

Stevanato Group signs an agreement with Nelson Labs to provide best-in-class Extractables & Leachables testing services at its US Technology Excellence Center

US TEC will add biocompatibility, microbiology, extractable & leachable testing, and toxicological evaluation to its analytical technique suite to investigate drug-container closure system interaction

Piombino Dese, Padua Italy and Salt Lake City, USA September 1, 2020: Italian-based Stevanato Group, a leading producer of glass primary packaging and provider of integrated capabilities for drug delivery systems, and **Nelson Laboratories, LLC, a global provider of lab testing and expert advisory services** signed today a partnership agreement that will provide **Extractables and Leachables testing at US Technology Excellence Center in Boston, MA.**

The collaboration combines the best-in-class knowledge, expertise, and capabilities of both companies. **The US TEC, opening in Boston on September 24th, will provide analytical services on material properties, physical and mechanical performances to investigate the potential interactions between drugs and glass-based primary packaging. Thanks to this collaborative agreement, Nelson Labs will support the US TEC with toxicological evaluation, biocompatibility, microbiology, and extractables and leachables testing.**

Over the years, Nelson Labs has built a set of advanced analytical methodologies, using cutting-edge technologies and state-of-the-art instrumentation. Besides, Nelson Labs boasts a **wide range of exclusive analytical and toxicological databases**, allowing its staff to optimize their methodologies and data interpretation further.

“With our laboratory in Italy, SG Lab, we have collaborated for many years with Nelson Labs’ European Center of Excellence, Nelson Labs Europe. We are glad to extend this collaboration also to our US customers. Its recognized expertise in extractables and leachables testing applied to biologics is crucial to ensure that the packaging system does not adulterate the drug product, ensuring drug efficacy, and patient safety. Combining US TEC skilled scientists with Nelson Labs’ experts and cutting-edge laboratory capabilities, we can now offer comprehensive analytical services assessing drug compatibility with container closure systems and devices/combination products.” says Abizer Harianawala, Site Leader at US TEC.

“When it comes to the E&L qualification process of the primary packaging, biologics face additional challenges compared to small-molecule drugs. The efficacy of the therapeutic biologic could be compromised through undesirable interaction of leachables with the drug

substance, resulting in side-effects and product recalls. Nelson Labs' in-depth scientific knowledge of extractables and leachables testing - including toxicological assessments - will allow biopharmaceutical companies to move much faster in the qualification and acceptance process of their selected container closure system." says Piet Christiaens, Scientific Director at Nelson Labs Europe.

About Stevanato Group:

Established in 1949, Stevanato Group is the world's largest, privately-owned designer and producer of glass primary packaging for the pharmaceutical industry. From its outset, the Group has developed its own glass converting technology to ensure the highest standards of quality. The Group comprises a wide set of capabilities dedicated to serving the biopharmaceutical and diagnostic industries: from glass containers with its historic brand Ompi, to high-precision plastic diagnostic and medical components, to contract manufacturing for drug delivery devices, to vision inspection systems, assembly, and packaging equipment.

The Group also provides analytical and testing services to study container closure integrity and integration into drug delivery devices, streamlining the drug development process. Thanks to its unique approach as a one-stop-shop, Stevanato Group is able to offer an unprecedented set of solutions to biopharma companies for a faster time to market and a reduced total cost of ownership.

For more information, please visit www.stevanatogroup.com

About Nelson Labs:

Nelson Labs, a Sotera Health company, is a leading, global provider of lab testing and expert advisory services. We perform microbiological and analytical laboratory tests across the medical device, pharmaceutical, and tissue industries. The company is regarded as a best-in-class provider with a strong track record of collaborating with customers to solve complex problems. We have over 500 scientists, technicians, and service specialists who diligently perform more than 800 rigorous tests in 13 global laboratory locations.

Based in Belgium, Nelson Labs Europe specializes in providing premium extractables & leachables testing services to the pharmaceutical and medical device industries. We also support pharmaceutical companies across the globe in developing worldwide compliance testing strategies to qualify container/closure applications and pharmaceutical production equipment from an extractables & leachables perspective.

With decades of expertise, we stand behind the quality of our results and the strength of our customer partnerships. Along with our sister companies Sterigenics and Nordion, we are part of Sotera Health, the leading protector of global health.

For more information, please visit www.nelsonlabs.com

