

Analyzing the Root Cause of Clamp Galling Required Customer Cooperation

In pharmaceutical production facilities, maintaining tight control over product purity is crucial. Contamination that compromises the integrity of a batch of a drug used in chemotherapy, for example, could easily mean a loss of hundreds of thousands or millions of dollars' worth of product. Connecting the complex network of vessels, piping, tubing, valves, pumps, compressors, etc. in a batch process facility demands reliable, long-lasting clamps that provide a consistent level of engagement around the circumference of the connection to prevent leaks. These clamps must also be able to be removed quickly and easily to maintain the high level of joint safety, cleanliness and efficiency that high pressure and high temperature manufacturing processes require.

A few years ago, one of L.J. Star's major pharmaceutical manufacturing customers in New England began reporting galling problems with clamps. In a galled clamp, the threads of the bolt and nut become fused and seized together, making it extremely difficult or impossible to open the clamp to inspect or service the connection. L.J. Star had a decades-long business relationship with this customer, which made quickly tracking down the source of the problem and correcting it a high priority.

Root Cause Analysis

The customer's clamp galling problem was, in a sense, an outgrowth of an earlier problem with accidental depressurizations. Their original clamps were expanding and contracting as the temperature and pressure

in the system cycled from cool and low pressure to hot and high pressure and back again. Over time, this expansion/ contraction cycle caused the previously used clamps to loosen, leading to several explosive depressurizations that had the potential to injure workers, damage equipment, and contaminate in-process product. In one case, a nearby sight glass was blown through the roof of the building by the force of the explosion.

To prevent these depressurization problems, I had recommended that they switch to L.J. Star's standard SH Series safety clamps, which are made of 316 grade stainless steel, an austenitic stainless steel





alloy that's widely used in the chemical processing industry. It offers higher performance than the 304 grade stainless steel used in most "commodity" clamps. The SH clamp's dual-pin hinge, single-bolt design is widely used in pharmaceutical plants because it offers excellent alignment of the clamp halves. Its special "Omega" profile allows for fuller engagement of the clamp around the circumference of the connection for a better and more repeatable 360° compression of the two mating faces without the



Clamp connections should seal two ferrules together quickly, securely and without creating pockets that allow particles to collect.

need to over-torque the nut when tightening the clamp. The purpose of the SH design is to prevent the clamp from loosening.

After our customer switched to the SH Series clamps to address the accidental depressurization problem, they started to notice increasing numbers of galled clamps that were requiring "extreme action" to open them. In some cases, maintenance personnel were forced to cut the clamps off their vessels and piping with bolt cutters to service or inspect equipment.

The search for answers

To track down the root cause of our customer's clamp galling problem, we explored a number of possibilities.



The first was the way maintenance personnel torqued the nuts that held the clamps in place around the ferrules. Under-torquing leads to a gasket that's under-compressed, making the joint prone to leaking and allowing for entrapment areas between the gasket and ferrule. When over-torqued, a clamp's bolts and nuts can fuse or bind to each other, so they are literally "cold-welded" together. Over-torqued clamps also exert too much friction and pressure on the connection, which can lead to gasket intrusions into the connection, interfering with the flow of



process material and allowing particles to collect. Over-torquing a clamp can even cause pieces of the gasket to shear off, contaminating the product.

Through working with our local distributor, we soon discovered that our customer's maintenance personnel had no established torquing procedure or specifications to follow. That meant that any clamp could be significantly over-torqued or under-torqued, depending on the physical strength of the person who closed it. Although this wasn't determined to be the root cause of the customer's galling problem, it led them to develop a validated and approved set of torquing procedures and settings, as well as to purchase tools for applying and checking for the proper amount of torque.

The next avenue we explored was the facility's parts cleaning procedure, which employed the same cleanin-place (CIP) solution that they were using to sanitize their vessels and piping. We discovered their practice of cleaning clamps in a parts washer using this CIP solution was leaving behind trace amounts of sodium hydroxide. Once the solution dried, the residue could build up in the threads of the nuts and bolts, which contributed to but wasn't the root cause of the galling problem. Given the cleaning protocol was a validated process, the maintenance team was reluctant to change it, so we continued to search for answers.

After further research, we concluded the source of the problem could be traced to the materials from which the bolt and nut were formed. Like the rest of the clamp, they were made of 316 grade stainless steel. Being made of the same material caused them to fuse and seize when over-torqued or exposed to high temperature, friction and pressure. That meant that the key to the solution was making sure that the bolt and the nut were made of two different types of steel of differing levels of hardness. However, we realized that if the nut was formed of the harder material, it would strip the bolt if it was over-torqued, which would have required scrapping the entire clamp. Preventing galling required forming the bolts out of harder material that wouldn't be deformed by over-torquing the nut.

SH Series clamps with the new antigalling option are constructed with bolts formed from Nitronic 60 stainless steel alloy to withstand over-torquing and sodium hydroxidebased cleaning solutions. They are now commercially available for use in pharmaceutical and biotechnology processing operations, as both original equipment and as replacement parts.





We recommended several alternative bolt materials, which our customer considered before countering with their own suggestion, Nitronic (\mathbf{R}) 60 stainless steel alloy. This hard, galling-resistant material was already being used in their production equipment, so it offered the advantage of not requiring a lengthy qualification process. We produced samples of a variety of clamps, some with Nitronic 60 bolts and the softer 316 grade stainless steel for the wing nut or hex nut. After repeated testing of how the experimental clamps performed in actual use and how they reacted to the customer's part washing process and new torquing procedure, the clamps with the Nitronic 60 bolts proved themselves substantially more resistant to galling in use, even when over-torqued.

Today, our customer has replaced thousands of our standard SH Series clamps in two of its North American and one European facilities with SH Series clamps with our new anti-galling option and is benefiting from simpler, more cost-effective maintenance as a result. These new clamps are now the facility's standard design and they must be used in any new processing equipment they purchase. They're also being specified for use in new facilities.

Are you confident you know how to maintain clean and safe process clamp connections? <u>Download your free copy of L.J. Star's "Sanitary Fittings Best Practices" white paper</u> to review the steps for installing a clamp connection correctly.