Untouched area of Data Integrity in Pharmaceutical Industry

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Now a days the topic "Data integrity and non compliance" is the hot topics. Lots of references available online that deals with the Data integrity issue.

One of the major example am going to give today, that can be control by the management only.

Extended shift/working hour or over time:

We know that "Human error" is the "Risk" for GMP. For this reason we always induced technology/automation everywhere and try to reduce the human intervention as much as we can.

Because humans are driven through emotion & sentiments. Mental peace and physical relaxation is just like a preventive maintenance for human being. As we sent our automobiles for maintenance or servicing with defined interval, same as our human body deserves too.

We know that during audit preparation or other priorities we need to stay for extended hour. But if it is a regular or routine job then it caused frustrations and from where the chances Non compliance or data integrity begins.

We should consider this as one of the reason of Data Integrity. Otherwise we can't able to trace and rectify the real root cause for non conformance. We should focus on the time management & work Vs man power planning.

For Example: One of the major regulatory body ask for the attendance register/log for all employee before one week of proposed audit date and they found that majority of the people are staying more than 12-14 hr in the organization. Same they have reverted as a major observation and they ask for a justification and proper CA-PA from the management. *Why employees are started staying for an extended hour before audit?*