



GETTING TO THE BOTTOM OF DATA INTEGRITY: FOUR TO EXPLORE

by Martin Lush

In our experience data integrity is usually the tip of a very big iceberg. Beneath the surface can be a number of contributing factors, rarely just one. These are mostly behavioral, not technical. If you don't want your business to be sunk by DI you have to fix what lies beneath the surface. So, in no order of priority, here are four major contributing factors:

1. IGNORANCE AND DISENGAGEMENT

As the old saying goes, ignorance breeds contempt. When people don't understand the "why" and the importance of what they do, they are more likely to just "check the box," no matter what.



KEY MESSAGES:

- > Make sure your training sessions provide context and the reasons behind the rules. Explain the potential consequences to the company and its patients when DI is not maintained. If you can't make these personal, emotional and relevant, you've failed
- > Education alone won't work. The job of leadership is to create the culture to make it work. The job of shop floor supervision is to maintain high levels of engagement to keep the check box mentality at bay. If your supervisors and first line managers are not visible, approachable and proven educators, don't be surprised if the team switches off

2. PROBLEMS ARE BAD, LEADING TO FEAR

For those of you who have attended our courses on Human Error Prevention and Deviation and CAPA Effectiveness, you already know our philosophy on problems, out of specifications and other such unplanned events. You will have heard our course tutors say, "Problems are great, the more the better," "The more problems you have, the greater your chance of success" and "You learn more from your problems and failures." But this is only true if:

- > You have an open and blame-free culture, one that encourages people to raise their hands when they make a mistake without fear of personal consequences



- > You have key performance indicators that drive the right behaviors rather than encouraging people to reduce deviation incidents. You actually want people to raise more because you can't fix problems you don't see
- > The incident investigation always focuses on the process, not the person
- > The actions taken concentrate on prevention of a recurring issue, not quick fixes

Contrast this with an alternative. I was curious about how a client improved its measure on "document right first time" from 70 to 95 percent with no apparent action taken to simplify or redesign the batch records. The reason for the improvement appeared obvious when I noticed that management had introduced a "three strikes and you're out" policy. On your third consecutive document error, you got fired. Of course, this drove human nature to seek ways of producing perfect documents regardless of the need for authenticity of entries, accuracy and timeliness. So, instead of looking for the real reasons for poor completion of batch records, management created a culture of fear that led to data integrity issues and, ultimately, risk to patients.



It's worth mentioning the impact of national culture here. It's a simple fact that in certain "saving face" cultures, notably in India and China, making a mistake can feel extremely uncomfortable. We may expect our colleagues to acknowledge their failures in front of their peers and bosses in public, but that's asking

a lot. Asking an organization to identify and seek continuous improvement, despite a historic prevailing local culture that often does not accept defaulting situations easily, is not at all straightforward. It requires a nurtured, long-term strategy that hardwires GMP into the organization's culture.

KEY MESSAGES:

- > When you have a culture of openness and transparency, you are well on the way to fewer DI issues. Providing that is, you always use mistakes and problems as a catalyst for continuous improvement. Remember, focus on the problem (not the person) and on performance improvement (not punishment)
- > Make sure your KPIs drive the right behavior and that your leadership, at every level, creates the see it, say it, solve it culture. If performance data is too good to be true, it probably is. Very low levels of deviations and OOSs? Zero counts from an old, low temperature purified water system? No calibration failures? Perfect environmental monitoring data, always? Start digging. Focus on the culture, leadership and KPIs first. Be curious and be challenging, even when the data looks good

3. OVER-COMPLEXITY, SYSTEMS NO LONGER FIT FOR PURPOSE AND THE DANGER OF THE WELL INTENTIONED SHORTCUTS

I can remember looking through a 420-page batch record impressed by how neat and aligned all the signatures were. There were precisely 175 signatures for each batch record. I counted them. Alarming, every page was pure white. Not a mark, stain or blemish anywhere to be seen. As an ex-production guy, I knew this was just too good to be true so I started to dig, looking at the signatures. The who, when and where. I eventually



found one operator who managed to be in four different rooms all at the same time. Because of the complexity of the batch record and the excessive number of check signatures required, it was physically impossible for the manufacturing team to make the product and fill in the batch record at the same time. That task was done over a cup of coffee during break time!

Here's another example of "too good to be true." While looking at final yield trends it was evident the liquid filling line was losing product somewhere, yet all in-process checks for fill weight were perfect. I went to the filling room and within seconds understood why. The batch record was on a table toward the back of the room, some 10 meters away. The operators couldn't operate the line and complete the IPC check list at the same time, so they just recorded the target weight. Why didn't they flag this? Fear of raising a problem, and a fear of flagging a need for change. Operator ownership, engagement and empowerment were also lacking.

KEY MESSAGES:

- > High levels of complexity increase the likelihood of data integrity problems. Win your war on complexity and you are a long way toward reducing your risk
- > If you want to start somewhere, focus on simplifying SOPs. In our experience most are overcomplicated, poorly designed and unworkable. So many production lines and labs rely on well intentioned shortcuts just to get the job done. SOPs written without user input will fail
- > Adding additional check signatures is not the answer. This creates a false sense of security and dilutes that all important accountability
- > Go to our Library <http://www.nsf.org/info/pblibrary> and watch our webinar 'The art and science of simplification – how to win your war on complexity'

4. THE HUMAN ELEMENT – COGNITIVE, PSYCHOLOGICAL AND PHYSIOLOGICAL FACTORS

People do the best they can with what they have. Even the most diligent staff makes mistakes that can easily be interpreted as a data integrity problem. Stress, fatigue and distraction are three contributing factors to making a mistake. Once again, your leadership skills are crucial in creating a culture that promotes accuracy and authenticity.

DI problems are a product of conscious as well as subconscious behaviors. Since 45 percent of decisions are habitual (subconscious), we really need to work hard to understand them. Remember, behaviors are a consequence of:

- > Our culture and our upbringing
- > Our education and training
- > The actions of our peers
- > The equipment, systems and procedures we have to use
- > Leadership behaviors at every level



If you're serious about reducing your risk of data integrity issues, you simply must understand the behaviors first. Address your "Four to Explore" and you will be well on your way to reducing data errors and data integrity risks.



ADDITIONAL RESOURCES:

Protect your business from the “Data Integrity Iceberg”, utilizing:



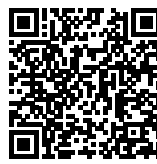
Our on-site and residential training programs on **Human Error Prevention** will provide invaluable guidance on human error, its causes and prevention.



We provide very comprehensive, customized on-site education in each of the areas mentioned in this article.



Get inspired and in the know by registering for our free webinars.



Our consultancy support on data integrity is second-to-none. We will help you to identify and remove the contributing factors that lead to data integrity problems.

ABOUT THE AUTHOR



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Cite as: NSF International. October 2017. Getting to the Bottom of Data Integrity. NSF: York, UK.

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