CAPA and Change Control

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What is CAPA?

Corrective and Preventative Action (CAPA) is a system of quality procedures required to eliminate the causes of an existing nonconformity and to prevent recurrence of nonconforming product, processes, and other quality problems.

Why Do We Need A CAPA System?

- Minimise the Risk to components and services.
- Requirement of quality management system
- Requirement of EU directive
  - Which the MHRA use to ensure compliance
- Continuous Improvement Tool

Why?

- Mistakes ARE made by all staff
- Very simple mistakes can have serious consequences
- Serious mistakes can harm an organisations reputation
- In an organisation with many steps in the process, mistakes can occur at any and multiple stages

Most Common Deadly Sins

Recent events have highlighted the following elements

- Failure to follow procedures
- Failure to complete documentation
- Errors in completion of documentation
- Failure to take effective corrective action
- Procedural shortfalls
- Inadequate training

Most Common Deadly Sins

Recent events have highlighted the following elements (Cont.)

- Failure to identify remedial action to contain problem
- Failure to identify root cause
- Failure to ensure closure of CAPA within an appropriate timescale

Aims of CAPA system

- Identify potential risk/problems/incidents before they happen
- Document errors to allow investigation
- Identify and record all incidents that occur
- Determine the root cause of the incident
- Implement action to prevent and/or correct the incident
- Identify recurring incidents
- Identify gaps and weaknesses in existing processes and procedures

Aims of CAPA system

- Identify training needs
- Prevent issue of non-compliant component's
- Prevent harm to patient or staff
- Identify failures in Quality Management System.
- Improve as an Organisation
- Not to assign blame or assess liability

Ensure Effective Preventative Action can be identified to reduce future risks.

CAPA System Overview

- Discover (Identify the Problem)
- Remedial Action/Immediate Correction
- Quality Review
- In Depth Investigate/Determine Cause
- Correct (Corrective/ Preventative Action)
- Follow Up (Effectiveness Evaluation)
- Closure (Track and Trend)

Mistakes do Happen

Step 1: Discovery

- Events may be discovered during:
  - Record Review
  - Staff Observation
  - QA Audits
  - External Audits

Step 1: Discovery

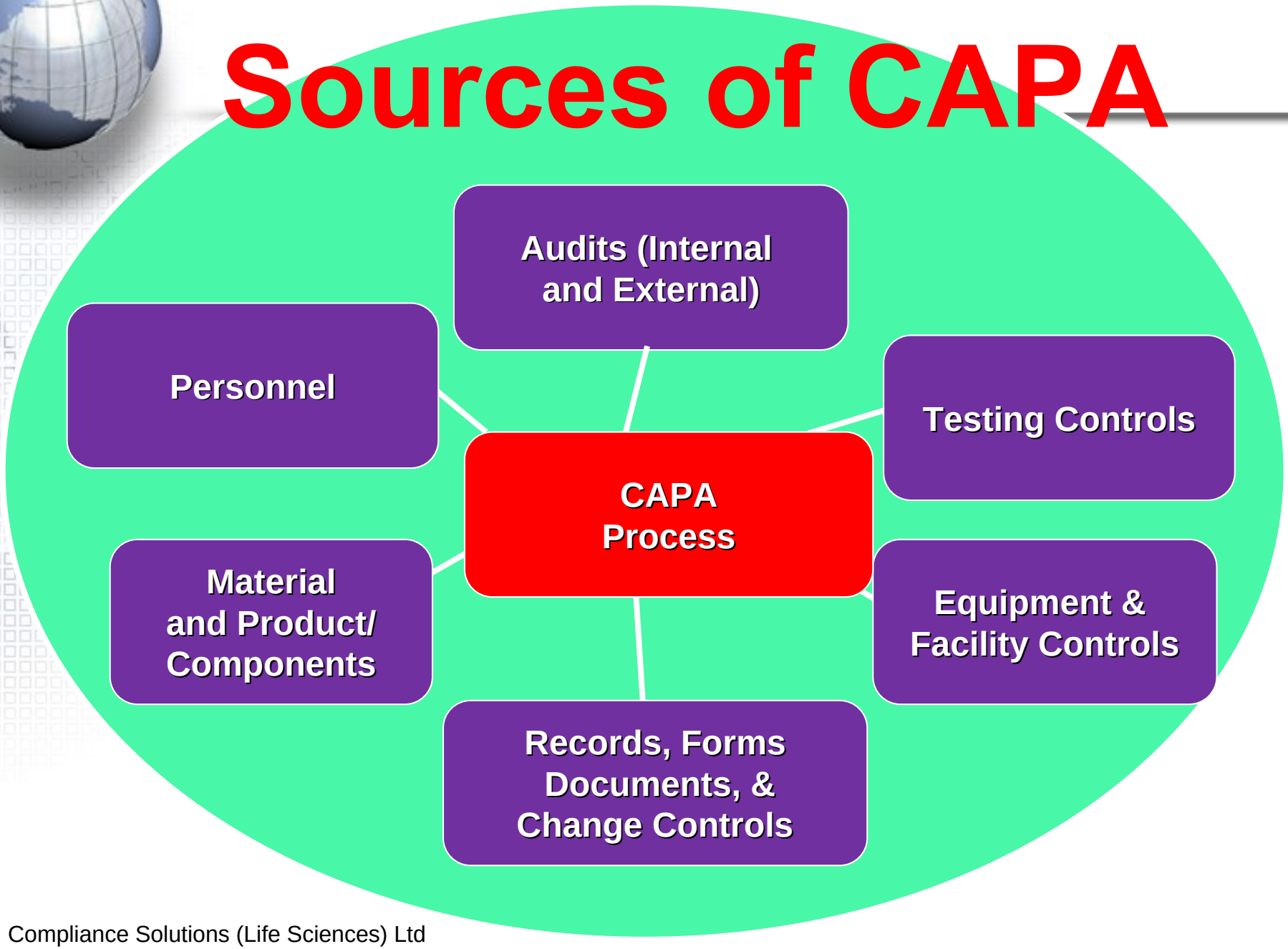
- Events may be discovered during:
  - Performing a Task
  - Notification by a hospital, blood transfusion service
  - Note:

