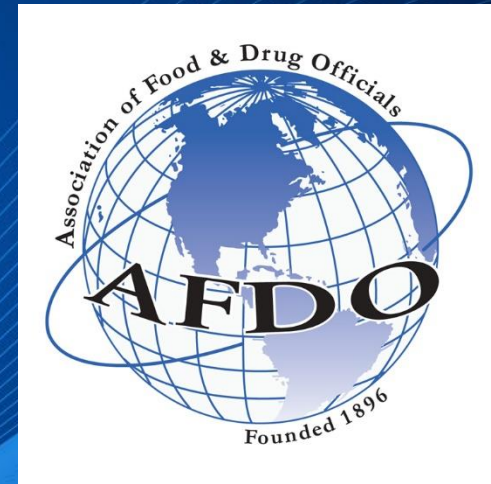


# Chief Quality Officers

## Redesigning Quality for the 21<sup>st</sup> Century

Association of Food and Drug Officials  
Atlanta Conference  
June 24, 2019



[www.Pathway4PH.org](http://www.Pathway4PH.org)

# The CQO Team



**Rosaleen  
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CSL Behring



**Pam Schofield**  
P&G



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Paykel  
Healthcare



**Peter  
Shearstone**  
Thermo  
Fisher



**Gary  
Workman**  
Illumina



**Jacques  
Zimmowitch**  
Elanco

- **Our cross-functional peers see us as:**
  - Impeding the business, not understanding the business, overcomplicating the processes
  - Themes identified by Xavier Graduate Students from industry-wide cross-functional survey. Quality needs to:
    - Improve ability to gain collaborative buy-in
    - Ability to articulate business case for quality
    - Focus on practical process development
- **Our CEOs want us:**
  - To be enablers of quality ownership throughout the enterprise with linkage to the business, and own the success of that business
- **Regulators recognize:**
  - The need for a change and are open to the “what if” discussion

# Top 5 FDA Citations Across 11 Years



One example of when it is not good to be consistent!

	FY06	FY14	FY15	FY16	FY17
1	211.22(d)	211.22(d)	211.22(d)	211.22(d)	211.22(d)
2	211.110(a)	211.160(b)	211.160(b)	211.160(b)	211.160(b)
3	211.192	211.192	211.192	211.192	211.192
4	211.160(b)	211.100(a)	211.113(b)	211.100(a)	211.100(a)
5	211.100(a)	211.67(b)	211.100(a)	211.42(c)(10)(iv)	211.67(b)

Presented by Dell Moller, FDA, during the March 2018 FDA/Xavier PharmaLink Conference



**“The definition of insanity is doing the same thing over and over again, but expecting different results”**

--Albert Einstein



## It's Time for Change

The paradigm can be shifted, and it starts with Quality

Let's explore.....

- **Create the Quality Organization for the 21<sup>st</sup> Century**
  - Leading-edge tools
  - Shift paradigms on the role of Quality such that Quality can maximize organizational agility to support product success
  - Include regulators on the path for input on a new face of Quality
  - Define “quality” such that all internal stakeholders can own and buy-in to the assurance of product quality
  
- **Develop Quality Science Education curriculum for undergraduate education globally**
  - Develop critically thinking professionals grounded in Quality Science who can lead in the device and pharma industries in the 21<sup>st</sup> Century
  - Free curriculum for universities, supported by industry SMEs, internships, co-ops and employment

