QMS, Change Control and Recall
'In search of Excellence'

[images removed for website]

Bill Chaffe FIBMS, Senior EQA Scientist, UK NEQAS (BTLP)   Jan/Feb 2013

Introduction to Presentation

- Historical approach to change
- Definitions
- Legal requirements
- Case Studies
- Summary
- Questions / Discussion

Historical Approach to Change
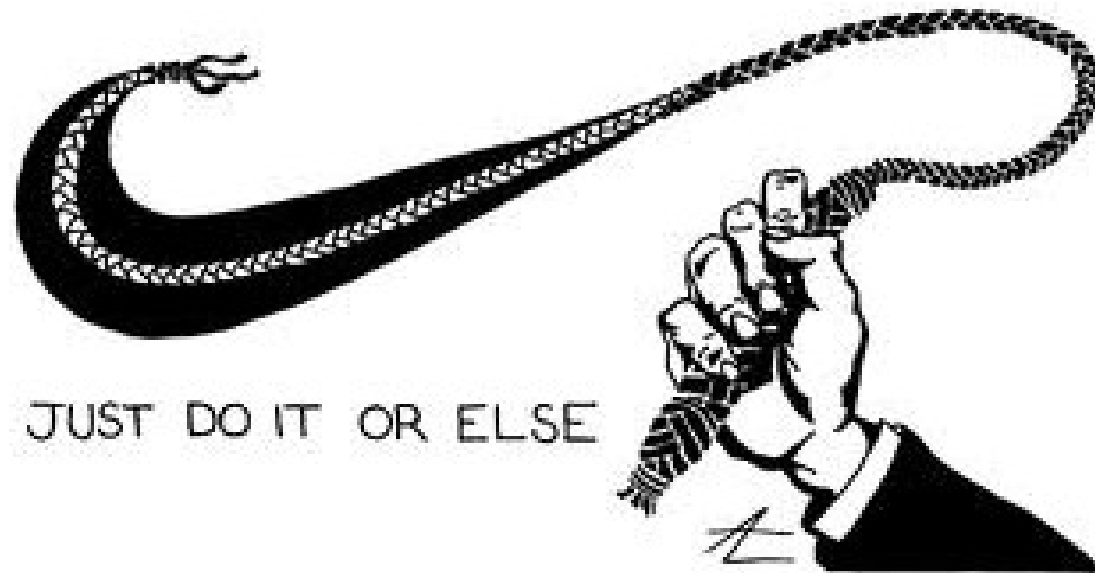
Historical Approach to Change

- 25 years ago change was achieved by PMLSO (?) simply saying 'do it'.

- As the 'leader', instructions were not questioned

- Employees knew that, 'to get on' do as the boss says

- Change was EASY?

[images removed for website]

How did things change?

- Quality circles, six sigma, Total Quality Management, employee empowerment,

- Employee no longer says 'Yes Sir' – more likely to say why? What's the impact on me? What's the impact on 'others'.

- New values require a different approach to change

It certainly wasn't controlled

[images removed for website]

Current Definitions

1. Quality Management System

   "A set of co-ordinated activities to direct and control an organisation in order to continually improve the effectiveness and efficiency of its performance."

2. Change Control

   is a formal process used within a Quality Management System, to ensure that changes to a product or system are introduced in a controlled and coordinated manner. It is performed in a structured, documented and well planned manner. It balances flexibility (what needs doing now) with stability (so the change doesn't 'break' anything).

