

RABT | GLOBAL

GLOBAL LIFE SCIENCES REGULATORY EXPERTS

Regulatory Consulting That Drives Global Market Entry

Trusted regulatory affairs consulting for pharmaceutical, medical device, cosmetics and life sciences companies across the USA, EU, UK, India and the Middle East.



Trusted by 200+ life sciences companies worldwide

www.rabtglobal.com

Your Trusted Regulatory Partner



Simplifying regulatory complexity for life sciences companies worldwide.

RABT Global is a compliance-driven regulatory affairs consulting firm, founded on the belief that expert regulatory guidance should be accessible, transparent and effective. We are a trusted partner for pharmaceutical, biotech, medical device and cosmetics companies operating across the USA, EU, UK, India and the Middle East.

Our team brings together specialists in FDA submissions, EMA regulations, MHRA compliance, CDSCO requirements and GCC regulatory frameworks. We are not generalists: we are pharmaceutical and life sciences compliance experts who live and breathe regulatory affairs every day.

500+

Regulatory submissions

200+

Global clients

40+

Countries covered

5+

Years of expertise

OUR JOURNEY

Founded

Established with a core team of regulatory affairs specialists serving the pharmaceutical sector.

First expansion

Launched medical device regulatory services and EU Authorised Representative services.

Middle East entry

Opened regional operations to serve GCC pharmaceutical and device manufacturers.

Asia-Pacific growth

Extended CDSCO, TGA and PMDA regulatory advisory capabilities.

Today

500+ successful submissions, 200+ global clients, 40+ countries covered.

THE RABT GLOBAL DIFFERENCE: OUR VALUES

1

Expertise first

Every engagement is led by qualified RA professionals, never passed to junior generalists.

2

Transparency

Clear timelines, honest feedback and regular project updates from day one.

3

Partnership mindset

We act as an extension of your internal regulatory team, not just a vendor.

4

Regulatory intelligence

We stay ahead of regulatory changes so you don't have to.

5

Quality without compromise

Every deliverable meets the highest regulatory and quality standards.

Our Regulatory Consulting Solutions



Comprehensive regulatory services across the full product lifecycle.



Regulatory Affairs Consulting

Full-spectrum RA support for pharmaceutical and medical device companies.



Submissions & Product Registration

CTD dossier preparation and health authority submissions across global markets.



Regulatory Strategy & Planning

Bespoke regulatory roadmaps and risk-mitigation strategies for market entry.



Regulatory Intelligence & Monitoring

Real-time updates on global regulatory changes affecting your products.



Quality Management & GMP/QMS

Audit-ready QMS implementation and GMP consulting for manufacturing compliance.



Medical Writing & Communications

Regulatory-grade documentation for submissions and post-market obligations.



eCTD Publishing Services

Lifecycle eCTD management and electronic submission publishing.



Regulatory Representation

EU Authorised Representative, US FDA Agent and global RA liaison services.

WHY LIFE SCIENCES COMPANIES CHOOSE RABT GLOBAL



End-to-end regulatory coverage

From regulatory strategy to post-approval lifecycle, one partner for the entire journey.



Multi-jurisdictional expertise

FDA, EMA, MHRA, CDSCO, SFDA. We operate where you need market access.



Dedicated regulatory teams

Your file is managed by qualified RA specialists, not generalist consultants.



Proven track record

500+ successful submissions across pharma, medical devices and biologics.



Regulatory intelligence access

Proactive monitoring of regulatory changes before they impact your programme.



Global + local presence

Offices and regional partners across the USA, EU, UK, India and the Middle East.

Industries and Product Types



Regulatory compliance advisory across all major life sciences sectors.

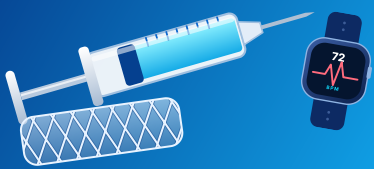
From a startup bringing its first product to market to an established multinational managing a complex pipeline, our services are designed to reduce risk, accelerate timelines and protect your market access.



Pharmaceutical & Biotech

NDA, ANDA, MAA, IND, CTAs and post-approval variations.

- NDA
- ANDA
- MAA
- IND
- CTAs
- Variations



Medical Devices

CE marking, FDA 510(k)/PMA, EU MDR/IVDR, ISO 13485 consulting.

- CE marking
- 510(k) / PMA
- MDR / IVDR
- ISO 13485



Clinical & Non-Clinical Regulatory

IND/CTA support, safety assessment, toxicology reports.

- IND / CTA
- Safety assessment
- Toxicology



Nutraceuticals & Cosmetics

Product notifications, labelling compliance, borderline product assessment.

- Product notifications
- Labelling compliance
- Borderline assessment
- Legal representation



Chemical Products

REACH compliance, safety data sheets, chemical product notifications.

- REACH
- Safety data sheets
- Product notifications

Whatever the product, the approach is the same: qualified RA specialists, a dedicated account manager and audit-ready deliverables, from first strategy to post-approval lifecycle.

GLOBAL PRESENCE

Expertise Across Every Major Market

Five continents. Dedicated specialists in FDA, EMA, MHRA, CDSCO and GCC frameworks.

