

BIOPHARMA INSIGHT

Human Factors in Biopharma Sealing

In any biopharma sealing system there are numerous factors that must be taken into consideration to ensure a good seal, including seal material, fastening method, ferrule condition, applied load and system pressure and temperature.

In addition to these mechanical factors, there are also numerous human factors that can influence the integrity of the sealing joint and lead to possible leakage if not properly managed, or eliminated. These can be as simple as reusing an apparently 'good' gasket, installing the wrong gasket, applying too much load, and even having uncertainty as to whether a seal has been changed out or not in a multi-seal system. In addition to this, poor or no recording of seal batch installation in a given location and/or date of installation removes all traceability in the event of a problem, making subsequent investigation more difficult, and hence more costly.

In the next series of articles we will cover these human factors in more detail, including how to manage, and indeed eliminate them from the system. Topics to be covered include:

OVERTORQUE

The use of too high an applied load is a common mistake in forming a sealing joint; higher loads are not better and can be detrimental, causing damage to the ferrules, fasteners and the seal, and thus compromising sealing integrity. Methods to eliminate this are discussed.

GUARANTEED GASKET CHANGE-OUT

It is essential to ensure each and every seal is changed out to avoid potential cross contamination, as well as ensure good sealing. In a system with numerous gaskets, all looking identical, some changes may be missed. Methods to minimise this are explored.

TRACEABILITY

Often poor, and in some cases no record of batch or date of installation is documented and in the event of a problem this makes the subsequent investigation very difficult and costly. Methods to ensure full traceability are investigated.