SAXOCON
Co-owned by Technical University of Denmark DTU

Assure safe and cost-efficient development of drug-device products

Devices intended to administer a drug product are combination products that must comply with the regional regulation of both medicinal and medical device products. Requirements for designing, testing, and documenting the safety of a final product are complex and not harmonised across global market regions.

SAXOCON provides you with a cost-effective strategy to combine and stage the development of your drug-device product to establish and document global compliance without excessive testing, including:

- A product development plan to justify your test strategy and align with drug product activities
- Selection, screening, and characterisation of delivery device construction materials
- Assistance in scientific advisory meetings with regulatory bodies
- Selecting appropriate laboratories, reviewing protocols, and monitoring extractables and leachables studies
- A toxicological risk assessment of the results

Why choose us?

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

- Best-in-class experience with the development of drug-device products in accordance with the complex landscape of international standards and regulatory guidelines
- High-level experience with state-of-the-art safety assessments of pharmaceutical products
- 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

Delivery

SAXOCON compiles all documentation necessary for your New Drug Application file to fulfil FDA and EMA requirements for drug-device combination products.

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