Building a strong Quality Culture

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Content

1. Why Quality matters
2. The impact of Culture
3. Quality attributes
4. What are the MHRA doing?
   ➢ Compliance Management
Convincing emission test figures - but where are the lie-detector results?
Impact on VW share price
Impact on Pharma Company
growth during 2012
Impact on Pharma Company

share price during 2013

Site 2 Inspection findings reach Press
Boehringer shuts Ben Venue unit
– Oct 2013
Most Important Impact?
Quality

Culture
Cognitive bias

We tend to:

• *have positive illusions* - the problem doesn’t exist or is not severe enough
• *be egocentric* - it’s not my problem
• *discount the future* – tomorrow is a long, long way off
• *dismiss problems we haven’t personally experienced* – it will never happen
• *be irrational* – simplified “short cuts” are OK

With apologies to Max H Bazerman & M.D.Watkins:
Predictable Surprises: The Disasters You Should Have Seen Coming and How to Prevent Them
Not to me!

• It won’t happen

• If it does happen, it won’t happen to me

• If it happens to me, it won’t be so bad

• If it happens to me and it is bad, there was nothing I could have done to stop it anyway!
What, Me Worry?
Is there a relationship between Quality Culture Behaviour and Mature Quality Attributes?
Summary of key Quality Attributes
(extracted from PDA’s 15 points)

• Leadership
• Transparent scorecard
• Employee engagement
• Striving to do better
Influencing Quality- MHRA Approaches

- Compliance Management Team established to review sites with marginal compliance
- Risk based escalation within Inspectorate
- Use of ‘warning’ letters to highlight required change
- Development of trending and communication
  - Annual stats
  - Symposia
  - Blog
- Cross Inspectorate Data Integrity Steering Group
- CMT Model presented to EMA Inspectors Working Group
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Missed Opportunities?

Problem:
Regulators may be missing opportunities to take early action / communication with manufacturers and PL holders

• Address compliance issues
• Change behaviour
• Maintain supply of quality medicines
MHRA Compliance Management Process

Defines a process for early supervisory authority intervention

Aim:
– Return the site to a state of compliance
– Build a robust regulatory action case if no improvement demonstrated
Linking Supervisory Processes

No change to thresholds for regulatory action
Compliance Management Process Overview
Compliance Management Process Overview

- Site inspection team central to process
- Discussion with senior colleagues:
  - Site history and risks
  - Agreement of case management actions.
Compliance Management Process
Overview

Agreed case management actions documented in inspection report:

• Measurable compliance-indicating objectives
• Rationale for actions
• Criteria for referral for regulatory action
Compliance Management Process
Overview

Communicate compliance escalation process to company
• Remind company of existing obligations
• Non-statutory ‘warning letters’
• Signed by senior staff

Company meeting with regulator to discuss their compliance
Compliance Management Process Overview

Implement monitoring via remote assessment of case-specific compliance indicators
Input into site inspection planning
• Frequency
• Scope
Compliance Management Process Overview

• Periodic meetings held to discuss cases and actions to ensure consistency.
MHRA experience of early action

Benefits:
Low administrative burden process
Effective in achieving manufacturer and MAH prioritisation
  • Initially
  • Maintaining focus
Particularly useful in the chronic compliance cases

Outcomes:
  • Avoidance of formal regulatory action
  • Additional benefits in maintaining supply likely, although difficult to measure
Cultural Attitudes

1. I do not know what I should do
2. I do not care
3. I cannot cope
4. It is what is expected of me
5. I will give what is measured
6. Rules do not apply to me
7. It is far too complicated

With apologies to Martin Lush:
GMP failure: A cultural problem
GMP Review 12 (2) 2013
Hallmarks of a Quality Culture

1. Values clear from the top – CEO and Board
2. Leadership by example – walking the talk
3. True priorities understood and owned – patient first
4. Openness and transparency – processes in place
5. Responsibilities defined and understood – training
6. Doing what is right is more important than looking good
7. Learning from mistakes is our most valuable investment – continuous improvement
THANK YOU FOR YOUR ATTENTION

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