Reducing Human Error for Manual Visual Inspection

- Aseptic Processing & Sterilization
- Quality & Regulatory

Oct 26, 2023 by Vanessa Vasadi Figueroa, QxP and VVF Science, and Robert Ferer, QxP

Manual visual inspection remains a vital component for ensuring that contaminated products do not enter the supply chain and that parenteral drug products are safe for patients. The method for performing manual visual inspection in the pharmaceutical space is largely dependent on a well-trained and disciplined workforce. Human error reduction in pharmaceutical manufacturing has recently been a hot topic in the industry. Where humans are involved, the potential for human-related errors is also naturally present. However, human errors can be greatly reduced when ensuring that the right technical skills and personality traits are paired up with effective training and qualifications. Nowhere is this truer than in manual visual inspection, where attention to detail and knowing the right details to focus on are keys to many successful inspection outcomes.

Human Error Reduction Principles

Human errors have always been a concern in the pharmaceutical industry. The critical processing steps and techniques required to produce much of our modern medicine supply require almost flawless execution. For example, in the cell and gene space where a patient's cells are harvested to make a personalized dose of life-saving medication, human error can directly lead to a patient not receiving the required therapy. In the most severe cases, when an error occurs, these critically ill patients may not have an opportunity for a new sample of their cells to be taken and the medicine produced. This is just one example of why human errors continue to have a tremendous impact on the patients who rely upon life-saving therapies.

Human error is not only a factor in manufacturing and filling the product. For sterile injectable medications (parenteral dosage forms), manual visual inspection is also an area where focus on reducing human error is critical. The *United States Pharmacopeia (USP) <1790> Visual Inspection of Injections* ***(1)*** states, "100% inspection refers to the complete non-destructive inspection of the container–closure system and its contents". Manual visual inspection is performed by picking up a filled and sealed container(s), inverting, swirling, and then looking for visible particulates using a standardized light intensity against black and white backgrounds. Often referred to as the inspection booth, this area must be set up properly to ensure materials do not reflect light or produce glare. The position of the light source (or the position of the inspector) should be adjustable so that the height of the seated person can be taken into consideration when ensuring zero glare or reflection. "For manual and semi-automated inspections, the inspection environment should be ergonomically designed for inspector comfort," states the U.S. FDA draft guidance on visual inspection called Inspection of *Injectable Products for Visible Particulates* ***(2)***. Semi-automated inspection, in which a machine conveys a product to a human viewing station, shall be considered in the same context as manual visual inspection, as the human is the "detector" in both techniques. While non-human dependent fully automated technologies are available for visual inspection, manual and semi-automated visual inspection remain common practice.

USP Chapter <1> Injections and Implanted Drug Products (Parenterals)-Product Quality Tests mentions, "Parenteral dosage forms include solutions, suspensions, emulsions, sterile powders for solutions and suspensions (including liposomes), implants (including microparticles), and products that consist of both a drug and a device, such as drug-eluting stents." Through this general chapter, the requirements for 100% visual inspection originate. "Each final container of all parenteral preparations should be inspected to the extent possible for the presence of observable foreign and particulate matter…" ***(3)***. Inspecting each and every container is no small feat and requires a very specific skill set.

Recruiting the Right Individuals

Obtaining the necessary skill set for manual visual inspection starts with recruiting the correct individuals. Manual visual inspection requires perfect eyesight (20/20 vision at the inspection point, corrective lenses permitted), keen attention to minute detail, and the ability to remain focused for extended periods. It also requires other soft skills that can be considered personality-dependent, such as being comfortable working independently, staying seated in one location for the inspection duration, and not speaking for extended periods of time. These individuals must remain laser-focused and not be easily distracted when someone walks by or overhears a conversation nearby. Even a momentary glance away from the inspection booth could permit defective products to go through the viewing area unseen, especially in the case of a semi-automated inspection process. This type of discipline is uncommon and requires a unique skill set that must be properly recruited.

In addition, employers need to make sure that they are transparent about the type of work required, how frequent eye breaks will be, and outline clear performance expectations. Learning about a person's personality and having this open and honest discussion will ensure time and resources are not wasted on candidates who do not fit the required criteria. It is likely that the individuals hired may not have any previous experience with manual visual inspection, and potentially even within the pharmaceutical industry. Therefore, recruiting employees with prior experience will still require some background education about the specific products that are being manufactured and their inspection requirements.

