Advanced PTFE gaskets for demanding applications

As a trusted supplier of high-performance sealing solutions to the pharmaceutical industry, the **Garlock** family of companies knows that gaskets can make or break a sanitary process. Stephen Doherty, global segment leader, talks to *World Pharmaceuticals Frontiers* about how material technology is evolving to meet manufacturing challenges and help pharmaceutical companies adapt to smaller batch sizes, frequent changeovers, leaner operations, vendor consolidation and stricter regulations.

"Gasket performance directly impacts a manufacturer's ability to safely and effectively operate a sanitary environment in pharmaceutical and bioprocessing industries," says Stephen Doherty, Garlock's global segment leader. "Regardless of whether the application is an integral part of the process, or within critical utilities such as clean steam, ultra-pure water (UPW) and water for injection (WFI), the demands on gasket material are tougher each year."

In multiproduct facilities, gaskets must hold up to frequent clean-in-place (CIP) and sterilisation-in-place (SIP) cycles involving harsh chemicals and high temperatures. Smaller batches, regular changeovers and a drive to minimise process downtime mean that gaskets are subjected to more frequent cleaning, a wider spectrum of process chemicals, extreme thermal cycling and fluctuating pressures during their expected performance life.

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"Frequent batch changes and cleaning cycles are placing more stress – mechanical and chemical – on gaskets and other soft parts used throughout the process," Doherty says. "A gasket may physically degrade, introducing fragments of material into the process and creating a contamination event.

"Most sanitary gaskets will also intrude or recede within hygienic couplings, leading to material build up and potential cross-contamination. With elastomers, this typically occurs due to over compression, but it is also common with standard PTFE gaskets due to the phenomenon of creep and cold flow."

Garlock's new GYLON BIO-PRO PLUS sanitary gasket eliminates these problems and sets the new standard in pharmaceutical sealing solutions. It is made of Garlock's proprietary GYLON Style 3522 modified polytetrafluoroethylene (PTFE) material, which is manufactured in a unique way to provide differentiated performance characteristics.

Unique in the market

"The revolutionary feature of the GYLON BIO-PRO PLUS is that it does not exhibit creep and cold flow, even if over-compressed, and is the only 100%-pure PTFE sanitary gasket to offer this benefit," Doherty says. "Because of this, it is fully compliant with ASME-BPE requirements for initial fit-up and dimensional stability over extended steam cycling."

GYLON BIO-PRO PLUS also delivers excellent material compliance, chemical compatibility and sealability. Cleanability is also essential for all process components, which should be non-additive and non-absorptive, so the ultra-low surface energy and high material density of the GYLON Style 3522 significantly reduces the potential for bioburden at the inner surface of the gasket. The colourless and translucent nature of the material also aids visual inspection and cleaning validation.

Supply chain benefits

While the primary benefits are offered within the production process itself, adopting an advanced gasket such as the GYLON BIO-PRO PLUS can also drive value across the whole operation. Specifying, validating and stocking a single gasket material can simplify the whole validation process, optimise the supply chain, eliminate the risk of incorrect gasket selection from inventory and facilitate vendor consolidation.

Pharmaceutical companies and their equipment vendors operate globally and face a complex patchwork of regulation. GYLON BIO-PRO PLUS delivers absolute compliance with FDA, USP Class VI, EN1935 and EC10/2011 as well as many other material requirements.

"As the pharmaceutical industry embraces lean manufacturing and seeks to improve operational efficiency, a next-generation sanitary gasket offers multiple benefits and can actually reduce overall product life-cycle cost," Doherty says. "No matter where your products are manufactured or processed, Garlock will be your global partner for product performance, process integrity and compliance." ■

Further information
Garlock
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