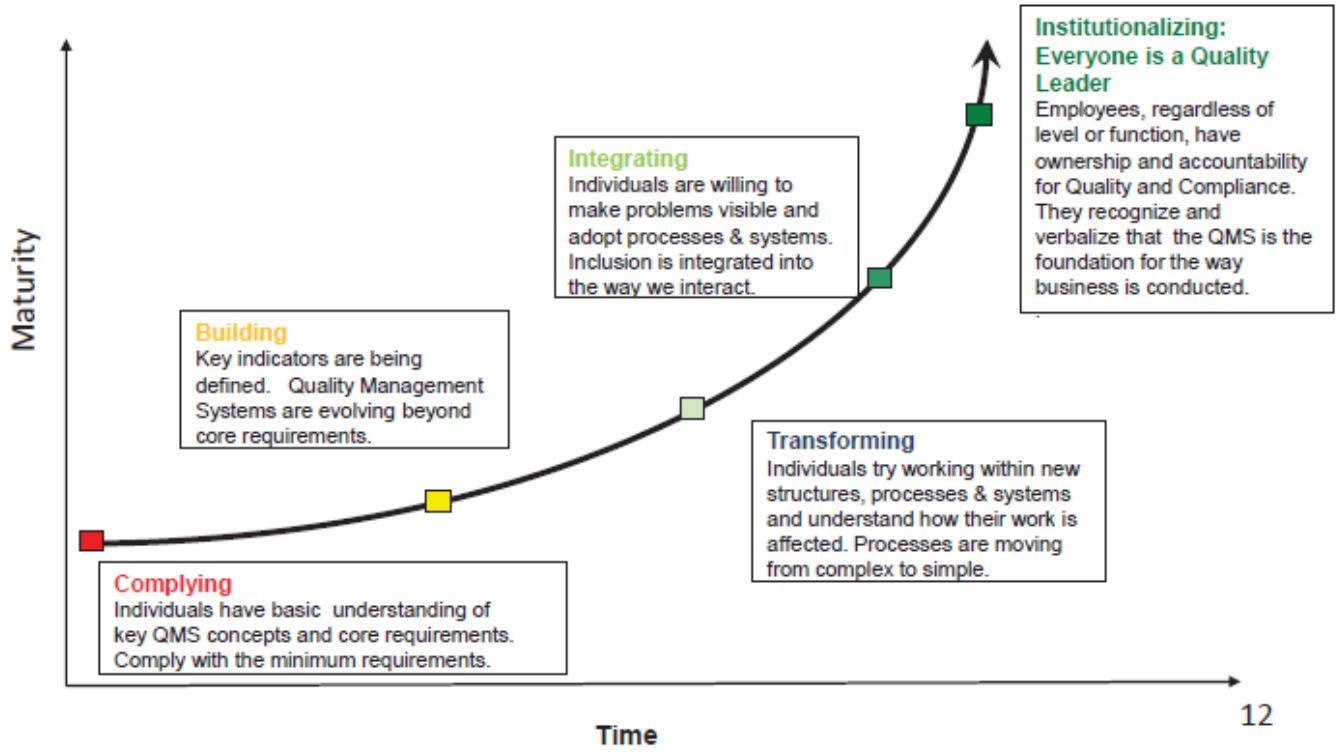
With thanks to the GPhA Quality Technical Group

Mylan
Seeing is believing

Jacqueline Elbonne: Merck

2014 PDA Pharmaceutical Quality Metrics Conference
Exploring Quality Culture and Quality Systems Maturity
December 2-4, 2014, Omni Shoreham Hotel, Washington DC
www.pda.org/metrics2014

