

INSPIRING PERFORMANCE

Integrated Compliance Management (improve ways of working AND the bottom line)

David Barnes

Principal Consultant

Fast Moving Consumer Goods & Life Sciences

Agenda

Part 1 – Let's agree the scope and problem

Break

Part 2 – Be compliant, drive continuous improvement
AND improve the bottom line with an Integrated
approach



Compliance Management Hats



Continuous Improvement



Performance Managers



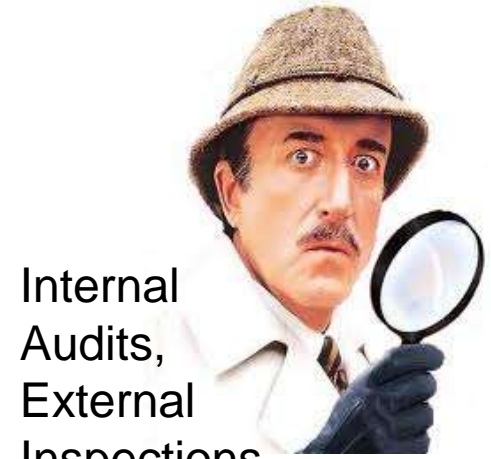
Compliance Managers



IT



Workers
(operations)



Internal
Audits,
External
Inspections

Scope of Compliance Requirements ?

International standards

USA Code of
Federal Regulations

Sarbanes-Oxley

Data protection

Financial Services

Health, Safety &
Environment



etc etc ...
Its any regulations !

Challenges of a non-integrated approach ?

Mr Line Manager



Mr Quality



Mr Lean



Line Manager

Workplace challenges today ?

- Responsibilities and interfaces unclear
- Documents hard to find and understand
- Turnover of staff – hard to educate in processes and compliance
- Compliance tell us we did it wrong or give extra work
- Too many audits – distraction from “real” work



Compliance and Quality Manager

Compliance challenges today ?

- Continuous state of audit, preparation cost high
- One business activity may impact multiple standards – how do we know ?
- Nightmare of tracking and closing audit gaps
- Compliance seen as additional to the day job



Lean / Continuous Improvement Manager

CI challenges ?

- No alignment with audit findings
- We keep improving the same thing over and over again
- Improvements can break our compliance



Consequences of non-integrated compliance

Compliance not part of peoples' day jobs

Unclear responsibilities

High cost of compliance

Compliance and continuous improvement
are separate initiatives

Lack of process transparency

High cost of audit management

Too many non-conformances

Relationship between processes and
Compliance not understood



Part 2 – An integrated approach



INSPIRING PERFORMANCE

Consequences of non-integrated compliance approach

Compliance not part of peoples' day jobs

Unclear responsibilities

High cost of compliance

Compliance and continuous improvement
are separate initiatives

Lack of process transparency

High cost of audit management

Too many non-conformances

Relationship between processes and
Compliance not understood



Integrated Compliance approach

Compliance is part of peoples' day jobs

Lower cost of compliance

Clear responsibilities

Compliance and continuous improvement
Initiatives are aligned

Process transparency

Lower cost of audit management

Reduced number of non-conformances

Relationship between processes and
Compliance understood



Turning the negatives into positives ?

Compliance is part of peoples' day jobs



Clear responsibilities

continuous improvement
gined

Lower

Process transparency
Integrated
Management
Platform
Lower cost of audit management
Reduced number of non-conformances

