Waygate Technologies
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Remote visual inspection for pharmaceutical applications

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Achieving and sustaining precision in pharmaceutical production

Pharmaceutical manufacturing strives for flawless precision in the construction and operation of production machinery. To achieve this, and to comply with the FDA (Food and Drug Administration) regulations that mandate it, there are two on-going quality inspection assessments that are vital forall pharmaceutical manufacturers.

1. Visual weld inspections during construction

Quality begins in the construction process for purity piping used in pharmaceutical production facilities. Whether offsite at a skid manufacturer's facility, or onsite construction of interconnecting pipes, the integrity of each and every weld's ID must be verified using a high-quality image to ensure compliance to standards prior to use.

For companies that manufacture pharmaceutical skids, quality documentation is required for acceptance by the end user. This means the quality and integrity of every weld needs to be tracked and documented per skid build. Because of the high number of welds, there is often a dedicated team of inspectors for this purpose. Likewise, for high purity pipe welding contractors engaged to construct expansions or new facilities, weld quality must be documented for all welds performed during construction to ensure the system is constructed with compliance to 21 CFR §211 Subpart D, or similar local codes. As the number of welds inspected can be in the thousands, welding contractors often hire third parties to efficiently and consistently perform weld inspections.

Weld inspection in high purity piping is a tall order, but critical to ensure flow of product over welds is as-designed to prevent product buildup in undercuts or porosity. In addition to thousands of welds existing within one plant, welds are also in obscure, difficult-to-access areas and remote visual inspection requires navigating sharp, often-90-degree bends in the piping.

2. Inspection and validation for clean-in-place programs

Pharmaceutical Clean-In-Place programs are required between production batches to ensure that internal surfaces are ultra-clean without disassembly. This prevents any product changeover cross contamination and it includes all piping, valves, process equipment and vessels used in production. Visual inspections must be performed after cleaning and before new-batch production to validate the cleanliness of product contact surfaces. The challenges of comprehensive visual inspections mirror those of weld inspections: internal production equipment surfaces are in difficult to access areas and encompass long, circuitous paths while simultaneously requiring high levels of inspection precision.

The challenge: visual details of inspection area

When inspecting complicated equipment for weld integrity, disassembly is not an option. Remote visual inspection equipment is used for access. The challenge is to obtain a consistently high quality image for inspectors to assess the weld. Typically, there are many inspectors on-site at the same time, so ease of operation and portability are essential.

For Clean-in-Place programs, complete disassembly is not an option either, necessitating the use of remote visual inspection equipment. In some environments, cover and caps can be removed to enable the use of inspection mirrors to gain additional visibility. The key challenge for Clean-in-Place programs is productivity. Since Clean-in-Place programs require downtime between batches, the sooner the Clean-in-Place program is complete, the sooner production is back up and running.

The requirement: mitigating risks and FDA mandates

In pharmaceutical production, the FDA mandates that specific and comprehensive cleanliness protocols – most notably validation – are in place. Explicit specifications are not dictated due to the wide variation in equipment, manufacturing and products. Instead, general requirements for pharmaceutical operations are comprised of steps covering these areas, as detailed in FDA Title 21 Chapter I, Subchapter C, Part 211 or other similar local regulations.

- Written procedures detailing each cleaning process used for various pieces of equipment, including variation between batches of the same product and between products.
- Written procedures on how cleaning processes will be validated
- Validation procedures that address who is responsible for performing and approving the validation study, acceptance criteria and when re-validation will be required.
- Written validation protocols, prepared in advance of studies on equipment and manufacturing system, that address issues such as sampling procedures, analytical methods to be used and sensitivity of those methods.
- Validation studies conducted in accordance with the protocols, along with documentation of the results.
- Final validation report, approved by management, which states the cleaning process is or is not valid. Data should support a conclusion that residues have been reduced to an "acceptable level.

The purpose of pharmaceutical Clean-In-Place programs is to address these on-going FDA requirements. *Please refer to the actual FDA or other local requirements as this is a summary for awareness and is not intended to constitute the full and accurate description of the FDA or other local requirements.*

The potential consequences of inadequate inspections

FDA regulations are developed and continually honed based on real-world events and strive to protect public safety. Such is the case for the pharmaceutical manufacturing regulations.

Substandard inspections that improperly assess cleanliness or weld integrity can carry a steep, and often irreversible cost, comprised of tangible, intangible and higher order costs. Tangible costs include unplanned downtime, product losses as well as labor and maintenance costs. In some cases, there are legal costs or noncompliance costs.

Intangible costs include brand damage from contaminated products that reach the marketplace. Higher order costs – in the worst possible case – cause human harm or fatalities and cannot be quantified. Higher order costs can also include on-going brand damage that may linger long-term.