Quality Culture Evolution Curve

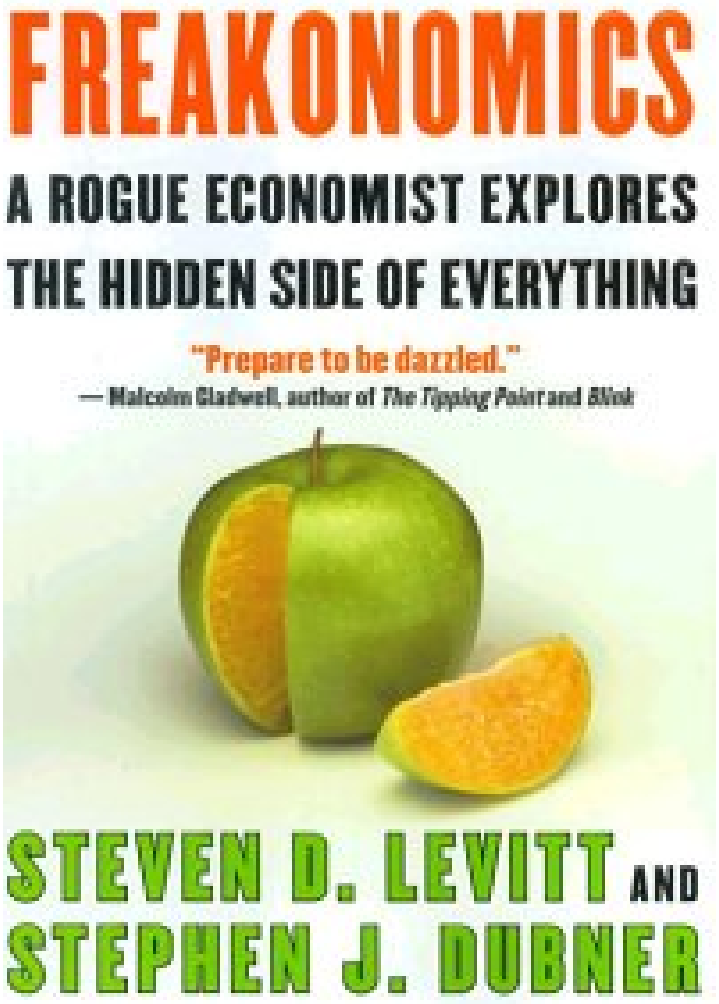


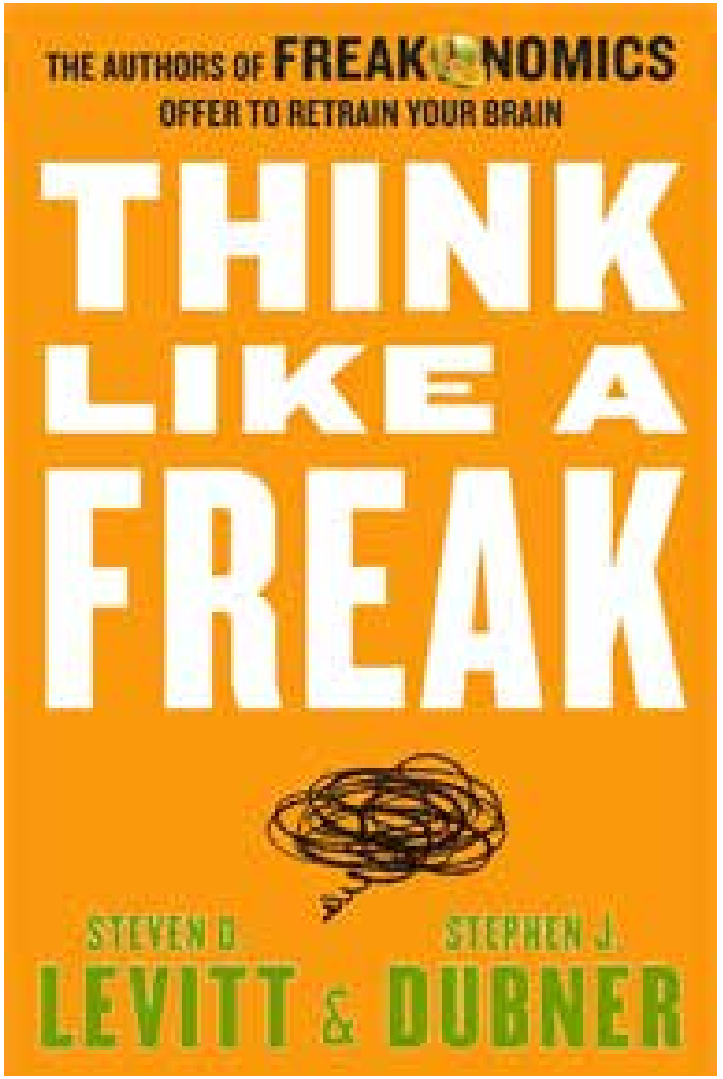
Common themes from Heads of Quality

- Companies have:
  - Different drivers for Quality Culture
  - Different yet similar elements
  - Different ways to define and measure progress
- Culture needs to be owned by the group
- Strong Quality Culture is driven from the Top

PDA's Quality Metric Task Force explored ways to measure Quality Culture as a possible metric.

