John Smiddy, Mechanical Seal Consultant at SMIDDY (IMSC) Ltd. explains how mechanical seals can pose a serious contamination risk on pharmaceutical production lines – and how that risk can easily be avoided.

Mechanical seals play a critical role in pharmaceutical production, preventing leakages from process pumps which could lead to costly downtime and product loss.

Yet, because they are component parts, seals are often overlooked when it comes to compliance with Food and Drug Administration (FDA) regulations and pharmaceutical current Good Manufacturing Practice (cGMP).

As a result, many manufacturers are unwittingly specifying mechanical seals manufactured from non-safe materials, creating a very real risk of contamination.

Crossover between the pharmaceutical, bio pharmaceutical and food and beverage sectors is routine – the use of the dairy by-product β-lactose as an excipient is a typical example. So, it makes sense that both cGMP and the regulations governing food contact materials (FCMs) must apply with equal weight in both sectors.

Regulation (EC) 1935/2004 on FCMs is unequivocal: “A name, reference number and batch or delivery number should identify each raw material, so that it can be traced, if necessary. The traceability of raw materials is achieved throughout the production chain and in-house by the delivery and/or batch reference numbers.”

In other words, every component in contact with an active pharmaceutical ingredient (API) must be 100% traceable and a statement of compliancy must be clearly marked on its packaging. That includes mechanical seals.

The main problem lies in the complexity of source materials and supply chains.

There are around 15 grades of carbon commonly used in the manufacture of seal faces, of which only a handful are compliant with FDA standards. Of the remainder, some are suited to chemical applications and don’t require FDA compliance, and finally there are antimony carbons, which are used in the oil and gas industry and, put simply, are poisonous and should never appear anywhere near pharmaceutical industry pumps. Yet we have seen this type of carbon on pharmaceutical sites.

A purchaser of component seals currently being imported into Europe from Asia might presume that the Original Equipment Manufacturer (OEM) has bought the product from the lowest cost source but be unaware that to achieve that low cost the product has been through so many links in the supply chain that all traceability has been lost by the time it reaches the end user.

The failure of FDA auditing to cover the supply chain of materials also means there are no proper checks and balances to demand proof, enabling less scrupulous companies to claim traceability erroneously.

Crucially, a seal made from unsafe materials looks identical to a seal which is 100% compliant. They can only be differentiated if their traceability is clearly stated on their packaging.

As a result, a pharmaceutical company which otherwise carries out stringent checks at every step of production might be unaware that there are a number of points of potential contamination risk – one for every pump fitted with non-compliant mechanical seals.

There are genuine reasons why companies fail to tackle this very real risk. There is often a lack of awareness, as well as poor communication between those responsible for compliance with FDA and EU regulations and operatives at the 'repair and replace' end of production.

But Regulation EC1935/2004 is clear – a mechanical seal is non-compliant if traceability is not visibly evidenced on the packaging and it should not be installed on a pharmaceutical production line.

Of course, there is a very simple solution to avoid both the risk of contamination and of falling foul of the law: Look at the label. And if the seal comes in packaging that doesn't clearly state its source, don't use it.

Seeking out compliant seals has benefits beyond legal compliance. A manufacturer which can guarantee its products are made from Generally Recognised as Safe (GRAS) materials is also highly likely to have invested in the most advanced technology to ensure optimum quality and reliability.

This makes the issue not just one of compliance, but of financial common sense.

Please contact SMIDDY (IMSC) Ltd to review your Component Seal applications.
We have lots of available options to help with overcoming this potential problem.

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