BioSpectrum ASIA EDITION
the business of Bio & Health Sciences

MilliporeSigma launches first software for complete data traceability in microbial quality control

May 28, 2024 | News

M-Trace Electronic Test Record Software offers digital cleanroom-friendly solution for sterility testing



MilliporeSigma, the US and Canada Life Science business of Merck KGaA, Darmstadt, Germany, a leading science and technology company, has launched its M-Trace Software & Mobile App, a comprehensive data tracking solution to digitise sterility testing. The software increases overall process safety by automatically documenting data for every step of the testing process. This reduces the likelihood of deviation, false positive results, and the possibility of human error.

“Microbiological quality control labs are critical to ensuring the safety of sterile medicine. Here, the consequences of noncompliance can be very serious,” said Jean-Charles Wirth, Head of Science & Lab Solutions for the Life Science business of Merck KGaA, Darmstadt, Germany. “Our job is to offer the solution that ensures drugs are safe and brought to market to the patients who need them the most, so data traceability is essential. Digital innovations like M-Tracebring us one step closer to making the ‘Lab of the Future’ a reality.”

Sterility Testing is the last step of the quality control workflow used by the pharmaceutical industry. It ensures that products such as vaccines, ophthalmic solutions, chemotherapies, and other injectables are 100% free of contaminants. Microbial contamination can expose patients to pathogens/toxins that cause serious metabolic harm or lead to death. Another possible effect is drug degradation resulting in reduced potency. M-Trace allows drug manufacturers to mitigate safety concerns by notifying of any errors spotted during the process. Furthermore, it provides a complete digital solution for documentation compliance. M-Trace generates comprehensive reports that enhance data analytics to track trends and ease investigations into out-of-specification results.