Designing and building Effective automated Change Control systems

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‘Whosoever desires constant success must change his conduct with the times’
Niccolo Machiavelli

Machiavelli is seen as the prototype of a modern **empirical scientist**, building generalisations from experience and historical facts, and emphasising the uselessness of theorising with the imagination.

Fischer, Markus (2000), *Well-ordered License: On the Unity of Machiavelli's Thought*, Lexington Book

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Change Control

Why should we talk about it?

Approximately 40% of regulatory issues, including warning letters, regulatory inspection observations or compliance observations (CAPA etc.) are attributed to changes.

http://www.fda.gov/

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Principles of change control process

- Completely **documented**, **reviewed** & **authorised**
- Stakeholders **consulted and informed** of changes
- **Mitigate risk** through careful consideration and planning
- **Continuous improvement** in an organisation

"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." - *Annex 15 of the EU GMP Guidelines*

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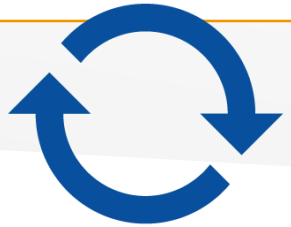
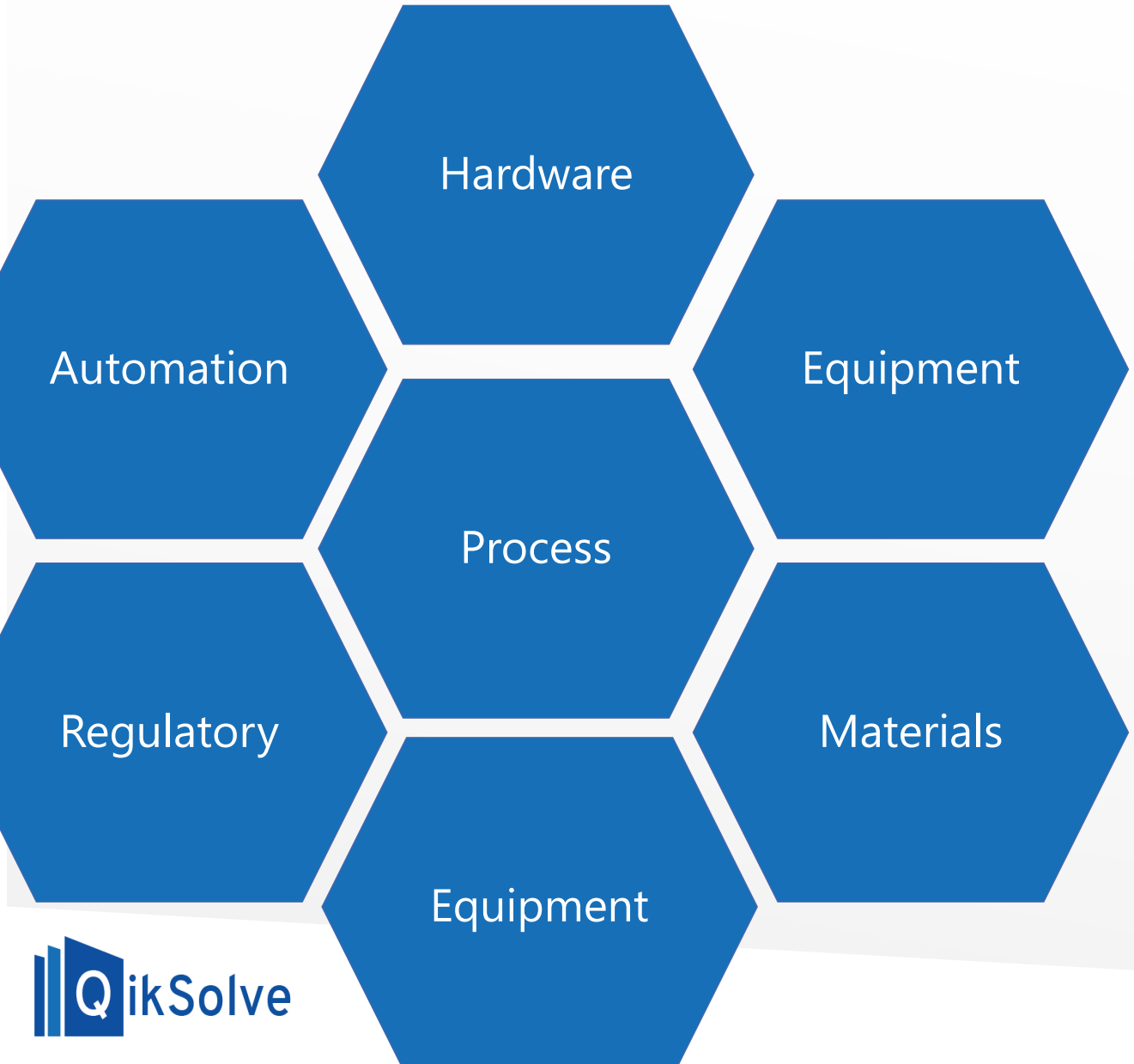