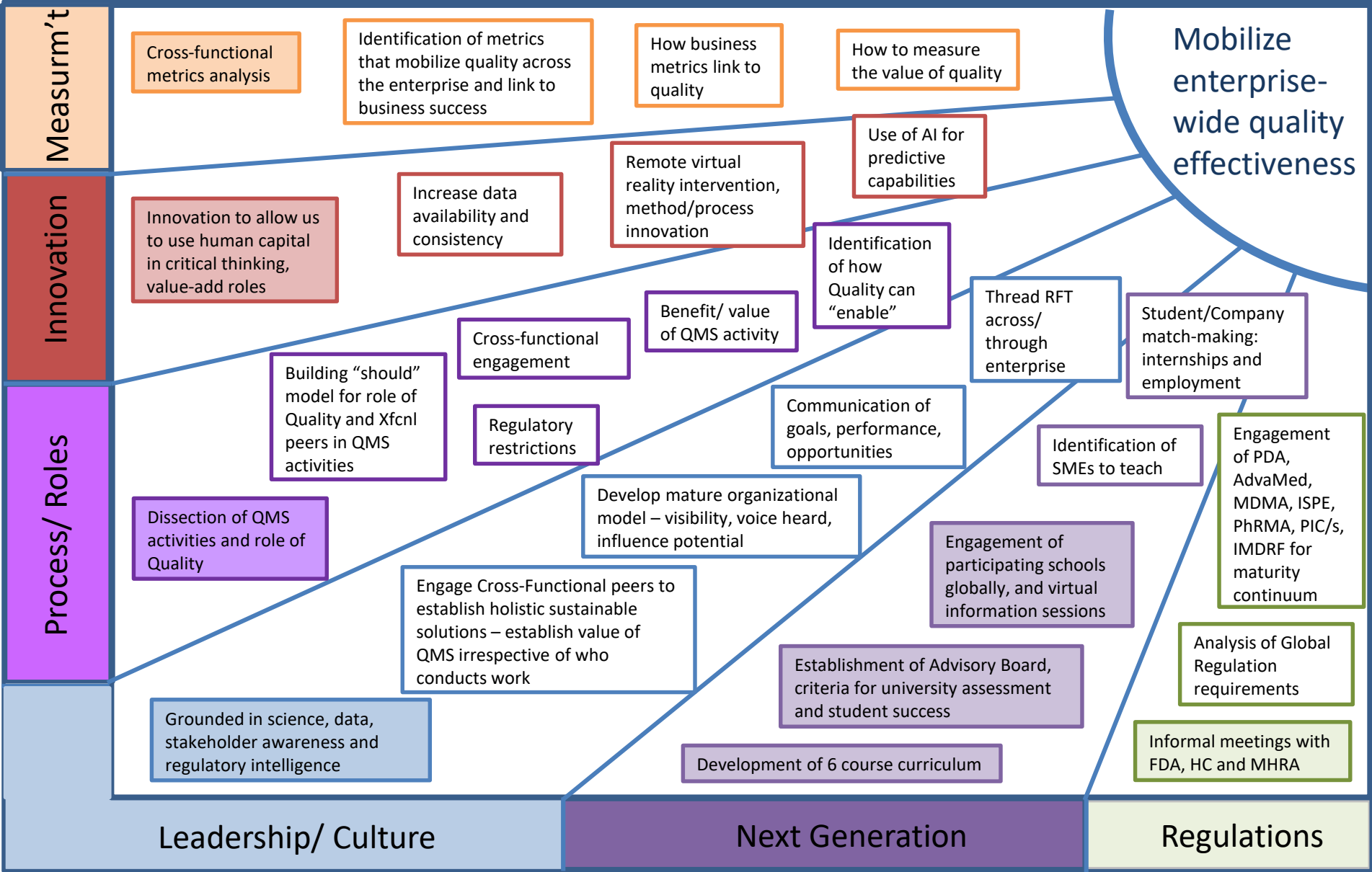


**What would you change to improve the effectiveness of Quality?**

**Small Group Discussion**



# Chief Quality Officer Transformation Map



# Case Study:

## Future State of Failure Investigations



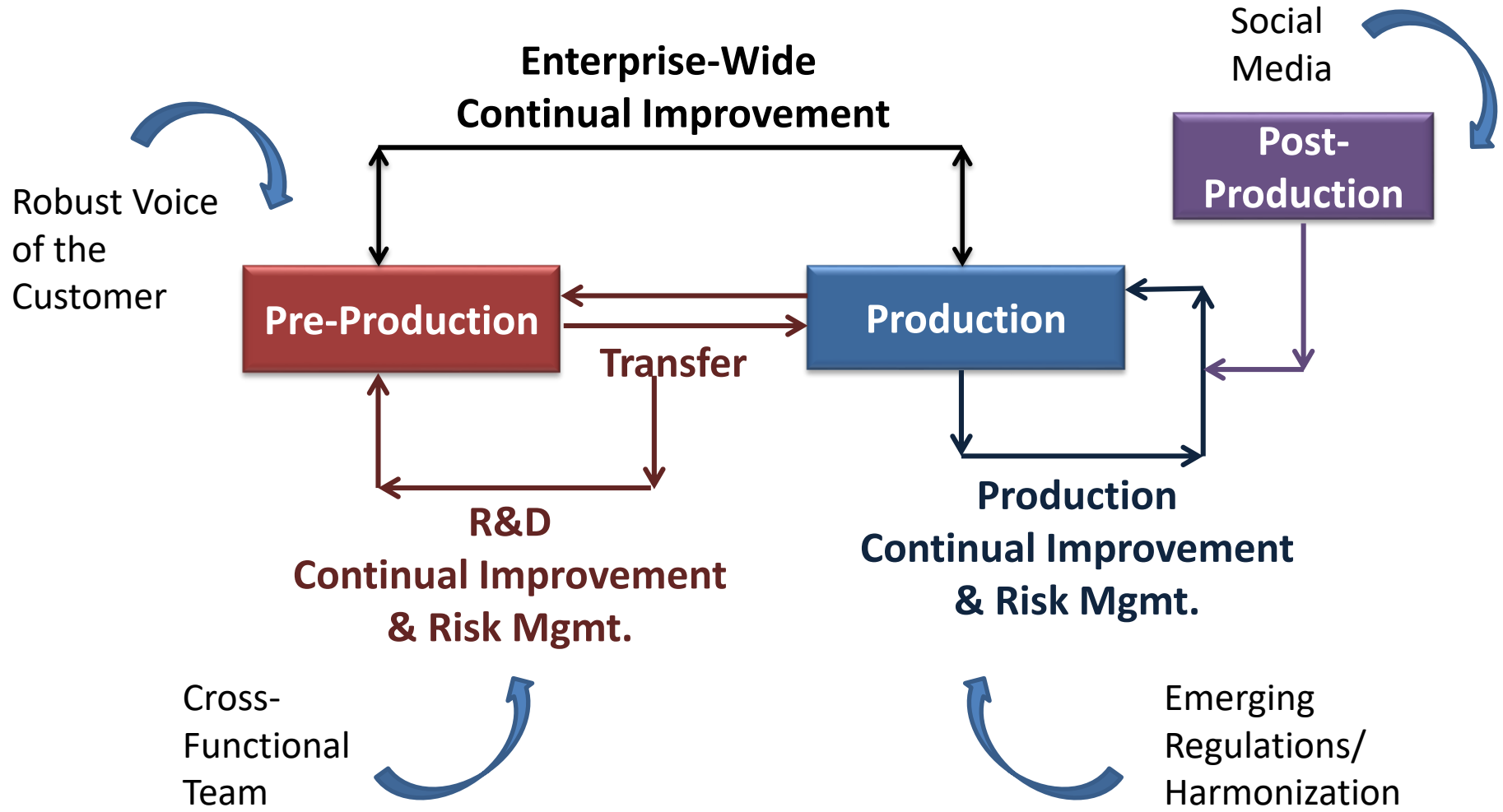
# Thoughts from the Panel

**Pam Schofield:**  
Enterprise-Wide Innovation  
to Increase VOC Robustness

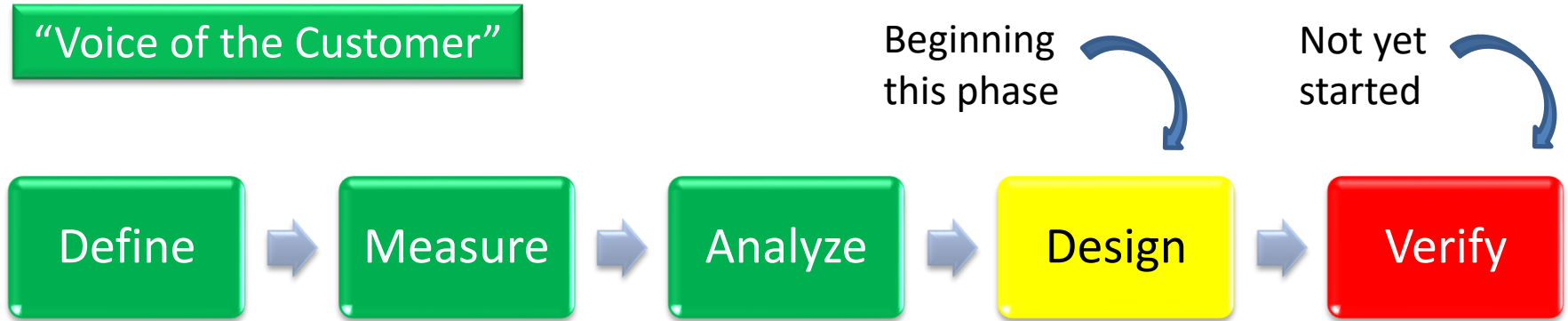
# Pam Schofield: Where to Start - Enterprise-wide Approach to Failure Mode Analysis



Develop an enterprise-wide system of robust product development input, and feedback loops for continual improvement



# DMADV Process – Engaging Stakeholders



- DMADV is used when a complete redesign is needed because the process, product or service is consistently incapable of meeting customer requirements
- The CQO Forum is formally engaging cross-functional peers in the process to develop a new approach to enterprise-wide quality effectiveness

**DMAIC is better for  
improving an existing system**

**DMADV is better for  
creating a new system**



# Thoughts from the Panel

**Georges France:**  
Quality Enabling the  
Advancement of  
Systems Innovation

# QUALITY NEED TO BE CUSTOMER/PATIENT FOCUS

## Pharmaceutical Quality Systems

Rick Friedman  
Deputy Director  
CDER/OC/OMQ

ISPE Quality Manufacturing Conference  
Mumbai, India (October, 2018)

### The Patient is the Customer

- **Voice of the Customer: Quality is customer-focused**
  - *What type of patient may receive this drug? What is its intended use? How do I design and control the operation to consistently meet customers' needs?*
- **Quality is achieved (and consumer risk minimized) by a robust Quality System**
  - *This requires Senior Management Commitment.*
- **In a strong quality system, senior management understands and leads with the philosophy that:**
  - *A proactive, preventative paradigm must be ingrained in the organization's daily operations (i.e., QA-mindset throughout organization)*
  - *Strong neural networks are needed to effectively communicate internally & throughout the supply chain (e.g., address OOT before OOS occurs)*