    Document any usual incidents that occurs (fridge door found open)

    Document any mistake identified (e.g. incorrect blood components sent out)

    Admit any mistakes (e.g. Forgot to calibrate scales)

Sources of CAPA



When Should CAPA Report be Raised?

- Immediately after the incident/issue/problem has occurred
  - memories are fresh
  - evidence is in place
  - immediate corrective actions can be initiated to protect others

Who Should Raise an CAPA Report?

Anybody within the organisation

Document the Problem

- A description of the problem is written that is concise - but complete.
- The description must contain enough information so that the specific problem can be easily understood

Evidence

- List the specific information, documents, or data available that demonstrates that the problem does exist.
  - This information will be very important during the investigation into the problem.

Examples of Incidents

- Wrong product code
- Incorrect expiration date
- Recalled unit not placed in quarantine
- Critical or Major audit findings
- Initials/dates omitted from record
- Documentation on alarm charts not clear
- Training documented on wrong form

Step 2: Remedial Action/Immediate Correction

- **Action.....**
- That is taken to quickly resolve or correct a discovered or potential incident/ problem.
- Minimises risk or achieve's short tem benefit
- Ensure what action taken is recorded
- Remedial Action

- Corrects the problem
- Stops the problem until the investigation/root cause analysis is carried out
- Gains control of the situation, products/components and/or donor information

Examples of Remedial Actions

- Products/Components Recalled and/or Quarantined
- QA Notified
- Equipment removed from service
- Products/Components discarded
- Donor Deferred

When you're in deep SHIT, DONT keep quiet and try to look like you know what you're doing

Step 3: Initial Quality Review - Classification of Incident

Recurrence

Severity	Rare	Unlikely	Possible	Likely	Almost Certain
Insignificant	1	2	3	4	5
Minor	2	4	6	8	10
Moderate	3	6	9	12	15
Major	4	8	12	16	20
Catastrophic	5	10	15	20	25

Step 4: Investigation

- To understand how or why the incident occurred
- To understand the circumstances at the time of the incident
- To determine if other products/ components were involved
- To help determine the root cause and effective corrective action

Assign Responsibility and Resources

- It is important to assign someone the responsibility for each aspect of the investigation.
- Any additional resources (financial, equipment, etc) should be identified and documented.