Global automated change control



Documentation

'95% of changes result in documentation updates'

IT Systems

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When would you need a change control

Anything that changes:

- Starting materials
- Product Components
- Process Equipment
- Process Environment
- Method of productions
- Method of testing

Ultimately any changes that **may affect product quality** and patient safety

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Change control process overview

Proposal for change

Impact & risk assessment

Develop plan for change

Test & review plan

Approval & implementation

Evaluate effectiveness & close

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Meet Bob

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Why automate your change control

- Create genuine culture for **continuous improvement**
- Improved visibility, **accountability** and responsibility
- Process is clearly **signposted** and **trackable**
- Enforced **business rules** and reduced risk of human error
- Better **access** to data
  - Product quality reviews

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Critical Success Factors

For implementing an automated change control process

How do you measure your change management process to ensure you are building a Quality focused culture?

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Getting the right people involved

Change control committee responsibilities include:

Assess if change is justified

Evaluate impact of change

Identify Risk

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Automated systems allow for simultaneous controlled access to information

Confirm and validate change is effective

(c) Proposed changes should be evaluated by expert teams contributing the appropriate expertise and knowledge from relevant areas (e.g., Pharmaceutical Development, Manufacturing, Quality, Regulatory Affairs and Medical), to ensure the change is technically justified. Prospective evaluation criteria for a proposed change should be set;

- ICH Q10 Pharmaceutical Quality System

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Assessing the impact

Change impact form:

- Assess if change is **technically justified**
- Document reason for change
- Assess for regulatory impact
- Prompt for potential Impacted systems
- Prompt for training/documentation changes

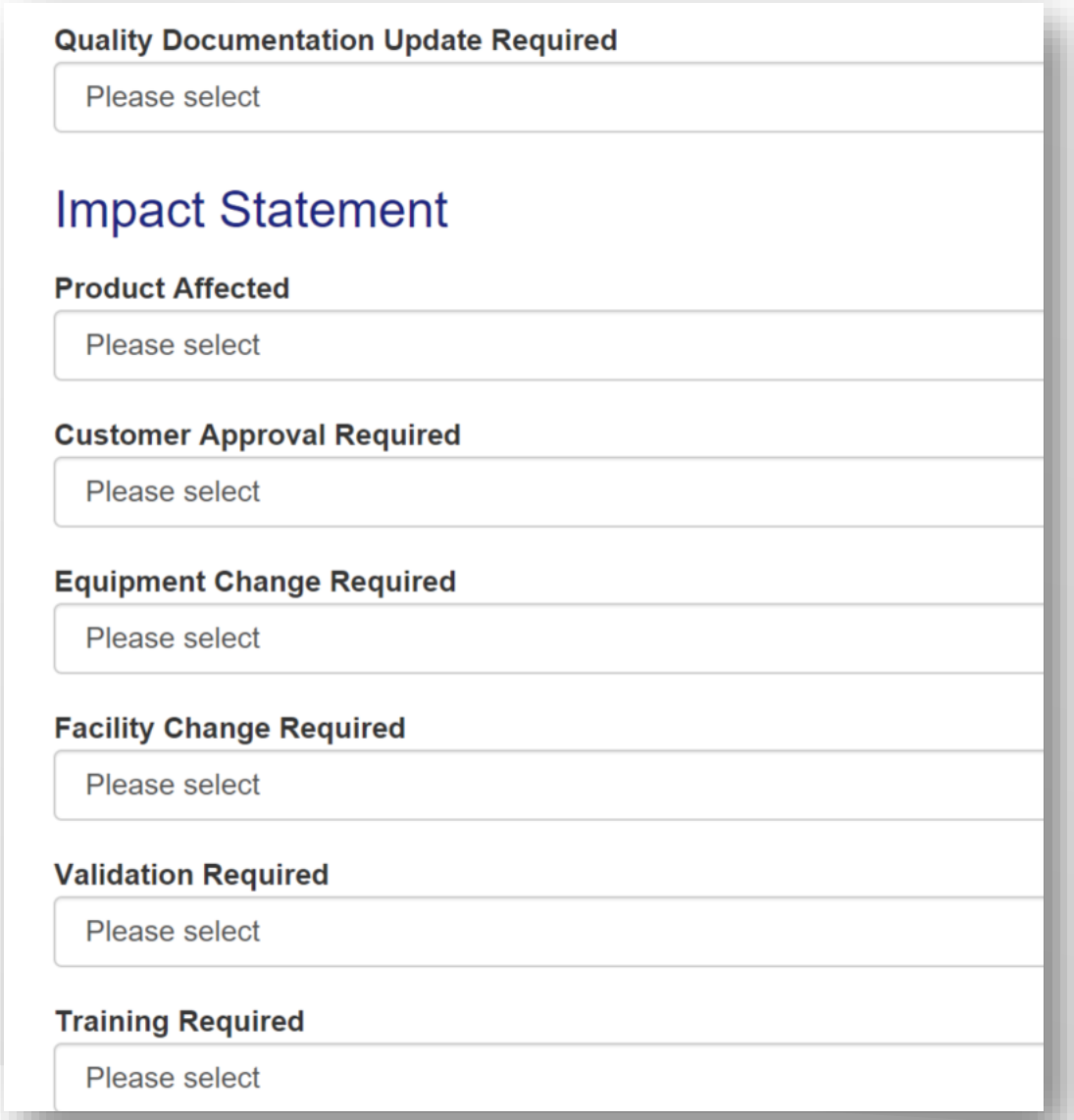
Change management system:

