Go faster...

with regulatory affairs under control

Personalised assistance for medical & in-vitro devices:

- > FDA 510(k) or PMA submissions
- > CE Marking
- > Chinese Registration
- > Quality Systems (QSR, ISO 13485, ISO 9001)

C-REG Medical

www.c-reg-medical.com

C-REG MEDICAL can assist you in tailor fitting the Regulatory obligations to your requirements

USA Market :
- 510k submissions
- PMA submissions
- QSR Regulations
- FDA Foreign & USA Inspections
- USA based Clinical Studies

European Market :
- Directives 93/42/CE & 98/79/CE
- Development of Technical Files
- ISO 9001 / ISO 13485
- Quality Assurance Audits
- Competent Authority Inspections

General Aspects :
- Product Qualification
- ISO 14971 : Risk Analysis
- Vigilance Systems
- Competent Authorities Interface
- Clinical Studies

Chinese Market Partnership :
- Product Classification
- Submissions to SFDA
- Product Quality Testing
- Translation into Mandarin
- Clinical studies

Should your needs be further afield, then C-REG MEDICAL can help in providing local regulatory support, via a network of professionals.

Any questions ? Feel free to telephone or send an email should you wish to discuss your needs.

I want more information:

Name: _____

Company name: _____

Fonction: _____

Tél.: _____

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