



bioMérieux launches 3P[®] ENTERPRISE, an innovative solution to address the daily challenges of environmental monitoring in the pharma industry

Marcy l'Étoile, France – July 7, 2022 – bioMérieux, a world leader in the field of *in vitro* diagnostics, launches 3P[®] ENTERPRISE, an innovative solution designed to ensure environmental monitoring processes are fully efficient and under control at all times.

Environmental Monitoring, a critical and challenging requirement

Environmental Monitoring (EM) is one of the main microbiological controls that biotechnology and pharmaceutical industries perform. This ensures the safety and efficacy of pharmaceutical products and is a critical control to consider when companies release their finished drug products to market. To efficiently control the quality of these products, companies must monitor for the presence of potential microbial contaminants. This is typically performed using irradiated culture media in Petri plates and monitoring is carried out along the whole production process, especially focusing on critical and highly controlled production environments.

The historical method is extremely manual, variable and error-prone, but it remains the standard procedure used in industry for hundreds of millions of samples per year. With this high number of samples, it often happens that errors occur – data integrity failures, incorrect enumerations, missed samples, all leading to time-consuming and expensive investigations which ultimately impacts patient safety.

As a strategic pillar, to ensure companies maintain compliance, EM must be robust and reliable at every single step. Every time a microorganism is found in a critical environment, there is a risk that the drug product itself could be contaminated.

Emerging technologies in the pharmaceutical industry mean that companies are now able to move towards greater digitalization and automation of their manufacturing processes. This elevates the level of data integrity that companies can maintain and also improves production efficiency as decisions to act on issues can be made much faster.

3P[®] ENTERPRISE: a new system is emerging

The 3P[®] ENTERPRISE* solution has been developed by bioMérieux to fully address the daily industrial challenges of EM. Developed and validated, in collaboration with major global pharmaceutical companies, 3P[®] ENTERPRISE provides an end-to-end solution that fully digitalizes and automates the EM process.

As highlighted by Michaël Reynier, Sr Vice President for the BioPharma QC Solutions Business “*At bioMérieux, we are strongly committed to empowering our customers to keep their production environment under control; digitalization and automation of the entire Environmental Monitoring process, from sampling to result, will support them in their willingness to limit uncertainty whilst enhancing productivity.*”



Empower the future with 3P[®] ENTERPRISE

3P[®] ENTERPRISE is a combination of three key products that, when validated and leveraged together, deliver significant value to companies looking to improve their processes.

The first part of the solution is the **3P[®] SMART PLATES**. Enhanced with a new ultra-clear design and GS1 barcode labelling, the plates form the heart of 3P[®] ENTERPRISE. To ensure the security of supply of 3P[®] SMART PLATES, dual-sourcing is built in to the solution; two, fully independent manufacturing sites (based in Europe and the USA) are both able to deliver to pharmaceutical sites around the world to avoid any supply disruption.

3P[®] CONNECT software** is the second part of the solution. The software automatically and immediately collects, tracks, and saves all the actions and data related to EM. This removes the paperwork process and so decreases the risk of errors and win time during the entire EM process. Ultimately this enable companies to make reliable decisions, maximize efficiency and improve compliance.

Finally there is the **3P[®] STATION**, an instrument that automates the incubation and counting of microbiological colonies on EM Petri dishes in real time. A combination of high performance algorithms and high definition images taken every hour mean that there is a standardized reading of plates - no human error - and alerts raised should a sample exceed its specification, allowing rapid corrective actions. The solution is able to deliver significant efficiency gains. Not only are all the manual reading steps, currently undertaken in a laboratory, removed, but as the 3P[®] STATION can be placed much closer to the manufacturing floor, incubation can start sooner and therefore results obtained more quickly, allowing users to take the right action, faster. The 3P[®] STATION system has been validated alongside the manual method and provides an end-to-end solution that has been proven to be at least as good as the manual method.

From planning to data reporting, pharmaceutical sites now have the ability to supervise EM control at all stages of the process. 3P[®] ENTERPRISE is the solution to get faster results, earlier product release as well as faster turnaround of production lines after cleaning validation. As a result: a greater peace of mind thanks to standardized EM control and financial savings!

To know more, discover the video: [link](#)

A dedicated range of services

We know that pharmaceutical industries are not just investing in a digital system that has a great range of features. Process changes are not always easy and so our experts are available to support the integration of 3P[®] ENTERPRISE at every stage with a customized approach, to ensure a successful and timely installation and validation.

"These changes are by no means an easy task for our partners in the pharmaceutical industry, but by collaborating with bioMérieux' experts, end-to-end automation and digitalization of Environmental Monitoring has now become a reality !" underlines Michaël Reynier.



*3P® meaning: *Pharmaceutical, Proven, Performance*. The 3P® legacy is one of delivering proven performance when it comes to effective pharmaceutical contamination control. Now it's going digital.

** 3P® CONNECT software is powered by Mirrhia®, a company dedicated to the international distribution of environmental monitoring & contamination control solutions.

ABOUT 3P® ENTERPRISE DISTRIBUTION

3P® ENTERPRISE will be progressively released, and might be not yet accessible in every country. Please contact your bioMérieux representative to have more information.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics since 1963, bioMérieux is present in 44 countries and serves more than 160 countries with the support of a large network of distributors. In 2021, revenues reached €3.4 billion, with over 90% of sales outside of France.

bioMérieux provides diagnostic solutions (systems, reagents, software and services) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

www.biomerieux.com.



bioMérieux is listed on the Euronext Paris stock market.

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