3i CONCEPT™

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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www.3iconcept.com

314 Vihav Trade Center, Near Waves Club, Vadodara – 391410, Gujarat, India

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.

FOUNDER: SUBHASH MEENA

With an experience of 15+ years as a Medical Device Professional and Drug Device Combination Product Development Expert, Subhash has designed and developed medical devices into various verticals. He has work experience of working with MNCs companies - Meril Life Sciences, Sun Pharmaceutical Industries Limited, Amneal Pharmaceuticals, and Dr. Reddy's Laboratories Limited. With vast knowledge of Research & Development and complete Product Life Cycle, he has led multiple products from development to commercialization. He is having an in-depth knowledge of working on several products from different verticals including cardiology, orthopedics, endosurgery. His extensive expertise in **developing, testing and documentation** for filing of drug device combination products including self-administration injection system (SAIS) devices pen injectors, auto injectors, prefilled syringes, MDI, DPI, Ophthalmic, tablet applicators has been crucial in getting the timely approvals from Notified Body and USFDA.

GOAL & PROJECT

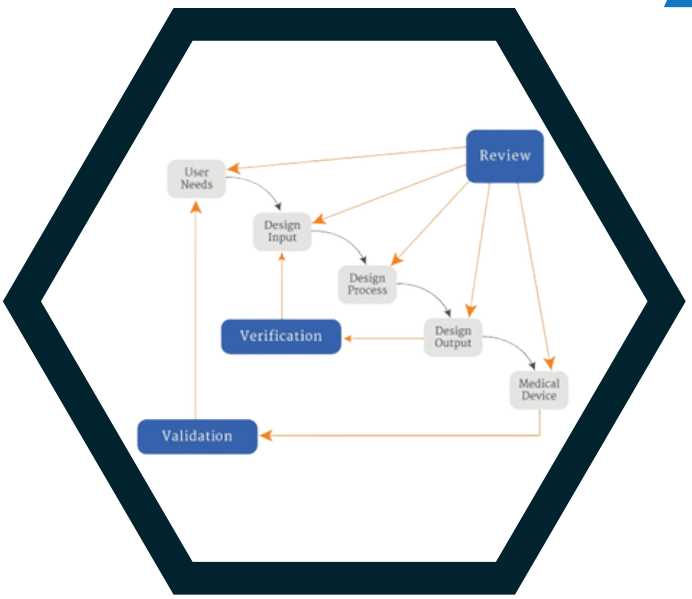
OUR GOALS

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

OUR SERVICES



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.

EU Medical Device Regulation (MDR 2017/745)

At 3i Concept, we specialize in providing expert consultancy for businesses seeking to file with the notified body in accordance with the EU Medical Device Regulation (MDR 2017/745). Our team of seasoned professionals ensures a smooth, compliant process, helping you navigate the complexities of regulatory requirements.

Our Services Include:

Regulatory Strategy Development: Tailored advice to ensure your product meets EU MDR standards and gets approved without unnecessary delays.

Documentation and Submission Support: Comprehensive assistance in preparing technical documentation and filing submissions to notified bodies.

Compliance Gap Analysis: In-depth review of your existing processes to identify areas for improvement, ensuring full adherence to the latest regulatory guidelines.

Ongoing Support and Monitoring: Continuous guidance throughout the lifecycle of your medical device to ensure sustained compliance.

Partner with 3i Concept to streamline your path to market and confidently meet EU MDR requirements. Let us take the regulatory burden off your shoulders so you can focus on what matters most—innovating and bringing your products to the patients who need them.

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.

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.

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.

3i CONCEPT™

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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