Current Definitions cont…

3. Recall

A recall is when a product is removed from distribution or a correction is made to the product because it is either defective or potentially harmful.
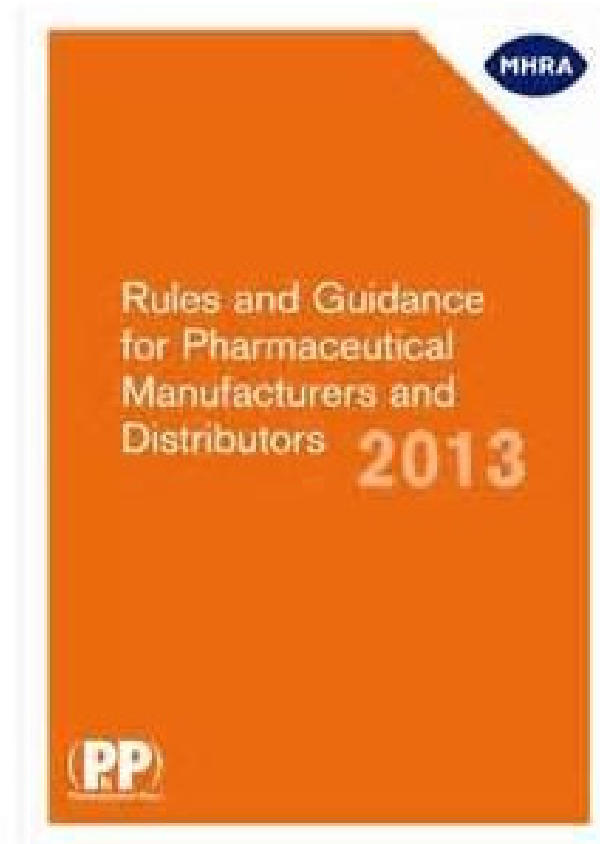
[images removed for website]

What are YOU legally required to do?

- Comply with BSQR's

[images removed for website]

What are YOU legally required to do?

- Comply with BSQR's
- How many of you knew that there was a new edition??

What are YOU legally required to do?

- Comply with BSQR's
- How many of you knew that there was a new edition??
- Time to get stuck in and read it

[images removed for website]

Change – is all change the same?

1. Planned change – example?

2. Unplanned(reactive) change – example?

3. Overt change – example?

4. Covert change – example?

5. In kind / Not in kind change – example?

External forces for change

- Government – NHS reforms
- Technology – Faster, cheaper, functionality
- Economy – Savings requirements
- Competition – Neighbouring trusts/networks
- Customers – Changing requirements eg trauma workload

Internal forces for change

- Nature of workforce – New staff with inadequate skills, ageing staff
- System dynamics – Technology, staff cliques
- Admin processes – Regulatory compliance
- Focused changes – Downsizing, centralisation
- Technology – Improved analysers, process sequencing
- Resource – Depletion, inadaequacy

Change Control

- The purpose of change control is?