Establishing a Learning and Development Plan

As adults, we learn differently than children. Becoming proficient at something new requires focus, repetitive practice, and sufficient time to absorb and retain the details. Manual visual inspection alone is not a complicated process. However, simple incorrect techniques, such as not gripping the container correctly, can cause an obscured area to not be seen by the inspector, and a defect could go unnoticed. Adults perform tasks better when they understand why they are doing something in a particular way. According to a study by Greater Good Magazine, "when people understand how their brains work and how to support their learning, they can learn just about anything" ***(4)***. Adult Learning Theory states "that adults will approach a training more enthusiastically if they can see how their skills will grow as a result" ***(5)***. Considering these two factors, a learning and development (L&D) plan should be established for visual inspection trainees. Individuals should have the opportunity to participate in building their curricula and have mentorship opportunities under other experienced inspectors as well.

Creating an appropriate L&D plan for new hires can also assist with educating individuals in a way that meets the person where they are in their learning journey. Using many training modes, having flexibility in delivering that content and a hierarchy of education can be advantageous when assigning L&D plans. The chosen individuals must undergo a multi-phased qualification process, which will be time-consuming for the individual, the company and the subject matter expert (SME) trainer(s). However, this detailed level of training is commensurate with the importance of visual inspection for parenteral dosage forms. This

process may include the following elements, a combination thereof, and perhaps more, as dictated by the company or its specific product(s):

Type of Learning	Understanding Why
General company knowledge and required training for employee orientation and good manufacturing practices (GMP).	Provide background and relevant regulations to establish context for visual inspection, as it relates to patient safety.
Specific knowledge about the pharmaceutical manufacturing process and perhaps the specific processes at the company.	This is necessary to assist in recognizing the types of defects that may be encountered such as flakes of stainless steel, glass particulate, fibers, pieces of elastomers, etc.
Fundamentals of sterility assurance, including container closure integrity testing.	Understand how and why contamination could enter the process or product, as well as how contamination is kept out of the product once it is sealed.
Learning about the equipment used for inspection, its operation, lighting, and the regulatory requirements for 100% manual visual inspection.	Ensure equipment, operating instructions for the equipment, and requirements for specific light intensity and backgrounds are fully understood, as they provide optimal inspection conditions.
Learning how to identify new defects and the various defect classifications.	Understand the possibilities for types of defects and how they present in various containers that are both general and specific to certain container-closure configurations.
Procedures for when to report potential defects and how to properly document their presence.	Provide inspectors with clear expectations on reporting defects and supporting documentation to ensure GMP.
Routine visual eye exams and prescription changes if needed for corrective lenses.	Ensure the visual acuity needed to detect fine details in various containers.
Repetitive practice with test kits.	Ensure that operators can remove defects with the required precision and at the required throughput that the organization has

Type of Learning	Understanding Why
	established for each product/defect classification.
Demonstrated performance qualification of the individual against predefined metrics for acceptability.	Provide documented GMP record of performance and release for routine execution of daily activities, thus ensuring product safety.
Routine requalification of individuals.	Ensure that individuals remain capable of performing this critical task to exacting standards.

Effective and Innovative Training

When evaluating different ways to train manual visual inspectors for parenteral dosage forms, consideration should be given to using new and interesting methods to engage these individuals. Incorporating multiple training modalities can be effective in embedding the lessons as well as turning an activity that is challenging and repetitive into a very positive experience. Examples of the various modalities include lecture-based videos by engaging SMEs or computer-based training that incorporates interesting visuals or stimulating graphics. These delivery modes can help adults learn by associating the topic with a positive learning experience, thus engaging more of the learners' senses by incorporating hearing, seeing, reading, and doing (hands-on). This ensures that the learning is more favorable towards retaining the necessary information. "Extensive hands-on training with containers that are defect-free and containers that have representative defects ***(6)***" is also required, according to **James Melchore's** article called *Sound Practices for Consistent Human Visual Inspection.* It is also possible to screen candidates using virtual adaptations of an inspection booth, thus reducing the burden on SMEs, equipment, and facilities. This can allow a company to ensure the right fit for the job while matching the candidate's desire with their abilities. Using an environment like virtual reality is risk-free and can even expose the candidate to the actual method's necessary rigors (i.e., duration, repetition, and conditions).

