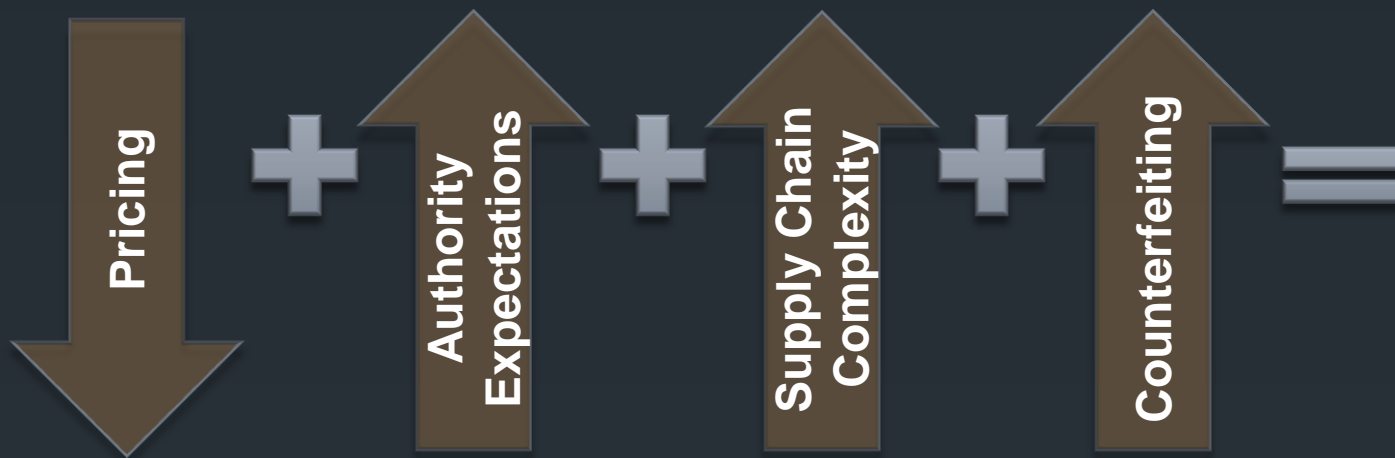


Can Quality Solve the Equation?



