



NEW PRODUCT INTRODUCTION INTO A CONTRACT MANUFACTURING ORGANIZATION

by Martin Lush

WHAT WE FOUND

- > Time from contract acceptance to release of first batch was six months; 50 percent more than the competition
- > Schedule adherence for release of first batch was <40 percent
- > High level of intervention was needed from the contract giver
- > Customer feedback was "Love your staff and respect your quality system but it's too expensive, too unpredictable and takes too long when introducing new formulations to your facility"

WHAT WE LEFT AFTER NSF SIMPLIFICATION

- > 60 percent reduction in lead time for project completion
- > 30 percent reduction in GMP deviations and change control requests
- > 15 percent reduction in cost of quotations associated with new product introductions
- > Customer base growth of 150 percent in two years, increasing plant utilization by 20 percent
- > Renewed confidence in the future working as a lean, client-focused contract manufacturing organization

STEPS TAKEN

- > Run a voice of the customer program
- > 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
- > Use risk management tools to identify key areas that may/have suffered from variation, error or GMP deviation
- > Modify the process flow chart accordingly and road test on a real or model new product
- > Update and simplify SOPs to include flow charts, indicators, clear job roles and expectations; all stakeholders review and buy in to the changes
- > Implement the SOPs and an effectiveness check on the first three projects and then quarterly for the next 18 months

TOOLS USED

- > Listen to tough feedback from people you trust, accept reality and act on it
- > Process flow charting/swim lane diagrams
- > Model plans, checklists and project charters



RETURN ON INVESTMENT

- > Investment was 108 staff days from start to end
- > Revenue grew over £1.5m over the next 12 months, promoting confidence in the company and allowing for inward investment elsewhere on site

BEHAVIORS CHANGED

- > Confidence in new, self-directed project teams
- > Belief in project status reviews; more trust and fewer recriminations
- > Customers came back, in less of a parent-child relationship with less oversight and verification needed

KEY MESSAGE

Less stuff = more love.

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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