

Rubber Fab

a Garlock Hygienic Technologies company

Case Study: Oncology Injectables GYLON® BIO-PRO PLUS™



INDUSTRY

Pharmaceutical production- Oncology injectables

CUSTOMER

Cytostatic injection manufacturer to treat oncological diseases

BACKGROUND

The customer struggled with a very short life time of the gaskets installed in his tri-clamp connections. The gaskets showed high creep and cold-flow behavior and needed to be retightened after every single SIP (Sterilization In Place) cycle. The previously used gaskets were either made from virgin PTFE or envelope gaskets consisting of FKM core and outer virgin PTFE layer. The lifetime of these gaskets was approximately 2 weeks.

CHALLENGES FACED

The aseptic production process for cytostatic injectables underlies strict rules concerning the systems hygienic design. Good cleanability and sterilizability of all system components are of decisive importance. The end products are directly injected into the human body. Due to strict compatibility tests only pure PTFE gaskets without any additives, fillers or pigments can be approved for the process-line. Virgin PTFE gaskets and envelope gaskets only had a very short lifetime (approx. 2 weeks) due to their very high creep. All connections had to be re-tightened after every SIP cycle and exchanged after 3 cycles. One cycle consists of: 1. CIP (Cleaning In Place), 2. Retorquing with 2 Nm, 3. SIP – re-torquing with 2Nm, 4. Leak test, 5. Production. This procedure takes about 4 hours.

SERVICE CONDITIONS

1. Product: Cytostatic injections
2. Cleaning Media: SIP process (30 min- Steam at 121° C (250° F)) and CIP (WFI-Water for Injection at 75° C (167° F))
3. Size: 34/DN15; 50.5/DN15; 50.5/DN25; 50.5/DN40
4. Temperature: Up to 131° C (268° F)
5. Pressure: 2 bar (29 psi) SIP and 3 bar (44 psi) CIP

SOLUTION AND BENEFITS

Since the installation of GYLON® BIO-PRO PLUS™ the re-torquing of connections is no longer necessary. The lifetime of the gaskets has increased significantly assuring a reliable performance at all times. After more than 100 cycles ran with GYLON® BIO-PRO PLUS™ the customer extended the gasket replacement period from 3 to 6 months. Even after 6 months in use the gaskets still looked very good so that the gasket replacement period can be prolonged in the future. Most importantly with GYLON® BIO-PRO PLUS™ the customer increased the plants productivity gaining 4 additional product batches per month which they were losing in the past due to gasket replacement and re-torquing efforts. GYLON® BIO-PRO PLUS™ with a very high density and low porosity easily passed the systems pressure/leak-testing cycle. During this test GYLON® BIO-PRO PLUS™ showed a steady result where previously used envelope gaskets showed a 10 times higher pressure drop.

For more information, please visit: www.rubberfab.com