



SIMPLIFICATION AND IMPROVEMENT OF A CHANGE CONTROL SYSTEM

WHAT WE FOUND

- > 56-page change control (CC) SOP that no one could understand. Even the process flows (there to simplify) caused brain freeze.
- > On average, change requests took 12–16 weeks to approve.
- > Because the system was so slow, there were various (some dangerous) workarounds and unofficial shortcuts.
- > The CC system approved everything.
- > Most approvals were based on gut feel.
- > The CC committee was made up of eight people who reviewed change requests remotely.
- > There was no follow-up of approved changes to measure success.
- > There was **no** control over routine changes.

WHAT WE LEFT AFTER NSF SIMPLIFICATION

- > The SOP was reduced to seven pages.
- > Approval time was reduced from months to 60 minutes.
- > Workarounds and shortcuts became obsolete.
- > The CC system rejected between 38–40 percent of change requests (a good indicator of an effective CC system).
- > Customized impact assessment forms were introduced to make decisions objective and business focused.



STEPS TAKEN

- > Gap analysis of the CC system vs. best industry practice.
- > A two-day, distraction-free workshop with all key stakeholders delivered to 25 participants to simplify the SOP.
- > Core purpose of the CC system agreed upon with a focus on speed and importance of objective decision-making.
- > CC system and unofficial systems process mapped.
- > Non-value-adding steps removed.
- > Customized impact assessment forms generated.



- > Role of the CC changed from discussion to decision-making; CC members reduced to just three who met weekly (minimum).
- > Agenda of the CC clinic simplified.
- > All approved changes followed up to assess ROI.

TOOLS USED

- > Gap analysis.
- > Process mapping.
- > Brutal thinking.
- > Risk assessment.
- > Customized impact assessment.

RETURN ON INVESTMENT

- > Everyone slept easier at night knowing they had, for the first time, control over routine changes.
- > Only changes delivering value were approved. This dramatically reduced initiative overload and freed up resources.

BEHAVIOR CHANGED

People recognized that the CC system was vital to the health of their business and was not just about compliance.

KEY MESSAGE

Simplification motivates and inspires. People went from loathing (and ignoring) the CC system to loving and using it.

For more information, contact pharmamail@nsf.org or visit www.nsfpharmabiotech.org

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Cite as: NSF International. January 2019. Simplification and Improvement of a Change Control System. NSF: York, UK.

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