



SUCCESS STORY – SIMPLIFICATION AND IMPROVEMENT OF DEVIATION AND CAPA SYSTEM

by Martin Lush

WHAT WE FOUND

- > 12 percent increase in deviations per year peaking at 2,890
- > 45 percent of these were repeat incidents
- > 67 percent of deviations attributed to human error
- > Corrective actions focused on retraining and adding more detail to SOPs
- > 27 percent of batches for product release delayed because of overdue investigations
- > Investigations completed by QA most of the time
- > 89 percent of investigations completed on day 29 to satisfy the 30-day KPI
- > Incidents not risk ranked
- > 46-page deviation reporting SOP
- > 11 different deviation categories
- > Absolute chaos

WHAT WE LEFT AFTER NSF SIMPLIFICATION

- > 87 percent reduction in repeat incidents
- > 92 percent reduction in human error deviations
- > In the first 12 months, less than five percent of batches were delayed being released
- > Investigations now done by certified investigators from multiple functions
- > 80 percent of investigations are started within 60 minutes



- > Incidents are risk ranked immediately
- > Deviation reporting SOP reduced to seven pages (excluding problem solving tool kit)
- > Number of deviation categories reduced to the two that matter (active and latent)

STEPS TAKEN

- > We first compared their deviation system with best industry practice, gaps closed within six months, then “train the trainer” sessions on problem solving and human error prevention
- > The term “root cause” was subsequently banned and replaced with “error chain”
- > The 30-day KPI was removed and replaced with KPIs that encouraged the right behavior
- > During the education programs the client re-designed its deviation reporting form and simplified their SOP. This included a simple problem solving tool kit



TOOLS USED

- > Culture change education. The client had, over many years, developed a firefighting mind set and culture. To change this, education had to precede simplification
- > Education focused on best industry practices, effective problem solving and human error prevention

RETURN ON INVESTMENT

Although a final monetary figure isn't available, it will be large. Just look at the reductions in repeat incidents and firefighting.

BEHAVIORS CHANGED

Before we started, deviations were perceived as an inconvenience. When we left every incident was viewed as a learning opportunity and catalyst for continuous improvement.

KEY MESSAGE

The key to this significant success was education. To simplify anything you must have a small group of educated and dedicated people to show others what to do. The rest will then follow.

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 or visit www.nsfpharmabiotech.org

Copyright © 2017 NSF International.

This document is the property of NSF International and is for NSF International purposes only. Unless given prior approval from NSF, it shall not be reproduced, circulated or quoted, in whole or in part, outside of NSF, its committees and its members.

Cite as: NSF International. December 2017. Success Story – Simplification and Improvement of Deviation and CAPA System. NSF: York, UK.

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

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

T +1 (202) 822 1850 | E USpharma@nsf.org

www.nsf.org | www.nsfpharmabiotech.org