SUCCESS STORY – SOP SIMPLIFICATION

by Martin Lush

WHAT WE FOUND

> Client had 2,456 SOPs
> 37 percent of their deviation incidents were related to SOP non-compliances. Widespread culture and acceptance of SOP non-compliance
> Average word count per SOP was 9,900
> SOPs were written for the inspector, not the user
> SOPs were usually written in isolation from the process
> SOPs were owned by QA, with no user involvement
> The average number of co-authors was five people per SOP
> How-to instructions started on page four
> SOPs were automatically given a two-year “expiry” date
> Average approval time per SOP was five days
> Five approval signatures were required per SOP
> Processes operated using “tribal knowledge” and shortcuts, not the SOPs

WHAT WE LEFT AFTER NSF SIMPLIFICATION

> SOPs reduced by 54 percent to 1,126 by removing non-essentials
> SOP non-compliances (deviations) reduced by 85 percent
> Average word count per SOP reduced by 98 percent to 220 words per page by using pictures and schematics
> SOPs now written for the users “on the line”. Content reflects their education levels and their requirements, not the inspectors
> Co-authors reduced from five to three
> How-to instructions start on page one
> SOPs tested before approval
> SOPs given six month expiry period to allow problems to be fixed and improvements made
> Approval time reduced to 30 minutes
> Five approval signatures reduced to two

STEPS TAKEN

> Identified high-risk SOPs using deviation data
> Asked the users “Which SOPs do you hate the most?”
> Ran a two-day (distraction-free) workshop with the users of 30 SOPs identified
TOOLS USED

- Nine-step simplification process
- Process mapping
- Risk assessment (FMEA)
- Six Hats Thinking methodology
- Brutal thinking
- NSF behavior change model (B= M.A.t.H.)

RETURN ON INVESTMENT

- £11.5 million in first year
- Workshop attendees then acted as simplification champions across site
- Simplification now extended to batch records

BEHAVIORS CHANGED

- Simplification now seen as vital to their future
- SOPs now used, not “tribal knowledge”
- Culture of demotivated non-compliance has changed to one of motivated compliance, the place is buzzing!

KEY MESSAGE

Use a distraction-free, high-intensity workshop to convince, educate, inspire and generate immediate return on investment.

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

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