**Manufacturing  
Reliability**

**Consistent  
Product Quality**

**Supply  
Dependability**

**Satisfied  
Customers  
(Patients)**

**Voice of the  
Customer**

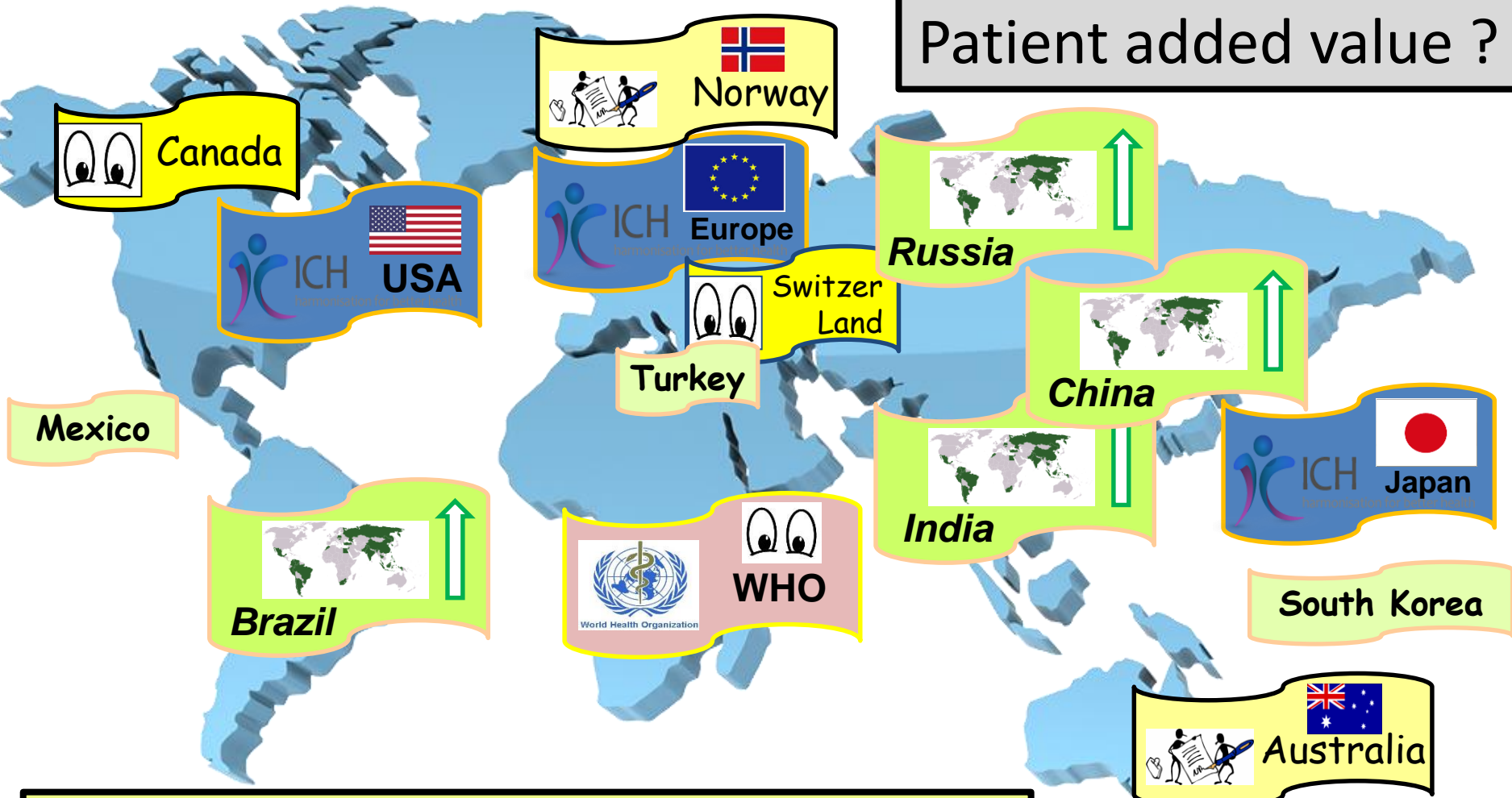
**Complaints  
Social Media  
Focus Group  
(Development)**

➤ **Patient In a global & Complex environment**

# REGULATORY GLOBAL LANDSCAPE

US FDA, ICH and Beyond

Patient added value ?



