



## Maintain safety in product manufacturing

Quality attributes are required to be controlled within critical limits during the complete life-cycle of pharmaceutical products. ICH Q7, Q8, and Q9 set requirements for 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 impact of changes, deviations or non-conformance including:

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

### Why choose us?

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

- Extensive experience in state-of-the-art safety assessment of pharmaceutical products in accordance with international standards and regulatory guidelines
- Best in class experience in using computer models for prediction of toxicological effects, i.e. (Q)SAR models
- 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.