A Model for Managing the Risk of Organisational Change

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SUMMARY

The paper presents a case study for a new system to manage the risk of organisational change in accordance with COMAH Regulations at Pharmaron Manufacturing Services UK, a high hazard pharmaceutical site.

KEYWORDS

Organisational Change, COMAH, Risk Assessment

Introduction

Organisational Change is a normal and inevitable part of running a business. Most organisations are in a constant state of change; personnel regularly join, leave or move within the business, internal processes may change, and business pressures initiate reviews to current work practices. Under the Control of Major Accident Hazards (COMAH) Regulations it is a requirement for high hazard process sites to assess the risks arising from such changes and manage them to ensure continued safe operation. Much of the literature on managing organisational change focusses on general management and HR best practice but there is little guidance on how to perform a risk assessment for a high hazard environment. The purpose of an organisational change management system is to provide a system that assesses the risks and develops an action plan to mitigate them. This paper demonstrates how the requirements of the COMAH regulations have been delivered on a pharmaceutical site, Pharmaron Manufacturing Services Ltd., to provide a robust risk assessment which is practical whilst not making excessive demands on the site.

Pharmaron provides comprehensive pharmaceutical development and manufacturing services on a global basis, offering complete end-to-end chemistry and manufacturing, with a fully integrated platform of services from drug discovery, process development and early-stage active pharmaceuticals ingredient (API) manufacturing, through to commercialisation and large-scale manufacture. The UK site in Cramlington is a lower tier COMAH site, manufacturing APIs and is the only COMAH site within the global organisation.

Reasons for Implementing an Organisational Change Risk Assessment

Organisational change, large and small, is generally initiated to provide a benefit to the business; for example, restructuring a team or department, implementing a new software system, or developing a new role. Additionally, change may be imposed on the organisation for reasons outside of their control such as new regulations, long-term sickness of key personnel, or staff resignations. In each case, there are many examples where the potential consequences have not been fully considered and the change is poorly managed so it does not deliver as expected. Some typical issues include:

- Additional responsibilities are allocated to staff who do not have the competence or experience to handle them effectively.

- Workload is increased without considering the impact on existing work responsibilities.
- Technical systems are put in without considering the impact on user confidence and time to learn the new system.
- Responsibilities are outsourced causing the organisation to lose sufficient understanding of what is being done on their behalf.
- The change is implemented without engaging with affected personnel and results in a lack of buy-in to the change.

Whilst these types of failure in managing organisational change effectively can have a detrimental effect on any business, for COMAH sites and other high hazard industries they can have catastrophic consequences.

Poorly managed organisational change is known to be a contributor to many high-profile incidents and investigations have demonstrated significant failures in this area, such as:

- Hickson & Welch (1992) - A company reorganisation led to an inexperienced team conducting a critical task which led to fires which killed five workers on the site.
- BP Texas City (2005) - Staffing cuts at the Texas City refinery meant that there was only one control room operator to manage the start-up of three complex plant units. Poor awareness of actual process conditions led to a major explosion killing 15 workers.
- Nimrod XV230 Aircraft Crash (2006) - Major changes to organisational structures and cuts in funding led to a lack of clear accountability, outsourcing of responsibilities and a diluted safety culture, which ultimately compromised the design of the aircraft. Aviation fuel came into contact with a hot ignition source, creating a fire which killed all 14 crew members on board.
- Tempi Train Crash (2023) – Delays in implementing the European Train Control System and limiting ways to raise safety concerns contributed to the crash which killed over 50 people.

Expectations for Managing the Risks of Organisational Change

Management systems for identifying and managing the risks associated with technical changes have been well established and practised for many years in the high hazard process industries. However, similar systems for managing organisational changes have not been implemented as effectively, if at all. Many systems concentrate on individual changes for starters, leavers and role changes, without considering the full breadth of changes which could have significant consequences.