  to provide a systematic method for assessing the impact of any change on any activity which might have an affect on the laboratories procedures, outputs and services. The policy must apply to all new equipment or current equipment used in a new way, computer systems, analytical methods, testing kits/systems and staffing arrangements.
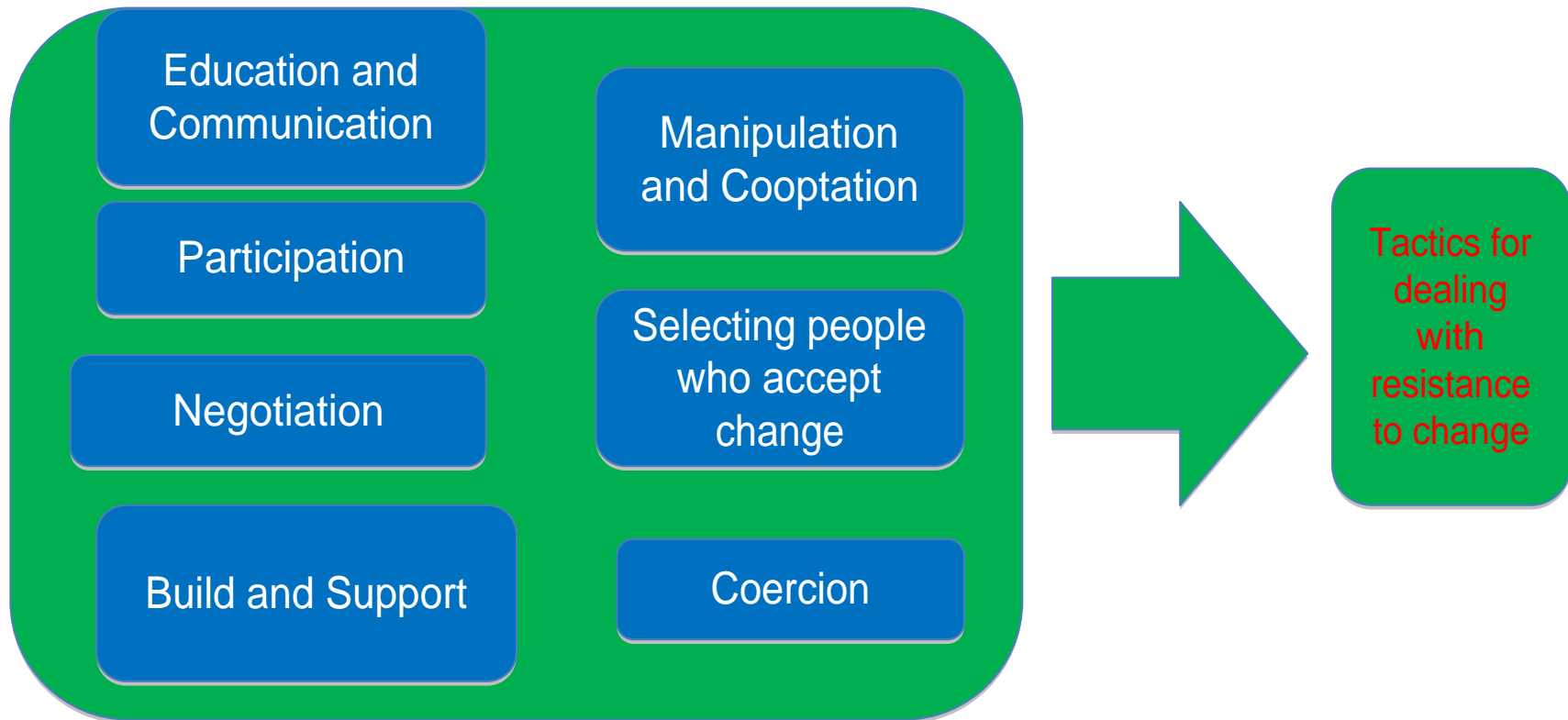
Reactions to change
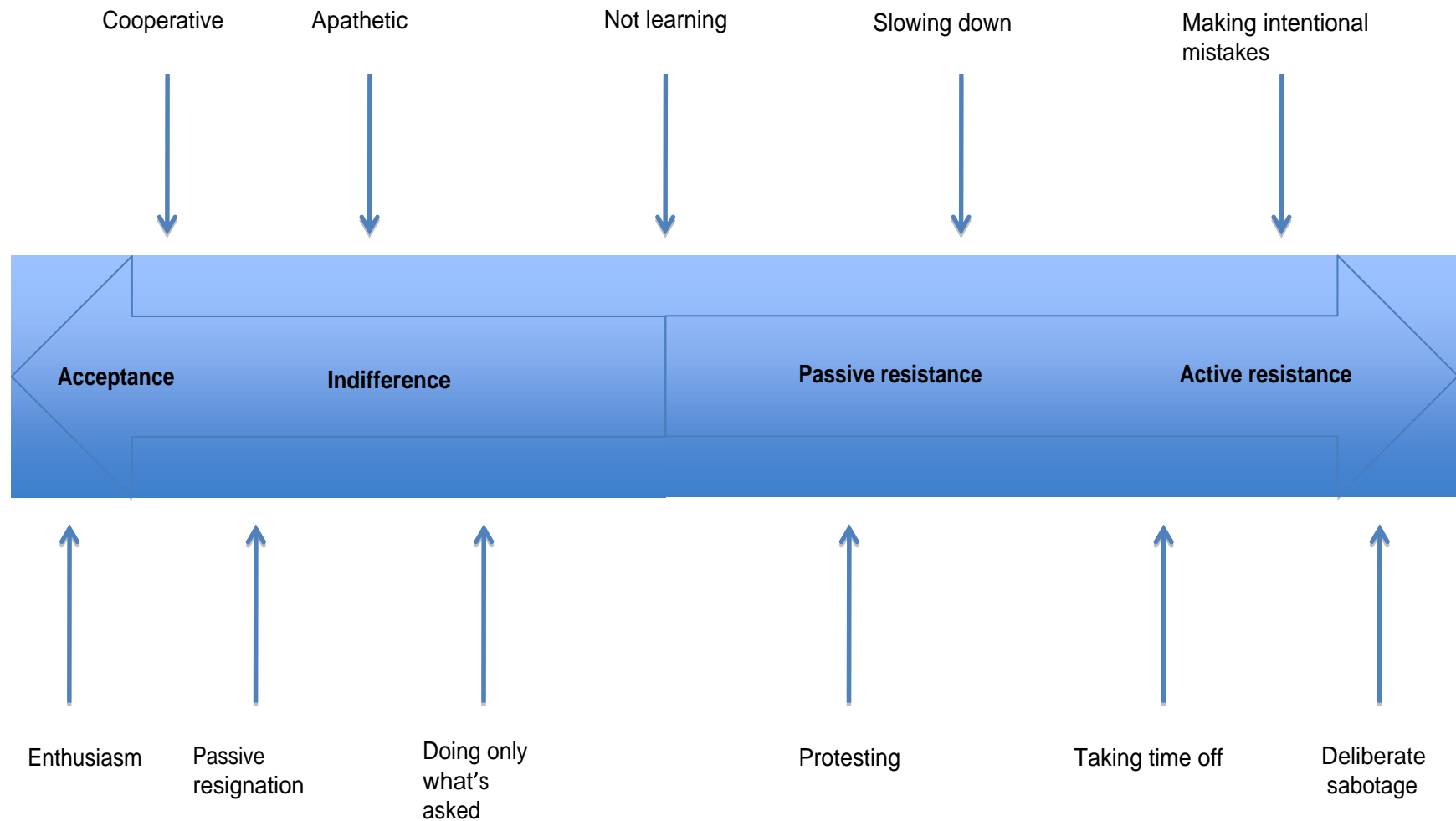
Resistance to Change

