# DID VISUAL INSPECTION **DELAY THE VACCINE?**

The risk of a global health pandemic had been discussed for years leading up to 2019. While it was understood there was always a potential threat of a new virus affecting society, few to zero measures were taken to manage the scenario prior to December 2019. As a result, the coronavirus COVID-19 reached global pandemic proportions in March 2020 and the world population was forced to behave reactively. As more was being discovered about the virus, scientists began the development for a vaccine and a race to release the miracle cure began.

While a very hot topic and a beacon of hope for everyone, the vaccine was intended for mass global distribution for billions of units. The medical supply chain was not prepared for this type of demand increase. As the world waited in isolation for a cure, medical manufacturers braced themselves to distribute billions more of their product within the year to come. The development of the vaccine was only the beginning of the solution. It was up to the medical supply chain to manufacture and distribute the vessels to store the vaccine. These supplies include glass vials, syringes, plungers, stoppers, needle covers and more. This article will analyze the main cause of

production ramp-up delays, the safety inspection requirements for medical vials and the processes in which inspection is executed.

## 1. PRODUCTION RAMP-UP DELAYS

To meet a sudden massive increase in demand, existing production facilities do not suffice. In addition to the emergency cry of COVID-19, distribution of supplies for other vaccinations including influenza, measles, mumps and so on must continue. Established diseases have not been eradicated with the introduction of a new virus. All new vials must be manufactured and distributed without affecting the existing demand.

### 1.a Didn't Manufacturers have a Head-Start?

It took roughly a year to develop the COVID-19 vaccine, which everyone knew was coming. Shouldn't this have been enough time to get facilities equipped and running once a vaccine is available? Unfortunately, the components within a vaccine can be affected by the container it is stored in. The material and coating on the molded parts can alter the make-up of the fluid within the vial. Prior to manufacturing, vials are designated to specific solutions and are not interchangeable.

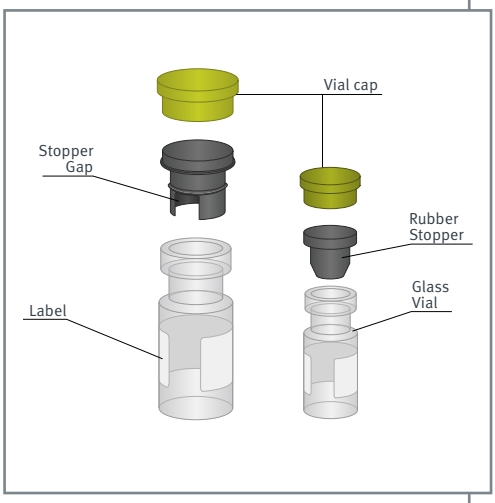
Without knowing what the final vaccine will be or when it will be ready, companies had to take huge monetary risks to manufacture in advance. Private institutions and governments stepped up with multibillion-dollar contributions to advance the development of the vaccine and its distribution, but without an approved solution, supply chain ramp-up could only go so far.

## 2. VACCINE VIALS MUST BE FLAWLESS

As with any substance entering the human body, the containers, receptacles, and distribution devices must be FDA approved to ensure:

- Contamination does not enter the vaccine/human body.
- The liquid inside will not be altered by the vial.
- The required amount of the fluid will be ejected from the capsule.
- The individual dispensing the fluid is protected and can do so safely.

It is not simply the material that houses the vaccine or medicine that can affect the make-up of the fluid but the state of it. Before vials can be filled, the glass and stoppers/crimps/plungers must be 100% inspected for dust, foreign particles, dents, scratches, discoloration, and shape perfection. Any of these factors can affect the integrity of the vaccine and impede a person's health.




**2.a Size and Shape Verification**

The size and shape of the glass vial must meet the exact design specification as the filling and labelling of the vials are automated for speed and accuracy. While on an assembly line, any inaccuracies may result in disproportions of the medicine patients are relying on. As expected, doses are measured precisely, and cannot be varied by any amount.

The same logic is applied to the stopper of the vial. The shape and size must fit the vial exactly to prevent leakage, but the stopper also protects the healthcare providers who manipulate the vials on a regular basis.

**2.b Protection from Foreign Substances**

Vaccines are created from a very specific combination of antigens, stabilizers, adjuvants, antibiotics, and preservatives. As with any recipe, a variation to the ingredients will alter the result. Appropriately, both the glass and the stopper must be completely clear of all foreign particles.