Historical events demonstrate the potential impacts of inadequate cleanliness and validation processes. In one example, a cholesterol-lowering drug, Cholestyramine Resin USP, was found to contain cross contamination from the production of agricultural pesticides. The reuse of recovered solvents in the cleaning process was deemed the source of contamination. Second order contamination was created when the compromised drug was sent to a packaging facility, spawning contamination in that additional location. Multiple batches of the product were recalled with an FDA alert and new protocols and procedures had to be established to restart production.

Another historical pharmaceutical example occurred when steroid and non-steroid products became cross-contaminated, posing a serious health risk to the public. The root cause issue was an inadequate validation process. To help ensure public safety, the FDA issued a product import alert until the cleanliness and validation protocols and procedures could be brought up to adequate FDA standards.

The solution: remote visual inspection

When the stakes are high and the consequences steep or irreversible, a purpose-built solution that delivers adequate, compliant validation is of paramount importance. In pharmaceutical manufacturing, validation of weld integrity and Clean-In-Place programs is enabled by Remote Visual Inspection (RVI).

RVI is required when a direct visual examination is not possible and when access is insufficient to place the eye within 24 in. (600mm) of the surface to be examined and at an angle not less than 30 degrees to the surface to be examined. The most widely used RVI technology in purity pipe contact surface examinations is the video borescope, which is made up of a small diameter camera in an articulating, small diameter flexible tube connected to a digital display. Much like a medical endoscope, which is used to probe the depths of the human body without surgical intervention, video borescopes are designed to discreetly yet accurately view obscure areas inside industrial equipment.

Video borescopes are commonly used where distance, angle of view and limited lighting may impair direct visual examination or where access is limited by complexity, security or sanitary constraints or atmospheric hazards – such as in pharmaceutical manufacturing. Because of their ability to offer up-close, high definition access to difficult-to-reach places without having to disassemble the equipment, video borescopes have proven to be invaluable tools for pharmaceutical RVI in both weld inspections and Clean-In-Place program validation.

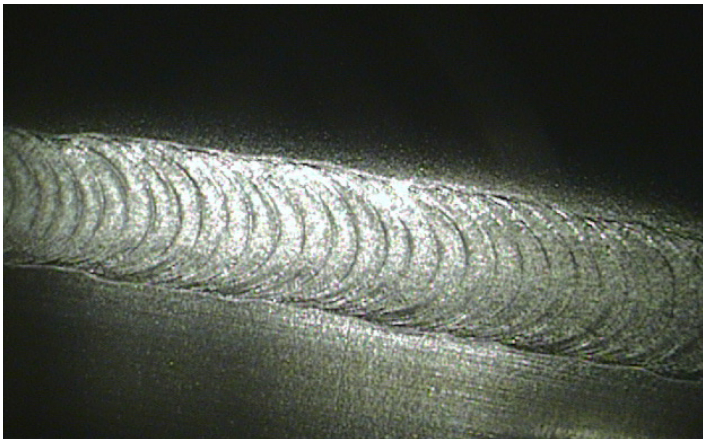
Video borescopes offer a flexible insertion tube with an articulating camera head that enables the user to navigate the challenging geometries of high purity piping, vessels, and valves. Even the simplest video borescope will have an illumination source, allowing a technician to visually inspect nooks, crannies and pathways within a dark environment. Some video borescopes offer advanced optical tip adapters that allow the user to choose the proper viewing angle and focus range based on specific application needs.

Across many industries, video borescopes have proven their efficacy for troubleshooting as well as routine equipment inspections of assets' condition and health. For pharmaceutical manufacturers, suppliers and inspection service providers, video borescopes are the standard for quality control and validation.

Pharmaceutical manufacturing and RVI

Video borescopes are finely crafted technological instruments with a wide range of features and capabilities. In high-value inspection cases, as in pharmaceutical manufacturing, the return on investment and risk mitigation value is significant, thus the most advanced video borescope features are employed.

Remote visual inspection provides quality assurance to the pharmaceutical manufacturing process that can increase safety, reduce downtime, improve quality and validation protocols, increase productivity and help avoid unplanned downtime. Modern video borescopes are the leading solution for the challenging environments and stringent regulations present in pharmaceutical manufacturing. Video borescopes help to achieve and maintain FDA compliance by providing consistent and comprehensive documentation of all inspections, resulting in increased manufacturing uptime.



The advantages of video borescope technology

Modern video borescopes are affordable tools that improve productivity by making it easy to ensure cleaning validation and verification, as well as provide weld quality assurance during expansion or new construction projects. The visual ability of video borescopes makes inspections more efficient, and many provide innovative ways of documenting inspection results so that problems are mitigated and legal compliance is met, thus increasing the uptime of equipment and productivity of inspectors.

