SAXOCON
Co-owned by Technical University of Denmark DTU

Maintain safety in product manufacturing

EU regulations require controlling the quality attributes of pharmaceutical products within critical limits over their entire life cycle. ICH Q7, Q8, and Q9 set requirements for the various elements that should be incorporated in order to maintain Good Manufacturing Practice (GMP) and proper risk management of product quality. Part of this assurance is evaluation for impact on product safety.

SAXOCON provides you with everything you need to evaluate the impact of changes, deviations or non-conformance, including:

- Searching, reviewing and summarising available toxicological data
- Fill data gaps using (Q)SAR and read-across methods
- Identification of major toxic hazards, such as substances with genotoxic potential
- Evaluating the safety concern for patients treated with affected finished drug products

Why choose us?

SAXOCON services for the manufacture of pharmaceutical products give you access to:

- Extensive experience with state-of-the-art safety assessments of pharmaceutical products in accordance with international standards and regulatory guidelines
- Best in class experience in using computational toxicology, including (Q)SAR modelling and read-across methods
- Smart, cost-effective test strategies that bring your products to market in a timely manner

Delivery

SAXOCON compiles a written toxicological risk assessment report necessary for fulfilling GMP requirements.

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