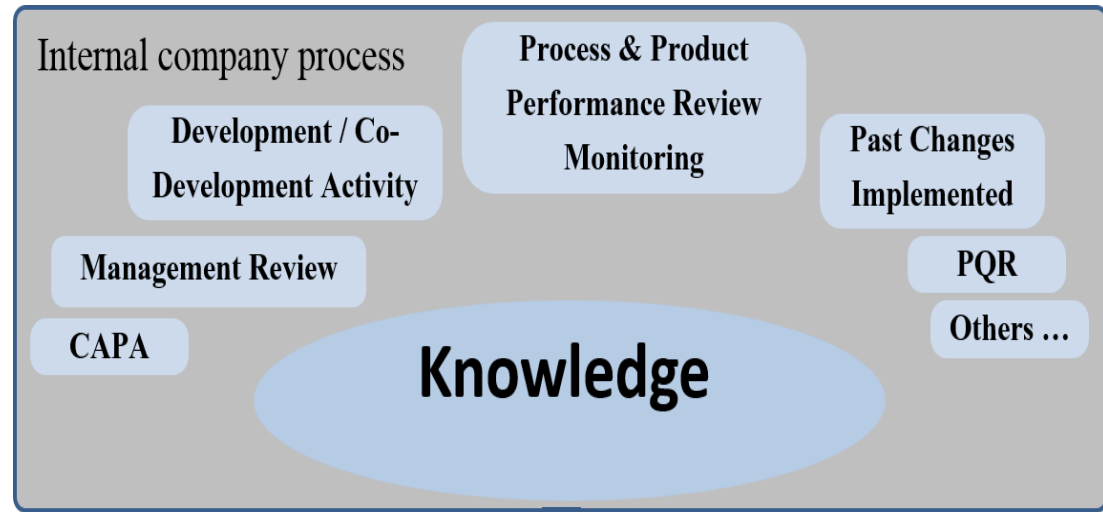
➤ Convergence and Harmonization



# DATA MANAGEMENT INTERNALLY AND EXTERNALLY



**Marketing Authorisation**



**GxP SOPs documentation**



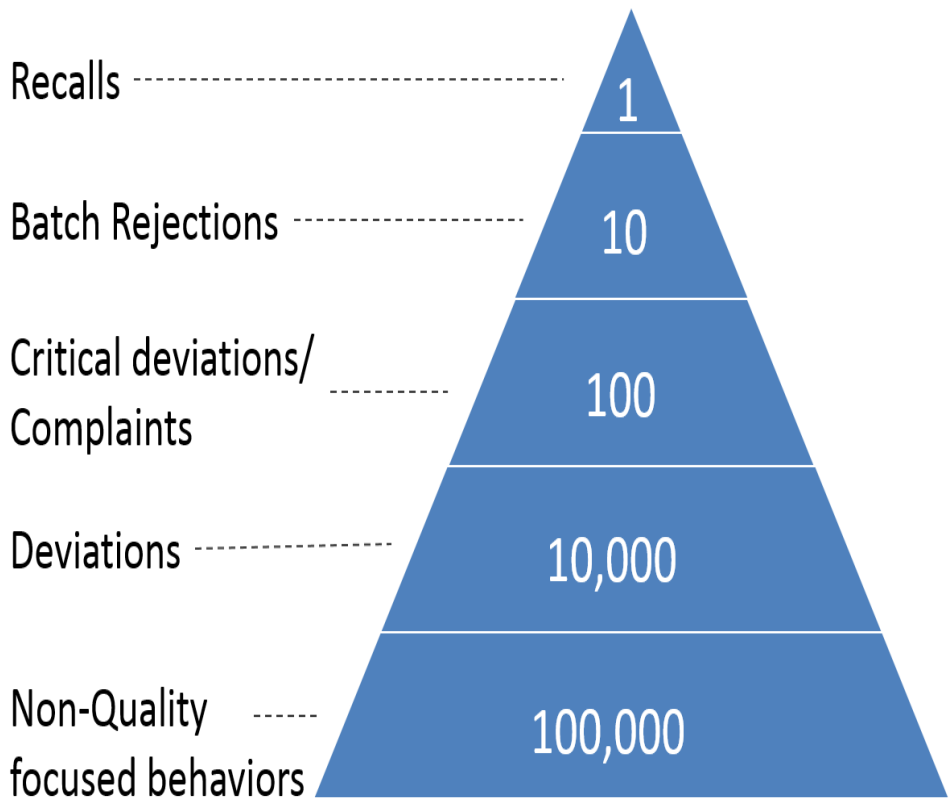
- From Data to **Relevant Information**
- Supported by **P.Q.S. & Ch. Mgt**
- **Innovative Data System ( Connected and E2E)**

# QUALITY PERFORMANCE MANAGEMENT FOCUSED ON THE BASE



Lagging  
KPI

Leading  
KPI



Beyond  
"Complaints"



**API**

Meeting Std

**Know-how**

Technical and previous  
knowledge

**People**  
Trained &  
Leaded

**Processes**  
Robust

- Quality can develop data systems **to make the Voice of the Customer accessible** across the enterprise throughout the Total Product Lifecycle to foster **Right-First-Time** (prevention of failure)
- Quality can foster **external and internal harmonization** to increase efficiency and decrease error
- Quality can conduct zero-based exercises to assess its role in order to increase **enterprise-wide ownership** of quality that reduces failure risk, and increases CAPA effectiveness



## New Definition for Role of Quality

### The Role of Quality for the 21<sup>st</sup> Century

To optimize patient health and business success by mobilizing enterprise-wide quality effectiveness grounded in science, data, stakeholder awareness and regulatory intelligence.



# Thoughts from the Panel

**Peter Shearstone:**

The Role of Quality in  
Failure Investigations –  
Today and Tomorrow

- **Quality owns and drives many facets of the QMS**
  - Administrative ownership
  - Often first stop for reactive solutions
- **We will never achieve co-ownership of quality outcomes across the enterprise if Quality continues to:**
  - “Oversee” and drive deviation and failure investigations
  - Require Quality-approval of root cause identification, conclusions and CAPA
- **Quality's goal is to enable the enterprise-wide organization to move toward a proactive quality culture**

- **Is Quality “special”?**

- No.
- Quality typically has a greater breadth of data and information at its fingertips than the SMEs in operations. This is a broken process that drives the wrong human behavior and culture.
- Need to focus on administrative efficiencies

- **Is *quality* “special”?**

- Yes. Massively.
- Need to ensure that regardless of who owns the investigation and subsequent actions they are done with the right level of rigor
- *quality* of work is vital



