Medical Devices EU Registration – Execution

We offer streamline execution of the activities related to the process of registering medical devices in the EU by handling key activities such as document creation, regulatory management, and project coordination. With our expertise, clients can face the complexities of EU registration efficiently and ensure compliance with regulatory standards

Document Creation

Developing comprehensive documentation, including technical files, quality management system (QMS) records, risk assessments, and validation reports, tailored to meet EU regulatory requirements. Ensuring all documents are accurately prepared, properly formatted, and contain the necessary information to support the registration process.

Regulatory Management and Contact

Serving as the primary liaison between the client and regulatory authorities, facilitating communication, submitting necessary documentation, and addressing inquiries or requests for additional information. Managing regulatory timelines to ensure timely submission and approval of registration applications, while proactively addressing any regulatory challenges or issues that may arise.

Project Management

Coordinating all aspects of the registration process, including task assignment, scheduling, resource allocation, and progress tracking, to ensure execution and completion of registration activities. Implementing project management methodologies to mitigate risks, resolve issues promptly, and optimize efficiency throughout the registration process.

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- Quality Consulting and Risk Management
- Qualification and Validation
- Personnel Qualification
- Customer-specific provision of QMS

Contact:
quality-services@zamann-pharma.com
www.zamann-pharma.com