Real-time Microbial Detection

THORNTON
Leading Pure Water Analytics

Five Process Control Advantages

of At-line Microbial Detection

For pharmaceutical manufacturers, on-line measurement allows for more effective responses to water quality challenges. Total Organic Carbon (TOC) and conductivity are two key process analytic parameters where on-line/at-line measurements have been possible for decades. However, when it comes to monitoring bioburden contamination in high purity water, the market has relied on laboratory-based methods developed over a century ago. The pharmaceutical industry and its regulators acknowledge, recognize and endorse the need for the ability to monitor bioburden contamination in real-time. Integrating at-line bioburden measurement offers significant advantages in process control.

Five Advantages

1. Real-time data allows for full visibility of excursions
2. React immediately to contamination
3. Optimize sanitization frequency
4. Determine sanitization effectiveness
5. Increased productivity and faster water release

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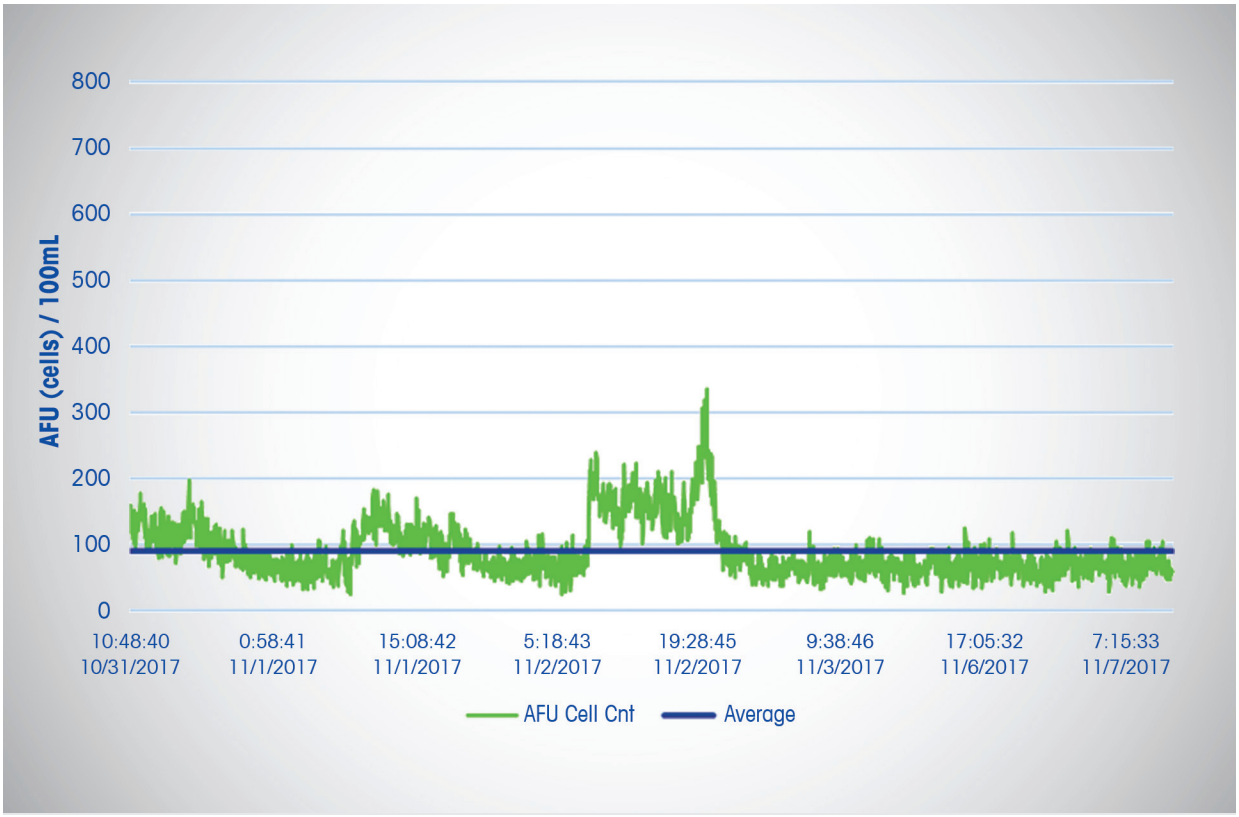