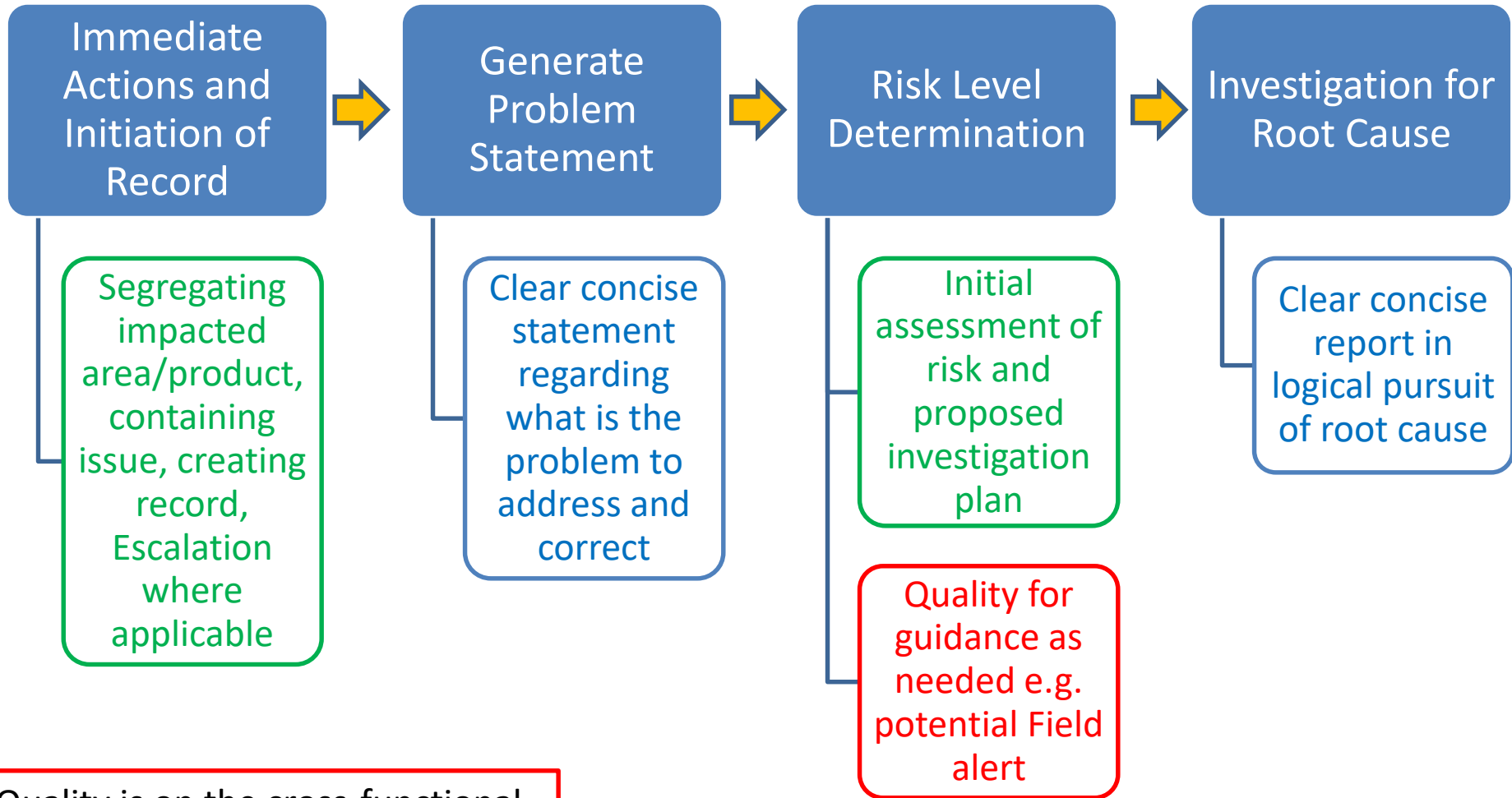
- **Internal Audits to verify success**
  - Must ensure that process is robust
  - Feedback loop to executive leadership
  
- **What are the next steps?**
  - System discipline and accountability
  - Metrics – CAPA FPY%

- 5** Countries
- 4** Industries
- 10** Companies
- 19** Professionals
- 1** Exploring Major Paradigm Shift
- 5** Quality Roles