- Assigns impact category
- Assigns appropriate risk class
- Identify and alert impacted departments

Critical to define process rules that align with business objectives early

(a) Quality risk management should be utilised to evaluate proposed changes. The level of effort and formality of the evaluation should be commensurate with the level of risk;

Example: Change control impact assessment



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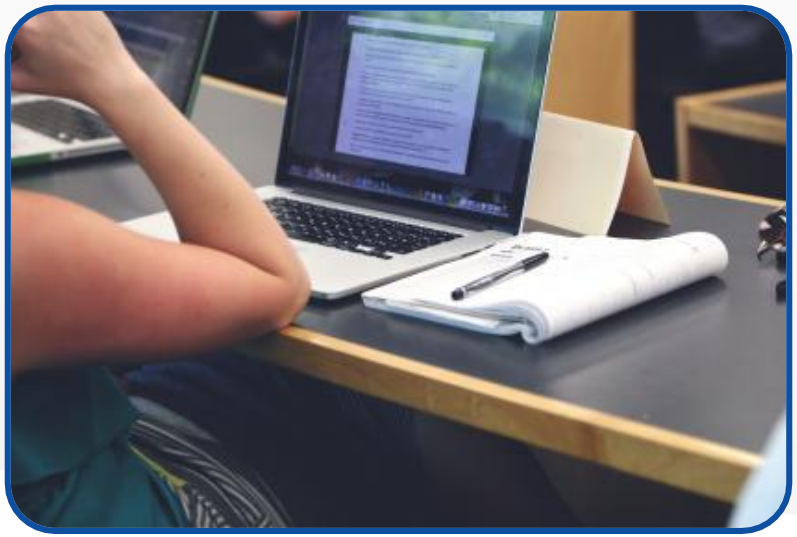
Integrated training and documentation

'95% of changes result in documentation updates'

Integrate document management updates as part of the change control process

Changes made that warrant training automatically kick off training module



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Defined trackable tasks

All tasks should be assigned to **appropriate** user with visibility as to the:

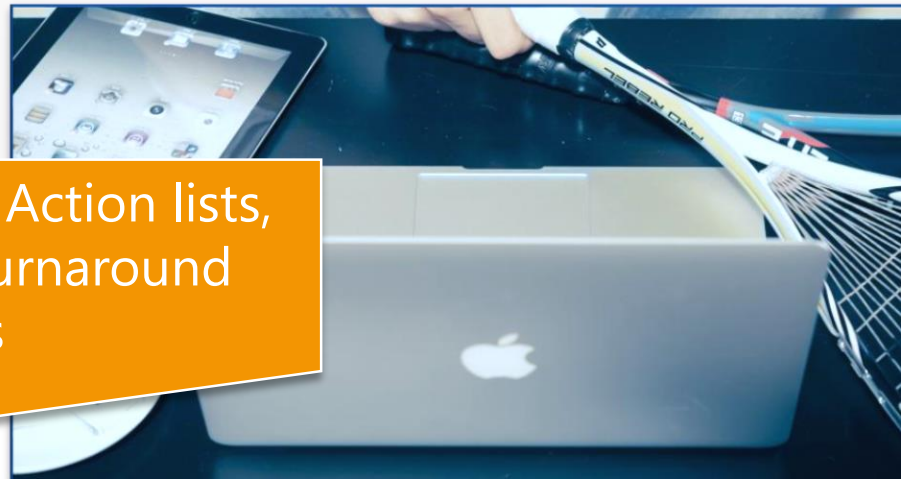
- Actions to be undertaken
- Due Date
- Assigned user

