



HUMAN ERROR: CAUSES AND PREVENTION

by Martin Lush

Martin Lush explores why people make mistakes and what can be done to reduce errors in the workplace.

Every year, the pharmaceutical industry wastes huge sums of money as a result of mistakes in the workplace – so-called “human error.”

Human error is often cited as the cause of product recalls, customer complaints, batch rejects, deviations and adverse audit findings. In most cases, however, human error is not the root cause, just a convenient excuse.

The good news is that such costly and risky mistakes can be prevented if you follow some very simple and practical rules.



RULE ONE: UNDERSTAND THE “PSYCHOLOGY” OF HUMAN ERROR

Why is it women are better at certain tasks than men? Why do we see only what we want to see? Why do we all make assumptions that result in mistakes being made? How can you prevent mistakes due to boredom? What “situations” and tasks actually encourage the brain to make the wrong decision?

The answers lie in understanding the psychology of human error.

RULE TWO: ADOPT A POSITIVE, BLAME-FREE ATTITUDE TO MISTAKES AND ERRORS

Every mistake is a free and invaluable lesson on what not to do! Providing, that is, you learn from the experience and don't do it again!

By creating a blame-free environment so that errors can be reported and prevented, you can go a long way towards stopping those deviations that just keep coming back again and again.

RULE THREE: DRIVE OUT COMPLEXITY IN EVERYTHING AT EVERY LEVEL

As complexity increases so does the number of mistakes. The pharmaceutical industry excels at overcomplicating the simplest of tasks and procedures. This costly and unnecessary complexity actually encourages people to make mistakes.

The answer? Keep things as simple as possible! Make the time to review and simplify your processes, procedures and systems (bearing in mind the psychology of human error) and you will see real benefits.

RULE FOUR: FOCUS ON USER-CENTRED DESIGN

Equipment procedures, processes and systems that work have one thing in common. They are designed by the users. This is far from easy.

By involving the users from the outset and adopting the principles of “user-centred design” it is possible to reduce the size of a batch manufacturing record by up to 50% and massively reduce documentation errors. Similarly, you can make SOPs easier to follow.

RULE FIVE: BUILD IN PLENTY OF “SYSTEM SAFEGUARDS”

When something goes wrong you must have plenty of system safeguards in place. These are designed to either prevent the error at source or to stop it getting through undetected.

You rely on your Quality System to do this. You all have systems for training, validation, maintenance, QC analysis, deviation reporting, audits and self-



inspections, to name but a few. But do these system safeguards always work? Not according to the FDA and EU regulatory agencies that cite deficiencies in Quality Systems in their “top three” regulatory concerns.

It is not how many system safeguards you have in place that is important, but choosing the right ones! Take the time to ensure that your safeguards are relevant, focused on the quality critical factors and above all are effective.

RULE SIX: REMOVE “RISK INCREASING FACTORS”

Factors present in our working environment can cause human error. These “stressors” can range from poor lighting, complex documentation, inconsistent processes, illogical material flows through to company culture, inadequate communication and inaccurate and insensitive performance measures.

Risk Increasing Factors (RIFs) must be identified and removed by using techniques such as RIF Audits, Failure Mode & Effect Analysis and Process Flow Evaluation.

RULE SEVEN: MAKE PEOPLE RESPONSIBLE AND ACCOUNTABLE

With responsibility and accountability come pride, ownership and discipline. The result? Very low error rates. As companies become larger and more “impersonal”, individual responsibility and accountability can be easily lost, with disastrous consequences. Don't ever let this happen!

RULE EIGHT: FOCUS ON “EDUCATING” YOUR WORKFORCE

“Your products are only as good as the people making them. Education is thus central to reducing error. It is essential to understand the difference between education

and training. A dog can be trained to sit up and beg, but it doesn't understand what it is doing or why it is doing it. You want educated staff, not trained staff!

Your training materials and training sessions should...

- > Take due account of the importance of the brain's “reticular activating system” in effective learning
- > Satisfy all four adult learning styles
 1. Auditory/visual
 2. Visual/intellectual
 3. Intellectual/somatic
 4. Somatic/auditory
- > Ensure “whole brain” training – that stimulates both the left and right sides of the brain

If they don't, you are not getting the most out of your training programme.

Do you want to learn more about how to apply these eight rules in an integrated way to reduce human error, increase “right first time” quality, reduce reworks, rejects and recalls and improve compliance?

If you do, you should attend our training course “Human Error: Causes and Prevention” visit www.nsf.org/info/pharma-training for more information on the next available course.

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. June 2017. Human Error: Causes and Prevention. 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 | www.nsf.org | www.nsfpharmabiotech.org

LPH-432-0517