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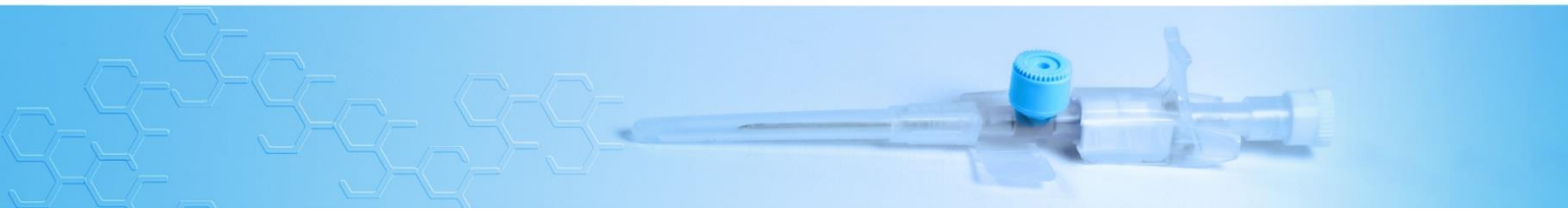

Manage change and stay safe

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 the control of design and development changes. A typical change requiring updated documentation would be introducing new raw materials and processing chemicals or changing a raw materials supplier. Another example is a change in the manufacturing processes, including at contract manufacturers. Also, change control requires evaluating the impact that changes made to product specifications or manufacturing processes on a product's biological safety and performance.

SAXOCON provides you with everything you need to evaluate the impact of design and manufacturing changes on 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 with 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 required documentation to support your Quality Management System. This documentation includes, but is not limited to, updating your Biological Evaluation Report and/or Biological Evaluation Plan if further information gathering or generation is required.

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bsi. ISO 13485:2016 Medical Device Quality Management