



# YOU MAY HAVE WON THE BATTLE, BUT HAVE YOU WON THE HEARTS AND MINDS?

by John Johnson

**John Johnson recounts an assignment where the easiest step to take was to change the SOPs and batch records, but would this alone lead to the business improvements that were so sorely needed?**

Everyone thought they knew the source of the problem, yet no one had articulated what the problem actually was. Everyone was pointing a finger at someone else, but no one was looking close to home. Everyone had tried to fix the SOPs at some point, but nothing had really improved very much or for very long. Alternative ways of working, some undocumented, were in place just to avoid having to tackle the real issue.

**THE PROBLEM WASN'T BETWEEN THE PAGES OF THE SOP, IT WAS BETWEEN THE EARS OF THE SUBJECT MATTER EXPERTS.**

If transformational change was only about changing work instructions and barking out the new way of working, wouldn't change happen much quicker? But it doesn't, does it? In fact, more and more SOPs, more complexity and more written guidance, more emailed podium statements and more corporate guidelines have a tendency to confuse, frustrate and distract us from doing the **right thing at the right time, for the right reasons**. Autocratic, single-layer solutions rarely solve anything. Yet in the heat of battle, some firms still lose sight of what is truly important to make transformational change proportionate, risk-based, owned by the team and durable for the long term.

Our client knew that the batch record had grown incrementally over the past five years, having reached version 24 in no time at all! But all attempts to improve right first time, batch release lead times, operational performance and yields had failed at the first attempt. Why? Because they had not considered the single most influential and complex factor in the operation: **the team of workers who actually do the jobs each day!**



Once NSF was engaged, we set out to experience the production process ourselves through observing the shop floor, talking to staff who do the tasks and seeing the process from end to end. We watched the ridiculously complex nature of the processes the operators had to follow, the overly complex SOPs no one read, and the completion of the batch record sheets. The batch record, for a single shift operation, had over 90 pages and over 500 separate entries. We evaluated the tools the operators were given to use (largely ancient and in poor repair). We watched the techniques they were expected to perform (many irrelevant or fraught with error modes) and we evaluated some of the workarounds they had to do to get the job done (many of which were not prescribed in SOPs or recorded in GMP worksheets).

We also spoke to the team who was responsible for performing the work, asking questions, listening to the answers and asking for input. **We solved problems for them immediately and this rapidly built trust and credibility.**



Utilizing a range of techniques including voice of the customer and FMEA, over a three-week intensive period, we were able to propose (in full support of the line managers and with full input from the shop floor) a new batch record that stripped out as much complexity, error mode, transcription requirements, calculations and ambiguity as possible. This proposal reduced the number of pages by almost 60 percent to less than 35, and reduced documentation entries to less than 200 with 10 fewer transcriptions and no need to divide and reassemble the batch record. We utilized a regulatory compliance expert to tackle any local concerns regarding the registration and to help manage the batch record upgrade project as a change with only minor regulatory impact. The new batch record was clearer on what is important (inventory, critical process parameters, second person checks and process monitoring) and stripped out everything that didn't add value to the quality and GMP compliance of the process and product.

But, did this alone have the desired effect?

**If we had stopped there, the answer would be no.**

What made all the difference?

- > We got staff at all levels talking to each other, **and listening to each other.**
- > We made it more natural for line managers to coach their team, explain their concerns openly and consult/act on the feedback from the shop floor.
- > We helped line managers engender a new level of engagement with the shop floor, helping everyone to see the value they bring to the organization and why they should speak up, listen and act for the benefit of the organization and ultimately for the patients they serve.
- > We performed specialist customized training in root cause analysis, human error reduction, simplification and cGMP so that the team was left with the skills and confidence to find other projects that needed their rigor and attention. We also coached people on how to speak to each

other in a way that supports a blame-free culture.

- > Once the batch record was approved and in use, we came back and ran further checks to verify the change was effective and durable. We provided solutions to areas of further concern and we helped the team form a habit; a simple habit to seek simplification in every change being contemplated.

The results speak for themselves:

- > Right first time in documentation increased from 65 to 94 percent.
- > The number of deviations per manufacturing process performed was reduced by 45 percent.
- > QA batch release lead time for batch review and approval was reduced by an average of three weeks.
- > On time in full and schedule adherence improved markedly, with costly inventory reductions made too.

But what made us especially proud? It is quite simple. We loved the fact that late finishes in the evening dropped 30 percent, meaning people left work on time more often than ever before. Why was that so important?

Again, it is very simple. What does your family remember most...

- > The elegance and complexity of a deviation investigation report you had to stay late to write again, or
- > The fact that you made it in time for your child's school play, their birthday dinner or your parents' anniversary celebration?

Focus on what is important and make changes that help your organization and your team, and most of all, that benefit you personally. This approach, and a focus on human behavior, is what really drives long-lasting change.



## ABOUT THE AUTHOR



John Johnson is passionate about helping organizations foresee and overcome the barriers to sustainable long-term growth. He brings 28 years' experience across a range of companies in the pharmaceutical and healthcare industry. He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms. He has senior operational and corporate-level experience in operations and quality assurance and has led multinational companies in strategic projects associated with:

- > Inspection readiness and remediation (in UK, Italy, France, Australia, Singapore, India and USA)
- > Crisis management including handling of regulatory authority actions, multinational recall and import bans
- > Major culture change to improve customer service, quality, cost or "on time in full"
- > Installation, monitoring and periodic effectiveness checks on site or company quality management systems
- > Paradigm shifts including downsizing, upsizing, mergers and acquisitions
- > QP development, training, mentoring and resource management
- > Lean projects in QC laboratories and OSD facilities
- > Management review and escalation processes from shop floor to boardroom level

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Cite as: NSF International. January 2019. You May Have Won the Battle, But Have You Won the Hearts and Minds? NSF: York, UK.

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