ten23 health® QC lab to support commercial product testing for U.S. customer following FDA approvals

Basel, Switzerland. December 9, 2025 – ten23 health, the human-centric and sustainable CDMO partner of choice for the pharmaceutical and biotechnology industries, today announced that its recently established and Swissmedic approved Quality Control (QC) laboratories in both Basel and Visp, Switzerland, have been formally approved by the U.S. Food and Drug Administration (FDA). The approval was granted in connection with registering ten23's QC labs for the U.S. market for a U.S. customer. This pivotal regulatory milestone enables FDA-compliant release and stability testing for injectable drug products throughout the clinical and commercial phases, in addition to manufacturing the commercial product.

Key Highlights

- The FDA approval relates to a U.S. customer's commercial product, and recognizes that ten23 health's Basel (BASE®) and Visp (VIVA2®) QC labs can be used to perform GMP-compliant analytical release testing and stability studies, including microbiology, content, purity, identity and pharmacopeial testing.
- This milestone further confirms ten23 health's vertically integrated offerings — from formulation and process development to fill/finish and now FDA-approved QC testing — supporting clients across the full lifecycle of injectable and sterile drug products.
- The achievement underscores ten23 health's commitment to rigorous regulatory standards, quality assurance, and scientific expertise, aligned with its mission to serve Patients, People, Planet.

"*We are delighted to have achieved FDA acceptance of our QC laboratories, on top of our Swissmedic GMP certifications*," affirms **Hanns-Christian Mahler, CEO of ten23 health** . "*Our pharmaceutical and biotech clients can now rely on our analytical team and infrastructure to meet U.S. regulatory expectations—without requiring duplicate arrangements elsewhere. Our testing and QC offerings, integrated with our development*

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and manufacturing activities, will reduce complexity, accelerate timelines and help to supply products to patients in the U.S."

"*Recognition by the FDA is a great reward for the hard work of everyone in our Quality Control team, and an important signal that we can meet the standards of the U.S regulatory agency. We are excited to grow the business as ten23 health becomes more international*," remarks **Ivana Heckel, Head of QC at ten23** .

Strategic Impact and Client Benefits

- Full range of service offering: ten23 health offers a truly integrated platform formulation, process development, sterile manufacturing and analytical testing — all under one roof.
- Regulatory readiness: Clients leveraging ten23 health's services can now benefit from QC standards which align with FDA expectations for clinical and commercial submissions.
- Quality & sustainability: Reflecting its purpose-driven agenda, ten23 health continues to invest in high-quality infrastructure and sustainable operations, thereby offering not only technical excellence but also responsible manufacturing practices.
- Global access, Swiss Excellence: Based in Basel and Visp, Switzerland, ten23 health delivers to clients around the world while leveraging Swiss regulatory standards, precision and culture of quality.

About ten23 health

ten23 health®, located in Basel and Visp, 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.
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 a B Corp member and solidly financed through the long-term commitment of 3i Group, an internationally reputable equity partner.

About 3i Group

3i is an investment company with two complementary businesses, Private Equity and Infrastructure, and invests in mid-market companies headquartered in Europe and North America. 3i's Private Equity team provides investment solutions for growing companies, backing entrepreneurs and management teams of companies with an EV typically between €100m - €500m. 3i backs international growth plans, providing access to its network and expertise to accelerate the growth of companies across the consumer, healthcare, industrial and private label, and services and software industries.

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