Pharmaceutical processing

A Materials Science Evolution (The Lowly Gasket)

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The earliest sanitary process systems and lines used by the dairy, food, beverage and fine chemical or pharmaceutical processors were glass. Glass was an obvious choice, because it was an established technology, and glass was inert and virtually unaffected by the products being processed and the necessary, frequently used cleaning chemicals employed. Packing was used as the sealing agent between the joints of the fittings, lengths of pipe, vessels and other equipment comprising the system. These joints did entrap product and the packing was a possible source of contamination so the systems were frequently dismantled and cleaned.

Because glass was expensive, somewhat fragile and not a particularly versatile material, brass plated and nickel alloy fittings, tubing, vessels and equipment began to replace glass in the dairy, food and beverage processing industries in the 1920's. A male, female union with a captive nut, named bevel seat, was the connection employed. It did not use packing or a gasket but the joint design did allow product entrapment and bacterial growth and thus had to be dismantled and cleaned frequently. Nicks and scratches occurred during tear down, cleaning and reassembly which eventually caused leaks. Paper gaskets were introduced as a solution and later design improvements to the bevel seat union incorporated elastomeric gaskets. Brass and nickel alloys did not have the inertness or chemical resistance of glass and the fine chemical industry continued to prefer and use glass systems.

It is interesting to note that 18-8 stainless steel was a known entity at this time but it was extremely expensive, very difficult to machine and virtually impossible to weld and therefore it took well into the 1940's before its use became somewhat commonplace.

In 1951 Tri-Clover introduced the Tri-Clamp® sanitary union and the materials science, technology evolution truly began. A variety of gasketed clamp style systems were introduced over the following years, but the Tri-clamp® union and 304 stainless steel gained dominance with the largest installed base in the general sanitary industry.

A very important milestone took place in the early 1960's with the introduction of the CIP, or clean in place system, made possible by advancing technology in conjunction with the new union designs especially Tri-Clamp® and I-Line®. CIP dramatically reduced downtime and the associated costs.

In the early 1970's the pharmaceutical sector began to phase out the, by then, gasketed, glass process systems and to replace them with gasketed, stainless steel, Tri-Clamp® process lines. S.I.P. or steams in place systems were developed at this time. Glass is still used in many pharmaceutical and biopharmaceutical R&D and pilot systems.

During the sixties and seventies, stainless steel was also evolving from 304 to 316 to 316L to reduce extractables and leechables, provide better chemical resistance, less rouging and longer service life. Surface finishes went from a #7 (polished), to a 180 grit, to specific Ra readings. 20 Ra for was specified for food and beverage and a 15Ra or better for pharmaceutical applications. Electro polishing was introduced to remove free carbon from the stainless surface and to enhance chromium surface concentrations. In the late 1970's rigid, Tri-Clamp® thermoplastic fittings and tubing were introduced. They provided an inert product contact surface and dramatically reduced extractables and leechables.

Elastomers and thermoplastic technology also evolved concurrently with the progress being made in the sanitary industry. EPDM, Silicone, FKM and PTFE compounds were introduced to enable gaskets to withstand a wider variety of chemicals, higher temperatures and steam while minimizing extractables and leechables and extending service life.

By the mid seventies there were many manufacturers, all over the world, providing equipment for sanitary processors. Bio-processing, the ultimate sanitary industry was becoming a fast growing, worldwide activity, but its requirements for uniform, repeatable, controllable product quality were far more stringent than those of dairy, food, beverage and fine chemicals although the bio-processors were using the same equipment and stainless steel Tri-Clamp® process lines.

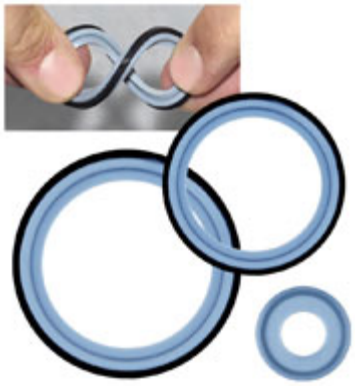
This resulted in the Tri-Clamp union coming under intense scrutiny. The union itself has four components: two ferrules, a clamp and a gasket. As the clamp is tightened it compresses the gasket between the ferrules making the seal. A 30 inch pound of torque is recommended for elastomer gaskets and a 50 inch pound for PTFE gaskets. Theoretically the seal is made and the gasket aligns perfectly with the ferrule I.D. With each manufacturer having slightly different dimensions, angles and tolerances this proved to be an impossibility which resulted in the gasket protruding into the I.D. or product flow area. The more the gasket protrudes the greater the chance for particulates and leechables to get into the product and the more area for the product, CIP or SIP to work on the gasket compound.

If you consider the aggregate of all the gaskets in your system, they represent a relatively large product contact surface which has the greatest effect on consistent product quality, downtime and your production costs.

The first ASME-BPE specification detailing ferrule and clamp dimensions, angles and tolerances was approved in 1997. In 2007, 10 years later, ASME-BPE adopted a specification limiting gasket intrusion to two categories: Category I +/- .025 and Category II +/-.008. It is left to the processor as to which category they wish to specify for their particular application, while the implications are very obvious. In 2009 ASME-BPE will specify the radii and depth of the locating grove in the ferrule and hence the size and location of the ring of the gasket.

It has become apparent over time that the lowly gasket is a crucial element in the construction and operation of a viable sanitary system and has a major impact on the cost of operating that system. It has also become apparent that elastomers have more negative attributes than thermoplastics as a sanitary gasket.

State of the art gasket products are available now. In the year 2000 a gasket comprised of a 50/50 homogonous blend of TFM and atomic particles of 316L stainless was introduced. This gasket does not cold flow or creep, is basically inert, metal detectable, virtually impervious to steam, has high chemical resistance and meets ASME-BPE Category II intrusion specifications standards. In 2004 a gasket comprised of a thin, virgin PTFE shell with an integral, bonded EPDM core was marketed. This gasket has all the positives of PTFE with the mechanical characteristics of an elastomer gasket. This gasket meets ASME BPE Category I specifications. It is the responsibility of the processor to make an informed decision concerning which technology best fits their application requirements.



Tri-Clamp® is the registered trade name of the Tri-Clover Division of Alfa Laval. I-Line® is the registered trade name of the Waukesha Cherry-Burrell Division of the SPX Corporation

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