Regulators across a number of different sectors, including nuclear, defence, and rail, stipulate a requirement to assess the risks of organisational change. The HSE have provided guidance to the process industries in Chemical Information Sheet CHIS7 for managing organisational change for all high hazard sites. Additional expectations have recently been added to the Human Factors Delivery Guide:

- Every site should have a clearly documented standard for managing organisational change.
- Hazards from proposed changes are risk assessed.
- The risk assessment identifies Human Factor studies where appropriate.
- The site can demonstrate that they have implemented their procedure when considering a change.
- The risk assessment realistically considers the potential impact of the change.
- Change management includes employee participation, recognising their knowledge and expertise.
- Systems are in place to monitor, audit, and review the change management process.

COMAH sites are expected to have a high level of reliability in the planning and decision making of changes. A demonstration is required that all direct and indirect effects of the change on the hazards associated with the site are identified and risk assessed. All changes should be planned in a thorough, systematic and realistic way, as would be done for process changes. The planning should consider actual capabilities, not what is assumed to be the case. Key tasks and responsibilities need to be identified and reassigned. The planning should include consultation with those affected by the change as far as possible, including contractors, and encourages people to challenge the plan if the risk assessment identifies unacceptable risks which have not been addressed. The risk assessment should consider not only the outcome of the change but also the transitional phase as the change is being implemented.

It is expected that a site should be aware of the changes that are going on and should limit the number of changes occurring simultaneously to ensure that each individual change and the effects of cumulative change are being managed effectively. However, there may be hazards arising from not implementing changes. If a company does not address the risk of a long-term absence, for example, there will come a point when the risks associated with doing nothing outweigh the risks of making a change.

Pharmaron Manufacturing Services UK – Organisational Change Management System

Pharmaron did not have an existing process for managing organisational change at the start of the project. However, they were clear that they wanted to achieve a robust system which met the COMAH requirements without creating excessive workload for managers and other personnel. The project was initiated in December 2022 and went live in November 2023.

The Risk Assessment

Rather than trying to state what should or should not be included in the process, it was agreed that every organisational change should have some level of risk assessment which would initiate the process. Therefore, Pharmaron defined Organisational Change as:

> *'any change which will affect the way in which people work. This may include new starters, resignations, re-assignment, job re-design, secondment, department restructuring, automation, outsourcing or changes that may affect the whole workforce, such as plant closure, mergers, centralisation of functions, changes to key contract suppliers, etc'*

Changes were then categorised as: Leaver, New Starter, Secondment, Role Change, Long Term Absence, System Change, Shift Move, Location Change, Restructure, Outsourcing, In-housing, or Flexible Working.

An initial risk assessment was designed which comprises 14 screening questions, focussing predominantly on the areas which may affect Safety, Quality, Regulatory Affairs, Site Security and IT Systems. The questions are set up to give Yes or No answers. The questions are consistently phrased so that a 'Yes' answer indicates that a potential risk has been identified and needs to be assessed further. If all the answers are 'No' then no further assessment is required. This provides a simple and quick process to assess the risk. The initial screening assessment determines if a full detailed risk assessment is required for the change. If the initial screening assessment does not identify a risk, the organisational change assessment (OCA) can be submitted for final approval and closed. If the initial screening assessment indicates there is a risk associated with the change, then a full detailed risk assessment must be completed by a team of assessors.

If further assessment is required, then a new set of questions is generated, incorporating three elements:

- Standard questions relevant to all changes

- Questions related to the answers given in the screening assessment
- Questions related to the type of change selected, including the relevant Performance Influencing Factors (PIFs)

The assessors select a change category, which determines the risk assessment questions for that category. The OCA requires the assessors to consider the practical effects of the change and the impact on Performance Influencing Factors (PIFs) which can shape individual behaviours. The risk assessment also requires consideration of the risk associated with not making the change.

The risk assessment must consider both the risks arising from the implementation of the change AND the risks during the transition phase of the change process. Both stages may not apply to all types of changes (e.g. new starters) but will provide invaluable insight to bigger changes such as a restructure, where there is a definite transition.

