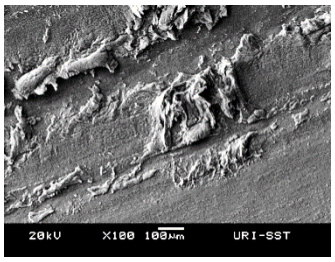
Component Exposure Analysis Project

THE CHALLENGE:

The BioProcess Institute was approached to perform component exposure tests on tubing and valves for two separate clients with two different issues. One client needed us to compare wear results between their new and their existing component, while other client needed to find the root cause of shavings that were found within their valve.

OUR SOLUTION:



The Scanning Electron Microscopy (SEM) is an important tool for materials and failure analysis because it provides high resolution images of samples at magnifications up to 50,000x. Energy Dispersive X-ray analysis (EDS or EDX) can be applied in conjunction with SEM analysis and is a technique used to identify the elemental composition of a sample or small area of interest on the sample. At left is an SEM image which represented tubing that was exposed to a 24-hour continuous duty with deionized water. It shows how the interior of the tubing was affected by the mechanical shear forces within the pump. The physical wear was determined to be from the impingement of the tubing on the pump housing. By capturing and analyzing these images, **The BioProcess Institute** proved that the tubing is not intended for continuous-duty use. Moreover, EDX analysis on the particulate collected inside the water solution proved that the inner surface of the tubing experienced shedding to the process solution and environment.

On the right another SEM image depicts the surface of a valve bellows that was installed inside an automated pulsing sterile valve. It shows how the surface of the bellows was affected by the mechanical forces within the pulsed valve and therefore proved that the particulate shavings that were found after 500 SIP cycles' exposure were the bellows' material of construction and not foreign particulate. The shavings formed along a transition region between a machined/tooled surface area and a smoother area of the bellows.

THE RESULTS:

BPI's was able to help their tubing client redefine the parameters for their product's use while also making them aware of a key shedding issue. For our valve client, **The BioProcess Institute** recommended some potential design changes, i.e. retool this merged/ transition area to address the problem of frays coming off and entering the biopharmaceutical process. This allowed the client to increase the performance of this valve before it went to market. BPI's report also helped to support the client's marketing claim.

For more information on testing and analysis or marketing claim support, please contact:

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