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Human Reliability Improvement:
How to Reduce Documentation Errors

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In a world where we are consumed by data transmitted electronically to every device imaginable, how is it that we continue to be plagued by documentation errors? Despite the availability of technology and the sophistication of manufacturers in their use of eBRS and LIMS systems, most manufacturers continue to rely heavily on paper-based systems. Furthermore, many of the design flaws embedded in paper-based documentation systems exist in electronic systems. Remember the adage, "Garbage in – garbage out." Often electronic systems are designed around what was managed on paper as opposed to best practices for electronic data input, and the same weaknesses persist in electronic form.

In pharmaceutical manufacturing, the impact of documentation errors can range from being a nuisance to stopping product release and putting patients and company reputation at risk. Consider the following scenario:

> *Operator signatures confirming filter integrity testing are found to be missing during the final batch record review. The batch records had recently been modified to capture filter integrity testing in the batch record as opposed to documenting the results using a separate form. In this case, the day shift filling operator had requested that integrity testing be completed by the second shift operator. These instructions were misunderstood and the second shift personnel skipped the new section of the batch record and therefore failed to document post-use filter integrity test data. Despite passing sterility test results, the manufacturer could not develop credible evidence that the filters used passed integrity testing after sterile filling. This put sterility assurance of the batch into question and QA had little choice but to reject the batch!*

This simple error in documentation ultimately would have a significant impact on the company, both financially and in planning a replacement batch. Worse, had the omission not been caught prior to product release, patients might have been put at risk.

Whether the documentation error represents a minor or serious incident as in the above example, there are steps companies can take to reduce the probability of error. While this paper will offer a number of recommended actions, it is necessary to put these actions into context. Pharmaceutical manufacturing demands attention to detail and yet personnel typically operate in an environment prone to distraction, interruption, schedule changes and a demanding workload. In general, people's mental capacity is limited and frequently personnel are simply overloaded; therefore, whatever can be done to standardize and simplify work will go a long way. Consider the following actions which can be taken to reduce the probability of documentation error.

- Apply judicious and consistent attention cues in documentation
- Develop a user-friendly documentation structure
- Ensure documentation is accessible to the users
- Ensure training programs are effective

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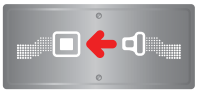

Attention Cues

An attention cue is any label, device or mechanism that gets our attention to perform an action, to highlight a difference between things or to distinguish a change. An example of an attention cue in daily life is the traffic signal, whose colors alert us to stop, go through or slow down. Another example is the biohazard symbol used on waste containers in a hospital which warn us to include only the appropriate materials and avoid contact with the contents. The "fasten your seatbelt" symbol on commercial airlines is yet another example of an attention cue in daily life. As companies develop their manufacturing process documentation, it's wise to consider the effectiveness of various attention cues.

Some attention cues are more effective than others as the human brain processes different types of attention cues in different ways. Indeed, some cues are universally given a higher priority than others as shown below. For example, sound is processed by the brain as the highest priority. Motion, colors and shapes are higher priorities than simple text. The example of the missing integrity test signature illustrates that written instructions alone are not the most effective way to get someone's attention to perform an action, especially when the text is new. A way for the company to have flagged the required signatures might have been to highlight the new text in a colored font or enclose the section of text in a box.

Companies need to be sensitive to two things – changes can be overlooked due to habits that are already formed, and cues should be used to flag differences until new habits are formed. This knowledge helps companies design process and control documentation that will minimize the probability of omission error and improve "right-first-time" metrics.

1. Sound
2. Motion or Pattern Change
3. Colors
4. Shapes
5. Text

Documentation Structure and Accessibility

Attention cues such as images, color and shapes can be integrated into text-based documents to draw attention to key actions. Attention cues should be consistently and judiciously used. Too many will overwhelm the user and the inconsistent application of attention cues will only lead to confusion. The visual structure of a document can also impact the reader's attention. The following factors influence our visual attention and focus:

- **Area of interest –** Where the information is located
- **Saliency –** How the information stands out from its environment
- **Effort –** How much eye and body movement is involved to gather the information
- **Expectancy –** How often something expected happens

These factors become even more important when you consider how quickly we scan documents when looking for information that we need to carry out a task. For optimum attention we should develop documents using:

- Changes in pattern, which helps the reader easily locate missing info
- Lines, boxes, highlighting, colors and shading to draw attention to key actions
- An information flow from top left to bottom right
- An information flow that follows the end user's process
- Embedded error detection and logic requiring data to be entered in a specific format. For example:

a. Record final Waste Tank reading and enter it in the **Final Reading** boxes.

b. Determine the volume transferred by subtracting the **Final Reading** from the **Initial Reading**.

Initial Reading: □□□□.□□
Final Reading: – □□□□.□□

Transferred Volume: □□□□.□□

* Volume should be approximately XXXX gallons more than starting volume.

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Additionally, documentation should be organized according to user roles and type of document. A documentation hierarchy should ensure information is cascaded so that the user can easily find the most relevant information, for example in this format: ***policies > procedures > work instructions > forms***. Basically, we should strive to make documentation as simple and uncluttered as possible and, importantly, available at the workplace – not in a supervisor's office down the production hall!

Effective Training

Once effective documentation has been developed and tested, end users must be trained in the proper use of the new documentation. The goal of an effective training program is to create patterns or habits that are consistently prompted by attention cues. Sensitivity to the ways people learn, and the importance of linking new information to what they already know, will ensure new habits are formed. Testing for proficiency will ensure personnel at least understand what they are being asked to do.

Conclusion

In conclusion, the significant oversight in the example above (missing integrity test data) is not only the omission by the operator(s) responsible but also the organization's failure to introduce a critical change in an appropriate way such as embedding attention cues where new elements of the record are inserted for critical steps, properly communicating and training personnel regarding the documentation change, and improving the "hand-off" which occurs between shifts. As in many cases where "human error" is cited, one can take the position that it is not the people who failed, but rather the system that failed the people. A well designed documentation system, combined with the appropriate introduction of documentation changes, will reduce and frequently eliminate documentation errors altogether.

About the Author

Jim Morris, MBA, MA. 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.

About NSF's Consulting and Human Reliability Improvement Program

NSF Health Sciences offers consulting services across the product lifecycle including quality systems assessment, preapproval inspection preparation, remediation, regulatory services, auditing and GMP training.

NSF Health Sciences' Human Reliability Programs provide a methodology that facilitates the identification of contributing factors and robust CAPAs to prevent re-occurrence. The program builds on investigation best practices with the ultimate goal of significantly reducing deviation re-occurrence rates.

References

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