By answering YES or NO to each question of the risk assessment, the risk associated with that question is defined as follows:

> **NO = Low Risk** No issues or concerns have been identified associated with the change or the question is not relevant to the change
>
> **YES = High Risk** The question is relevant to the change and the risks identified will need to be managed

For every HIGH risk item identified, the assessor must either raise an action or provide an explanation of how that risk is being managed already.

If the risk associated with the change is not acceptable, the change must not be implemented.

Actions can then be raised to address the concerns.

Stages of the Organisational Change Management System

Figure 1 display the workflow of the Organisational Change Management System, which is divided into 5 distinct phases:

1. Assessing the Risk arising from the Change
2. Risk Review
3. Implementation Approval
4. Action Management
5. Closure Approval

1. Assessing the Risk arising from the Change

The risk assessment form is hosted and documented within the site's Lotus/HCL Notes system. Basic information about the change is required to carry out an OCA, including, but not limited to:

- Role Description
- Outstanding EHS and/or quality actions, change reports, events or investigations
- Site's organogram
- List of Safety Critical Tasks potentially affected by the change

The Risk Assessment is a consultative process involving the people/department affected by the change and should include personnel who have a good working knowledge of the work processes affected by the change. If the change is not confidential, EHS and quality departments must be included in the process. When handling sensitive data, it is critical to only involve the parties that need to be aware of the change.

