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A Better Way To Document QMS Procedures & Work Instructions In Life Sciences Manufacturing

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Probably the most significant concern for anyone responsible for implementing, deploying, and maintaining a quality management system (QMS) is effectively and clearly documenting procedures and work instructions that are easy to understand and execute.

This article will first present the requirements regarding documentation of QMS procedures and work instructions and then introduce some methods that can be utilized to effectively and clearly document compliant procedures and work instructions.

Procedures were traditionally completely text only, occasionally supplemented by tables, figures, and process flow charts. With the advent of digital technology, organizations quickly realized that pictures could be integrated to help facilitate manufacturing, assembly, packaging, inspection, labeling, storage, and distribution activities. The future of procedures and work instruction will inevitably migrate to video.

Definitions And Background

There several ISO standards, FDA regulations, and international guidance documents that provide direction and lay out the framework for successfully implementing, maintaining, and sustaining an effective and robust quality management system, regardless of its type or size, or the products and services it provides, requiring the use of risk-based thinking and planning.

ISO 9001:2015 *Quality management systems* — To the extent necessary, the organization shall maintain documented information to support the operation of its processes, and the organization's quality management system shall include documented information determined by the organization as being necessary for the effectiveness of the quality management system.

ISO 13485:2016 Medical devices — *Quality management systems* —Requires the organization to document a quality management system and maintain its effectiveness and maintain procedures for manufacturing, packaging, storage, handling, and distribution.

ISO/IEC 17025:2017 requires the laboratory to establish, document, implement, and maintain a management system that can support and demonstrate the consistent achievement of the requirements of this document and assure the quality of the laboratory results.

FDA 21 CFR Part 211, *Current Good Manufacturing Practice For Finished Pharmaceuticals,* requires written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

FDA 21 CFR Part 820, *Quality System Regulation,* requires each manufacturer to establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured. The regulation further defines "establish" as define, document (in writing or electronically), and implement.

ICH Harmonised Tripartite Guideline *Pharmaceutical Quality System Q10* requires the design, organization, and documentation of the pharmaceutical quality system should be well structured and clear, to facilitate common understanding and consistent application.

The Evolution Of Procedures and Work Instructions

"Tell me and I forget, teach me and I may remember, involve me and I learn." — Benjamin Franklin

Studies reveal that individuals retain 10 percent of what they read, 20 percent of what they hear, 30 percent of what they see, and 50 percent of what they see and hear. Life sciences companies should consider embracing this information to improve their competence, awareness, and training activities by enhancing the format and technology behind procedures and work instructions.

There are many ways in which procedures and work instructions are used to facilitate manufacturing, assembly, packaging, labeling, storage, and distribution activities. Traditionally, procedures and work instructions were documented using text-only files, which can be very difficult for an operator to consistently use and execute on a regular basis, leading many operators to not read, or even not utilize, the procedures and work instructions.

The next step in the evolution of procedures and work instruction was the integration of digital photographs with text to communicate the necessary requirements, providing more information to the operator. This was a drastic improvement upon the text-only procedure and work instructions, because it effectively communicates more information. Procedures and work instructions that include digital photographs are now very common. But what is the next logical progression to communicate the requirements of procedures and work instructions? Embedded video.

Binders with paper procedures and work instructions were the traditional way most companies ensured operators and inspectors had point of use access to procedures and work instructions. However, with wireless inter- and intranets, many companies are now providing procedure and work instruction access through computers and tablets. With the transition from paper to electronics, now is the time to begin integrating and embedding digital video and voice into procedures and work instructions.

The Future Of Procedures And Work Instructions

According to James McQuivey's "equation," if a picture is worth a thousand words, then a 1-minute video has to be worth exactly 1.8 million words.

1. 1 picture = 1,000 words
2. 1 second of video (30 frames per second) = 30,000 words
3. 30,000 words x 60 seconds = 1.8 million.

Camera glasses are an excellent tool to record video and audio of the subject matter expert (SME) or lead operator performing manufacturing, assembly, packaging, inspection, labeling, storage, and distribution activities. The process for creating videos procedures or work instructions consists of the following eight steps:

1. Script the procedure or work instruction
2. Decide who will record and narrate the video
3. Record the video
4. Edit the video
5. Verify/validate the contents
6. Control the procedure or work instruction
7. Train the operators and inspectors as appropriate
8. Monitor the performance of the process

