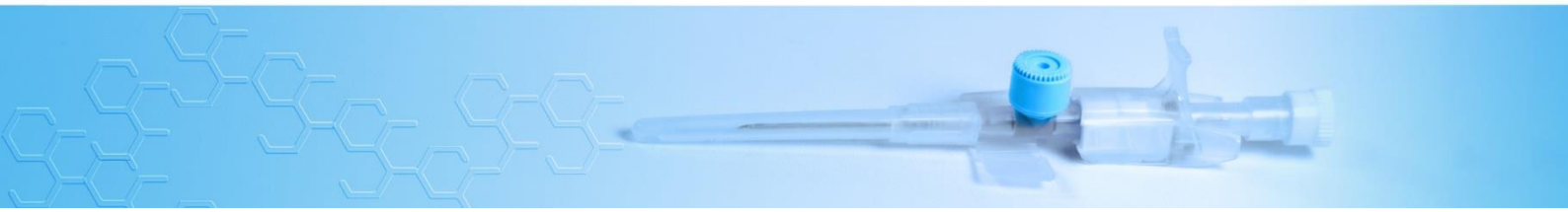
SAXOCON
Co-owned by Technical University of Denmark DTU



Assure safe devices for drug products

Medical devices intended for the administration of medicinal products can impact the quality, safety, and efficacy profile of medicinal products. In the EU, additional information is required for devices that are co-packaged or cross-labelled as intended for drug delivery. SAXOCON provides you with everything you need to test and document compatibility with the drug product in compliance with regulatory requirements including:

- The selection, screening, and characterisation of delivery device construction materials
- The selection of appropriate laboratories, review of protocols, and monitoring of extractable and leachable studies
- A toxicological risk assessment of results

Why choose us?

SAXOCON services for development of drug-device products give you access to

- Extensive, best in class experience in the development of drug-device products in accordance with the complex landscape of international standards and regulatory guidelines
- A multidisciplinary team of highly skilled toxicologists, material scientists, and supply chain professionals
- Safety evaluations based on proprietary information obtained from our world-wide network of materials suppliers
- Smart, cost-effective test strategies that bring your products to market in a timely manner

Delivery

SAXOCON compiles all additional documentation necessary for a new Drug Application file in accordance with EMA requirements.

hfm@saxocon.com +45 40 11 20 27 www.saxocon.com