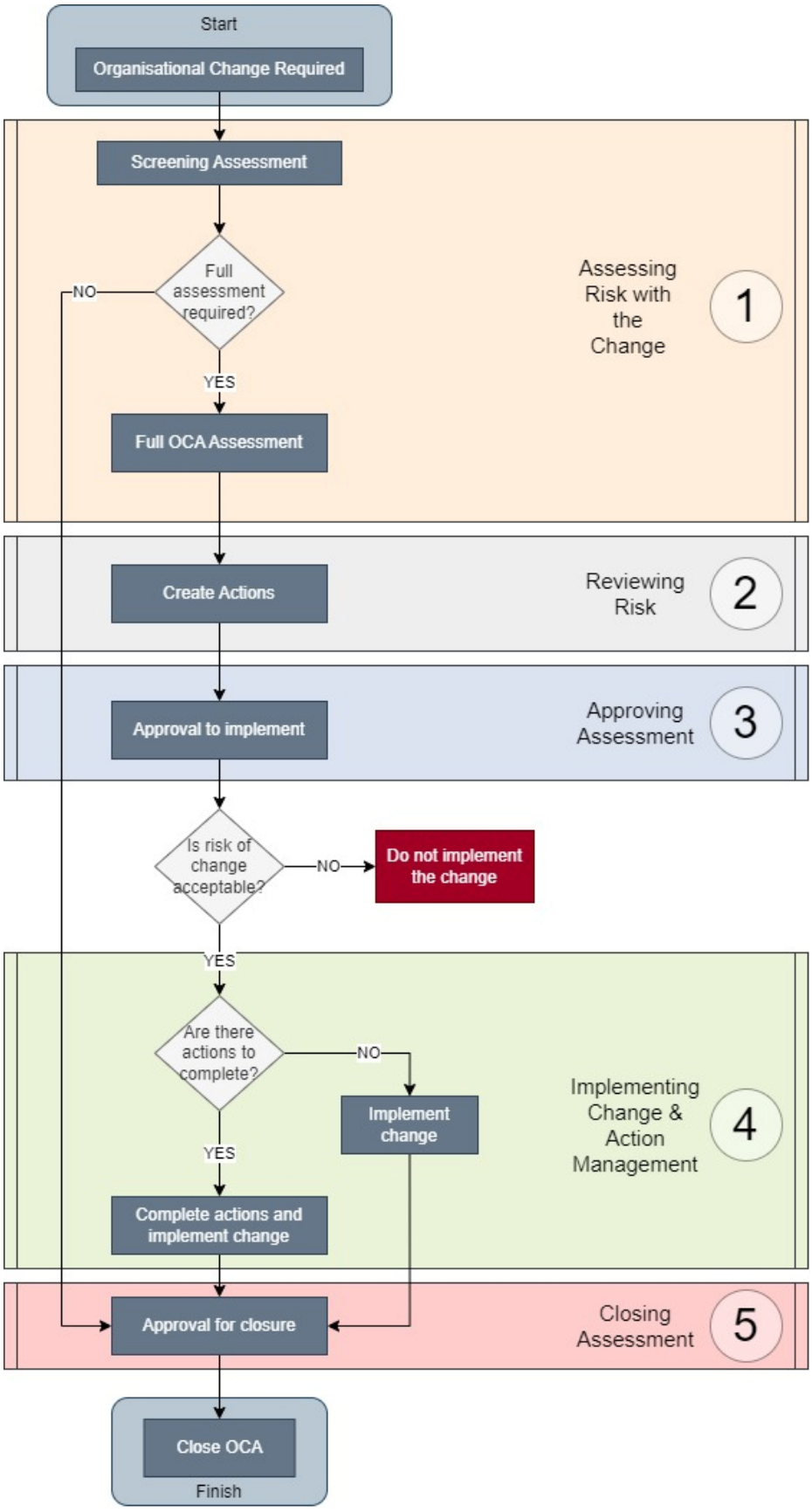

Figure 1: Workflow for the Pharmaron Cramlington Organisational Change Management System

2. Risk Review

All risks identified are reviewed and their impact on the business assessed as described above. The assessor must look at the processes and systems available on site that can mitigate or prevent the risk. This is a pivotal step which can often be the downfall of such a system and render the assessment ineffective. It is imperative that the assessor and approvers understand that risks do not equate to actions. If the current systems cannot fully address the issues identified, the assessor must then raise actions to address or mitigate them.

3. Implementation Approval

The OCA shall be authorised at two points as per the workflow in Figure 1:

- 'Approval to Implement' after the risk assessment has been completed
- 'Approval for Closure' after the change has been implemented and all actions completed

The authorisation at 'Approval to Implement' implies that the approver believes the risk assessment has identified the appropriate risks and that the actions are adequate to manage those risks.

4. Action Management

Once the OCA is completed, all actions can be assigned in the risk assessment.

All actions identified shall have a prioritisation system applied to them:

- P1: Actions which must be completed prior to the implementation of the change.
- P2: Actions which are considered less urgent and shall be completed in accordance with the target date allocated (which may be after change is implemented).

An example of this differentiation is as follows:

A person undertaking a new role does not currently have the skills required to undertake a Safety Critical task. The P1 action to complete prior to implementation would be to arrange for a competent co-worker to complete this task until the new starter is deemed competent. A P2 action would be to train the new starter on the new task and prove their competence.

Due dates are aligned with the intended implementation date or earlier for all actions to be completed prior to change implementation. For P2 actions, a clear completion date shall be established which can be after change is implemented. It is the assessor's responsibility to ensure that actions are completed on time to ensure no detrimental safety implications arise due to outstanding actions. If issues are identified, further actions to address them should be raised and the OCA remain open.

The system flags up when an action is due within the next week and if it is overdue. The system also sends a message to the OCA assessor when all actions have been completed and the OCA is ready for closure.

5. Closure Approval

Once all actions have been completed, the OCA shall be reviewed and approved for closure. OCA shall be reviewed by different departments to ensure all risks were addressed. Once closed, the assessment and associated actions are archived and will only be visible to originator, approvers and database owners, in compliance with the Data Protection Act requirements.

Confidentiality and Data Protection

It is recognised that some organisational changes may not be appropriate for general communication, especially during initial planning stages of the change. Therefore, when initiating the OCA process, the default option is 'Confidential'. This will restrict access to the change and its details, as well as the selection of individuals who can review and approve the change.