Once a candidate or trainee has completed the necessary screening and process training, they are ready for the hands-on portion of the learning plan. A complete set of containers with various defective characteristics and defect-free containers are provided to the trainee. The containers should align with the types of container closure configurations that are routine for inspecting that particular company’s product. The trainee is expected to identify and differentiate each of the defects. This is also an opportunity for the trainee to pose thoughtful questions to an instructor or to discuss other related defect categories. The interaction between an instructor, an experienced SME, and the trainee is critical to learning, understanding, and appreciating the criticality and subtleties of inspecting parenteral products. “There is no substitute for personal interaction between the instructor and student at various time points along the training,” says Melchore ***(6)***. Exchanging technical learning with an SME is vital to the future inspector’s success.

Implementing Quality Culture

The industry is increasingly focused on quality culture as regulators also place importance on culture as a cornerstone to ensure a consistent global product supply. More importantly, we are realizing how fewer human errors can often be associated with an overall healthier quality culture. Culture, in general, is a set of behaviors and beliefs representing what is important to a company's ethos. Quality culture does not stop once the product is sealed into its final container. So, integrating manual visual inspection and those performing the work into the overall quality culture is just as important as manufacturing the product itself.

Performance and accuracy, and how they are measured, are important aspects of assessing the health of the manual visual inspection program within our quality culture. Are individuals pushed to increase throughput (which decreases the inspection time for each unit)? Is productivity rewarded over inspection accuracy? Do procedures allude to downplaying the importance of inspection integrity in any way? Are individuals supported by being given adequate eye breaks and physical breaks to move their bodies to prevent fatigue? These are all great questions to consider when evaluating the health of a manual visual inspection program. Establishing the significance of visual inspection and its criticality to the company requires integrating it into the company's quality culture, thus fostering good decision-making and ownership over the process.

Conclusion

Despite technological advances throughout the pharmaceutical industry, manual visual inspection remains an ever-important program for releasing parenteral drug products. As mentioned, when developing a program and recruiting individuals to perform a manual visual inspection, it is important that some key elements should be considered: proper eyesight, specific skills (like paying attention to detail), and the ability to focus for long periods of time, as well as the right personality disposition. These all play a role when hiring (and retaining) inspectors. Once hired, however, it is the company's responsibility to ensure the development of an appropriate learning plan and deliver that education and training in a modern, engaging way. Time again, the criticality for learning the "why" behind performing key tasks has been proven to reduce human errors. When people understand the process details as well as the importance of doing them in a specific, diligent manner, errors are effectively reduced. Most importantly, reducing human errors in manual visual inspection of parenteral products will ensure a robust and safe supply chain.

References

1. United States Pharmacopeia – National Formulary (USP-NF) Informational Chapter <1790>. *Visual Inspection of Injections*. Official as of 01-Dec-2023, currently official 11-Aug-23. (accessed 18Jul2023).
2. U.S. Food & Drug Administration, Inspection of Injectable Products for Visible Particulates, Draft Guidance for Industry, December 2021, Pharmaceutical Quality/CMC. **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/inspection-injectable-products-visible-particulates.** (accessed 23 Jul 2023).
3. United States Pharmacopeia – National Formulary (USP-NF) General Chapter <1>, *Injections and Implanted Drug Products (Parenterals)—Product Quality Tests*. Official as of 01-Dec-2023, currently official 11-Aug-23. (accessed 11 Aug 2023)
4. Suttie, Jill. October 2019. Greater Good Magazine, Berkley Great Good Science Center. *How Understanding Your Brain Can Help You Learn*. **https://greatergood.berkeley.edu/article/item/how_understanding_your_brain_can_help_you_learn**.

5. Bleich, Corey. July 2018. eLearning Industry. How Understanding The Adult Learning Theory Helps Us Create Better. **https://elearningindustry.com/adult-learning-theory-helps-elearning-development**.
6. Melchore, James. Sound Practices for Consistent Human Visual Inspection. AAPS PharmSciTech. 2011 Mar;12(1):215-21. doi: 10.1208/s12249-010-9577-7. **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3066354**.