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

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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.

ABOUT THE AUTHOR

Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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