SAXOCON
Co-owned by Technical University of Denmark DTU

Safe cleaning in multipurpose facilities

The manufacture of medicinal products in shared facilities can accidentally result in cross-contamination due to uncontrolled carry-over of active substances or other starting materials. Good Manufacturing Practice (GMP) requires a “toxicological evaluation” to establish threshold values for proper risk identification during cleaning validation.

SAXOCON provides you with everything you need to establish and document Permitted Daily Exposure (PDE) in accordance with regulatory requirements, including:

- A review of available non-clinical and clinical data
- Finding critical data using QSAR and other in silico models
- Establishing PDE based on the methods and principles in the EMA guidelines for setting health-based exposure limits for use in risk identification when manufacturing various medicinal products in shared facilities (EMA/CHMP/CVMP/SWP/169430/2012)
- Identifying major toxic hazards, such as substances with a sensitizing and/or genotoxic potential
- The control of mutagenic impurities using the methods and principles found in ICH M7

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 according to international standards and regulatory guidelines
- Best-in-class experience with using computational toxicology, including the modelling of biological effects based on chemical structure
- Smart, cost-effective test strategies that bring your products to market in a timely manner

Delivery

SAXOCON compiles a written report comprising a PDE Determination Strategy that is necessary for fulfilling GMP requirements.

hfm@saxocon.com +45 40 11 20 27 www.saxocon.com