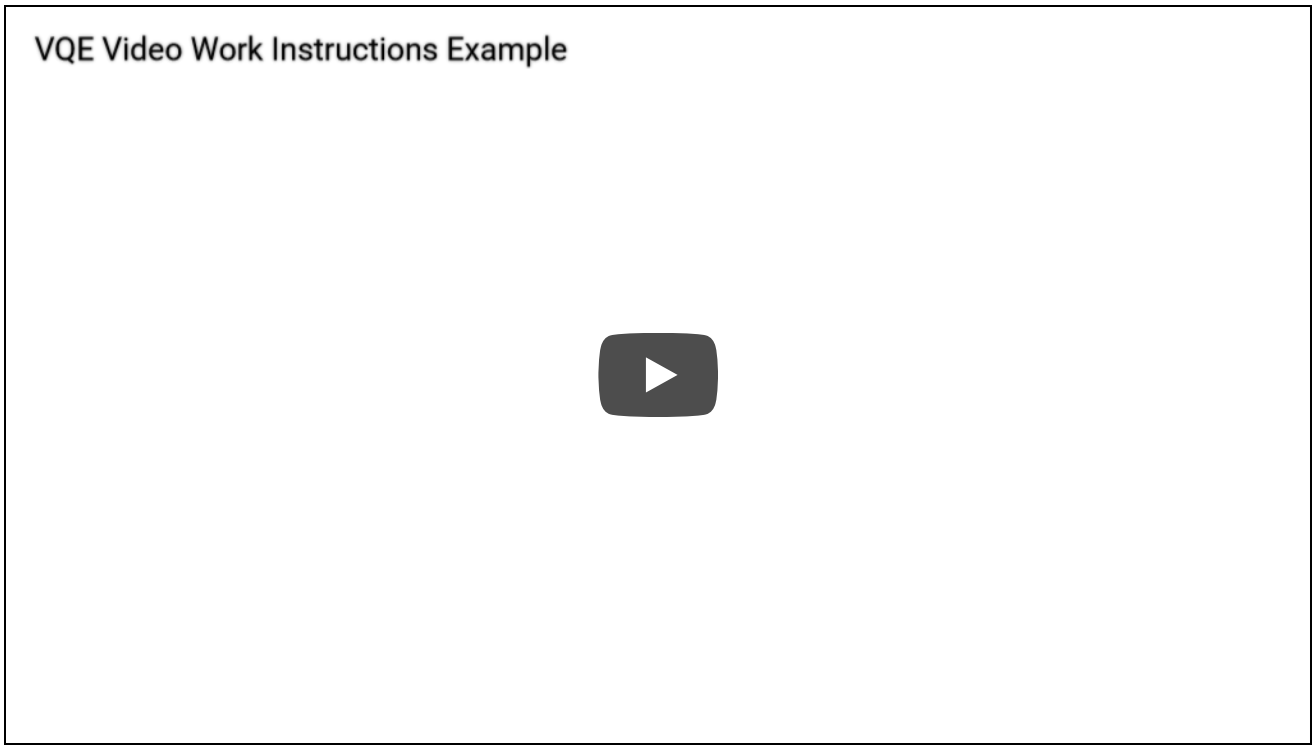
Once the raw video is recorded, the video can be edited to include references to drawings and specifications, zooming in to features for additional clarity, and even the inclusion of quality alerts. The video procedures and work instructions should be subject to the organization's document control and training requirements.

Video procedures and work instructions can be streamed to a computer, tablet, or even a cell phone at the point of use, ensuring the latest information is available when and where the operator or inspector is performing their task.

The camera glasses can also be used to record operators and inspectors performing their activities for critiquing and/or optimizing the sequence of operations. There may also be instances in which the organization may find value retaining the videos of the operators and inspectors performing their activities to support and become part of the production record, as well as for non-conforming reports (NCRs) and corrective and preventive action (CAPA) investigations.

Other possible uses of digital video could be recording data entry and query instructions for enterprise resource planning (ERP) transactions, demonstrating and teaching good documentation practices (GDPs), and even performing utility, equipment, and process validation and qualification activities.

Here is a sample video work instruction:



Conclusion

The discussion above has demonstrated how using digital video technology can facilitate manufacturing, assembly, packaging, inspection, labeling, storage, and distribution activities that support the QMS.

We cannot emphasize enough the importance of documenting the tools and methods used. The requirements and tools presented in this article can and should be utilized based upon industry practice, guidance documents, and regulatory requirements.

References:

1. McQuivey, James L.,de Lussanet, Michelle., Wilkos, Dan. '*How Video Will Take Over The World, What The Rise Of OmniVideo Means For Consumer Product Strategy Professionals*'. https://www.forrester.com, June 17, 2008.

About the Authors:

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