Data driven analysis in search of the truth



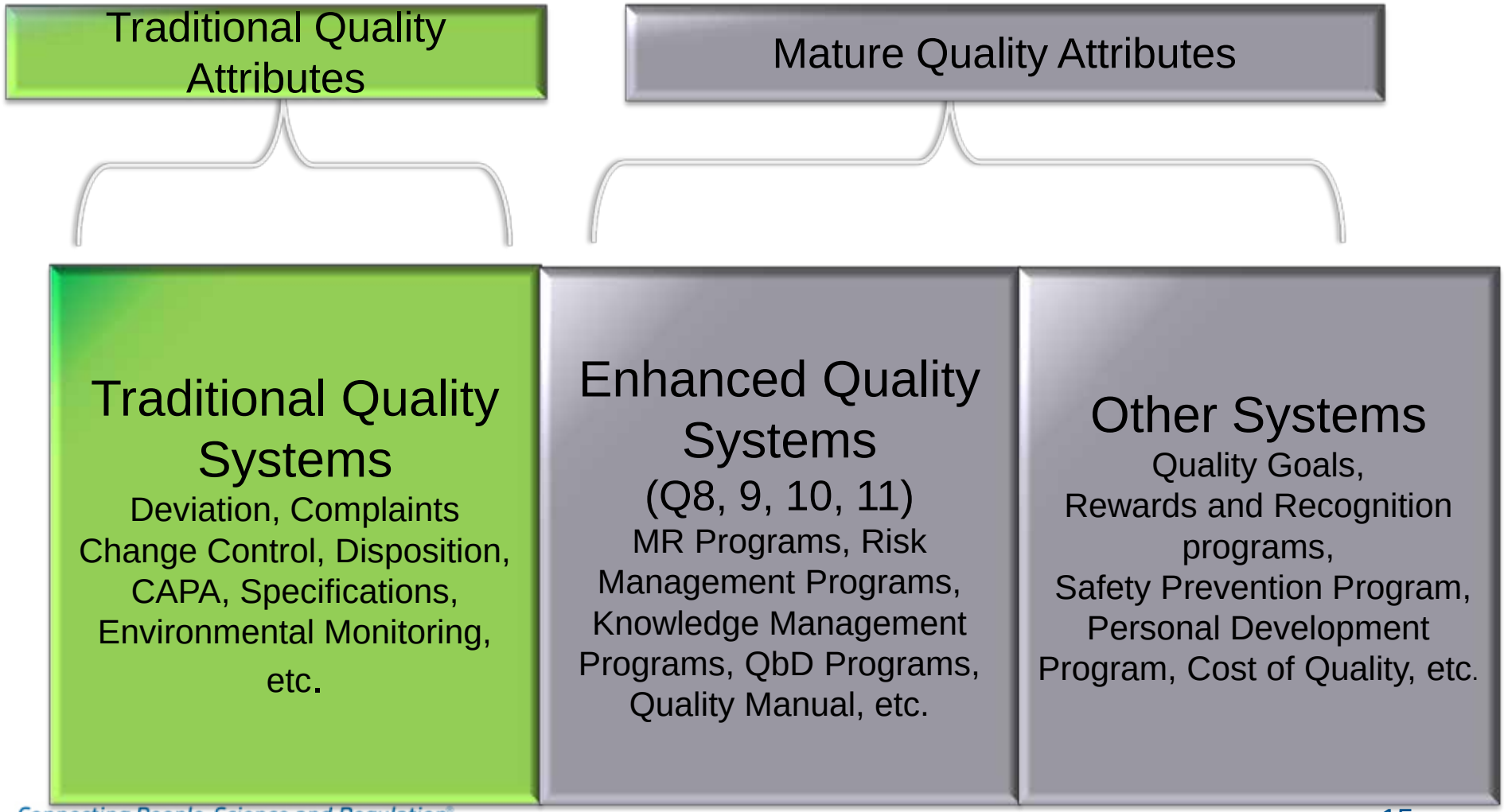


PDA Collected Quality Culture Survey Data
Can you objectively measure Quality Culture?

