IMPLEMENTING A NEW VENDOR ASSURANCE SYSTEM

by Martin Lush

WHAT WE FOUND

- Purchasing can place orders from unapproved suppliers
- QA is not aware of changes until the consignment arrives
- Audit of suppliers revealed considerable quality risks, or required additional checks and controls
- Unapproved materials are used in formulations, meaning 20 percent of products are held in quarantine pending QA
- Current process poses quality and financial risks to the company

WHAT WE LEFT AFTER NSF SIMPLIFICATION

- Installed an end-to-end process for introducing new suppliers (pending, approved and certified), aligned to GMP and business needs
- Built relationships and awareness of role across QA, planning, operations and purchasing; recognizing shared success against mutually agreed objectives
- No products held in quarantine pending QA due to vendor-related issues

STEPS TAKEN

- Generate a swim lane diagram showing process flow, utilizing inputs from all stakeholders
- Analyze the swim lane diagram to identify gaps, overlaps, complexity and ambiguity
- Analyze the outputs to ensure the process is made parallel where possible, not linear
- Triage risk to allow resource to focus on high-risk changes

- Modify the process flow chart accordingly and road test on a real or model new supplier
- Update and simplify SOPs to include flow charts, indicators, clear job roles and expectations; all stakeholders review and "buy in" to the changes. Take time to educate stakeholders on the "know why" not just the "know how"
- Implement the SOPs and implement an effectiveness check on the first three supplier changes and then quarterly for the next 18 months

TOOLS USED

- Process flow charting
- Model plans, checklists and routing/gateway charts
- Project management taking account of all perspectives/drivers from each stakeholder in the business
- Rapid decision making to exclude high-risk, unengaged suppliers quickly before investing too much in advance

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RETURN ON INVESTMENT

- Investment was 45 staff days from start to end
- Inventory and working capital was reduced by £400k, also negating the need for additional rented warehouse space
- QA batch release lead times of batches associated with supplier changes were reduced by over ten weeks
- Utilizing clearly defined gateways to certified status, the cost of incoming QC testing of materials from the best suppliers was reduced by >80 percent and cut time waiting for QC by no less than ten days
- No high-risk, unengaged suppliers are used in the supply chain, leading to fewer quality investigations, fewer supplier audits and less reliance on oversight or a person in plant

BEHAVIORS CHANGED

- Quality group seen as facilitating the business, not restricting it
- Holistic return on investment to be defined for every change; changes based on value, not cost
- More teamwork and less decision making in silos

KEY MESSAGE

Buy together, save together.

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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