Resolving Cleanability Issues with Aseptic Design

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Background

Nearly 50% of warning letters posted on the FDA website contain citations for cleaning or contamination-related issues. While a manufacturer's natural first response to a cleaning issue is to increase the cleaning agent concentration, temperature, or cleaning cycle duration, this might not address the problem. Instead, a review of the hygienic design of the existing process equipment might be required to solve the cleanability issue.

CIP systems are engineered to provide cleaning solutions at the appropriate concentration, temperature, and flow rate for a length of time that removes production residues from process equipment surfaces. The system design must provide adequate turbulence to remove the residue, the system must drain well to prevent pooling of the solution, and the design must account for hard-to-clean features such as side drain ports and agitators. When a cleanability issue is identified, each of these design considerations must be looked at in detail.

Imparting Energy to the Cleaning Process through Turbulent Flow

To remove all production residue, the cleaning system must be designed to deliver an adequate amount of turbulent solution flow in the pipes and in the falling film that flows down the sidewalls of the process vessels (see Figure 1). Turbulence is measured by a quantity known as the *Reynolds number*. In pipes, a Reynolds number of 20,000 or greater is desirable for adequate cleaning. A Reynolds number greater than 2000 is required to achieve adequate turbulence in the uniform falling film created by the cleaning solution flowing down the sides of the vessel.

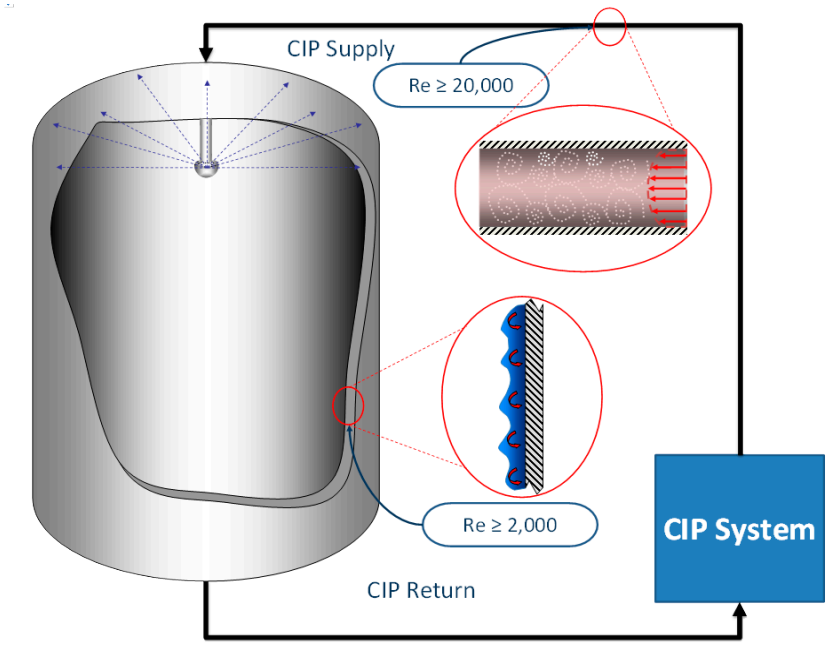

Figure 1: Ideal tank CIP circuit conditions

Ensuring adequate turbulence is required for proper cleaning, but it is not sufficient. Many other factors play a part.

Ensuring Drainability

To maintain a turbulent film over the process vessel surface, it is important to minimize the amount of fluid pooling in the bottom of the vessel. Cleaning rates are significantly reduced in laminar flows and quiescent pools. Accordingly, equipment design must ensure that cleaning solutions drain freely from all product contact surfaces, thereby assuring that production residues cannot be retained or carried over from batch to batch.

Commonly, draining problems lead to what is known as *bathtub ring* cleaning failures. To diagnose whether excess solutions accumulate in the tank, note the amount of liquid collected in process vessels during washes and drain steps. When a draining problem is identified, the root cause of the problem must be diagnosed to determine the appropriate corrective action. The inability to sufficiently drain solutions from process vessels during CIP cycles can be caused by several factors:

Improperly sized drain valves. If the drain is undersized and cannot keep up with the CIP flow, the obvious solution is to replace the tank bottom valve with a larger one; however, this might not be necessary if the vessel is pressure rated. Creating a small amount of head or overlay pressure can possibly increase the flow through the drain enough to solve the pooling issue.

Piping Restrictions. Even though the vessel drain is adequately sized, downstream reducers or valves can lead to restricted flow out of the vessel. If this is the case, restrictions must be eliminated to facilitate flow from the vessel.

Pipe Sloping. Improper pipe sloping can lead to conditions in which a column of water can back up into the vessel after the completion of the CIP cycle. The situation can be corrected by increasing the pipe slope downstream of the vessel.

Dead legs. Dead legs (low, stagnant spots) can lead to a small pool of solution that is still in the vessel after completion of the CIP cycle. The situation can often be corrected by equipping the pipe with a low-point drain valve.

Inadequate drain times. Barring any physical problems with process vessels, incomplete draining can be a result of a cleaning circuit with improper hydraulic balancing. Make sure that the drain steps in the CIP cycle are long enough to permit full evacuation of cleaning and rinsing solutions from process vessels. In addition, the evacuation rate from vessels should meet or slightly exceed the rate at which cleaning solutions are supplied.

After drainability issues with process equipment are addressed and corrected, it is time to look at components with complicated geometric configurations that have the potential to retain residue.

Issues with Side Ports and Incorrectly Placed O-rings

Side ports can present a problem when they are not designed with an angle adequate enough to allow them to drain freely. For side ports that are poorly drained or have residue issues, the solution is to fabricate and install specialized spray devices that adequately clean the port and blow out any cleaning and rinsing solutions.

