STREAMLINING THE PHARMACEUTICAL QUALITY SYSTEM

by John Johnson

WHAT WE FOUND

- The structure and function of a pharmaceutical quality system (PQS) were not well understood; the PQS was disengaged from the business and seen as a business obstacle
- The PQS contained 2,300 policies, SOPs, instructions and records with multiple GMP documents for single processes
- The site struggled with multiple GMP deviations, repeat regulatory audit observations and suspected data integrity issues due to staff finding it difficult to follow the documented instructions
- Batch and GMP record 'right first time (RFT)' was <70 percent and contributed to the lagging release lead times and poor schedule adherence
- Quality director and QP were seen as 'law enforcement officers'

WHAT WE LEFT AFTER NSF SIMPLIFICATION

- Identified 200 SOPs that could be deleted immediately and reduced cross-references
- Identified 50 high complexity SOPs that were causing 80 percent of the GMP deviations and reduced the number of pages by 60 percent by using symbols, color, diagrams and photos
- Trained 20 critical position holders on how to simplify process instructions and SOPs, and produced a custom toolkit to ensure each team member simplified at least 10 SOPs each year

- Reduced the number of test methods and specifications by 60 percent using process mapping

STEPS TAKEN: HOW WAS THIS ACHIEVED?

- Created the 'burning platform' that motivates document owners to take charge of their GMP documents
- Trained and hosted simplification workshops targeting high complexity, high impact SOPs, instructions and records
- Installed meaningful leading indicators for documentation 'RFT' and shared them widely
- Mapped the PQS against ICH Q10, FDA QSIT 7356.002 and other cGMP references to look for gaps, overlaps and duplication
- Trained and installed practical guidance on how to establish internal customer relationships

TOOLS USED

- Fedex days (24-hour exercises in innovation) to select processes best suited for simplification; allowing the biggest impact for the widest group of people
- Process flow charting and swim lane diagrams
- SOP simplification and model plans, checklists and routing/gateway charts

RETURN ON INVESTMENT

- Over the course of two years, the number of GMP documents was reduced to 1,650, i.e. a 28 percent reduction in the documentation burden
- RFT for batch records grew to >85 percent and batch release lead times dropped on average by seven days, driving a corresponding drop in 20 percent of finished product inventory
- GMP non-compliance and client audit observations were reduced, including the site achieving its first blank FDA 483

BEHAVIORS CHANGED

- The quality group became integrated into the business and is now seen as a facilitator
- The company spun off a new project concerning cost of quality – known as 'war on waste'
- Visibility of priorities and critical process steps led to more staff ownership, less tolerance of waste and more engagement in making valued change without fear of being overcome by the inertia or complexity of the PQS

ABOUT THE AUTHOR

John Johnson is passionate about helping organizations foresee and overcome the barriers to sustainable longterm growth. He brings 28 years' experience across a range of companies in the pharmaceutical and healthcare industry. He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms, holding senior operational and corporate-level experience in operations and quality assurance and leading multinational companies in many strategic projects.

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