Determine Root Causes! Evaluate:

- Environment
  - Work conditions, work flow, facility problems
- Equipment and Materials
  - Are there any problems related to equipment, reagents etc
  - Are instructions for use clear
- Resources
  - Adequate supervision
  - Staff Trained
- Methods
  - Do the steps performed match the SOP/form
  - Has the process recently changed

Root Cause Analysis

- Use the data to complete a Root Cause Analysis
- This involves finding the actual cause of the problem rather than simply dealing with the symptoms.
- Finding the primary cause is essential for determining appropriate corrective and/or preventive actions.
- Conclusions should be based upon evidence.

Examples of Areas to Investigate

- Interview staff, drivers, hospital staff
- Review policies and procedures
- Review records: training, quality, testing
- Check equipment records or files
- Check computer records
- Determine if other products/ components , equipment, records and/or donors involved.

Root Cause Analysis

- Suitable analytical methodology used to facilitate determination of root cause(s)
  - Timeline of events
  - Brainstorming
  - Fishbone (cause and effect)
  - Five Why's
  - Contributory/Human factors

Root Cause Analysis

- Root Cause Analysis is a methodology that allows you to ask the questions ‘what, how, why’ in a structured way.

- Aim is to learn and must be addressed to prevent an incident re-occurring

Simple Root Cause Analysis

- 5w’s
  - Who, what, when, where, why?
- 1C Consequences

5W – Describe the event

- Who:
  - Was involved?
  - Note: Staff involvement does not necessarily mean staff responsibility

5W – Describe the event

- What :
  - The truth “warts and all” – What was discovered
  - Describe the problem or the event. Include form numbers, donation numbers equipment ID etc
  - How the event was discovered

    i.e. During an Audit, During a process, procedure, observation ..be specific
  - Those involved must feel safe and must feel its worthwhile

5W – Describe the event

- When:
  - Did the event occur
  - Specific time of day and shift when the event occurred
  - How Frequently did the event occur
    - QA can assist in determining frequency

5W – Describe the event

- Where and Why:
  - Did the event happen?
  - Identify the department where the event occurred
  - Indentify the process involved

Root Cause Analysis – 5 Why's

Advantages

- Simple to perform
- No statistical analysis
- Useful when problems involve people (Human Factors)

Disadvantages

- There may be more than one answer to the question
- Some of the answers obtained may be incorrect.

1C: Describe the Event

- Consequences:
  - Of findings
  - Did the incident result in loss of products/components
  - Did the incident result in the release of inappropriate products/components
  - Did any donor problems result, such as notification, deferral, or re-entry

Reporting the Investigation

Do not assign blame, assess liability or offer opinions in any written documentation

The Titanic

Was it just the iceberg?

Titanic Conditions

- Inadequate number of lifeboats

Titanic Conditions

- No training for officers on handling large single rudder ships

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Step 5: Corrective Action

- Corrective
  - Eliminate problem identified
  - Takes care of immediate problem
  - Reactive
- Preventive
  - Avoids quality problems through planned activities
  - Take care of the recurrence of the problem
  - To prevent potential incidents/problems
  - Proactive

Step 5: Corrective Action

- Revise process, SOP/form, system
- Train staff
- Address material, reagent, equipment issues

No Corrective Action Required

- Investigate with immediate correction only
- Typically no root cause
- Avoids performing unnecessary documentation, root cause analysis, corrective action, effectiveness evaluation

Step 6: Follow Up (Effectiveness Evaluation)

- Checks or follow-up plans to verify that corrective actions were effective
- Consider:
  - Follow up step
  - How will you measure it
  - How will you know if the action was implemented
  - How will you know if it was successful in preventing recurrence

Follow Up

- One of the most fundamental steps is completing an evaluation of the actions that were taken.
- This evaluation must not only verify the successful completion of the identified tasks, but also assess the appropriateness and effectiveness of the actions taken.

Key Questions

- Have all of the objectives been met? (Did the actions correct or prevent the problem with assurances that the same situation will not happen again?)
- Have all recommended changes been completed and verified?
- Has training and appropriate communications been implemented to assure that all relevant employees understand the situation and the changes that have been made?
- Has an investigation demonstrated that that the actions taken have not had any additional adverse effect on the product or service?

Validation of Results

- A validation/verification of the action is done. This must document that:
  - The root cause of the problem has been solved,
  - Any resulting secondary situations have been corrected,
  - Proper controls have been established to prevent a future occurrence,
  - The actions taken had no other adverse effects.
  - Adequate monitoring of the situation is in place.

