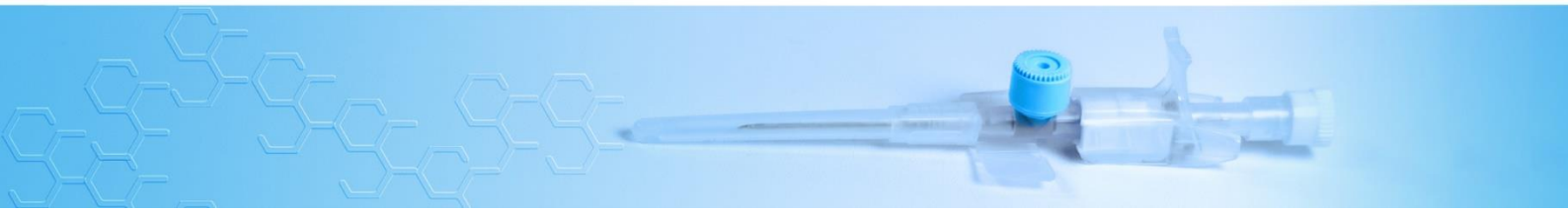
SAXOCON
Co-owned by Technical University of Denmark DTU



Manage change and stay safe

Updated medical device files are required to maintain legal access to most regulatory regions in the world, including the EU and the US. ISO 13485 and 14971 set requirements for risk management and control of design and development changes. An example of a typical change would be the introduction of new raw materials and processing chemicals, including suppliers of these. A change in manufacturing processes, including at contract manufacturers, should also be controlled. An important aspect of change control is evaluating the impact on the biological safety and performance of products when changes are made to product specifications or manufacturing processes. SAXOCON provides you with everything you need to evaluate the impact of design and manufacturing changes for compliance with regulatory safety requirements including:

- Assessing the impact on existing biological evaluation in accordance with ISO 10993-1
- A toxicological risk assessment of new or changed level of substances

Why choose us?

SAXOCON services for medical device manufacturers give you access to:

- A multidisciplinary team of highly skilled toxicologists, material scientists, and supply chain professionals
- Extensive experience in state-of-the-art safety evaluations according to international standards and regional regulatory guidelines
- Safety evaluations based on non-disclosed information obtained from our world-wide network of material suppliers
- Smart, cost-effective test strategies that bring your products to market in a timely manner

Delivery

SAXOCON compiles a toxicological statement that includes all documentation required to support your Quality Management System. This can include an update of your Biological Evaluation Report and/or Biological Evaluation Plan, if further information gathering or generation will be required.

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