



Assure **safe** devices for drug products

Medical devices intended for delivering medicinal products can impact the quality, safety, and efficacy profile of said medicinal products. The EU requires additional information 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
- Selecting appropriate laboratories, reviewing protocols, and monitoring extractable and leachable studies
- A toxicological risk assessment of the results

Why choose us?

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

- Extensive, best-in-class experience with the development of drug-device products in accordance with the complex international landscape of 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 worldwide 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 to create a new Drug Application file in accordance with EMA requirements.