Step 7: Closure (QA)

- When the Follow Up has been finished, the Incident can be reviewed by Quality for Completeness

- Review should ensure that the incident is not MHRA reportable?
  - Mandatory reporting to MHRA will include blood bank testing errors, storage and distribution errors and Incorrect Blood Components Transfused.

- Tracking and Trending

Tracking and Trending

- Leads to Preventative Action

- Areas which can be recorded and analysed:
  - Where
  - Departmental Area
  - What
  - Problem
  - Why
  - Cause

Summary of Process

- Identify the Problem
- Immediate/remedial action performed to contain problem
- Initial quality review (to determine severity of the incident)
- Investigate incident – root cause analysis
- Determine the risk to quality, safety and efficacy of blood components or services provided
- Conduct Corrective Action/ Preventative Action (CAPA)
- Review effectiveness of action taken
- Quality review and closure of incident file
- Tracking and trending of all incidents recorded

Common incidents reported

- Labelling errors *eg label missing, torn or in wrong place*
- ID errors
- Errors / missing documentation *eg documents not filled out correctly, overwriting of mistakes*

In Conclusion

- **We must stop blaming people and start looking at our systems. We must look at how we do things that cause errors and keep us from discovering them…..before they cause further injury'**

Lucian Leape

Error in Medicine

JAMA 1994 : 272 1851-1857

This must be a never-ending process.

In Summary

PROBLEM

Non Conformance → Deviation → Customer Complaints → Component Recall

INVESTIGATION

ROOT CAUSE ANALYSIS (RCA)

Gain Data

Identify Problem(s)

Find Root Cause

CORRECTIVE ACTION PREVENTIVE ACTION (CAPA)

Action

Eliminate Problems

Change Control

- A formal system to evaluate, document, approve and implement changes that might affect the validated status of facilities, equipment and processes.

- A change is a permanent planned alteration to any approved process or procedure that may affect the safety, quality and efficacy of blood components.

Why is Change Control required?

Change Control, as a key element of any Quality Management System, is a regulatory requirement required and is inspected by the MHRA/CPA/HTA

Minimises risk to an organisation

What Happens if Change isn't Managed

and

Recent Criticisms

What happens if change isn’t managed

- Increased risk to patients/
- Crisis management
- Change takes longer to introduce and not done in a coordinated way
- Change not implemented fully or correctly
- Incomplete training
- Increased stress for staff
- Non Compliance

Criticisms of the Current Process

- Change controls forms absent, late and/or inadequate
- Staff unaware of changes
- Change controls have no specified owner and are often not followed up completely
- Changes not introduced in a coordinated way
- Necessary actions are missed and then are rushed through
- No formal tracking of completion or timelines
- Equipment specification/validation etc incomplete, absent or late

What's Covered ?

Any planned activity which results in a change to any activity regulated by MHRA, CPA or HTA which affects, testing, storage, distribution, clinical services and IT processes

What's Covered ?

- Software upgrades which affect GMP processes/systems
- Changes affecting GMP systems that require qualification/validation
- Temporary planned deviations from currently approved procedures
- Changes to facilities including repairs to GMP areas.

Documentation Required

- Formal Change Request.
- Assessment of the impact of the change / Risk Analysis Approval to implement change.
- Details of implementation
- Change reference number / Date change raised
- Full details of the proposed change
- Reasons for the proposed change maintained.

