



# 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](mailto:pharmamail@nsf.org) or visit [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)

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