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Stevanato Group will be able to offer extended analytical and extractables & leachables testing services to determine the drug integrity during its entire life cycle

Piombino Dese (Padua, Italy), March 14, 2017 – Italian Stevanato Group, through its laboratory SG Lab, **has signed a partnership agreement with Toxikon Europe**, the Belgian Contract Research Organization (CRO), to include **extractables and leachables analysis** to its chemical-analytical testing services.

The **collaboration** is based on a **mutual exchange of best-in-class knowledge, expertise and capabilities**. **SG Lab** is specialized in analytical chemistry, material properties, physical and mechanical performances to study the potential **interactions between drugs and glass containers**.

Over 35 years, **Toxikon Europe** has built a suite of world-class scientific services (extractables & leachables, toxicological assessments, impurity identifications and biocompatibility testing) to support the pharmaceutical companies. This service is based upon unique set of advanced analytical methodologies, using cutting-edge technologies and state-of-the-art instrumentation. In addition, Toxikon Europe developed a wide range of exclusive analytical and toxicological databases, which allow their staff to further optimize their methodologies and data interpretation.

The joint offer provides pharma companies with certification services able to address increasingly demanding global regulatory requirements. It also allows optimizing and customizing the glass container and its closure based on the study of the entire drug container's life cycle.

"Thanks to this agreement, SG Lab can support pharmaceutical customers since the early stages of a new drug development. We help them in the selection of the best glass container including closure system, taking into account all the relevant aspects (compatibility, stability, quality)." - says **Odra Pinato**, **SG Lab Analytics Coordinator** – "Combining skilled glass experts with Toxikon's experienced scientists and cutting edge laboratory capabilities, we now can offer a comprehensive analytical service support".

"By bundling forces with SG Lab now we can leverage the collective expertise of SG Lab (glass testing, physical testing and container/closure integrity testing) with our in-depth scientific knowledge and expertise in extractables and leachables testing (including subsequent toxicological assessments) and container/drug interaction evaluations. This unmatched technical and scientific combined support should allow pharmaceutical and

biopharmaceutical companies moving much faster in the qualification and acceptance process of their selected container and closure systems. At the end, it is all about guaranteeing patient safety and well-being, and we hope we can make a substantial contribution to achieve this.” – says **Piet Christiaens**, *Toxikon Europe’s Scientific Director*“.

About SG Lab

With a comprehensive expertise on research projects and science behind the primary packaging, SG Lab is the laboratory of Stevanato Group focused on analytical chemistry, material properties, physical and mechanical performances. With a skilled team of experts having the best-in-class expertise in primary packaging, it can help the customer understand the potential interactions between the pharmaceutical products and the containers. Some examples of SG Lab scientific activity are: delamination propensity investigation, surfaces and silicone coating characterization (silicone layer coverage, thickness and distribution), container performances and drug-container interaction.

www.stevanatogroup.com/services/sglab

About Stevanato Group

Founded in 1949, Stevanato Group is committed to create systems, processes and services that guarantee the integrity of parenteral medicines.

It comprises two operational divisions dedicated to serve the pharmaceutical industry: Pharmaceutical Systems with Ompi specialized in glass primary packaging and Balda, focused on specialty plastics and delivery devices; Engineering Systems with Spami, Optrel, InnoScan and SVM, specialized in glass processing, inspection systems, assembly and packaging solutions.

www.stevanatogroup.com

About Toxikon Europe NV

Toxikon Europe is an independent, privately owned Contract Research Organisation, specialized in providing premium Extractable & Leachable Services to the Pharmaceutical Industry. Based in Belgium, Toxikon Europe supports Pharma Companies - across the Globe - in developing worldwide compliant (FDA, EMA) Testing Strategies to qualify Container/Closure Applications and Pharmaceutical Production Equipment from an Extractable & Leachable Perspective. In addition, the Toxikon group also provides Biocompatibility Testing Services (In-Vivo and In-Vitro testing) to both the Medical Device and the Pharmaceutical Industries.

Toxikon is ISO 17025 Accredited, GLP-Certified and GMP Accredited. Toxikon is also FDA registered.

