Rubber Fab

a Garlock Hygienic Technologies company

Case Study: Torquing Issues Torque-Rite® and Torque Tee

INDUSTRY

Life Sciences

CUSTOMER

World-leading International Animal Healthcare biotechnology company that develops and commercializes high-value innovative bioprocessing solutions.

BACKGROUND

Utilizing aseptic pharmaceutical manufacturing methods, this US Based customer develops and manufactures biological drugs for the Animal Healthcare Processing Industry. These methods of manufacturing, also known as fill-finish manufacturing, are most commonly used for vaccines, biologics, injectable drugs, cancer drugs, ear and eye drops and nasal sprays. Aseptic manufacturing minimizes the risk of introducing bacteria and contaminants into the body while administering medication. In order to minimize these risks the FDA stipulates cGMP where aseptic manufacturing practices are applied to the entire drug manufacturing process. Aseptic manufacturing usually takes place in specialized facilities, with cleanrooms and highly trained personnel who wear sterile outer garments to prevent particle shedding. These facilities are under regulatory scrutiny because of the complexity of the process and the risk to consumers should these drugs carry live pathogens.

Due to these stringent barriers, equipment and preparation, environmental controls, and contact guidelines, it is essential to have standard operating procedures for fluid sealing products that align with aseptic pharmaceutical manufacturing methods.

CHALLENGES FACED

Many regulatory challenges exist in these manufacturing facilities that over shadow basic fluid sealing product installation guidelines that ultimately saves time, money and prevents potential product contamination. The customer was experiencing a few of these challenges. First challenge that existed was the lack of a gasket installation procedure that included guidelines for applied torque. Without this procedure, most of the installation technique included the use of a hand held ratchet set where recommended torque would never have been achieved. Being an Aseptic Manufacturing Process, it is imperative to have this information documented and readily available. Hard-to-reach areas were also posing complicated challenges when it came to proper installation of gaskets. In a one size fits all world the customer is looking for a cost effective answer to these issues.

OPERATING CONDITIONS

1. Temperature - Tri-Clamp Gasket Material Rating
2. Application - Tri-Clover Connections
3. Media - Tri-Clamp Gasket Material Chemical Compatibility range
4. Pressure - Tri-Clamp Gasket Material Rating
5. Size - Various

SOLUTION AND BENEFITS

The quickest and easiest way to meet regulatory challenges at installation can be achieved with proper torque procedures utilizing Rubber Fab's Controlled Compression System family of products. These specialized tools are cost effective and easy to use helping to eliminate the human decision factor while limiting the need for calibrated expensive torque wrenches. Writing the group of products into your standard operating procedures based on cGMP is as easy as the seal itself.

Starting with Rubber Fab's Torque-Rite® hinge clamp tightening mechanism, available in 3 pre-set calibrated torque settings - 30, 40, and 50 in/lbs., once specified eliminates problems associated with over/under tightening a seal that can lead to failures and potential bacterial growth. Additional customizable handles are available allowing all of the standard features to be used along with the ability to reach areas that are not accessible with a standard set of wrenches.

If something more traditional is desired, Rubber Fab's Torque Tee and universal socket are designed to aid in clamp installation and removal. Available with a family of components, the Torque Tee handle creates effective tightening advantage and aids in reaching tight spaces, including overhead and behind tanks. In conjunction with a 3-piece extension kit, the Torque Tee allows customers to reach hard-to-access areas potentially reducing cost where traditionally they may have needed to perform work around processes. Multiple torque settings are available including: 20, 30, 40, 50, and 70 in/lbs. Rubber Fab has a Torque Tee for every situation.

Rubber Fab's line of Controlled Compression tools are rated for Buna, EPDM, FKM, Silicone, Tuf-Flex®, Tuf-Steel®, PTFE Envelope, BIO-PRO® and BIO-PRO PLUS™ gaskets. Please consult our technical representatives for proper recommendations based on sealing materials.

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