Here are five process control advantages of at-line microbial detection:

1. Real-time data allows for full visibility of excursions
Plate counting, the traditional method of bioburden measurement, provides an estimation of microorganisms present more than five days after a sample is taken. In contrast, by combining the techniques of laser induced fluorescence and Mie scattering, it is possible to continuously count the microorganisms present in a water system in terms of Auto Fluorescent Units (AFUs). Using this method, personnel can observe changes and excursions in their water system in real-time.

2. React immediately to contamination
Traditionally, microbial investigations and recall of water are reactions to plate counting results that are unable to provide excursion details, including timing and severity of contamination. Action may not be taken for several days after an excursion has occurred. However, with continuous AFU data, trend information can be used proactively to reduce and mitigate the risk of releasing contaminated water. Once a facility has established a baseline or average AFU level during normal operation, a user can analyze how water system dynamics can impact the amount of microorganisms in the water system.

This results in greater process transparency and a better understanding of how changes to the water system such as hydraulic events, fluctuations in demand, maintenance, and so on can impact the risk of contamination.

3. Optimize sanitization frequency

Sanitization of a water system can be costly, can increase wear on certain components, and limits the time water can be produced or released. Typically, sanitization frequency is based on historical information related to water system control across a multitude of parameters that provide continuous on-line results, such as TOC and conductivity.

With the traditional plate counting method of laboratory-based bioburden measurements, only a snapshot of water system contamination is provided five or more days after the sample is taken. This limits the ability to understand when sanitization is needed on a water system. With real-time measurement, facility personnel can use continuous trending data to analyze baseline shifts before and after sanitization. This also allows optimization of sanitization frequency by determining if a sanitization cycle is needed due to a measured increase in bioburden in a water system. By optimizing sanitization frequency, a facility can reduce sanitization costs and decrease the wear on certain components of their water system.

4. Determine sanitization effectiveness

Duration of sanitization cycles are also based on historical information, often delaying water production and release for longer than necessary. For example, a facility may use a standard of six hours of sanitization when, in reality, sanitization is sufficient after four hours.

Using real-time data and an established baseline, a facility can monitor changes in AFU count when heat sanitization occurs. With this process transparency, a user can observe an increase in AFU counts and an upward trend, indicating that sanitization is removing the bioburden and biofilm that has built up in the system. As sanitization continues, the AFU trend will come back down to its established baseline. This monitoring of the increase then decline of the AFU data allows personnel to be confident in sanitization cycle effectiveness.

5. Increased productivity and faster water release
When relying on laboratory-based bioburden measurements, water quality and risk level can be uncertain. Using at-line measurement that provides real-time data, the baseline for a water system is always available for optimization of sanitization frequency and management of the rinse cycle after sanitization. With the ability to see the data trending down and the AFU count returning to the baseline, personnel can determine when they are no longer at risk. Production is positively impacted by the ability to release water sooner because the operator is confident that rinse time was sufficient and that the water system is in control.

At-line analyzer provides continuous microbial detection
METTLER TOLEDO Thornton's 7000RMS™ Microbial Detection Analyzer is an innovative solution to the industry and market's need for better process control for bioburden monitoring. As described here, this at-line analyzer counts individual microorganisms, or AFUs, in high purity water in real time using two established optical measurement techniques: laser induced fluorescence, related to the metabolites NADH and riboflavin, and Mie scatting. This technique has the ability to provide these bioburden counts as frequently as every two seconds, or 1 mL of sample stream, making it possible to observe trends.

The 7000RMS provides real-time data and process transparency into the dynamics of a facility's water system, allowing proactive monitoring of bioburden. Ultimately, the 7000RMS increases process control, reduces risk and allows for greater sensitivity of bioburden measurements, while reducing costs and increasing productivity.

Find out more...

Download our white paper on
Real-time Release of Pharmaceutical Waters with On-line Microbial Monitoring

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