



# GETTING TO THE BOTTOM OF DATA INTEGRITY

## UNDERSTANDING THE THINKING THAT DRIVES THE BEHAVIOR

by Martin Lush

Many years ago I had the pleasure of being audited by Dr Ronald Tetzlaff, one of the most systematic, organized and methodical FDA investigators I've ever met. He could find problems you didn't even know you had. Ron reputedly said "If it's not documented, it hasn't been done." Well, reading about the data integrity issues exposed by regulators, it seems that even if it has been documented, you can never be sure! Before we go any further, let's get a few things straight...

Firstly, data integrity is a global issue and not restricted to one particular marketplace or region of the world. It is also not new. Problems with data integrity have been around for years. Secondly, data integrity problems are not restricted to the QC labs.

### DATA INTEGRITY: ARE YOU AT RISK?

Just answer the following questions to see if your ship is heading toward the "data integrity iceberg." Get together with your colleagues and answer yes or no – don't do this in isolation!

- > Have you seen data that is just too good to be true?
- > Are your batch records or QC records pristine and beautifully presented?
- > Do you consider deviations, OOSs and the like to be an inconvenience or just plain bad news?
- > Are you focused on driving down deviation incidents?
- > Is the root cause of many of your deviations so called human error?
- > Do you have a blame culture? Ask people on the shop floor before you answer this!
- > Do you train your people to push the right buttons, without explaining the why?



- > Do you blame people for mistakes, rather than focusing on the systems and procedures?
- > Are your systems and procedures overly complex?
- > Is your company's primary focus to get product out of the door no matter what?

**If you have too many yes's, start taking action now** – you are on course for a data integrity problem.

We help a lot of companies permanently resolve their data integrity problems by first understanding the root causes for the behaviors that drive the actions. Only when you understand the "why" can you make a difference. In our experience very few people are truly malicious in their intent. OK, there are always, thankfully very rare exceptions but most people go to work to do the best they can, with the knowledge they have and the tools (the systems, procedures and practices) at their disposal. Let's start with a few examples:

### COMPANY A:

Each 25 kg container of API had to be identified using NIR. The only problem was that the NIR test station was on the other side of the warehouse. So, instead of testing all 250 containers and moving 6,250 kg (my back is already twinging), samplers devised a cunning plan. They took all 250 samples from one container instead. Although they had been trained on how to take samples, they were not empowered and had not



been educated as to the reasons why and, in particular, the impact on product quality and patient safety. Whether the samples were representative or not didn't even enter their minds. Now, you may be shaking your heads in disbelief, but you can understand where the samplers were coming from. The solution? Better education, and investment in a portable NIR scanner. NOT adding additional checks, additional procedures or worse still, disciplining those involved. You must do all you can to avoid driving problems underground.

## COMPANY B:

During completion of a batch record, a page containing raw data was replaced. The original contained multiple errors and looked, in the words of the operator, "embarrassing, untidy, and shameful." All the data was transcribed accurately, just without the multiple corrections and supporting signatures and dates. Most of you will be shaking your heads (even more vigorously this time), thinking signed and dated corrections are fine. Well, not in this "saving face" culture where overbearing hierarchy, deference to authority and poor education as to the "why" led to a very different behavior. The solution? Not so simple this time, so please read on!

## DATA INTEGRITY: WHAT DOES IT MEAN ANYWAY?

Most people care about what they do. When they understand the "why" and they are risk-aware, then they really understand the impact of getting it wrong on patients and end users. The term data integrity, or DI, suggests a basic accuracy or authenticity concern when in fact that is the symptom, not the cause. The true root cause of DI issues lies with education and the culture of supervision and management.

I sat through a client's DI training session the other month that emphasized "its vital importance for compliance and license protection", and how data integrity was an "essential part of Good Manufacturing Practice." I'm sure everyone left the room as disengaged from DI as when they entered. I doubt if behaviors changed. Contrast this with another client, who, with our input, took a very different and more personal approach. "Data integrity" didn't even appear in the session title. This highly interactive session entitled Personal Integrity: Telling the truth and nothing but, addressed:

- > How the medicines they manufactured worked and the difference each made to the quality of life of their patients
- > The trust patients place in each and every one of them... to get it right every time
- > The complete product lifecycle from research to commercialization. Who did what and why, and where specifications and procedures originated from
- > How manufacturing and marketing licenses (their licenses to operate) are granted based on DATA and TRUST
- > How regulatory inspectors assessed the company's competency to operate based on the data they review, what they observe and TRUST
- > What can go wrong when the data trail (story line) is either corrupted or lost and how this also erodes regulatory TRUST, which then takes years to rebuild
- > Personal accountability for making sure the data recorded is factually accurate and tells the whole truth and nothing but the truth
- > How QA relies on data to release each batch; inaccurate data can lead to wrong decision making
- > Practical examples of what could go wrong if data was inaccurate or unreliable, always linking back to patient impact
- > That data integrity is about the documentation and the data telling the story of the what, who, how, where and what if

Participants were provided with a fictitious batch record with errors and mistakes and given 30 minutes to find them and come to a decision. Release to market or not?

The most memorable part of the session was the 15-minute wrap-up by a member of the leadership team who emphasized that "we are only as good as our data" and that "everyone is accountable for its accuracy." One point struck a chord with me: "Whenever you record or sign anything, just tell yourself that, by doing so, you are releasing the



batch. You are each accountable.” She also said that leadership was responsible for “providing the systems, education and culture to ensure this happens every single day.

## KEY MESSAGES:

- > The term data integrity hardly does it justice. If you want people to really get it, make it personal, emotional, meaningful. If they don't see the “what's in it for me” and feel connected, why should they bother? It's not about compliance, it's about the patient
- > Always check that your culture, systems and practices drive the right behaviors. Use anonymous surveys, walk the floor – anything that gets you to the truth
- > Train your auditors in how to detect the real causes of data integrity issues, most of which are behavioral, not technical

## 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.



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



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



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



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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