



# SUCCESS STORY – SIMPLIFICATION OF BATCH MANUFACTURING RECORD

by Martin Lush

## WHAT WE FOUND

- > BMR had grown to 237 pages
- > Time to review and approve was 1.5 hours
- > BMRs right first time were 62 percent
- > Average number of errors per BMR were 28
- > Number of signatures required was 110
- > Due to complexity, BMRs were often completed at the end of the shift
- > Order due date performance was 76 percent



## WHAT WE LEFT AFTER NSF SIMPLIFICATION

- > Number of pages reduced to 72
- > Review and approval time reduced to 30 minutes for each BMR
- > BMRs right first time increased to 96 percent
- > Average number of errors per BMR reduced by 89 percent to three per batch
- > Number of signatures reduced by 79 percent to 23
- > BMRs completed in real time during the manufacturing process
- > BMRs now owned by users/manufacturing
- > 99 percent of orders released on time
- > Workshop participants then took responsibility for simplifying other BMRs
- > Deviation incidents reduced
- > Steps Taken
- > Got the right people in a room with no distractions for a focused three-day workshop
- > All stakeholder groups were represented
- > Selected a BMR to simplify
- > Agreed on core purpose of the BMR
- > Each stakeholder listed their user requirements. This list was then drastically reduced using brutal thinking
- > Stakeholders reviewed BMRs to identify only essential instructions, GMPs and license requirements, everything else was removed
- > Smaller BMRs were then redesigned to make them easy to follow
- > Approval checklists were generated
- > Simplified BMR was tested (piloted) on-line



## 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.)

## KEY MESSAGE

Brutal thinking is key. Remove the non-essential. BMRs have multiple stakeholders who want different things, most of which are non-essential. BMR simplification creates considerable fear, particularly in QA. The sensible use of FMEA helps to remove these fears. When simplifying BMRs, be prepared for lots of resistance and emotion

## RETURN ON INVESTMENT

Annual savings of £2.5 million for just one product line.

## BEHAVIORS CHANGED

- > Manufacturing ownership of BMRs
- > Improved accountability
- > More attention to detail through checklists
- > Dramatically improved levels of trust.

## 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.

For more information, contact [pharmamail@nsf.org](mailto:pharmamail@nsf.org) or visit [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)

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## NSF INTERNATIONAL | PHARMA BIOTECH

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF

T +44 (0) 1751 432 999 | E [pharmamail@nsf.org](mailto:pharmamail@nsf.org)

2001 Pennsylvania Avenue NW, Suite 950, Washington, DC 20006 USA

T +1 (202) 822 1850 | E [USpharma@nsf.org](mailto:USpharma@nsf.org)

[www.nsf.org](http://www.nsf.org) | [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)