Designing and building Effective automated Change Control systems

11th August 2015

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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.
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/
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
Global automated change control

- Hardware
- Equipment
- Process
- Materials
- Regulatory
- Automation

‘95% of changes result in documentation updates’

IT Systems
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
Change control process overview

- Proposal for change
- Impact & risk assessment
- Develop plan for change
- Test & review plan
- Approval & implementation
- Evaluate effectiveness & close
Meet Bob
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
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?
Getting the right people involved

Change control committee responsibilities include:

- Assess if change is justified
- Evaluate impact of change
- Identify Risks
- Confirm and validate change is effective
- Automated systems allow for simultaneous controlled access to information

(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
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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<thead>
<tr>
<th>Quality Documentation Update Required</th>
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**Impact Statement**

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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
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
Change Control planned actions

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<td>Documentation Change</td>
<td>Shaun Pitt</td>
<td>19/08/2015</td>
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<td>Install valves</td>
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<td>21/08/2015</td>
<td>X</td>
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<tr>
<td>Validation of process change</td>
<td>Anindya Chattopadhyay</td>
<td>22/08/2015</td>
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</table>
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
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.
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?
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.
Any Questions?

Thank you