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Lessons Learned: Change Control Post-Implementation - Ensuring Documentation and Workflow Align to Compliance Requirements

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This article discusses:

- Key learnings regarding change control
- Hidden challenges with change control paperwork
- Adapting change control to best practices, such as the PMBOK Guide 6th Edition
- Workflow and systematic processes for change control
- Opportunities to become more effective and efficient with change control

Regulatory agencies such as the FDA stress the importance of periodically holding lessons learned discussions to review compliance in change control. Change control is a systematic approach to managing changes to a Procedure (SOP), Quality System Policy (QSP), process, product, service or system. Change control should ensure the established process for change is followed, compliance is followed under a Right First Time methodology and resources are used effectively and efficiently.

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