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 accross global market regions. SAXOCON provides you with a smart, cost-effective strategy to combine and stage the development of your drug-device product to establish and document global compliance without excessive testing. This includes:

- 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
- 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:

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