Video borescopes offer distinct advantages over even the best external examination, especially when used for industrial maintenance that calls for sanitary internal inspection as well as those in challenging environments. Video borescopes can be configured with shorter or longer camera insertion tubes, diameters for small passage access, more lighting or greater "push-ability", and a variety of interchangeable optical tips to adjust the viewing angle and focus range to fit a variety of applications.

Because video borescopes record what they see, they are a tremendous help in inspection reporting, making it easy to save and share information without requiring the separate step of tallying results and preparing them in a readable format. Video borescopes enabled with Menu Directed Inspection (MDI) software guides users through the inspection process while automatically annotating images with asset-specific data metatags providing organized results. At the end of an inspection, the technician can simply click to generate a report in Word docx and pdf formats to save time, improve quality, and streamline the decision-making process. Often this information can be used to analyze trends in equipment wear or use.

Using a camera insertion tube steered with a joystick to navigate inside of assets can be challenging. A live, on-screen Tip Map aids inspectors in guiding the camera during the inspection. A grid shows the tip's direction and helps inspectors maintain orientation for easier navigation. As inspections sometimes need to be performed on equipment that has been recently shut down and may have operating temperatures exceeding limits for even the most rugged video borescope, it's important that the device have a temperature warning system to alert the user and avoid damage to the instrument. When time is critical, external cooling sleeves can allow camera access in temperatures greater than standard operating temperatures. Many video borescopes will include substantial memory capacity along with USB and microphone ports to allow you to describe observations at the same time they are being captured.

What to look for in a video borescope

There are several characteristics that help define a best-in-class video borescope solution in pharmaceutical manufacturing:

Image quality. The combination of light output, whether it be white light or UV light, camera resolution, display resolution, optics, and image processing are the five key components that are required to generate a great video borescope image. Clean-In-Place programs rely on image quality to achieve proper validation. In order to properly evaluate the integrity of a weld, image quality along with accurate on-screen color rendition are critical in searching for possible defects including; overheating, undercut, sugaring, porosity, surface cracks, and lack of weld penetration.

Cost of ownership. The nature of high purity weld inspection and Clean-In-Place validations require that the borescope insertion tube be constantly stressed while being pushed, twisted, and maneuvered around corners. A video borescope with a supple bending section, and a torsion relief section, that allows easy navigation around 90-degree bends helps to reduce wear are tear on the device while increasing inspection efficiency.

Ease of use. An ergonomically-designed video borescope without a complicated set-up is best suited for pharmaceutical applications. During inspection events, there are most likely multiple inspectors with different skill levels. It's important all inspectors are able to provide assessment consistently.

Portability. Pharmaceutical production visual Inspectors must access small spaces to ensure comprehensive validations. Some video borescopes are heavy or awkward, making it difficult to access and inspect small spaces. A portable and streamlined video borescope with a long battery run time is ideal for hard-to-access inspection areas and often provides improved ergonomics for longer inspections.

Service and support. Expertise in high stakes manufacturing environments can be a make or break decision. Adding service, support and training to assist in video borescope optimization helps to facilitate implementation and aid when challenging inspection situations emerge.

Features. Each application has its own unique inspection needs. Optimizing a video borescope selection that offers the features and capabilities to match inspection needs is important, today and for emerging developments. For example, some video borescopes offer Dark Boost to aid in weld inspection. Advanced image processing tools such as Dark Boost and High Dynamic Range (HDR) automatically adjust gamma and exposure in darker scenes to optimize brightness levels providing the user the best possible image quality without sacrificing contrast.

Measurement options. Many video borescopes offer the ability to measure the size of indications with incredible precision and accuracy. Several different measurement technologies are available, ranging from basic comparison measurements, traditional stereo measurement with 3D xyz coordinate calculations at the cursors, to fully-surfaced 3D point cloud visualizations. Not all measurement technologies are created equally, so it is important to understand and align inspection requirements around indication measurement and levels of accuracy and precision.

Image tagging and reporting capability. The ability to record meta-tagged images and videos that show where, when, and by whom images were captured, and automatically create an inspection report can save both time and money. The data gathered can be invaluable in improving efficiency, meeting compliance and ensuring quality of output. Over time, trend analysis and creating easily searchable records of traceability becomes inherently easier.

Summary

In pharmaceutical manufacturing, remote visual inspection via video borescopes has become an industry standard. Although video borescopes incorporate the very latest and highly sophisticated technology, they are not difficult to master and can be useful in both simple and complicated inspections. Video borescopes help save money by reducing the time and resources formerly used to disassemble working equipment, and they are highly effective in ensuring quality, safety and meeting FDA regulations.

Video borescopes range from a simple utility video borescope to those that provide the latest in measurement technology and are designed to work in harsh operating environments that would otherwise be impossible to access. The environments found in pharmaceutical manufacturing rely on video borescopes to provide high quality images with minimal training to keep equipment in working order, production running smoothly while concurrently increasing safety and efficiency.

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