

Non-destructive particle counting – ten23 health and Bionter collaborate to improve testing of particulates in sterile products.

Basel, 2nd of May 2023 ten23 health, a global contract development and manufacturing organization, and Bionter, a premium supplier of analytical testing technology, announced today their collaboration to advance innovative testing methods of particulate matter.

- Bionter has launched EVE, a fully automated particle testing system, to assess sub-visible particulate contamination for parenteral drug applications based on light obscuration.
- ten23 health has been running customer samples on an EVE system and is also acting as an application center for Bionter.
- Due to the non-destructive nature of Bionter’s EVE particle testing equipment, the same sample can be further analyzed with orthogonal analyzing methods whilst minimizing sample volume needed.
- The Bionter installation complements ten23 health’s comprehensive method and equipment panel for the characterization and assessment of aggregates and particulates, including light obscuration, automated flow imaging, nano-tracking analysis (NTA), Dynamic or Static light scattering stand-alone or coupled with chromatographic separation techniques, as well as identification of visible particles by spectroscopic methods.

Dr. Björn Boll, Senior Director for Particle Characterization and Drug Product Design at ten23 health commented: *“We are excited to offer this new technology to our customers. It offers several advantages over established methods that*

could improve workflows due to automation and reduction of sample consumption.”

Dr. Tobias Werk, CEO of Bionter, stated: “We strive to develop innovative solutions for our customers. The partnership with ten23 gives us insight into the daily challenges of biologics analytics and allows and inspires us to further tailor our solutions to the true needs.”

About ten23 health

ten23 health®, located in Basel, Switzerland, is the human-centric and sustainable strategic partner of choice for the pharmaceutical industry and biotech start-ups: we develop, manufacture, and test modern medicines. We support our clients in developing differentiated, stable, usable, and safe injectable treatment options for patients. Our second site, located in Visp, Switzerland, is a world leader in the sterile production of complex pharmaceutical dosage forms and a wholly owned subsidiary of ten23 health.

ten23 health combines the latest scientific findings with proven and tested world-class industry and regulatory expertise to forge new paths for supporting clients. We provide our innovative services in a fair and sustainable manner, respecting people’s health and the future of our planet. ten23 health is solidly financed through the long-term commitment of 3i Group, an internationally reputable equity partner.

About Bionter

Bionter is a Swiss-based Biotech start-up. Since the foundation in 2020, Bionter has established successful prototype testing with 4 global Pharma companies, received successful seed funding from a US investor and launched their first product in Europe and the US. The team has significant experience in particle analytics as well as the commercialization of biotech products. Bionter’s first product, EVE, is a fully automated particulate matter detection system, that works non-destructive with the sample used and is fully compliant with current regulations.

Bionter is a premium supplier of analytical testing solutions and contributes to the benefit of people's health by helping pharma companies and their service providers to bring drugs faster and safer to the market.

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