

News Release

Your Contact

Media Relations

rachel.bloom-baglin@milliporesigma.com

Phone: +1 978 436 1725

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MilliporeSigma Launches First Software for Complete Data Traceability in Microbial Quality Control

- **M-Trace® Electronic Test Record Software offers digital cleanroom-friendly solution for sterility testing**
- **Digitizes pharmaceutical microbial quality control workflows**
- **Enables complete, real-time, comprehensive data traceability and regulatory compliance, reducing deviations and human error**

Burlington, Massachusetts, May 28, 2024 – MilliporeSigma, the U.S. 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 digitize 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-Trace® bring 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.

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400 Summit Drive
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emdgroup.com

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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.

Merck KGaA, Darmstadt, Germany is invested in enabling the “Lab of the Future” through innovative workflows to revolutionize scientific research and development. To extract insights from vast amounts of data, solutions are becoming more automated, more autonomous and more continuous. Some of these technologies include AI-powered software pieces focused on digital chemistry and drug discovery, like AIDDISON™ AI powered drug discovery software and SYNTHIA™ Retrosynthesis Software. Other tools digitize processes that have always been manual, like the Digital Reference Materials ChemisTwin™ platform or cell counting systems like MilliCell® DCI and Scepter™ 3.0. With the addition of M-Trace®, our company continues to support scientists at all stages with solutions that can increase efficiency, safety and success rates of delivering new, safer therapies for patients.

More information is available at:

<https://www.sigmaaldrich.com/US/en/services/software-and-digital-platforms/m-trace-electronic-test-record-software>.

* M-Trace® is available in North America and Western Europe and will be available globally by the end of 2024.

About the Life Science business of Merck KGaA, Darmstadt, Germany

The Life Science business of Merck KGaA, Darmstadt, Germany, which operates as MilliporeSigma in the U.S. and Canada, has more than 28,000 employees and more than 55 total manufacturing and testing sites worldwide, with a portfolio of more than 300,000 products focused on scientific discovery, biomanufacturing and testing services. Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and electronics.

Around 63,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2023, Merck KGaA, Darmstadt, Germany, generated sales of € 21 billion in 65 countries.



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The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company. For more information about Merck KGaA, Darmstadt, Germany, visit www.emdgroup.com.

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