# What if Quality's Role Changed?

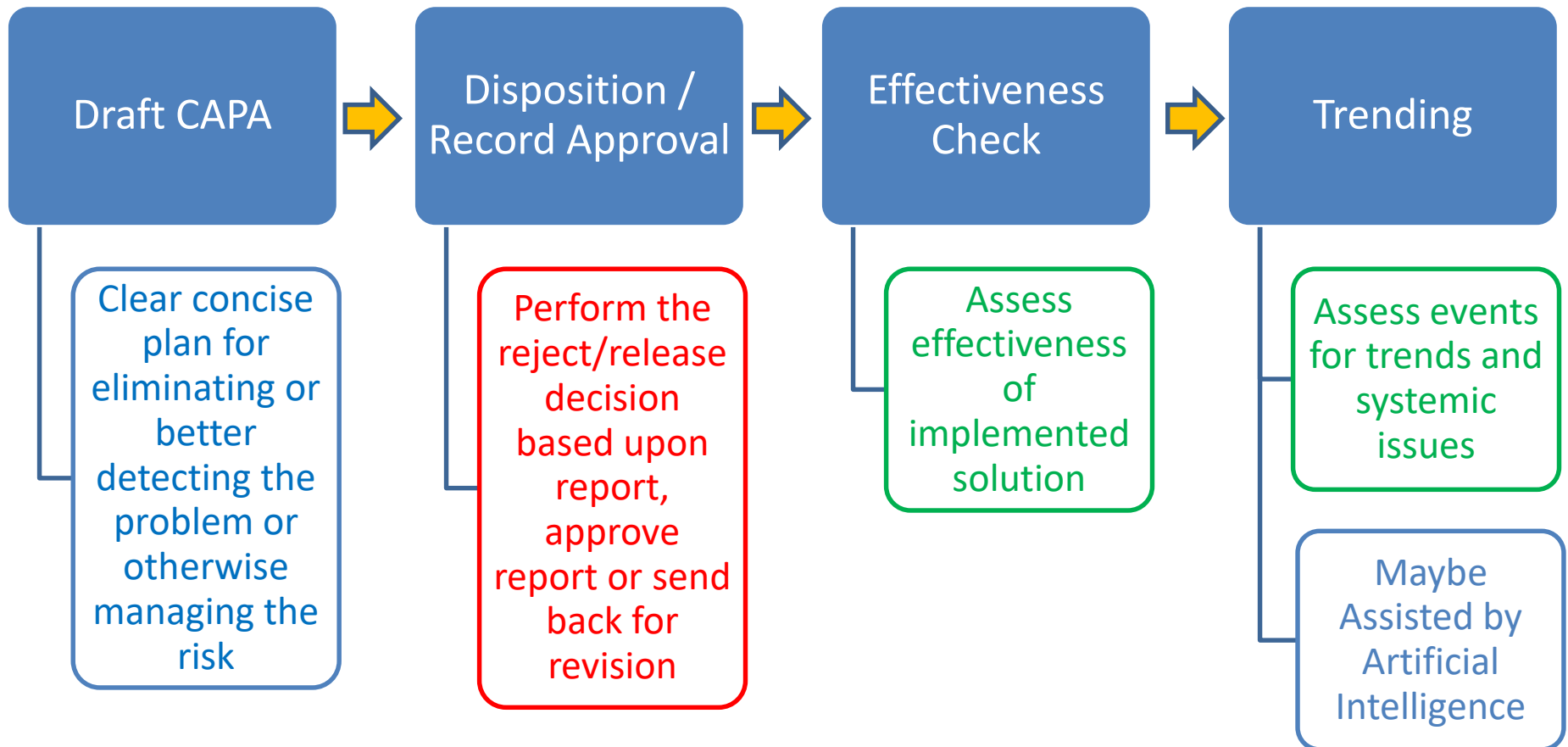
RED = Quality Function    Green = Qualified SME    Blue = Critical, Expert Required



Quality is on the cross-functional team, but is not driving the work

# What if Quality's Role Changed?

RED = Quality Function    Green = Qualified SME    Blue = Critical, Expert Required



Quality is on the cross-functional team, but is not driving the work

# Important to Remember:

## Our Current Model Is Not Working

- Repeat failures
- Repeat regulatory findings and warning letters
- Repeat recalls

- Develop a maturity continuum of models that eventually reach “ideal” state
  - In a mature Quality state, how would your company assure quality?
  - What enables Quality to do their job today, and then, how can we get the information/data/visibility/skills to the functional owners?
  - Define “ideal” state for each activity
  - Innovation of Quality – what does the new role of Quality look like, and what are the skillsets needed?
  - What is the messaging needed to convey the value of this change for the organization and gain true buy-in?
- Articulate the value of the activity (i.e. internal audits, batch record review, complaint management, failure investigations, and change control) – Business of Quality/Culture
- Articulate the value Quality brings to the activity
- Articulate the skillsets needed for each functional role for each activity

# Now we Need to:

**Create the next  
generation of  
critically-thinking  
professionals  
grounded in the  
science of Quality**

**Starting at the Undergraduate Level**

‘Society has reached the point where one can push a button and be immediately deluged with technical and managerial information. This is all very convenient, of course, but if one is not careful **there is a danger of losing *the ability to think*. We must remember that in the end it is the individual human being who must solve the problems’**

