



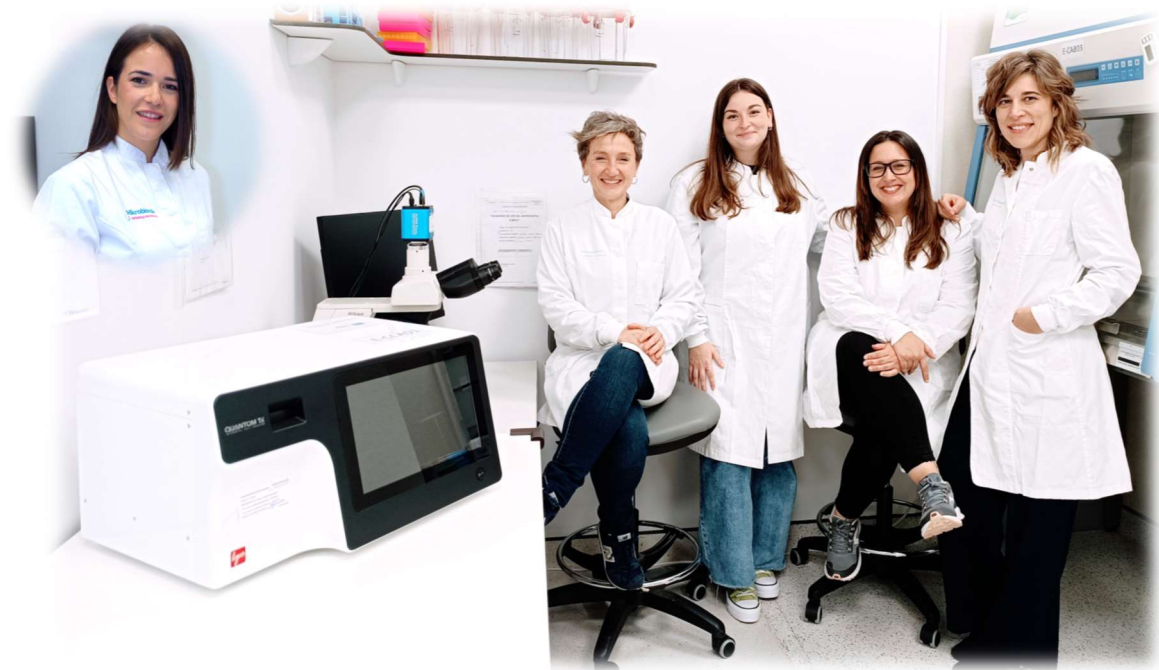
A new validation that brings excellence to Mikrobiomik and to the pharmaceutical industry

Mikrobiomik is a biopharmaceutical company founded in 2018, based in Derio Technology Park (Vizcaya, Spain), being a pioneer in the country and Europe, promoting an **innovative therapeutic approach based on the human microbiome** to improve people's health and well-being. Its activity focuses on the research, development, and production of a new generation of biological medicines based on the intestinal microbiota, aimed at serious diseases without an effective therapeutic alternative.

“At Mikrobiomik, we are pioneers in the field of microbiota research, and we will be the first company worldwide to commercialize in Europe the first biological medicine based on intestinal microbiota (MBK-01), as a treatment for primary or recurrent *Clostridioides difficile* infection,” says its CEO and co-founder, Dr. Juan Basterra.

Mikrobiomik has the **first GMP (Good Manufacturing Practice) facility** in Europe to produce intestinal microbiota-based medicines, approved by the AEMPS (Spanish Agency for Medicines and Medical Devices), at a pilot scale, exclusively dedicated to supplying medicines for ongoing clinical trials.

As a disruptive and pioneering company, Mikrobiomik has achieved a significant milestone by introducing the **QUANTOM Tx™** Microbial Cell Counter device and validating the method for counting total microorganisms as a quality control within the production process of the investigational biological medicine MBK-01.



In 2022, Mikrobiomik acquired the **QUANTOM Tx™** Microbial Cell Counter (**Logos Biosystems, part of Aligned Genetics**), from the local distribution company, **Isogen Life Science (Netherlands)**. This device counts fluorescently stained cells by automatically acquiring images of the light emitted by the stained cells and provides objective counts of the cells detected in the images.

In 2023, experts from the Quality Control Department, with the assistance of the Quality Assurance Manager, have carried out the fine-tuning and subsequent **development and validation of the method**, following the ICH standards (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use), to maintain the high standards required to produce under GMP regulations.

"We are extremely pleased that the **QUANTOM TX™** Microbial cell counter has been successfully validated and incorporated in the production process of the biological medicine MBK-01 of Mikrobiomik", said Neon Jung, CEO of Logos Biosystems (the Aligned Genetics company). "This is a significant advancement as it allows us to meet the high standards required for GMP regulations."

This validation represents added value, not only for Mikrobiomik, but also in the future for the pharmaceutical industry and other industries associated with microorganisms, as this application had not been carried out until now. For Mikrobiomik this development represents another step in the search for excellence in its processes, providing speed, effectiveness, and an extra level of innovation