SAXOCON
Co-owned by Technical University of Denmark DTU

Safe cleaning in multipurpose facilities

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” in order 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
- Fill data in critical data using QSAR and other in silico models
- Establishing PDE, based on the methods and principles in the EMA guideline for setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (EMA/CHMP/CVMP/SWP/169430/2012)
- Identification of major toxic hazards such as substances with a sensitizing and/or genotoxic potential
- Control of mutagenic impurities using the methods and principles in ICH M7

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 according to international standards and regulatory guidelines
- Best in class experience in using computational toxicology including 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 the PDE Determination Strategy necessary for fulfilling GMP requirements.

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