IMPROVING HUMAN RELIABILITY: BATCH RECORD SIMPLIFICATION

A CASE STUDY OF WHAT IS POSSIBLE!

by Martin Lush

For those of you who have attended our very popular *Human Error Prevention* course, you will know that many errors are caused by the very documents designed to prevent them. This applies to batch manufacturing records (BMRs) and SOPs in particular. These documents can often be:

- Poorly designed
- Difficult to follow with too many words and not enough pictures and schematics
- Written by the wrong person using language the users simply can't understand
- Often written for the auditor rather than the user
- Too complicated, leading to brain overload

We worked with a major pharmaceutical company recently to help simplify its BMRs. This is what their staff have achieved using the tools and techniques we provided on a three-day simplification workshop.

Not a bad return on investment!

This is the process we used:

1. **Get the right people** in a room, off-site (no distractions) and with lots of flipcharts, food and drink! By the right people, I mean those who are knowledgeable, will speak their mind but are open to new ideas. Key representatives are needed from:
   - Manufacturing, the primary user group. The presence of operators is vital
   - QA (including the QP)
   - Development
   - Regulatory Affairs

2. **Select the BMR you want to simplify with care.** Don't go for the largest or most complicated. Cut your teeth on something a little easier in the first instance. You want to succeed. The more challenging BMRs can wait until later
3. **Get the group to agree on the core purpose of the BMR.** This is not as easy as it sounds, as everyone has a view. But for clarity, the BMR exists to:
   - Provide essential instruction for the users
   - Provide a reliable history of events: the who, what, when, where, how and what if (problems)

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Starting point: The BMR in 2011	→	Progress so far: The BMR in 2014
Review and approval time = 1.5 hours	→	Review and approval time reduced to 30 mins
237 pages	→	Simplification reduced BMR size to 72 pages
Right first time = 62%	→	Right first time = 96%
Number of signatures 110(!)	→	Signatures reduced to 23
BMR owned by QA	→	BMR owned by Manufacturing
Average number of errors/BMR = 28	→	Errors reduced to an average of 3
Order due date performance 76%		99% of batches released on time

- Provide enough information for QA releasing officers (QPs) to confirm the batch has been made to GMP and is safe, effective and of the right quality

4. **Get the individual groups working.** Ask each group to take a copy of the BMR and a fistful of highlighter pens (low-tech is always simpler, better).
   - The regulatory affairs team focuses on highlighting parts of the BMR that are referenced in licensed documents
   - Your development people are charged with highlighting process critical control points that directly impact on product quality
   - Your operators and manufacturing colleagues' job is to highlight essential instructions needed to do the job
   - Your QA folks focus on highlighting essential GMP requirements
5. **Managing the input: Starting the simplification process.**
   - Get an electronic copy of the BMR up on a screen for all to see
   - Go through the BMR line by line, page by page
   - Each group decides what must stay (the highlighted text) and what can be removed to the electronic waste bin
   - Take a break (trust me, you will need it) and revisit the waste bin. Apply simple risk assessment to see if what you have removed should stay removed, or not. Resist putting information back "just in case"
   - At the end of this process you have taken the BMR back to basics. Now that you have removed unnecessary content, you can focus on…
6. **Redesign of the BMR.**
   - Print out the information
   - Grab some scissors and glue (this is the bit most adults really enjoy)
   - Redesign the BMR the old fashioned way, ie by cutting out the key steps and arranging them in a chronological flow chart

One health warning. This is not as simple as it sounds – it's actually very hard work. Follow this process and you will get differences of opinion, arguments and resistance to change driven by fear of the unknown and, on occasions, lack of trust. But simplification reduces ambiguity and error; and everyone will always agree to avoid complexity.

If you would like more information on the above process, please do get in touch with our simplification experts, Martin Lush (martinlush@nsf. org) or John Johnson (johnjohnson@nsf.org). We have hard-won experience in this field and a proven approach used across a range of cultures, pharma dosage forms and technologies.

If you are passionate about simplification listen to our free webinar, scan the code alongside.

…and don't miss NSF Health Sciences' Human Error Prevention group on LinkedIn, scan the code alongside.

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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