



SIMPLIFICATION AND IMPROVEMENT OF A CHANGE CONTROL SYSTEM

WHAT WE FOUND

- > A 56-page change control SOP that no one understood
- > Change requests that took 12–16 weeks to approve
- > Workarounds (some dangerous) and unofficial shortcuts
- > CC system that approved everything
- > Approvals based on gut feel
- > An eight-person CC committee remotely reviewing change requests
- > No follow-up of approved changes to measure success
- > No control over routine changes
- > CC system rejecting 38–40 percent of change requests
- > Customized impact assessment forms 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 to 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
- > Three CC members meet weekly to make decisions

WHAT WE LEFT AFTER NSF SIMPLIFICATION

- > SOP reduced to seven pages
- > Approval time reduced from months to 60 minutes
- > No more workarounds and short-cuts



- > 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 control over routine changes
- > Only changes delivering value were approved, dramatically reducing initiative overload and freeing 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. June 2017. Simplification and Improvement of a Change Control System. NSF: York, UK.

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LPH-433-0517