Chief Quality Officers

Redesigning the Field of Quality for the 21st Century

www.Pathway4PH.org
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Mission of the Chief Quality Officer Forum

Creating Quality for the 21st Century – Optimizing the Total Enterprise
Today’s Quality
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!

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

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What's the use of running, if you are not on the right road

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

--Albert Einstein
Important to Remember:

Our Current Model Is Not Working

- Repeat failures
- Repeat regulatory findings and warning letters
- Repeat recalls
It’s Time for Change

The paradigm can be shifted, and it starts with Quality

Let’s explore............
Why do you think our current system “isn’t working”?
Thoughts from the Panel

• **Georges France:** Advancing Innovation and Technology

• **Peter Shearstone:** Culture and Leadership
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)

Patient In a global environment

 Manufacturing Reliability

 Consistent Product Quality

 Supply Dependability

 Satisfied Customers (Patients)
REGULATORY GLOBAL LANDSCAPE
US FDA, ICH and Beyond

Patient added value?

Convergence and Harmonization
SUPPLY CHAIN COMPLEXITY

API Manufacturer Site

X 2

X 3

X 4

API, Excipients, Packaging Outsourcing

Manufacturer

Sub-Contractor

FP Manufacturing

Distribution & Export

Local Distributor

Hospital

Pharmacist

Patient

Upstream

Downstream

Role and Responsibility of MAH

Xavier University, Cincinnati May 1st 2019, Georges FRANCE
CHALLENGE: DATA MANAGEMENT

Marketing Authorisation

GxP SOPs documentation

From Data to Relevant Information
QUALITY DECISION

Provide appropriate information

- Good information (Reliable)
- Good timing
- Good person

Not too simple

Leaving some place for a relevant decision and provide appropriate information for:

- Good understanding
- Giving sense to data
- Facilitate flawless execution
- Keeping focus the final outcome

TECH & AI Support

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QUALITY BEYOND COMPLIANCE

Assessing Quality improvement

Measuring Compliance

Training

Complaints

Product & Process Review

Out of Specification

Deviation

Product Defect

Non Quality Focus behavior

Product Recall

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QUALITY PERFORMANCE MANAGEMENT
FOCUSED ON THE BASE

Recalls
Batch Rejections
Critical deviations/
Complaints
Deviations
Non-Quality focused behaviors

1
10
100
10,000
100,000

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Recipe « Opera »

Sirop
• 20cl de café filtre
• 75g de sucre semoule
• 5g de café semoule

Biscuit Joconde
• 220g d’œufs
• 80g de jaunes d’œufs
• 220g de poudre d’amandes
• 175g de sucre semoule
• 125g de blancs d’œufs
• 100g de sucre semoule
• 100g de farine

Ganache Chocolat
• 170g de chocolat noir
• 12cl de lait
• 40g de crème liquide
• 20g de beurre

Crème au Beurre
• 600g de crème au beurre
• 10g de café soluble

Glaçage
• 200g de chocolat noir à 52%
• 25g de végétalienne
• 25g d’huile d’arachide
HOWEVER, NOT ENOUGH WITHOUT A VALID IMPLEMENTATION
When Boeing developed its 737 Max, regulators determined that pilots could fly the planes without extensive additional training because they were essentially the same as the previous generation.

*Boeing’s Rush to Finish New Jet Left Little Time for Pilot Training*  
Natalie Kitroeff, David Gelles, Jack Nicas, Thomas Kaplan, and Maggie Haberman | March 17, 2019
SOME THOUGHT

Re focusing Regulatory approach integrating key drivers

- Global Patient impact (Recognizing globalization of access and supply chain)
- Regulatory Convergence
- Science and risk management based

Knowledge and Data Management (support by TECH Tool, AI, ...)

“Zero Based” Quality approach

- Global Principle and Secure the basic (Quality Culture, DI, )
- Always consider shop floor and end user (Simple and not simplistic)
- Robust implementation and execution
- “Fit to purpose”: Product type specific and Risk Management based
- Pro Active versus Reactive
‘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
Thank You

Acknowledgements

Teri Lyng
Rick Freidman FDA ICH Q10
Ferdinando Aspesi
Q12 EWG
Peter Shearstone

- Quality consciousness not optimal
  - How do we inspire people to care?
- Pressure to deliver results
  - Month/Quarter end
- Lack of leadership at all levels
  - Honest and transparent feedback
- Conflicting priorities within enterprise
  - Resource challenges
- QMS that is not harmonized/simplified
  - Lack of system maintenance
Sustainability of Change Includes:

• **Leadership Buy-in**
  – Policies, Processes and Procedures to formally support the change
  – Communicate, communicate, communicate
  – Accountability

• **HR Processes Needed to Support Change**
  – Objectives setting
  – Authority, Responsibility and Accountability
  – Performance Appraisals

• **Metrics**
  – Enterprise-wide
  – Corporate
  – Functional
  – Individual
New Definition for Role of Quality

The Role of Quality for the 21st Century

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

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Thoughts from the Panel

• **Brian Shultz:** What Could Quality for the 21st Century Look Like?

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• The evolution of the F&P Quality Unit – an unusual path

• The value that Quality can bring to the table, and how

1. If there was no regulatory expectation for the company to have a Quality function, would the company want one?  
   YES?

2. If our peers could choose any Quality group from across the industry, would they choose us?  
   YES?
CQO Forum – Quality Role Team

5 Countries
4 Industries
10 Companies
19 Professionals
1 Exploring Major Paradigm Shift
5 Quality Roles
What Could/Should the Role of Quality be:

1. Deviation Investigations
2. Complaints
3. Change Control
4. Internal Audits
5. Batch Record Review
Now we Need to:
Create the next generation of critical-thinking professionals grounded in the science of Quality

Starting at the Undergraduate Level
Creating the next generation of professionals requires:

- Reaching them early
- Fostering opportunities to strengthen critical thinking
- Grounding them in the science of quality

Training and retraining is not enough to delivery 21st century outcomes that must be achieved.

Business acumen is a key element in the development of quality professionals.

The aspiration of “why”!

(We can only afford to do things right)
Quality Science Education Model – Current and Future

High School Summer Camp

- Summer Internships
- Co-Ops

4 Year Bachelor of Science (Chemistry, Biology, Engineering, etc.)

- Undergraduate Quality Science Minor
- Industry Mentors

Quality Science Certificate Program

2 Year Masters of Quality Science

- Summer Internships
- Co-Ops
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.

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.
### Questions for the Panel?

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Thank You for Your Passion!