If the change does not involve sensitive information either from an individual or for the business, the assessment can be changed to 'Not Confidential'. If the change is marked as 'Not Confidential', it will be available for site personnel to view it throughout all stages. The change is clearly visible as demonstrated below in Figure 2:

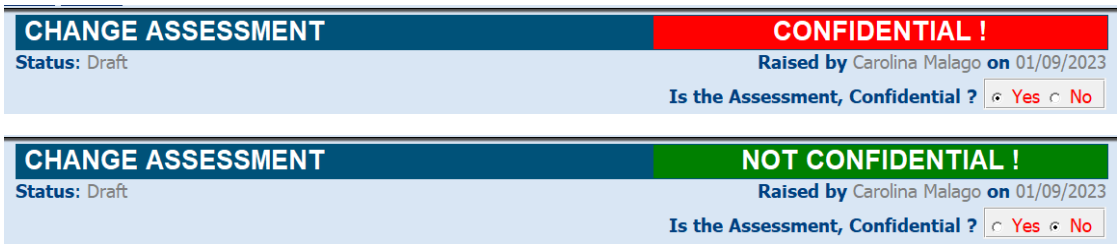

Figure 2: Visual indication on changes of confidentiality settings in an OCA.

When assigning actions in confidential changes, the originator can assign actions to anyone on site, however the assignee will only be able to access and see their own action and not the full OCA.

At the Approval for Implementation phase, there is the option to limit the number of approvers to protect sensitive information that might be recorded in the assessment. This feature ensures that sensitive information is shared only with people that should have that information.

At the "Approval for closure" stage, there is an opportunity to make the assessment visible to all site personnel once closed using the field "After Closure Confidentiality". By selecting "confidential" the OCA will be closed and will continue not to be visible to site personnel who were not involved in creating and approving the assessment. By selecting "open" the OCA will be no longer be treated as confidential and will be visible to all site personnel once closed.

System Implementation

The OCA software was developed internally in Lotus Notes, with the support of the IT department, so it enabled the system to be built around the needs of the business. It also allows for internal modifications to the database layout, questions content and numerous other features to ensure the process remains dynamic and robust. Furthermore, as an in-house system, no external party has access to confidential and/or identifiable personal information of any Pharmaron employee.

To support the users of the new process and facilitate navigation through the various stages of the system, guidance manuals have been developed. These have been a useful reference for personnel during the implementation of the process. A detailed training pack, encompassing all database features, category definition, responsibilities under the process, exercises on identifying the changes that are in and out of its scope, and competency assessment was also created and rolled out prior to the system going live to ensure users are competent.

Routine reviews and audits of the system are conducted quarterly by the Safety Manager and the site's Human Factors Lead, and findings shall be used to identify continuous improvements.

Feedback on the System

Initial feedback is very positive not only on the benefits of the system but also on the practical and sleek way the assessment can be done. One manager commented that the system "… provides a safety net for all non-chemical process related changes without being overly onerous and time-consuming for managers". Table 1 shows the statistics so far on the system.

Table 1: Statistics on number of OCAs and actions raised as of February 2024

OCAs raised	OCAs closed	OCAs rejected	Actions raised	Actions closed
12	3	2	16	8

Conclusions

The system has been in use for over three months and first assessments demonstrate a good understanding of the process and the requirements of the risk assessment from managers and the leadership team. Site personnel have embraced the process, not as requirement but as a benefit; virtually all OCAs have been raised and assessed without seeking support from or needing to be prompted by the Human Factors Lead or Safety Manager. This demonstrates that the training and competency package was effective and that the system is user-friendly, robust, and does not require excessive effort to complete.

The next steps are to improve usability of the process based on routine audits and user feedback. By developing the system in-house, Pharmaron have the flexibility to tailor the Organisational Change system and features to meet business requirements now and in the future.

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