Relationship between processes and
Compliance understood

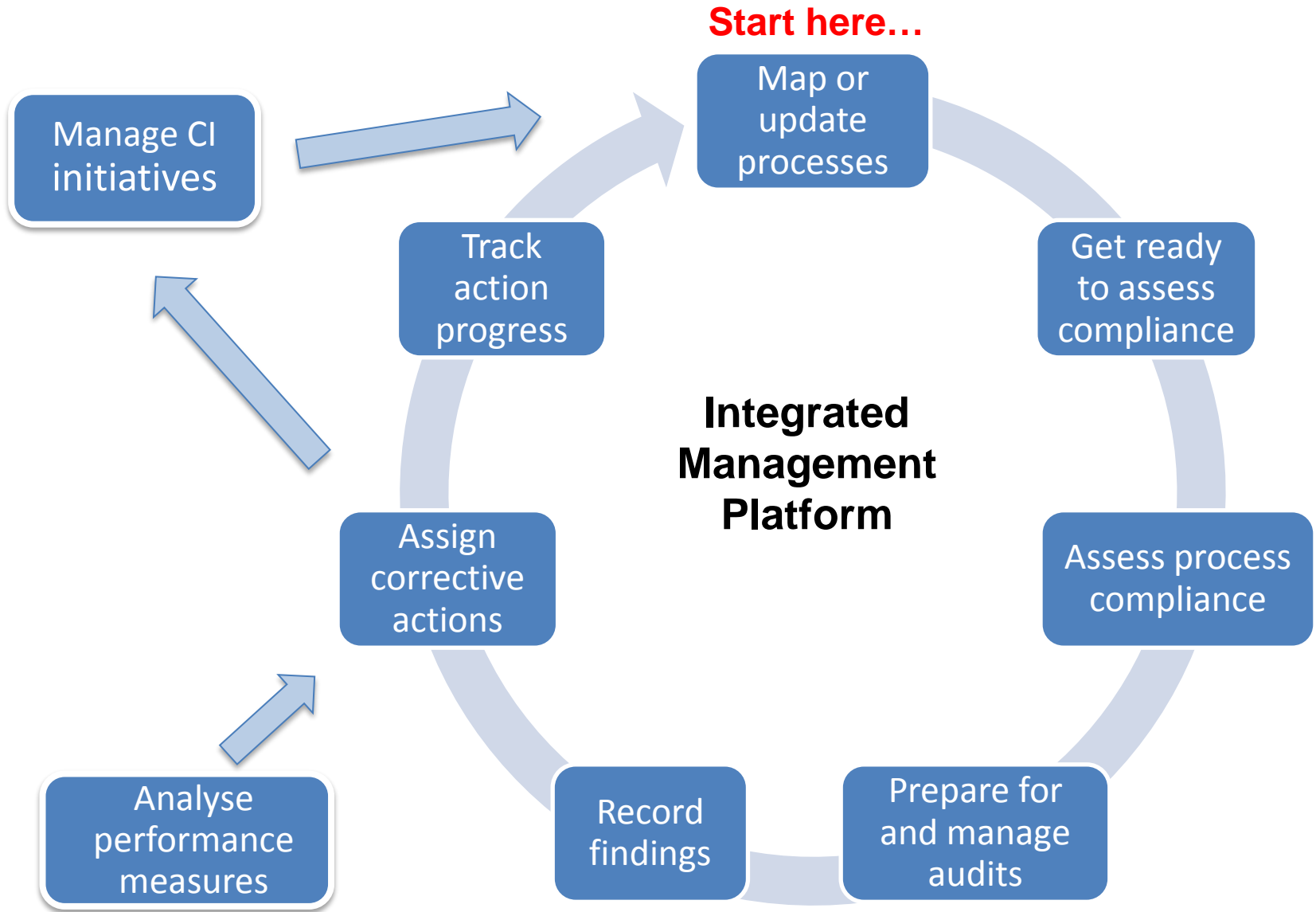
Integrate the Hats !



Single platform
for process,
performance and
compliance



Methodology



From regulation to action...

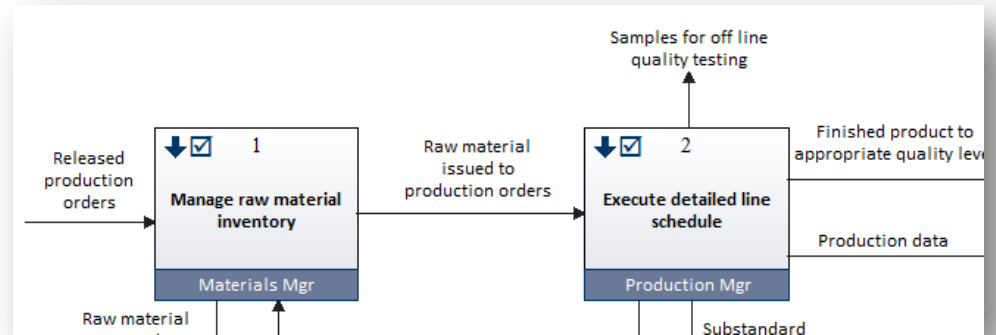
Sec. 810.13 Mandatory recall order.

