

# Strategiqua

Paris (75008), France



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Strategiqua 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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18 Rue Pasquier,  
75008 Paris  
France