Jennifer Magnani & Anders Vinther

Article in PDA Journal of Science & Technology, Nov/Dec 2012

The traditional role of Quality



The future role of Quality

Financial Officer



Motivational Speaker



Operations Officer



Compliance Officer

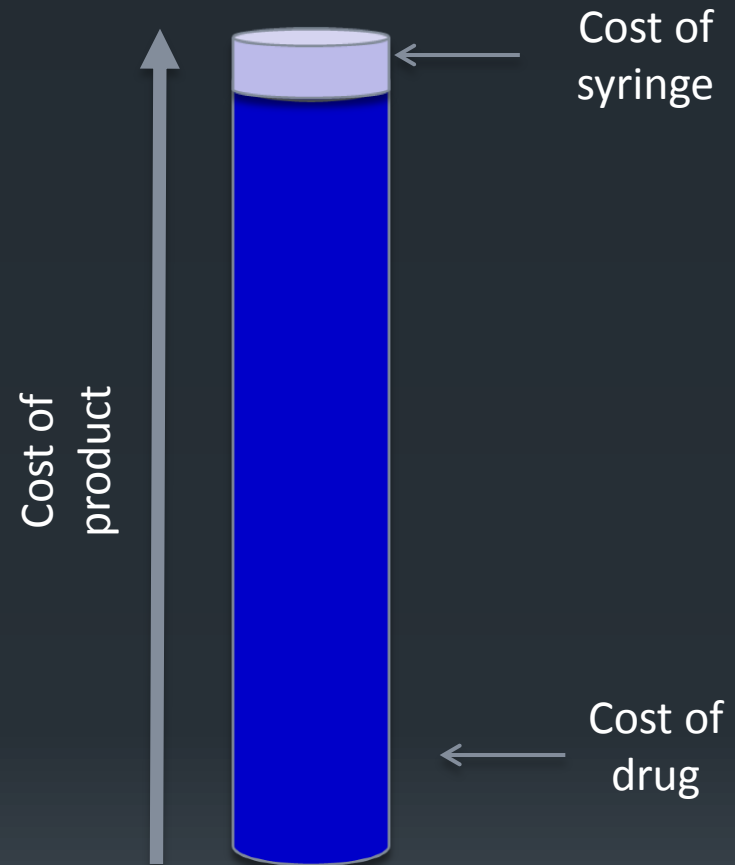


Educator



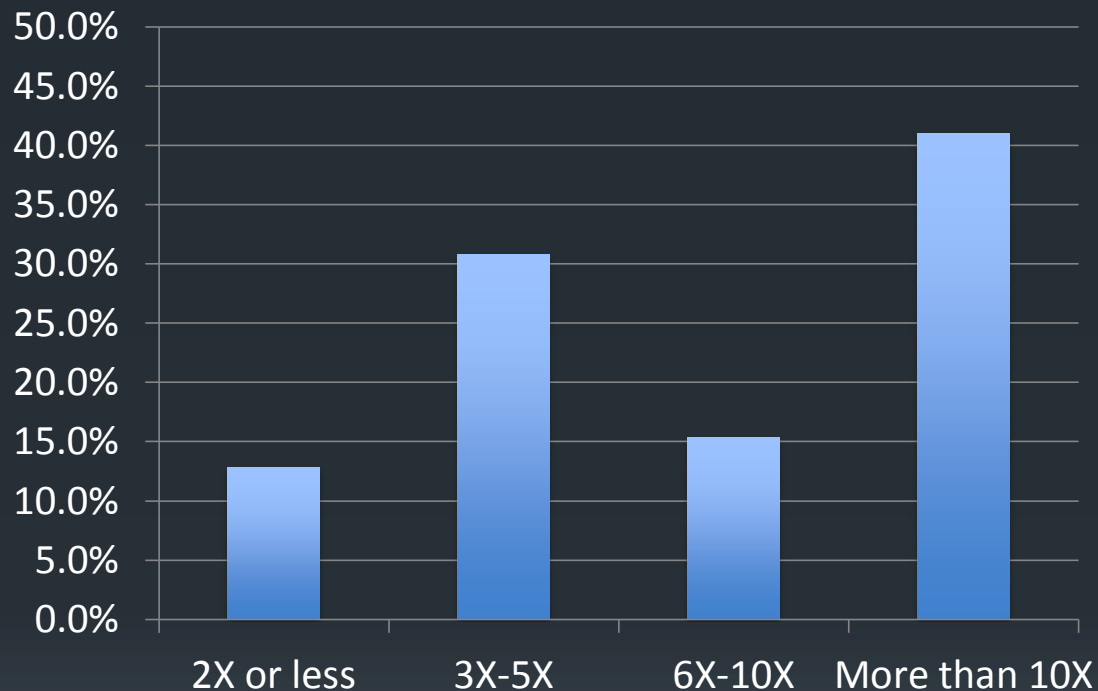
Financial Officer

- 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



**The cost of
fixing
versus
preventing
a problem**

Source: PDA Survey, Business Case for
Pharmaceutical Quality

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

Financial Officer



Prevention	Appraisal	Internal Failure	External Failure
<ul style="list-style-type: none">Preventive ActionInternal AuditsValidationMaintenance	<ul style="list-style-type: none">Change ControlBatch Record ReviewLot ReleaseProduct TestingStability TestEnvironmental MonitoringRaw Mat. Test	<ul style="list-style-type: none">DeviationInvestigationsCorrective ActionRejected LotsScrap/WasteRe-filtrationRe-testingExpired Product	<ul style="list-style-type: none">Product ReturnsProduct ComplaintsReportable FailuresRegulatory Response activities

- ▶ 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

Financial Officer

- 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

Educator

- 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



Financial Officer

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

Operations Officer

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

Compliance Officer

- Institutionalize knowledge and use QRM to drive preventive actions
- Leads effective QSMR
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Motivational Speaker

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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

Financial Officer

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

Your Company

Operations Officer

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

Your Company

Compliance Officer

- Institutionalize knowledge and use QRM to drive preventive actions
- Leads effective QSMR
- One common PQS to deliver cGMP and harmonization

Your Company

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Your Company



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- Establish Cost of Quality Model
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[your name here]

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Contact Information

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