3i CONCEPT
MEDICAL DEVICE CONSULTANCY

We are dedicated team of experienced experts in the medical and pharmaceutical industry providing comprehensive quality management and design history file services to ensure regulatory compliance, risk reduction, and improved product quality. We take immense pride in our strong team comprising of talented engineers that have worked with large medical device manufacturers in USA, EU and Asia. Let us support your business in achieving success by contacting us today

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ABOUT COMPANY

We are a team of experts in the medical device industry, dedicated to providing quality management and design history file support to companies producing medical devices. With a combined experience of many years in the industry, we have a deep understanding of the unique challenges and requirements of the medical device sector.

We offer a full suite of quality management and design history file services, including risk management, process validation, design control, and change management. Our team of experts will work closely with you to understand your needs and develop a customized solution that meets your specific requirements.

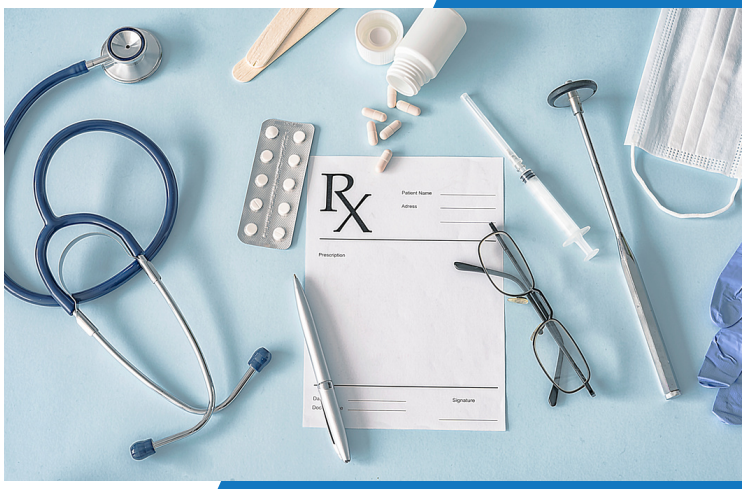
GOAL & PROJECT

OUR GOALS

Our goal is to help our clients achieve regulatory compliance, reduce risk, and improve the overall quality of their products. With our support, you can be confident that your medical devices are designed, developed, and manufactured to meet the highest standards of quality and safety.

OUR VALUES

We prioritize quality services, integrity, expertise, continuous improvement, and safety in the medical device industry. With a focus on client satisfaction, regulatory compliance, and risk reduction, we deliver exceptional solutions and services



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OUR SERVICES

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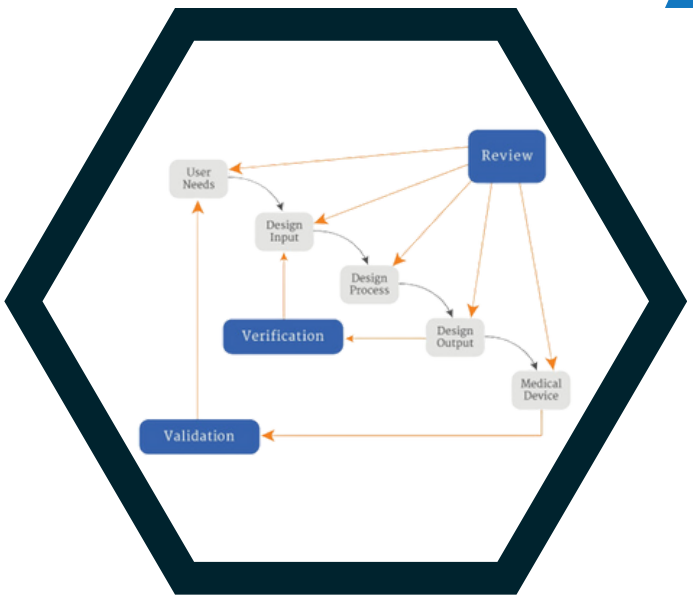

Design Controls For Medical Devices as per 21 CFR 820.30

Compliance with numerous requirements is crucial in the medical device industry. Design controls oversee the device's lifecycle, from requirements to obsolescence. Design controls involve nine phases, including user needs, design and development, design input and output, design review, verification, validation, transfer, and design changes. These controls ensure safety, effectiveness, and adherence to international regulations and standards.

Technical Services For Design And Development Of Medical Devices

The Support Design and Development Activities service provides comprehensive assistance to organizations in creating high-quality products, services, or systems. It includes assessing needs, developing customized plans, offering technical support, and managing risks, resulting in successful projects delivered on time and within budget.

QMS Development and Support as per ISO 13485

The QMS Development and Support service assists organizations in enhancing quality processes and meeting customer requirements. It involves designing, implementing, and maintaining a customized QMS, providing training and support. Medical device QMS ensures safety, effectiveness, and regulatory compliance, following ISO 13485 standards. The service helps organizations improve efficiency, reduce errors, and align with their goals. Contact 3iConcept for comprehensive QMS solutions and support.

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04

OUR SERVICE

Risk Management Service as per ISO 14971

The Risk Management Process and Risk Management File service assists organizations in managing and mitigating risks comprehensively. It involves developing a customized risk management process and creating a risk management file to document risks and mitigation strategies. The service provider assesses current processes, identifies areas for improvement, and helps organizations align their risk management practices with their goals. The service aims to reduce the impact of risks, enhance performance, and promote organizational success.

Training and Educating your Staff

The Training and Educating Your Staff service helps organizations improve employee skills and knowledge through customized training programs. It begins with assessing needs and identifying skills gaps, followed by creating a tailored plan. By collaborating with a service provider, organizations ensure their employees receive the necessary training to excel and enhance overall performance

General Support

The General Support service provides comprehensive assistance to organizations in operations, administration, and technology. It starts with assessing needs and identifying areas for improvement, followed by developing a tailored support plan. By collaborating with a service provider, organizations can enhance operations, minimize disruptions, and improve performance and reputation

Testing Of Medical Devices And Drug Device Testing Support

Performance Testing evaluates a medical device's accuracy, precision, sensitivity, specificity, and response time. Environmental Testing assesses durability under different conditions. Sterility Testing ensures freedom from viable microorganisms. Drug Device Testing Support encompasses customized testing strategies, compatibility evaluation, and rigorous performance and safety testing.

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CONNECT WITH US, LET'S MAKE YOUR VISION A REALITY

Thank you for considering us as your partner. If you have any questions or would like to learn more about how we can support you, please don't hesitate to reach out to us. Our team is always ready to assist you.

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