(a) If the person named in a cease distribution and notification order requests a hearing or submit a request for agency review of the order, the Director of the Center for Drug Evaluation and Research or the presiding officer denies a request for a hearing under 810.11 or completing agency review of the order under 810.12, FDA determines that the order should be amended with respect to which the order was issued, FDA shall amend the order to require such a recall within 15 working days of distribution and notification order if a regulatory hearing is requested, or within 15 working days of denying a request for review of a cease distribution and notification order if a regulatory hearing is not requested, or within 15 working days of completing a regulatory hearing under 810.11, or within 15 working days of completing a request for review of a cease distribution and notification order if a regulatory hearing is not requested.

(b) In a mandatory recall order, FDA may:

- (1) Specify that the recall is to extend to the wholesaler, distributor, or retailer;
- (2) Specify a timetable in accordance with which the recall is to be completed;
- (3) Require the person named in the order to submit to the Director of the Center for Drug Evaluation and Research, or the presiding officer, periodic reports describing the progress of the recall as described in 810.14, and periodic reports describing the progress of the recall as described in 810.16; and
- (4) Provide the person named in the order with a model form containing the key elements of information that FDA has determined to be necessary for the recall and device user facilities.

link
↔



the reality ?

observations

actions



Number	Subject	Category
8	Sent out regulation on NCCL cases	NCIA Content Management
13	Retail Store: Cash Banked	Retail Store Compliance Tax
14	Retail Store: Staff Rota	Retail Store Compliance Tax
19	Retail Store: Cash Banked	Retail Store Compliance Tax
20	Retail Store: Cash Banked	Retail Store Compliance Tax
21	Retail Store: Cash Banked	Retail Store Compliance Tax
22	Retail Store: Cash Banked	Retail Store Compliance Tax
23	Retail Store: Cash Banked	Retail Store Compliance Tax
24	Retail Store: Cash Banked	Retail Store Compliance Tax
25	Retail Store: Cash Banked	Retail Store Compliance Tax
26	Retail Store: Cash Banked	Retail Store Compliance Tax
27	Retail Store: Cash Banked	Retail Store Compliance Tax
28	Retail Store: Staff Rota	Retail Store Compliance Tax

How does an integrated compliance management approach help these people ?

Mr Line Manager



Mr Quality



Mr Lean



Line Manager

“How does the Integrated Management Platform help you ?”

- Compliance is part of everyone’s day job
- Easier to train people
- Easier to manage change
- Being compliant means being faster (not being stopped)



Compliance and Quality Manager

“How does the Integrated Management Platform help you ?”



- Process is a living asset
- Significant reduction in audit preparation time
- Easier to track and manage gap closure
- More successful audit outcomes
- People more knowledgeable and confident during audits

Lean / Continuous Improvement Manager

“How does the Integrated Management Platform help you ?”

- Easier to assess impact of change – know where the goalposts are
- Audit findings become an input to CI initiatives
- Achieve consistency across the business





Case Study

- ~ \$5 billion for world's most efficient steel mill
- Target: automobile:
 - high quality standards
 - low tolerance for supply chain disruption
- Thousands of work instructions, reports and procedures to be captured
- Links to SAP, ISO and other certification standards
- Foundation for future Lean/Six Sigma continuous improvement efforts





Approach

- Executive policy for business process management
- End to end processes (based on APQC Process Classification Framework)
- Short timeline plus complexity of requirements

Built on Nimbus Control + APQC accelerator





Competing on Compliance

- Sales message: uninterrupted supply chain backed by quality, environmental, health, safety, IT and BPM standards
- Used their transparent, compliant system as selling point
 - Invited customers
 - Demonstrated transparency of processes and compliance management

“Most transparent and thorough compliance processes they have ever seen”



Summary

Working in a non-integrated way:

- Higher audit costs
- High risk of non-compliance

An integrated approach:

- Compliance “part of the day job”
- Reduced cost of compliance
- Driver for continuous improvement
- Improved bottom line