- Quality Culture (subjective)
- Mature Quality Attributes (objective)
- Hypothesis – Mature Quality Attributes has a strong relationship to positive Quality Culture behavior

Identify a set of Mature Quality Attributes that are a surrogate for Quality Culture Behaviors

Mature Quality Attributes provides the framework for a strong Quality Culture



Creating PDA's Quality Culture Survey

- Draft Survey June / July 2014
- Launched Sept 4th – Oct 20th 2014
- Two surveys (Executive Survey & Open to All Survey)
- Three Sections
    A. Demographic (product, site, size)
    B. Quality Culture Behavior
    C. Mature Quality Attributes

137 responses that met the criteria of a GMP operation

Section B: Quality Culture Behavior

Seven Areas of Behavior Questions

1. Communication & Transparency
2. Commitment & Engagement
3. Technical Excellence
4. Standardization of Criteria or Requirements
5. Cross Functional Vision
6. Rewards and Recognition
7. Speak Up for Quality Culture

These 7 areas identify 42 specific behaviors

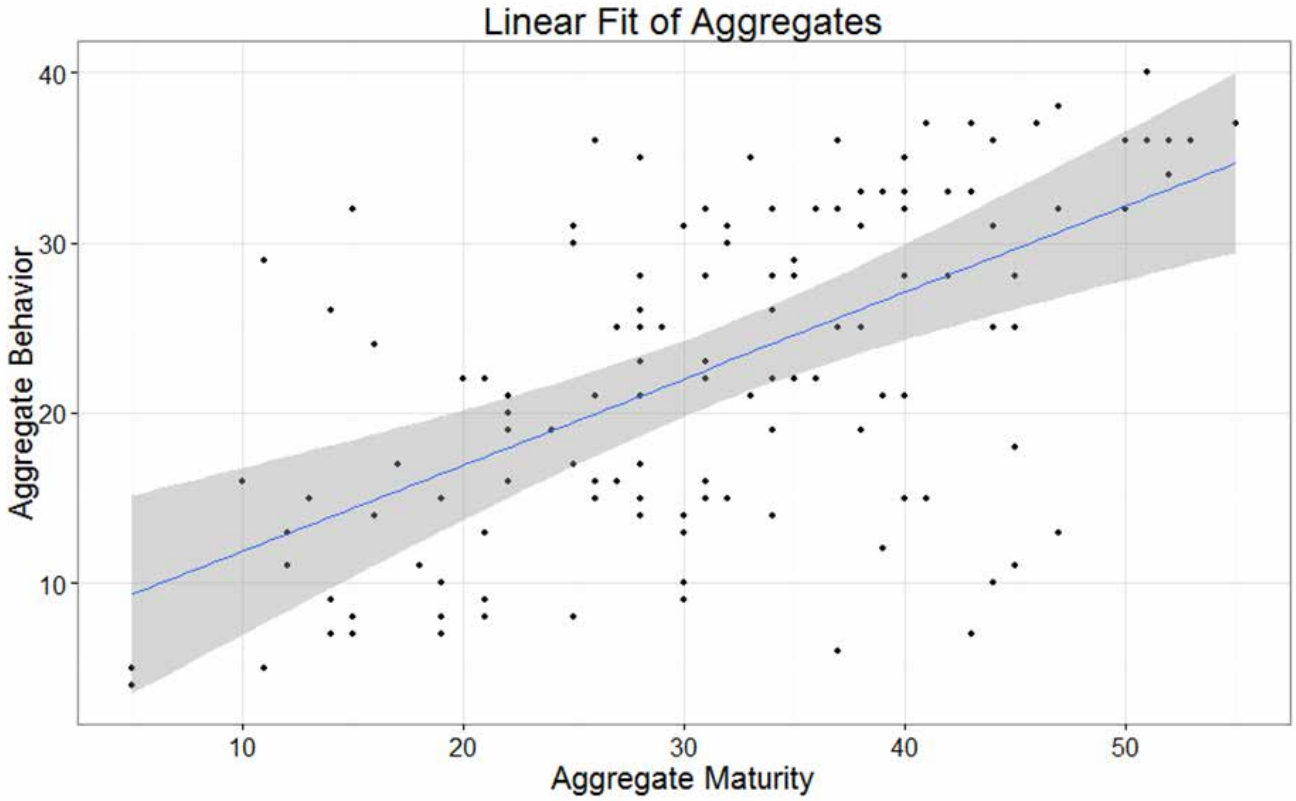
Section C: Mature Quality Attributes

Seven Areas of Questions

1. Prevention Programs
2. Quality Management and Issue Escalation
3. Training and Personnel Development
4. Quality System Management
5. People and Communication
6. Continuous Improvement
7. Site Metric Reporting

These 7 areas identified 55 Mature Quality Attributes

Is there a relationship between Quality Culture Behavior and Mature Quality Attributes?



Higher MQA score the higher the behavioral score

Given this is a Social Science Analysis, this is a strong relationship

Confirms Hypothesis #1

Confirmed objective measures for Quality Culture

- Strong relationship between Mature Quality Attributes and positive quality culture behavior.
- However, just having Mature Quality Attributes doesn't quantify robustness / maturity of programs
- Quality Culture is better assessed in a "maturity matrix" for the identified Mature Quality Attributes
- This becomes one of the focuses of PDA Sub-team on Quality Culture Assessment

Journey continues: PDA's Quality Metric & Quality Culture Conference Nov 9-10, 2015

Metric initiatives are embracing Quality Culture

Xavier/PwC – Measuring the "Obvious"

- Strong sentiment that the following are indicative of a Culture of Quality:
  - Companies need to assure quality at the source by designing quality in
  - Quality objectives and rewards/consequences should be shared across functional groups