**2.c The Consequences of Imperfections**

Materials housing a vaccine are coated in a distinct substance to protect the fluid from interacting with the vial or container. The coating varies depending on the make-up of the liquid; it is known in advance what each vial will contain, and the completed vial must be 100% covered.

Therefore, the appearance of scratches, dents, or bubbles in any component of the receptacle is dangerous. Imperfections make the coating vulnerable. The coating

itself can flake or peel and mix with the fluid or the defect can leave the receptacle exposed to the vaccine. Containers must also be verified for imperfections such as discolorations, as this is an indicator that a foreign substance has penetrated the manufacturing of the component, rendering it unusable.

**2.d Proper Identification**

Each vial must be labelled correctly prior to distribution. If mis-labelled, the medication becomes both useless and dangerous. Medical vials cannot be released without confirmation of its contents.

## 3. INSPECTION PROCESSES FOR VACCINATION SUPPLIES

Products whether it be glass, plastic or rubber can be inspected by spot checks representing batches or inspection of 100% of production. Today, the two methods to inspect vaccine vials are manual inspection and automated vision inspection.

**3.a Acceptable Quality Limit (AQL)**

There is an AQL using ANSI/ASQ Z1.4 or ISO 2859-1 - general inspection level II, that permits a batch through to the public. As per the Parenteral Drug Association (PDA) defects are classified into the following categories:

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|---|---|
| **Critical** | Product is rendered unusable and/or may have an impact on the health of the patient. *Example: Liquid leakage.* |
| **Major** | Performance of the product may be affected due to the impact on handling or functionality but patient safety is not compromised. *Example: Particle embedded in product.* |
| **Minor** | Defect does not affect the functionality of the product. *Example: Dirt on outside of vial.* |

**3.b Manual Inspection**

Factors affecting manual inspection include illumination, ambient conditions, personnel training or certification and operation/manipulation of the item.

These factors can be very costly and time consuming for the inspection process. Multiple operators are required for inspection of each item, one at a time. They need to have time allotted to not only inspect each part properly, but time in between to rest their eyes. When working with any manual operation, results may be subjective to the opinion of the inspector and run the risk of overlooking defects, rejecting good parts resulting in inconsistency within a brand. Inspectors need to have their eyesight checked regularly and periodically requalify their expertise regarding different defect scenarios.

In addition to the manipulation of the part, the inspection environment needs to be equally monitored. The room must maintain a comfortable temperature, humidity level, air velocity and noise level for appropriate working conditions. The lighting in the room is a major factor in flaw detection and must be lit and angled appropriately. Adjustments to the lighting must be made accurately for each product type. Inspections need to have the right tools available to be able to inspect each piece for at least 5 seconds against both a white background and then a black background for a thorough examination.

**3.c Automated Vision Inspection**

There are several benefits to automated vision inspection including high-speeds, consistency with the removal of subjectivity, risk reduction and higher return on investment. At the core, an automated system must perform equally or better than a person. The initial qualification process should be repeated several times and then compared to the results of a human inspector.

The installation of a semi or fully automated system can be done inline or separately. The system itself can be encased to fully control and automate the lighting, temperature and other environmental factors. As a result, inspection location becomes more flexible.

Once a system is designed, the metrics can be manipulated based on the product under inspection. With this data, the same equipment can be leveraged for multiple product types with minor tweaks to the hardware. Using vision software, limits and requirements are set automatically and the system can run independently with zero operator intervention. As a result, the machine can run 24/7 and work at speeds fast enough to inspect over 1 000 units per minute in the case of smaller plastic parts like stoppers.

In addition, inspection results are automatically logged and organized for increased traceability and insight into the product and manufacturing line.

*High-speed vision inspection system inspects over 1,000 pieces per minute*


## CONCLUSION

In the year 2020, there was no greater global priority than a quick release and distribution of the COVID-19 vaccine. While the wait was frustrating, the compliance measures put in place are there to prevent devastating results. While this is straightforward in the case of medicines, medical devices, and instruments, it is harder to appreciate in the case of a small rubber stopper. But as with anything that is intended to heal the human body, the manufacturing of vials requires precision and detail. The process itself is set up for optimization, and can be executed quickly, it is simply a question of making a proactive investment.