REGION	REGULATORY COVERAGE
United States	FDA: 21 CFR, 510(k), PMA, NDA, ANDA and IND submissions
Europe & United Kingdom	EMA and MHRA: EU MDR, IVDR, CTD submissions, CE marking, EUDAMED, UKCA
India	CDSCO: drug and device registration, clinical trial applications
Middle East (GCC)	SFDA (KSA), MOHAP (UAE), MOH Kuwait and Qatar MOPH: device and pharma registration

COUNTRIES AND REGIONS WE SUPPORT

USA

Medical devices and medicinal products

European Union

Medicinal products and registration services

CIS countries

Medical devices and pharmaceuticals

India

Medical devices and medicinal products

Thailand

Medical devices and pharmaceuticals

APAC

Pharmaceutical regulatory services

Middle East

Medical devices and pharmaceuticals

UAE

Medical devices and medicinal products

ASEAN

Medical devices and pharmaceuticals

Africa

Medical devices and pharmaceuticals

GLOBAL + LOCAL PRESENCE

FDA

EMA

MHRA

CDSCO

GCC

Offices and regional partners across the USA, EU, UK, India and the Middle East, with delivery centres in the US and EU, so your regulatory programme is managed close to the authorities that matter.



A Proven Five-Step Approach

How RABT Global delivers regulatory success.



RABT GLOBAL VS OTHER REGULATORY CONSULTING FIRMS

CAPABILITY	RABT GLOBAL	TYPICAL COMPETITOR
Multi-jurisdiction coverage	Yes: FDA, EMA, MHRA, CDSCO, GCC	Often limited to 1-2 regions
End-to-end lifecycle support	Yes: strategy to post-approval	Submission support only
Dedicated account team	Yes: named specialists per client	Shared resource pools
Regulatory intelligence	Proactive monitoring included	Reactive, on-request only
In-house medical writing	Yes: integrated with RA team	Outsourced to third party
Global market entry strategy	Multi-country sequencing	Country-by-country, isolated

Start with a conversation. Speak with a RABT Global regulatory expert for a free consultation, with no commitment. We will review your product and target markets and outline the right route to approval.

WHAT YOU CAN EXPECT



Named specialists

A dedicated account manager per client, with regular project updates from day one.



Transparent timelines

Clear timelines, honest feedback and transparent project management.



Audit-ready deliverables

ISO-compliant quality management systems for all regulatory deliverables.

Specialist Services, Delivered End to End



Deep expertise behind every sector we serve.



Pharmaceutical lifecycle

- ✚ ANDA, NDS, MAA and NDA submissions
- ✚ Post-approval CMC and lifecycle management
- ✚ Health authority queries and interactions
- ✚ eCTD authoring, publishing and tracking
- ✚ EU Centralised, Decentralised, MRP and National procedures
- ✚ India: CDSCO new drug, generic and clinical trial permissions



Medical devices

- ✚ CE marking under EU MDR and IVDR
- ✚ FDA 510(k), PMA and De Novo
- ✚ UK MHRA registration and UKCA support
- ✚ ISO 13485 QMS consulting and MDSAP
- ✚ GCC device registration
- ✚ Clinical evaluation and post-market surveillance



Cosmetics & nutraceuticals

- ✚ Product notifications and labelling compliance
- ✚ Borderline product assessment
- ✚ EU/UK Responsible Person appointment
- ✚ PIF custodianship and CPNP/OPSS notifications
- ✚ Go-to-market compliance roadmap
- ✚ Post-launch compliance monitoring



Regulatory representation

- ✚ US FDA Agent for foreign device and drug establishments
- ✚ FDA correspondence forwarded within 24 hours
- ✚ EU Authorised Representative under MDR and IVDR
- ✚ Local representation in APAC where required
- ✚ Chemical products: REACH compliance and notifications
- ✚ Clinical and non-clinical: IND/CTA support, toxicology reports

Need a sector-specific view? Ask us for our medical device and food supplement brochures, with deeper detail on each service line.

Why Clients Trust RABT Global



Qualified regulatory affairs professionals with RAC, MSc and PhD credentials



ISO-compliant quality management systems for all regulatory deliverables



Member of TOPRA (The Organisation for Professionals in Regulatory Affairs)



Experience across FDA, EMA, MHRA, CDSCO, SFDA and Health Canada frameworks



Transparent project management with a dedicated account manager per client



Confidentiality protected by signed NDAs across all engagements



RABT Global transformed our regulatory approach. Their team managed our EU MDR submission from gap analysis to CE mark efficiently and on schedule. We couldn't have achieved this without their expertise.

VP REGULATORY AFFAIRS, EUROPEAN MEDICAL DEVICE MANUFACTURER



We appointed RABT as our US FDA Agent and regulatory affairs partner when entering the US market. Their team's knowledge of FDA processes saved us significant time and cost.

HEAD OF GLOBAL REGULATORY, ASIAN PHARMACEUTICAL COMPANY

LET'S TALK

Ready to Simplify Your Global Regulatory Journey?

Speak with a RABT Global regulatory expert today. No commitment, no pressure, just clear regulatory guidance tailored to your product and your markets.

Book Your Free Regulatory Consultation

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