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"Thoughts about some Root Causes for Pitfalls in Data Integrity"

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Writing this article, I want to share my thoughts about some real Root Causes for Data Integrity problems, those which are usually not tackled or even dismissed!

DI (Data Integrity) is being a buzz word for a long time. Inspections find the significant gaps that led pharmaceutical companies to spend a lot of money and resources in order to deal with this matter.

Let's see the definition DI.

"Data integrity is the degree to which data are complete, consistent, accurate, trustworthy, reliable and that these characteristics of the data are maintained throughout the data life cycle. The data should be collected and maintained in a secure manner, so that they are attributable, legible, contemporaneously recorded, original (or a true copy) and accurate. Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices" (MHRA Guideline).

When we look into the documents, DI guidances, whether of health authorities' or companies', they are focused on:

1. Preventing unintentional mistakes or failures, e.g. transcription errors, data loss
2. Making the intentional change more difficult
3. Company's ability to ensure and prove that intentional and unintentional data change and loss are unlikely to happen

All the written in the guidelines is important, but I would like to address and focus on **the Root Causes for Intentional data change**, since this is inspections' and companies' main concern and the most severe case. We should take into account that even when all DI measures had been taken properly, but root causes missed, there will always be a way to "cheat". I refuse to believe that people cheat because they are "born to lie", at least, such assumption should not be considered seriously as the root cause for DI.

Today the **possible root causes for intentional data change receives very little, if at all, attention, or being defined too generally, e.g. "company's culture"**.

Some possible root causes for DI are discussed below. Some of them are not the final root causes rather the significant milestones on the way to take care of the root cause. Their order does not have any significance and they are frequently overlapped, and connected to each other etc.:

1. **Poorly developed and not reproducible analytical methods/ processes** wherever they come from to the site: being transferred from the other site, from R&D, methods from customers or clients, methods which became non-robust due to not fitting for the purpose because of, for example, changing the specification, e.g. tightening or introduction of the new impurity to the same method, or even compendial methods.

We should not rely on the "perfect" validation report, and not because of somebody might suspect possible data manipulation or "wishful thinking", rather the validation of analytical method is merely spike in the product's (method) life cycle which has been running for long years at site/s. BTW, this is exactly what product/method life cycle management is talking about.

2. **Department/Site/Company culture being, mostly, based on evaluation of people by execution**. They may include: downplaying person's attitude/role, probably unopened, criticizing atmosphere in the department/site/company not encouraging improvement and I do not mean the Operational Excellence, Lean processes/structures, 6 Sigma etc. People do not feel they are encouraged either to raise the problem or to solve the problem by themselves. Sometimes one may here from the "business-oriented managers" "We do not have a time, just release if the product is good, otherwise reject".

3. Sometimes one can hear from his/her manager or supervisor "**I do not neglect the problem, I do encourage to solve, but what can we do when…**" followed by various excuses. Partially, the "problem" is that the pharmaceutical industry is a strictly regulated environment in which continuous improvement, especially in the laboratory, is hindered by "local" regulation, marketing barriers etc. I mean **alleged regulation barriers**, those regulatory "barriers" which are sometimes created by site/company itself, e.g.:

- "Regulatory reason" claiming that the improvement is Prior Approval change, whereas the change is annually reportable (here FDA terminology is in use but similar in EMA in different words), e.g instead of "Do and Tell" the site is working "Tell and Do".
- "Money" reason "the submission of the change costs money"
- "Customer service and marketing reason" saying "the customer/s will not agree with the change"
- Another "Regulatory reason" saying "lets submit later because this is not the right time to submit the change" etc.

As a result of the above we can hardly expect people to feel encouraged and then, not surprisingly, there will be "the other solution" found to "solve the problem" and complete the task, e.g. release the product (batch record or test) for the next stage, release on the market etc. And this "the other solution" is a problem. You remember another buzz word "continuous improvement", we love to use, but do we really follow this?

4. **Professionalism of the next level managers and all personnel**. In simple words, if personnel on the shop floor is either incapable or not allowed to find and implement the correction/solution (actually this is the situation), whereas the next level manager is unavailable or incapable to professionally support the subordinates in problem solving, the problem will stay and the shop floor personnel (at the bench and production line) will continue live up with it. So, this is our/company choice whom we want to see at the bench, on supervisor, reviewer and managerial position. And if we prefer to see on the managerial level more managers/administrators than professional chemist/analyst/engineer/technician, we must take care to have/recruit the appropriate managerial personnel having sufficiently strong professional background. Then such managers will take care and be capable to facilitate the implementation of the correction/improvement. It will never work, if through the bottom (bottom level supervisors) to upper managers only administrative skills are valued. People at the bench, on the shop floor, need managers/supervisors who can understand the problem, otherwise the company has communication breakdowns.

These are just a few thoughts which we should consider in order to avoid inappropriate behaviors and create healthy environment/atmosphere when we talk about data integrity.

Note: references are not specified in this article, if needed, search the web, for "data integrity in pharma".