

Analytical & Testing Services

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Stevanato Group

MANAGING COMPLEXITY, DELIVERING VALUE

Stevanato Group

Analytical Services

As part of Stevanato Group's commitment to R&D, our analytical testing sites focus on investigating the physico-chemical properties and interactions of primary packaging materials and drug products.

Stevanato Group relies on a highly-skilled multi-disciplinary team of professionals, including: scientists, engineers, pharmaceutical chemists, and biotechnologists.

Their knowledge and experience cover a wide range of specializations, from drug formulation to drug delivery devices, assuring end-to-end support on the drug development journey.

Mission

Our mission is to provide analytical services to enhance the integrity of parenteral medicines, producing the leading edge in scientific and technological expertise for Stevanato Group and its customers.

We offer a wide range of chemical analysis, surface characterization, or container performance testing.



Bridging the gap from drug product development to commercialization

Our Technology Excellence Centers

Stevanato Group's Italian laboratory, EMEA TEC, is certified to ISO 9001 and ISO 13485.

Thanks to the Company's in-house process and machine manufacturing technologies, Stevanato Group has an unrivaled expertise on drug containment solutions. This know-how has been further strengthened by the network of collaborators and partnerships established with prestigious universities, research institutes, and scientific organizations.



Located in Boston, Massachusetts, the US Technology Excellence Center provides biopharma companies with integrated analytical services. It offers effective project management to support the drug development activities, from the early phase of drug discovery to commercialization and lifecycle management.

The laboratory is **certified for ISO 9001 and ISO 13485.**



Stevanato Group's Analytical Services Offering in a Snapshot

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Locations
Italy and USA.

40+

Technical & scientific experts perform hundreds of analytical tests each year.

10+

Years
of experience.




ZEISS
BRUKER
Chemical
Analysis
Surface

Services

By placing the primary packaging at the heart of each project, we can anticipate challenges and present viable, well-informed solutions thanks to a skilled team, our expertise on reserch projects, and science behind.



Primary Container Compatibility and Functionality with Drug Product

This series of characterization techniques aim to fully understand how the primary packaging behaves in the presence of the drug product and/or under specific applications or conditions with a deterministic approach.

Tests

- Sampling material availability
- Sub-visible particle analysis
- Climatic chambers for stability studies
- Surface morphology (sem-eds)
- Delamination studies
- Visual inspection
- Break-loose & gliding forces
- Silicone layer morphology
- Standard syringe tungsten solution
- Tungsten residual analysis
- Mechanical resistance tests
- Closure performances (pof)
- Pull-off force
- Failure test (burst test)
- Extractables & leachables
- Fractography
- Material identification
- Dose accuracy and hold-up volume
- Prototyping
- Device functionality tests



Container Closure Integrity

Methodologies and techniques that challenge the sealing integrity of a container closure system to ensure the correct compatibility of materials and storage conditions.

Tests

- Dye ingress
- Helium leak detection
- Internal pressure resistance



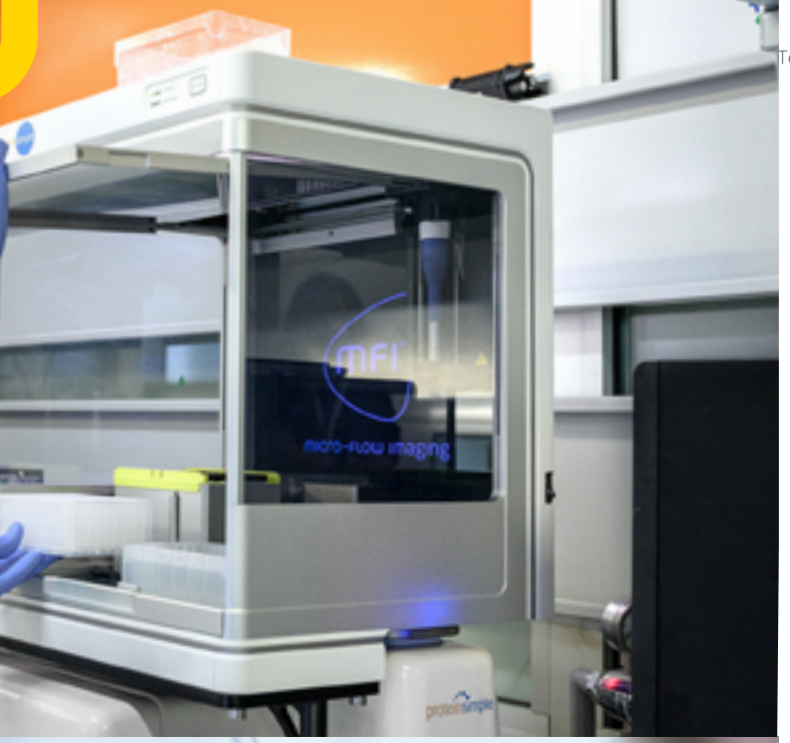
Fill & Finish Service (NFHU)

Suitable for syringes, cartridges and vials. NFHU fill & finish services provide commercially representative filled containers in small or large quantities. Representative samples support compatibility assessments between drug, container, device, and/or assembly. Our service also supports stability studies, process optimization, and downstream equipment qualification, helping reduce development risk and accelerate manufacturing readiness.

Available Technologies

- Peristaltic and rotary piston pumps to dispense a wide range of viscosities
- Vacuum and mechanical (vent-tube) stoppering compatible with various plungers/stoppers
- Filling can be done with water, surrogates or drug substances









Medical Devices/ Combination Products

Extensive testing to ensure the robustness of product functionality.

Tests

- Engineering verification test
- Design verification/maturity test
- Pilot-run verification test

Services



Consultancy (Regulatory, Compliant Support, Test Method Development & Transfer)

Ensuring all the technical, regulatory, and documental support for developing a drug product throughout its life cycle.

Services

- Design history file supportive documentation
- Drug master file
- Documentation about eu/us regulations
- Extractables & leachables report
- Test method readiness (development, validation, transfer)
- Forensic analysis



Partnerships:

> Nelson Labs

Stevanato Group signed an agreement with Nelson Labs Europe and Nelson Labs, in 2017 and 2020, based on the mutual exchange of state-of-the-art knowledge, expertise and capabilities. This strategic partnership enables to leverage the collective expertise in premium container/closure development for small volume parenteral, the in-depth scientific knowledge, and supporting cutting-edge analytical technologies.

Nelson Labs, a Sotera Health company, is a leading global lab testing provider and expert advisory services. It performs microbiological and analytical laboratory tests across the medical device, pharmaceutical, and tissue industries.



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Stevanato Group

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