Reglo
MEDICAL CONSULTING

COMPANY PROFILE & SERVICES

Global registration, with local regulatory insight.

One diverse, multilingual team for medical device and in vitro diagnostic (IVD) registration across the US, Europe, China and beyond.

Reglo Medical Consulting LLC
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US FDA · EU MDR / IVDR · International registrations
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Three regions, one team.

Reglo Medical Consulting LLC is a California-registered regulatory consulting company for medical device and IVD manufacturers, with representatives in the US, France and China working as one team.

EX **Emily Xiong** California, US

Emily Xiong leads Reglo's US services. She brings eight years of regulatory affairs experience at large multinational medical device companies, working on Class II and Class III devices in vascular and diabetes care, including PMA support, and led an EU MDD-to-MDR transition through to a successful global launch. She manages FDA submissions, US Agent service and client projects end to end. A certified ISO 13485 internal auditor, she has extensive experience with internal and external audits.

LA **Lya Ao** Paris, France

Lya Ao leads Reglo's European work. A biomedical engineer trained in France, she has managed regulatory projects since 2021, covering FDA 510(k), EU MDR, China NMPA and other international submissions for medical devices and software. Her experience spans EU MDR technical documentation, quality management systems (QMS), risk management and clinical investigation. A certified ISO 13485 internal auditor, she works directly with notified bodies, prepares manufacturers for audits and advises on EU reimbursement.

LZ **Lisa Zhang** Shenzhen, China

Lisa Zhang leads Reglo's work with manufacturers in China. She brings more than four years of global regulatory experience in consulting and in-house leadership roles. She has led more than 15 registration projects under FDA 510(k), EU MDR and China NMPA for active devices, software and IVD, and secured registrations in more than 20 countries and regions, including 11 for a single laser device. She has supported four FDA, EU MDR and MDSAP audits, each passed on the first attempt.

When your day ends, ours is still going.

California · Pacific Time | **Paris** · Central European Time | **Shenzhen** · China Standard Time

Every project has a lead and a second contact, chosen by where you are, and associate consultants support each representative. We work in English, Chinese and French.

Have you registered devices like mine?

Our team has filed across the categories below, from capital equipment and implants to wearable monitors, IVD and software.

Imaging & monitoring

CT, MRI, PET/CT, ophthalmic OCT, cerebral oximetry, wearable ECG, pulse oximeter and blood glucose monitoring devices

Surgical & therapeutic

Surgical robots and navigation, microwave and cryoablation, dental and aesthetic lasers, IPL

Critical care

Non-invasive ventilators, infusion and syringe pumps, blood warmers, neonatal incubators

Implants & passive

Hip and knee replacement systems, gastric balloons and bands, sterile syringes, ablation needles, PRP kits, device disinfectant

IVD

NT-proBNP heart failure assay, lab-on-chip and exosome microfluidic diagnostics

Software

Software as a Medical Device (SaMD), including medical image processing software

Orthopedics · Oncology · Dental · Aesthetics · Ophthalmology · Critical care · Cardiology

Can you guarantee clearance?

No consultant can guarantee a regulatory decision, and we do not. Regulators may raise questions on any submission. What we can do is reduce that risk and support you through to the final decision.

Find gaps first

We review your file the way a reviewer would, before it is submitted.

Ask early

Where appropriate, we confirm testing and strategy with FDA early through a Pre-Submission (Q-Sub).

Respond promptly

If the regulator raises questions, we prepare clear, complete responses with you.

Do you work with distributors?

Yes. We align with your distributors on requirements, documents and timelines so everyone works from one plan.

Who does the work?

Experienced regulatory affairs professionals. Translation is handled in-house; we coordinate test labs and work directly with notified bodies.

From first submission to life after approval.

Engage us for a single submission or a full market-access program, always under a written scope.

01

FDA market entry & submissions

Pathway strategy (510(k), De Novo, PMA), classification, Q-Sub, submission preparation and responses to FDA additional information requests.

02

US registration & US Agent

FDA establishment registration and device listing, annual renewal, and US Agent service for foreign manufacturers.

03

EU MDR / IVDR & CE marking

Technical documentation, General Safety and Performance Requirements (GSPR), clinical and performance evaluation, ISO 14971 risk management files and post-market surveillance plans. We work directly with notified bodies.

04

International registrations

Market sequencing, dossiers and submissions across North America, Europe, the Middle East and Asia, coordinated with your distributors. Country coverage is confirmed during scoping.

05

QMS & audit readiness

Certified ISO 13485 internal auditors help you prepare for notified body audits and FDA inspections. Technical file review and team training.

06

IRB, clinical & notary support

Institutional Review Board (IRB) packages and study documents, clinical pathway design, plus California notary public and apostille services.

After approval, we stay with you

Compliance continues long after the first clearance. We support the full product lifecycle.

- Registration renewals
- Post-market surveillance
- Vigilance & adverse event reporting
- Unique Device Identification (UDI) & EUDAMED
- Design change assessments
- Labeling & translation updates

Always know what comes next.

For a first 510(k), the hardest question is often "what now?" We map every step, from testing and documents to submission and FDA questions, give each one an owner and a date, and keep labs, translators and regulators moving on one plan.

1 Introductory call
Your device, target markets and distributors.

2 Written scope
Deliverables, timeline and fee, agreed before work starts.

3 Plan & submit
One project plan with owners and dates, and regular updates.

4 Review & lifecycle
Regulator questions, then support after approval.

EXAMPLE TIMELINE

US Class II device, 510(k)

~2 months	~90 FDA review days
Prepare submission	FDA review

Estimates only. FDA's review clock pauses while it waits for answers to its questions, so total time depends on the device, testing readiness and response speed. International timelines depend on each country's process; we map them during scoping.

Cost: every project is quoted individually, after we review your device documentation and understand your needs. Regulatory authority fees (such as FDA user fees) and third-party testing are paid separately and are not included in our fee.

Which markets are next for you?

Tell us about your device and where you want to sell it. In an introductory call we will walk through relevant experience and give you an honest view of the pathway and a first step.

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Registered entity	California LLC · Secretary of State Entity No. B20250201880

Reglo Medical Consulting LLC provides regulatory consulting services, not legal advice. Timelines are estimates. Regulatory decisions rest with the authorities; guidance reflects requirements in effect at the time of the engagement.