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NSF Health Sciences Pharma Biotech Consulting

Characteristics of Highly Reliable Work Units

by Jim Morris, Executive Director, NSF Health Sciences Pharma Biotech Consulting

This is the second installment in the NSF Health Sciences educational resource series on Human Reliability Improvement.

The traditional belief is that human performance is a worker focused phenomena. It is often assumed that if companies were to simply get rid of the poor performers everything will be fine. Furthermore, it is assumed that fault lies with the worker rather than with the company and its systems. Nothing could be further from the truth! While humans may be prone to error and whim, our work environment has a huge impact on our performance. Simply put, the risk of human error is a function of our performance, in the environment, while completing the task at hand.

Error Chain

Performance + Environment + Task =

Risk of Human Error

In order to reduce risk we need to understand the error chain or factors contributing to human error

If the task at hand is well understood and our environment conducive to carrying out the task; AND we arrive ready to perform the task, i.e. "fit for duty", the chance of error is close to nil. How do we consistently minimize the risk of human error as shown in the equation above?

This paper outlines five strategies to improve processes with the goal that no error should occur twice, let alone a third time! The basic premise is that ALL errors can be avoided and human reliability can be maximized if we plan, anticipate and help our personnel succeed in their work. If a unit operation experiences a repetitive error, it must be recognized that there are flaws somewhere in the operation. People must act accordingly to identify, remediate, and re-engineer the work processes to eliminate the root cause(s) of the error.

"No error should occur twice!"

Five areas of focus to reduce human error and build highly reliable work units:

1. Define the scope of work

Human error increases when expectations and tasks are not clearly defined. Boundary error is that error which occurs when roles and responsibilities (e.g. who does what) are not clearly defined. This is a common weakness in many organizations and work units. Supervisors and managers need to define the scope of work, clearly determine who is responsible and accountable for specific tasks, and clearly communicate these responsibilities verbally and in writing.

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2. Provide tools and resources

Our innate ability to be creative means that people come up with workarounds, i.e. short cuts to ensure the job gets done. We improvise! For some cultures improvisation is so engrained it is tantamount to survival, however in the pharmaceutical industry we should equip our work units so improvisation is not required. The right tools and supplies, in the right place, at the right time! One of the best unit operations I have seen was a tooling operation in a plant in Puerto Rico where every machine tool and die was neatly stored to facilitate inventory counting and, importantly, protect the tools from damage. Spare part inventory levels were color coded – green meant inventory levels were okay while yellow meant the unit had to submit a request for new parts. The unit was designed to ensure tool room personnel had the means to offer excellent customer service to their manufacturing colleagues.

3. Analyze and categorize error prone situations

Characteristics of work units which strive to be best-in-class include job side reviews, pre job briefings, and a questioning attitude. These teams are always improving, always communicating, and preparing for the upcoming work. They know that error prone situations are predictable, manageable and preventable. In conducting audits for error prone situations, the best team includes personnel close to the operation along with experts who have little knowledge of the operation. This combination of unbiased and "biased" personnel from the work unit helps uncover those areas most prone to error. These teams prepare for an audit, prioritize the area (s) they intend to focus on during the audit, and stay together during the audit challenging, probing and asking questions of personnel. It is fascinating to see how even those closest to a work unit overlook "error prone" situations until challenged by an unbiased, trained observer.

4. Performing work

Task execution is typically the function of a work unit operating cohesively across shifts or a project team operating cohesively across time-zones. Characteristics of work units intent on reducing the probability of error include:

- Checking, pausing and asking "am I doing this step correctly?"
- Culture to empower personnel to stop and ask when unsure
- Constant communication amongst the team members
- Consistent use of procedures
- Hand-offs between people and shifts are executed confidently

In these teams there is a high degree of assurance that the handoff between shifts will occur flawlessly. It's because they work hard at communication!

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5. Feedback and continuous improvement

Conducting a post job (or post action) review is probably one of the most important tools a supervisor or manager can deploy. In this exercise the team members come together and share what went well, and what didn't go so well, after an operation is completed. The team covers:

- Quality of work documents"
- Knowledge and skill shortcomings
- Unanticipated site conditions or surprises
- Adequacy of tools
- Clarity of the work plan

Th best work units and most effective organizations take post action reviews incredibly seriously. It is embedded and part of their planning processes. Once a batch or job is completed time should be taken to review what went well, what issues occurred, and what needs to be considered next time the operation is run.

If you have responsibility for a team or work unit undoubtedly you are juggling a myriad of tasks from scheduling to budgeting to project management. Meetings consume a lot of your time and you use the evenings and weekends to "catch up". If you put the principles outlined above into sharper focus and steadily work towards assuring these characteristics are embedded in your work units you will quickly see results. And, maybe even recover a few evenings and weekends for personal time!

About the Author

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Jim Morris has over 25 years of pharmaceutical management experience in both plant operations and corporate offices, working with Pfizer, Cilag AG and Mass Biologics in the U.S. and Europe. He has held positions as Deputy Director QA/QC and Regulatory Affairs while at Mass Biologics, Director of QA/QC for the Biologics business unit of Cilag AG and a number of quality assurance and manufacturing roles with Pfizer over a 16-year timeframe, culminating as the head of Quality Assurance for Pfizer in Latina, Italy.

His areas of expertise include quality leadership training, human error training, sterile manufacturing, quality management systems and auditing programs.

Cite as: NSF Health Sciences Pharma Biotech. August 2015.

Characteristics of Highly Reliable Work Units. NSF: Ann Arbor, MI.

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