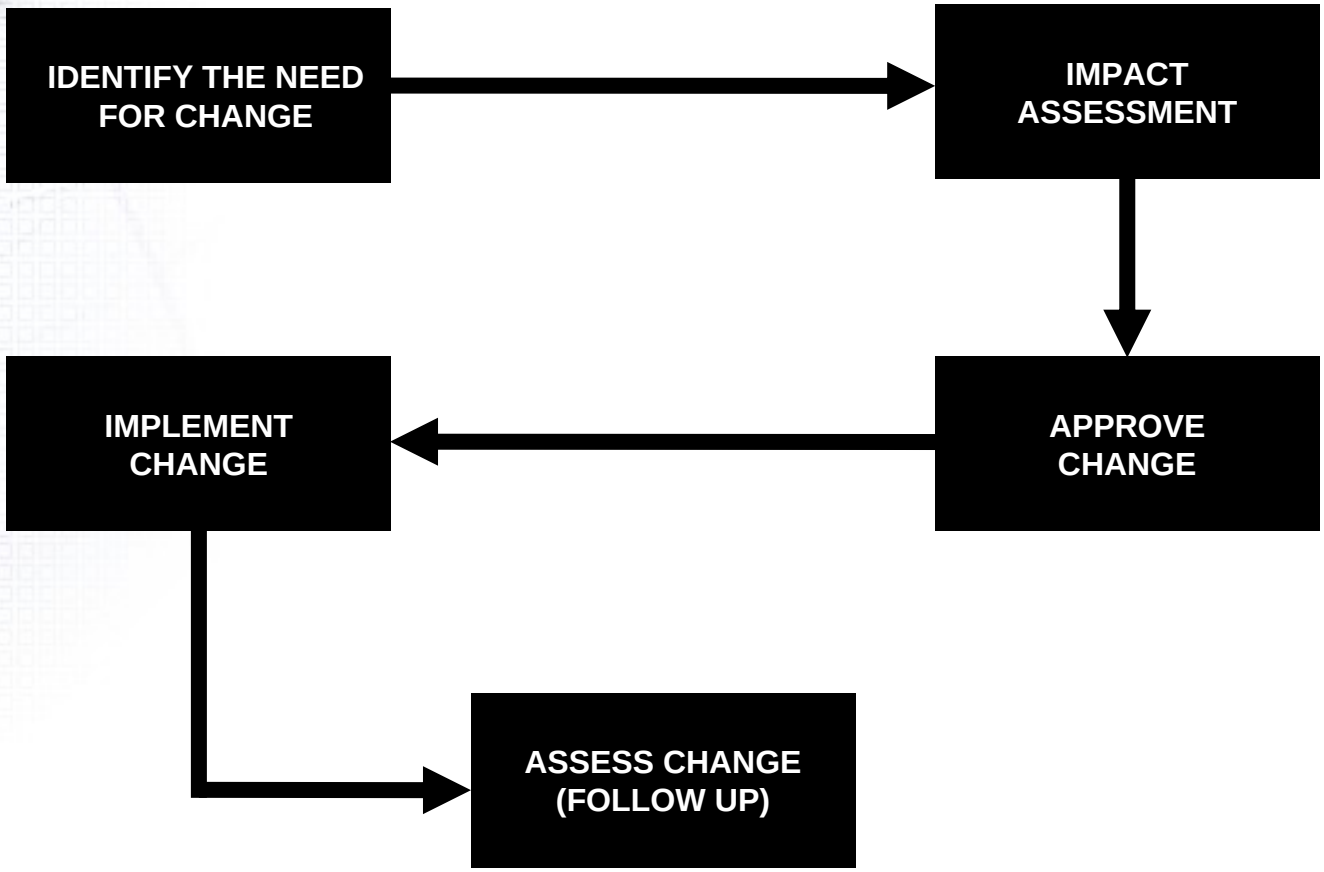
Documentation Required

- Policy in place defining process to be followed when making a change.
- Proposed Changes reviewed and approved prior to implementation.
- Formal assessment of the impact of the change, including the effects on validated processes.
- Record of changes

Should be a controlled document that:

- Defines the types of changes that need to be managed by Change Control
- Defines the process to be followed for different types of Changes
- Identifies personnel that will manage the Change
- Defines time frames for the Change process to be completed
- Provides details of the documentation required

Change Management Process



Assessment of the Impact of the Change

Things to consider:-

- Gap analysis.
- Effect on other Departments.
- Process flow.
- Personal training.
- SOPs.

Assessment of the Impact of the Change

- **Product (Components)**
- **Process**
- **Plant**
- **People**
- **Procedures**

When is a Change not a Change?

- **“Like - for - Like” Change**

- **This particularly applies to changes (replacements) made in premises, equipment and automated systems. It is important that:**

  - Replacement is manufactured to the same specifications as the original (dimension, materials, strength etc)
  - Replacement complies with in-house engineering
  - Replacement is listed as an equivalent part in the original design / user manual
  - Changes made to SOPs (managed through document control procedure)
  - Changes implemented during validation / qualification

When is a Change not a Change?

- **Changes with suppliers and/or contractors**

  These can be managed via the Service Level Agreements and confirmed/verified using the audit programme

- **Unplanned Changes**

  Deviations from processes and procedures should be managed through the Quality Incident/Non-conformance system

What happens if change isn’t managed?

- Crisis management
- Change not done in a co-ordinated way
- Change not implemented fully or correctly
- Incomplete training
- Increased stress for staff
- Increased risk to patients