Can Quality Solve the Equation?

Pricing + Authority Expectations + Supply Chain Complexity + Counterfeiting = Quality Drugs to Patients & An Engaged Workforce

Jennifer Magnani & Anders Vinther
Article in PDA Journal of Science & Technology, Nov/Dec 2012
The traditional role of Quality

Batch Record/Deviation Review

“You need to fix this before this batch can be released!”
The future role of Quality

Financial Officer

Compliance Officer

Motivational Speaker

Operations Officer

Educator
Financial Officer

- How is your company incentivized?
  - In Quality?
  - In Operations?
  - In Procurement?
  - In the Supply Chain?
  - In Management?
- Are incentives aligned across departments?
- Does Quality translate GMP to financial terms

- The quality of the primary packaging material is equally important as the quality of the product
- All staff should be incentivized to promote high quality products & trained in basic GMPs
- Speak the language of finance
Financial Officer

- Failures are costly and lead to drug shortages
- Regulatory actions are costly and impact the bottom-line
- Identify quality related financial risks

Source: PDA Survey, Business Case for Pharmaceutical Quality

The cost of fixing versus preventing a problem
- Know where the money goes - establish Cost of Quality Model
- Educate all staff in the benefit of preventing vs fixing problems
- Drive change from cost to value focus
Summary

• Establish Cost of Quality Model
• Invest in value driven proactive activities
• Identify quality related financial risks
Operations Officer

- Do you understand the complexity of your supply chain?
- Do you know your supplier’s…suppliers?
- Do you do your best to make your suppliers successful?
- Counterfeiters are smart – are you smarter?

- Know and control your end to end supply chain – ensure you have dual sourcing
- Think like a counterfeiter to identify the risks
- See suppliers as partners…build the relationship
Operations Officer

- Effective
  - Root Cause Analysis - avoiding failures from happening again
  - Move from CAPA to PACA
- Efficient
  - Lean – target waste reduction
- Predictable
  - 6 sigma of processes
  - Effective use of QRM – spend time on risk identification and mitigation

- Drive failure analysis down to the root cause
- Move from quality “tested in” (low sigma processes) to quality “built in” (high sigma processes)
- Facilitate manufacturing sciences & innovation
Summary

Operations Officer

- Know & control E2E supply chain…dual sourcing
- Build partnerships with suppliers
- Drive effective, efficient & predictable manufacture
- Facilitate manufacturing sciences
Compliance Officer

- Risk Management Plans
  - Do they exist for all products and processes?
  - Are they known to relevant people?
  - Are they kept up to date?

- Knowledge Management
  - Does product and process knowledge leave the company when the expert does?
  - Is knowledge shared?

- Make QRM relevant to operation, kept current and increase preventive vs corrective actions
- Institutionalize process and product knowledge through strong manufacturing science processes, documentation and tools
- Investigation are a great training opportunity, share across company/industry
Compliance Officer

- Does senior management attend the Quality System Management reviews?
  - Are the right topics discussed, do you have the right dialog and metrics?
- Are SOPs easy to follow? Do they make sense? Do they work as intended?
- Who writes the documentation? Users?
- Does the PQS drive harmonization in your company?

- The PQS is the foundation for quality products and drives a healthy quality culture
- The PQS integrates cGMP with business process and delivers harmonization
- Leads the development, implementation, understanding and continual development of the PQS
Summary

Compliance Officer

- Institutionalize knowledge and use QRM to drive preventative actions
- Leads effective Quality System Management reviews
- One common PQS to deliver cGMP and harmonization
Educator

- Do you explain why a requirement exists in ‘quality language’ (you must comply with 211.160) or in technical terms with context?
- Are the right people in place with the right training and expertise?
- Does the Quality Professional teach to all professions across the company?

- Convert the quality role from an authority to a partner
- Quality’s role of educator applies to all functions from purchasing to operations and distribution
- Know the cGMPs in detail and teach, why we are doing what we are doing
Educator

- Does your company invest in employee education? Certification programs?
- Does Quality act in a “coaching” role for other employees?
- Are you allowed to spend time learning a new skill or technical discipline?

Certification Programs (Quality/Investigator) and specialized trainings enhance and increase the depth and breadth of knowledge across the organization.

- Formalize coaching opportunities
Summary

- Teach formally & coach informally
- Provide not just the what but the how and WHY
- Become a partner to learn/develop/improve together
- Make learning a priority
Motivational Speaker

- Is the Quality Role compensated and seen as equivalent to manufacturing or R&D roles?
- Are the Quality professionals engaged at the right level?
- Are problems in operations called “Quality Issues” or “Manufacturing Issues”? Who presents them to the CEO…Head of Quality or Head of Operations?
- Are goals shared between Quality & Operations?
- Do people speak up about quality improvement opportunities? Are the right incentives in place to catch, report and fix problems?
- Are lessons learned from investigations shared?

- Foster an environment of “speaking up” to continue to improve
- Ensure Quality reports into the right level in the organization
- Serving patients everyday, every decision is what matters
Summary

Motivational Speaker

• Quality *is* owned by all
• Make Quality a preferred place to work
• Create safe environment to speak about issues because human lives are our bottom-line
The New Role of Quality

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Connecting People, Science and Regulation

J. Magnani & A. Vinther: Can Quality Solve the Equation (The New Role of Quality)
PDA J. Pharm Sci and Tech, Nov 2012

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