Individual Source

- Habit
- Security
- Economic factors
- Fear of the unknown
- Selective Information Processing

Organisational Scource

- Threat to expertise
- Threat to existing power relationships
- Threat to established alloctaion of resources

Overcoming Resistance to Change

Education and Communication

Participation

Negotiation

Build and Support

Manipulation and Cooptation

Selecting people who accept change

Coercion

Tactics for dealing with resistance to change

Change Control cont...

- SYSTEMATIC – how might this be achieved?
- Have a plan!
  - Initial request for change recorded
  - Assess the request (all involved groups)
  - Plan (needs a multidisciplinary team), communication, mapping, training, resistance
  - Agree solution, trial, evaluate before implementation, support for staff,
  - Agree implementation date
  - Post implementation review
  - Close
  - Now change something else!!!

Industrial case study
British Airways

Pre 2005

- 1924 Founded as Imperial Airways
- 1972 BOAC+BEA = BA
- 1987 Privatised
- Two hubs
- Frequent Flyer Programme
- Executive Club by invitation only
- Some lounge facilities
- Fleet of 235 (+62 on order)
- Tense relationship with Virgin
- Ranked 17/21 for long haul delays
- 2007 Heathrow voted worlds least favourite airport

Root cause?

Industrial case study
British Airways

Post 2005

- 2005 New CEO appointed
- Terminal 5 commissioned
- 2006 Skytrax airline of the year
- 2007 OAG Airline of the year
- 2007 Best airline based in Western Europe
- 2007 Best Transatlantic Airline
- 2007 Best Europe-Asia/Australasia airline

New broom sweeps clean

WILLIE'S WORRIES

£ Fuel costs rise to £2.1bn

bmi Must persuade Lufthansa to sell BMI

Landing fees increase to £515m

€ EU duties spark overseas anger

Industrial case study
British Airways

2008 – Terminal 5 opens but .....   **Terminal 5**

[images removed for website]

Industrial case study
British Airways

Problems

- Staff unable to find car parks
- Insufficient parking space
- Long queues for security
- Baggage handling system malfunctioned on several levels
- Baggage didn't go on same flight as passengers
- 300 flights cancelled in first 5 days
- £millions 'lost' in compensation claims and loss of 'goodwill'

Why?

