



Medicines & Healthcare products  
Regulatory Agency



# 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



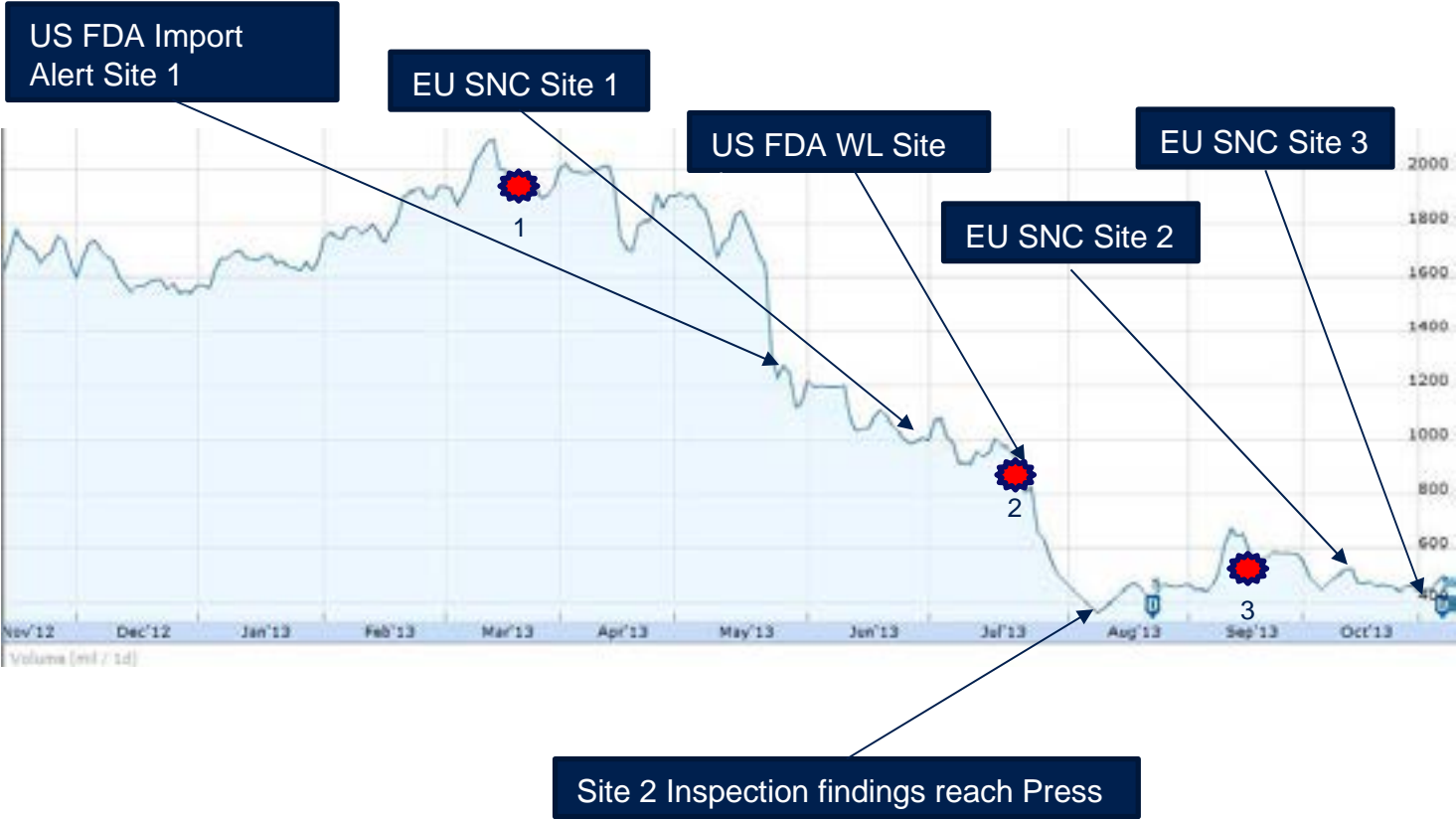
# Impact on Pharma Company

growth during 2012



# Impact on Pharma Company

share price during 2013



# 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* - its 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!

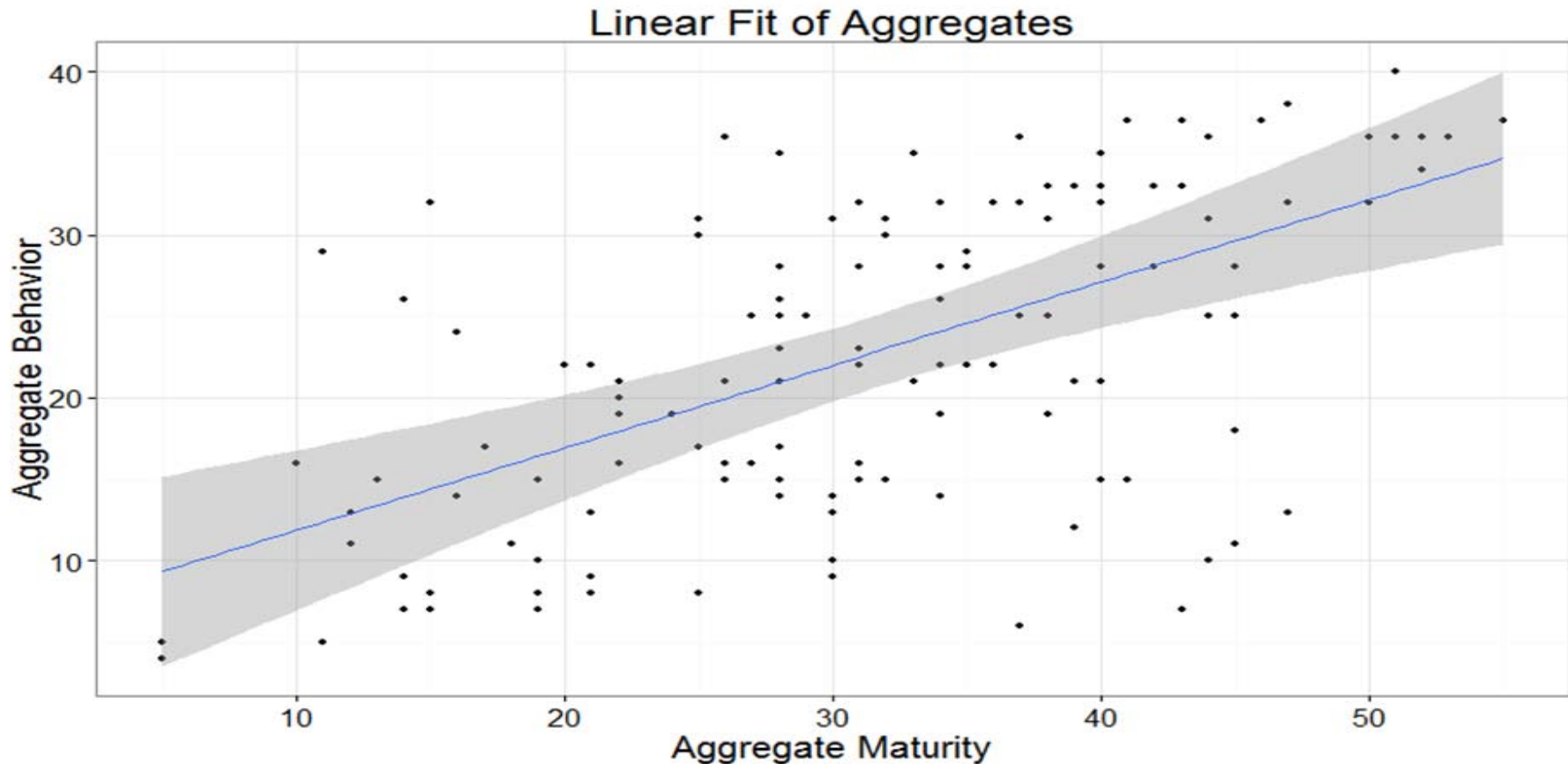
*What, Me Worry?*







# 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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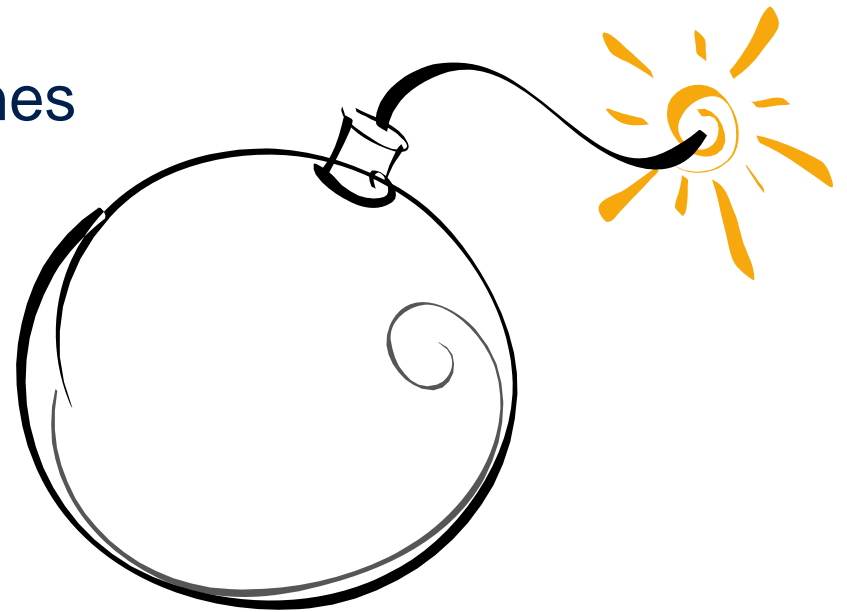
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# Missed Opportunities?

## 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

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- 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:**

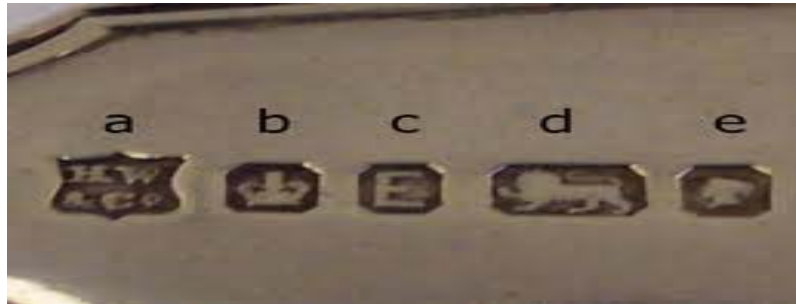
- Avoidance of formal regulatory action
- Additional benefits in maintaining supply likely, although difficult to measure

# 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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