Clear communication

Continuous feedback

Ability to transfer tasks

Dashboards and Action lists, drive quicker turnaround times



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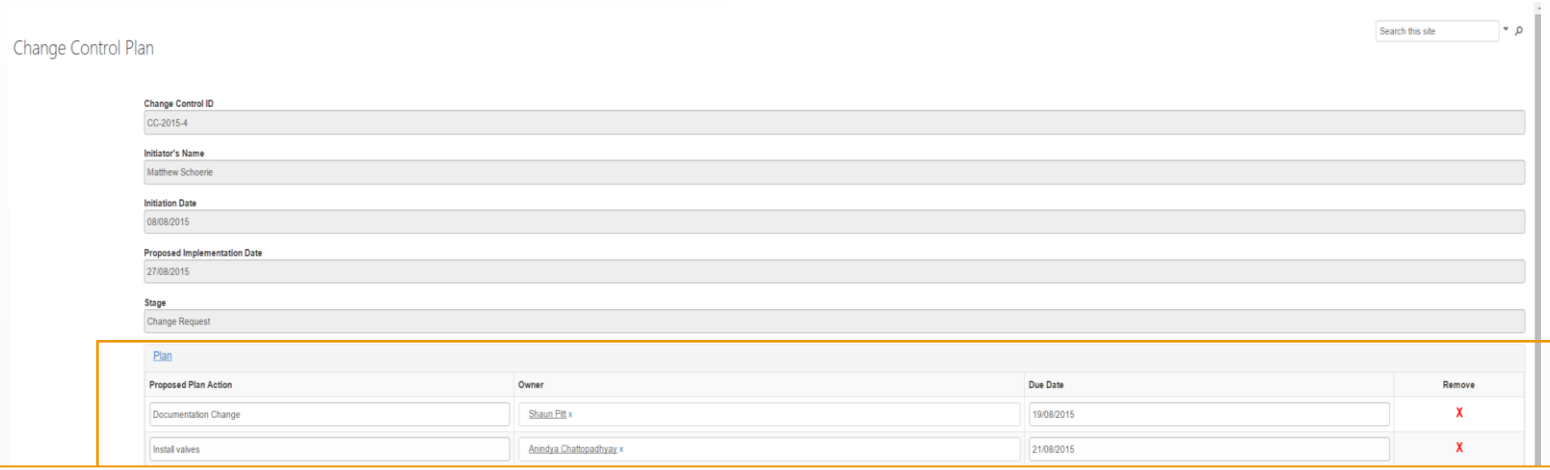
Change Control planned actions



Plan

Proposed Plan Action	Owner	Due Date
Documentation Change	Shaun Pitt x	19/08/2015
Install valves	Anindya Chattopadhyay x	21/08/2015
Validation of process change	Anindya Chattopadhyay x	22/08/2015

Add New Task

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Evaluating the change

After implementation it is **critical** to evaluate changes against initial objectives and assigned tasks.

Deviations from initial plan to be documented, and explained

Opportunity to review process

(d) After implementation, an evaluation of the change should be undertaken to confirm the change objectives were achieved and that there was no deleterious impact on product quality.

- ICH Q10 Pharmaceutical Quality System

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Centralised change management

- Central register maintains appropriate change controls across the entire enterprise
- Change controls are able to be classified with **metadata** for improved product quality reviews and continuous improvement
- Critical and **outstanding** changes are easily identified and are able to be escalated if required

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What does success look like?

- Connected system
- Quick turnaround
- Integrated with other critical process

How do you measure your change management process to ensure you are building a Quality focused culture?

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Open Forum

Should pharmaceutical change management follow ITIL best practice and implement "*Back-out strategy*" when planning for change?

Back Out – contingency plan for when the intended patch/change introduces unforeseen detrimental changes to the system.

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Any Questions?

Thank you

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