**Eiji Toyoda**, the Toyota Way, Chapter 14

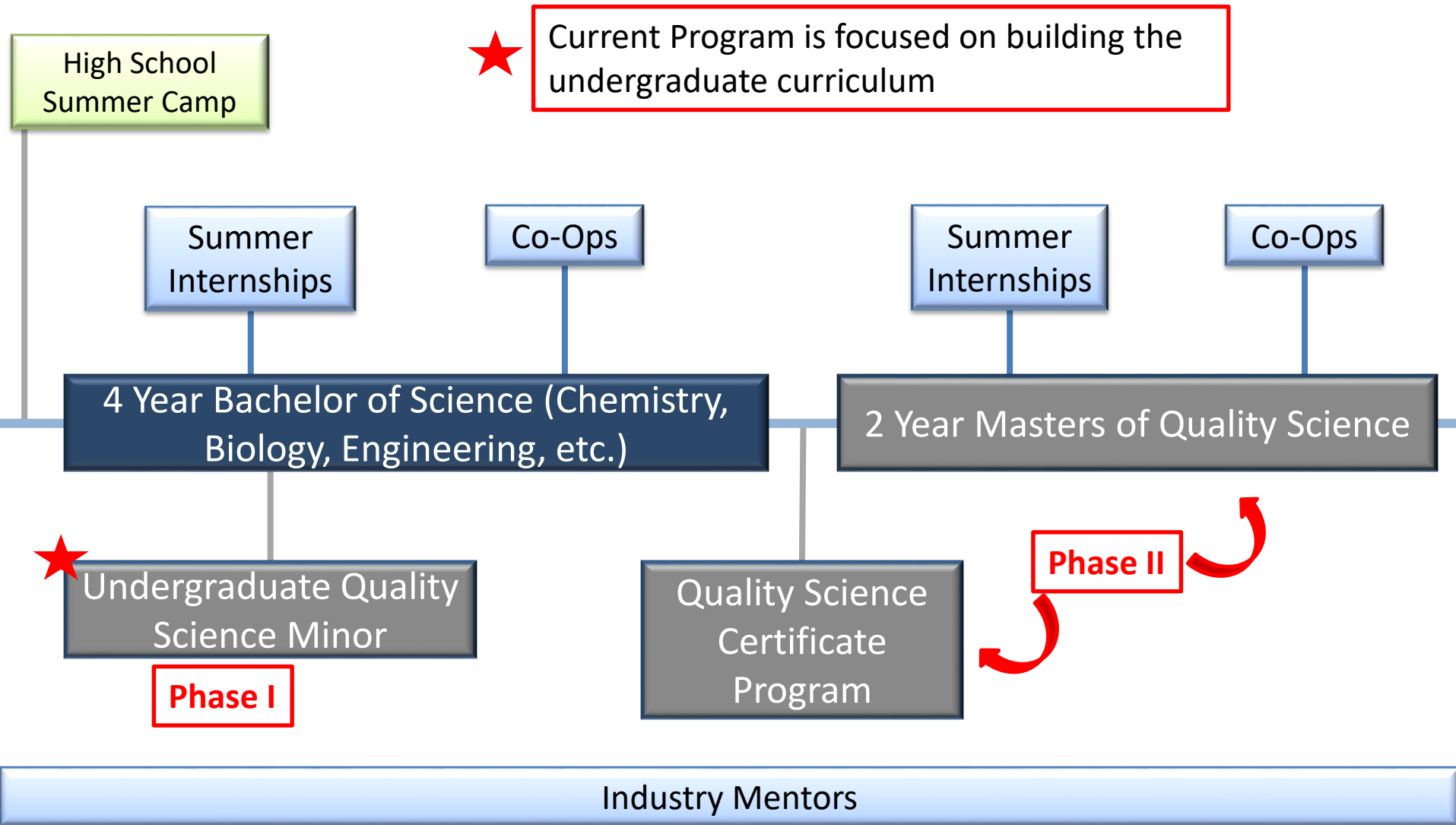




# Thoughts from the Panel

**Bob Miller:**  
Enterprise-Wide Skillsets  
Needed for the 21<sup>st</sup>  
Century

# Quality Science Education Model – Current and Future



- 1. Global Regulatory and Legal Requirements of Quality** focused on “why” global regulations were adopted, and the evolution of the quality systems grounded in science. **prerequisite**
- 2. Business Acumen** focused on financial concepts and applications, such as operating and capital expenses, fixed assets and liabilities, cash flow, profit and net worth.
- 3. Product Development, Specifications, Process and Validation** to include criticality of inputs, risk controls and assessment, specifications, testing, clinical trials, transfer, scalability, yield and validation.
- 4. Risk and Failure Analysis** gained while on internship so as to learn the investigation process and writing scientifically justified conclusions linked to laboratory experiments and data.
- 5. Microbiology and Microbiology Laboratory** courses focused on controls, testing, and aseptic techniques. [Expanding to include all non-major sciences that are relevant – engineering, chemistry, polymer science, data science, etc.]

- Would you like your alma mater to offer this curriculum?
- Would you like to be an SME teacher supporting universities that want to participate?
- Does your organization have paid internships anywhere in the world?
- Would your organization like visibility to students all over the world going through this curriculum at their respective universities?
- Would you like to mentor a student at any university?

**Contact Us!**

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**513-238-4338**

# Panel Q&A

# Questions for the Panel?

Panel Member	Topic Covered
Pam Schofield	Enterprise-Wide Innovation to Increase Voice-of-Customer Robustness
Georges France	Quality Enabling the Advancement of Systems Innovation
Peter Shearstone	The Role of Quality in Failure Investigations - Today and Tomorrow
Bob Miller	Enterprise-Wide Skillsets Needed for the 21 <sup>st</sup> Century

*Thank You  
for Your  
Passion!*