  - A quality culture includes "doing the right thing when no one's looking"
- These opinions seem "Obvious" or "Basic".....but no one is measuring them!

Xavier/PwC – Next Steps

A lot done, a lot more to do…

- **Pre-Production, Production, Post-Production, Definitions**
  - Finalize Metrics list
  - Detailed definitions for selected metrics
  - Unintended consequences

- **Quality Culture**
  - Ways to measure top opinions
  - Algorithms
  - Frequency

ISPE's Pilot includes Culture Questions

Update from ISPE Quality Culture Team

Update from recent Quality Metrics Summit, April 2015 where the work of the ISPE Quality Culture Team was presented

"ISPE's Current Position on Quality Culture acknowledges that each organisation will have a different context, within which their Quality Culture exists, based on organisational ownership, supply chain configuration, maturity, product mix and regional influences."

Knowledge of cultural context is crucial

ISPE's Six Dimensions of Quality Culture

A Model for Cultural Excellence

- The ISPE Quality Culture Sub -Team proposes that the promotion of a '*relentless restlessness*' towards improvement in Quality Culture necessitates a 360° approach to *Cultural Excellence*
- A holistic *Cultural Excellence Framework* has been developed, entitled the *Six Dimensions of Quality Culture*
- A white paper is planned for publication in 2015 to outline the work of the team and the framework
- Future work streams planned for development of Tools, Templates and Training within each dimension

Final Thoughts

- No single metric captures Quality Culture
- Quality Culture / Mature Quality Attributes may go beyond cGMP requirements
- PDA is publishing complete Quality Culture Survey results in Sept PDA Journal
- PDA is focusing on those attributes that had the best correlate to positive behavior for an evaluation tool (maturity model) for Quality Culture

"Many of the things you can count don't count. Many of the things you can't count really count" Albert Einstein

Acknowledgements

Steven Mendivil, PDA Quality Metric Task Force Leader

PDA Quality Metric Task Force

Joyce Bloomfield (Merck)
Cylia Chen-Ooi (Amgen)
Veronique Davoust (Pfizer)
Gabriele Gori (GSK)
Robert Keiffer (Consultant)
Edwin Rivera Martinez (Sanofi)
Marty Nealey (Hospira)
Pritesh Patel (Consultant)
Anil Sawant (J&J)
Sue Schniepp (Consultant)
Anders Vinther (Sanofi Pasteur)
Glenn Wright (Lilly)

PDA Staff: Denyse Baker, Jon Hill, Morgan Holland, Rich Levy

PDA Quality Culture Survey Respondents

THANK YOU