- List the things that BA didn't appear to have undertaken properly

So what are the essentials of effective change control?

Your list

Your list

So what are the essentials of effective change control?

What the BSQR's say

- A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect the validated status of facilities, systems, equipment or processes. The intent is to determine the need for action that would ensure and document that the system is maintained in a validated state

What the BSQR's say

- All changes that may affect product quality or reproducibility of the process should be formally requested, documented and accepted. The likely impact of the change of facilities, systems and equipment on the product should be evaluated, including risk analysis. The need for, and the extent of, re-qualification and re-validation should be determined.

Then things go wrong....

Recall

- A recall is when a product is removed from distribution or a correction is made to the product because it is either defective or potentially harmful.

- 'We all make mistakes'
- 'Nobody is perfevt'
- 'He/she's only human'

Top 12 worst product recalls

1. Tylenol – 7 deaths, laced with potassium cyanide
2. Firestone tyres – 200 deaths, recommended changes not implemented
3. YoYo ball – 400 cases of near strangulation
4. Dell notebook batteries causing laptop to burst into flames
5. Worcestershire sauce- contaminated with carcinogenic dye Sudan 1
6. Cadbury's Dairy Milk – salmonella contamination

Then things go wrong....

Recall

- A recall is when a product is removed from distribution or a correction is made to the product because it is either defective or potentially harmful.

- 'We all make mistakes'
- 'Nobody is perfevt'
- 'He/she's only human'

Top 12 worst product recalls

7. Peanut butter – salmonella contamination. 430 serious illness, 6 deaths
8. Pistachios – Salmonella scare. Acted before anyone affected
9. Nestle Toll House cookies – E coli causing 25 hospitalisations (7 with kidney failure)
10. Westland/Hallmark beef - recalled as cattle hadn't been properly inspected before slaughter
11. Chocolate worms – Chinese counterfeits of a popular brand
12. Mattel toys – Lead paint and magnet scares concerning toys made in China. 1 death and several needing surgery

Then things go wrong….

- What do you notice about the list I've just highlighted?

Then things go wrong....

- What do you notice about the list I've just highlighted?

    ANYTHING may be subject to recall – even products that have many years of high standing in the community

Tesco 'Beef' Burgers

- What do you call a burnt Tesco beef burger?

Tesco 'Beef' Burgers

- What do you call a burnt Tesco beef burger?

BLACK BEAUTY

Tesco 'Beef' Burgers

- What do you call a burnt Tesco beef burger?

BLACK BEAUTY

Tesco 'Beef' Burgers

- What do you call a burnt Tesco beef burger?

BLACK BEAUTY

- My doctor told me to watch what I eat, so I went out and bought tickets for the Grand National – BOOM BOOM!!

How did Tesco find out? What did they (and others) do?

- Food safety authority of Ireland (FSAI) found horse and pig DNA when performing authenticity studies on retails outlet products

- FSAI questioned traceabilty of ingredients

- What, in your opinion is the biggest problem with this 'gaff'?

- Should retail outlets initiate 'spot' DNA testing on their merchandise? – Self Inspection

How did Tesco find out? What did they (and others) do?

- Tesco – major recall of 'Beef' products with national newspaper reassurances
- Sainsbury / Asda / Aldi – recall products and reassure
- Morrisons - ??

How did Tesco find out? What did they (and others) do?

- Morrisons – exploited a gap in the market!!

- Just shows that there is always someone willing to take your market share if things go wrong

[images removed for website]

Summary

- Essentials of a QMS will not list Change Control and Recall

- Without Change Control and recall risks increase

- WE i.e. YOU are actually doing it all the time but missing the essential ingredients
  - a system
  - documentation

And finally.....

- Any questions or comments

[images removed for website]

THANK YOU