Valve and plug assemblies with incorrect O-rings can also cause residue issues. Frequently, cleaning failures occur at the O-rings on the Ingold fittings. To be effective, the O-rings must be correctly positioned as well as properly sized for the retaining gland.

- O-rings located too far from the internal tank wall prevent cleaning solutions from effectively reaching and removing residues.
- O-rings too small for the retaining gland are prone to retain residues forced into the annular gap between the Ingold port walls and the inserted probe.
- Overly large O-rings can lead to deformation and pinching of the seal, which can render it ineffective.

Specific O-ring design heuristics to accommodate cleaning requirements are contained in the ASME BPE; O-ring seals should be fitted in grooves located at a distance of less than **6d** from the nearest major cavity where the seal is at its point of maximum travel. The distance ***d*** is defined as the radial gap between the Ingold plug or sensor and the Ingold port wall (see Figure 2). The grooves must also accommodate seal expansion without causing extrusion.

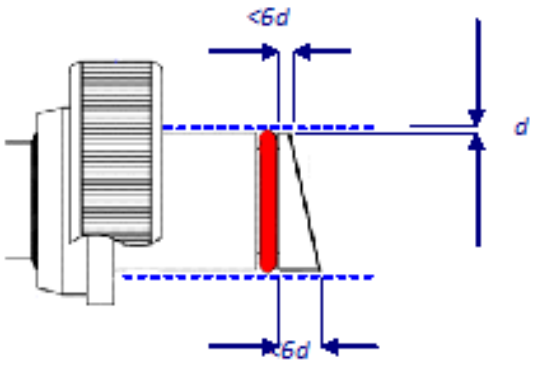

Figure 2: O-ring sizing and placement

To properly size an O-ring, the gland volume (O-ring groove) should be between 60-85% filled with an ideal fill of 75%. The percentage of gland volume that an O-ring cross-section displaces in its confining gland is called *gland fill*. Seals specified or selected should allow at least a 10% void in any sealing gland to account for swelling of the elastomers used to seal the ports.

Agitator Design

Agitators also present a unique challenge to the cleaning process. The specific measures necessary to ensure proper cleaning of an agitator are dependent on the agitator design. Agitators can be either top or bottom mounted. Bottom-mounted agitators can either be directly driven by a driveshaft penetrating the vessel or magnetically driven without directly penetrating the vessel.

For top-mounted agitators, the cleaning process must remove residues from the impellers, shaft, seals, and agitator collar. The specific design of each agitator should be evaluated to ensure that it meets

hygienic design criteria. For example, an agitator mounted to the shaft by means of a set screw is undesirable, because threaded fittings are difficult to clean and invite bioburden growth. While this sort of issue is relatively easily to resolve by permanently welding the agitator blades to the shaft and filling the set screw hole to seal gaps and crevices that compromise overall hygienic design (see Figure 3), this seemingly inconsequential detail can have extremely negative results. Vessels should not be flooded to maintain a turbulent falling film on the sidewalls, so for top-mounted agitators, spray devices must be designed to distribute spray along the shaft and in the top collar of the agitator.

By nature, bottom-mounted agitators have minimal clearance between the bottom of the agitator and the vessel bottom. This area of low clearance can also retain contaminants unless the cleaning process is configured to address this issue or the design is specifically engineered for CIP. The solution is to adjust the CIP flow rate or tank drain rate so that the agitator is submerged during cleaning. This submersion enables effective cleaning of the underside of the agitator and coupling pin.

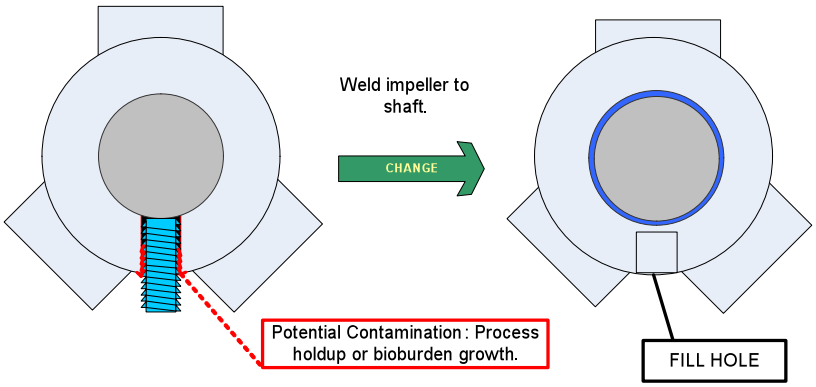

Figure 3: Remediation of a non-hygienic agitator design

Agitators designed specifically to combat cross contamination of batches incorporate an open mixing head structure. An open structure permits cleaning solutions to contact all surfaces of the agitator, including the bearing surfaces. In addition, because the dimension between bearing surfaces is small in most agitators, the open structure allows process fluid into the interstitial space as a lubricant. For agitators with this design, immersion is unnecessary if spray devices are designed to direct cleaning solution into the open head structure.

Spray Device Design

Finally, close attention must be paid to spray devices to ensure that they are both properly designed and used in accordance with manufacturer specifications. Frequently, spray devices are employed at supply pressures below those recommended by the manufacturer. This type of error can cause or contribute significantly to cleaning failures. When conducting spray coverage testing or developing cleaning cycles, it is of paramount importance to confirm that cleaning and rinsing solution supply pressures meet the manufacturer specifications.

Confirmation of proper spray device orientation can also be critical, especially in the case of custom-designed spray devices. To ensure optimal performance, spray devices should be physically keyed to the specific port and orientation for which they are designed.

In this short article, we have listed the most common design issues that affect cleanability and how to address them. Of course, less common problems do exist. But the important thing to remember is,

without a cleanable and aseptic design, no combination of cleaning cycle parameter enhancements can produce satisfactory results.

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