Strategiqual

Paris (75008), France

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Strategiqual is a consulting and service firm at the crossroads of the worlds of medicine and medical devices. We offer an innovative and personalized approach to missions. Our main assets: expertise, dynamism and responsiveness. It is in this spirit that we offer high-end and recognized services in the fields of regulatory affairs, quality management, market access and training.
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Medical devices

Development, clinical and regulatory
• Regulatory strategies, registrations and market access: Europe, USA and International
• Support in the development and preclinical and clinical strategy
• Operational implementation of market access: Technical File, PMA & 510k
• E-health specialist, DM software and validation of computerized systems
• Transition strategy to the new European MD and IVD regulations (MDR, IVDR)

Market Access Strategy and Reimbursement
• Evaluation of new innovative technologies
• Strategic analysis of market access and reimbursement in Europe
• Operational support in the realization of the request files for support for the France
• Training in reimbursement terms and knowledge of key players
• Interviews and meetings with decision-makers (HAS, MoH, KoLs, ect)

Quality Management & Inspection Authorities
• Creation and upgrade of the quality system: EN ISO 13485 and 21 CFR part 80
• Preparation Inspection Authority (ANSM, ANVISA) and notified body audits
• Control of advertising and promotion of medical devices
• Personalized regulatory, technical and clinical monitoring
• DMOS process and link transparency

Company's information

Year of foundation : 2012
Company size : PME < à 250 personnes

Target audience

Healthcare

Strengths

Assets 1 : Expertise
Assets 2 : Dynamisme
Assets 3 : Réactivité

Target audience

All sizes companies

Consulting activities

Data management consulting
Strategy consulting
Traceability consulting
Management and organisation consulting
Supply Chain Management consulting
IT consulting

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