

Press release, March 27, 2017

## **Datwyler and Toxikon Europe NV to further develop their partnership**

- **Toxikon, as a leading contract lab, has been a reliable partner for Datwyler for over 10 years, bringing analytical and rubber compounding experts together offering the best services**
- **A joint Research & Development Programme will be set up for faster risk assessment of extractable results**
- **The extended partnership will result in faster time-to-market**

Datwyler and Toxikon Europe NV have announced to further strengthen their partnership in the health care sector. The preclinical contract research organisation has grown to be the number one in analytical services for extractables and leachables in the last ten years and also offers a variety of other testing services, e.g. for medical devices and product development. Since the reduction of extractables and leachables is a main focus in the development of rubber formulations, Toxikon is the ideal partner for Datwyler to further improve its health care offering: Among other products, Datwyler manufactures rubber components for primary packaging for parenterals. The partnership with Toxikon will reduce the time that (bio)-pharmaceutical products incorporating Datwyler components need for scientific and regulatory acceptance. As a result, it will accelerate time-to-market for pharmaceutical and bio-pharmaceutical drugs.

“I am extremely pleased that Datwyler and Toxikon Europe NV have jointly taken the decision to renew and prolong their partnership”, said Piet Christiaens, Scientific Director at Toxikon Europe NV. He was very impressed with Datwyler’s product developments, the high level of expertise, and the resulting corporate growth. “We are convinced that offering a premium service to Datwyler’s customers will provide them with the state-of-the-art solutions and testing strategies they require for safe and fast regulatory approval.”

### **R&D programme for quick risk assessments**

Datwyler and Toxikon will set up a Research and Development Programme that is intended to better understand the composition of rubber components, particularly the compounds so far reported as “unknowns”. Highly sensitive drugs can interact and react with leachables leading to changes which might render the drug ineffective. Therefore, researching the extraction profiles of rubber components and their potential impurities is of the highest importance to reduce risks. A quick and reliable risk assessment can ultimately allow a much faster scientific and regulatory acceptance.

“Enhancing the partnership underlines our common ambition to offer the best-in-class knowledge and expertise in pharmaceutical elastomer formulations”, said Bram Jongen, Head of Research and Development for the health care business at Datwyler. “To have Toxikon on our side enables Datwyler to continue providing our customers with the superb world leading analytical services that we want to offer.”

**Toxikon Europe NV ([www.toxikon.be](http://www.toxikon.be))**

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.

**Datwyler ([www.sealing.datwyler.com](http://www.sealing.datwyler.com))**

Datwyler is a leading industrial supplier and a key player in the health care world. Our state-of-the-art solutions for drug packaging and medical devices, build on over 100 years of experience. We provide a unique range of products and services including the most advanced elastomer formulations, coatings, aluminum seals, and processing technologies. Partnering up with the world's top pharmaceutical and medical companies, we stand by our mission to improve patients' lives.

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**Photos (in print quality):** <http://www.datwyler.com/en/media/image-library/>