

REGULATORY COMPLIANCE FOR INDIAN, US AND EUROPEAN MARKETS

RIFC aims to inform and assist **bio-entrepreneurs** in planning, seeking and securing regulatory approvals



**Joint initiative of BIRAC & Venture Center under the
BIRAC Regional Bio-Innovation Center (BRBC) Program**

At RIFC

- ✓ Regulatory compliance for the Indian, European and US markets
- ✓ Competent team with diverse group of experts
- ✓ Specializes in Medical devices
- ✓ Regular events and clinics for our beneficiaries

Why Choose Us

- 26 National/International Standards (E.g. ISO 13485, ISO 10993, ISO 14971, ISO 9001, ISO 27001)
- 200+ ISO 13485, ISO 27001 and ISO 9001 QMS Templates
- 250+ Dossier Templates (For India, EU and US regulations)
- Database of the Testing Labs and Certification Bodies*
- 250+ startups impacted
- 15+ dedicated regulatory experts
- 11 ISO 13485 Certifications assisted out of which 5 certifications received



With the RIFC team guidance and support, you can confidently navigate complex regulatory requirements and empower your business with compliance.

RIFC team works to offer a comprehensive support & strategic guidance for your medical device startup, not only to ensure compliance but also to leverage regulatory frameworks as a competitive advantage for your business and enhance investor confidence.

Services offered by RIFC team



No	ACTIVITIES	INDIAN	EUROPEAN	US FDA
1	General Advisory	✓	✓	✓
2	Planning Regulatory Pathway	✓	✓	✓
3	Standards Interpretation	✓	✓	✓
4	ISO 13485 Document Preparation	✓	✓	✓
5	ISO 13485 Document Review	✓	✓	✓
6	Risk Management	✓	✓	✓
7	Clinical Trial Study Plan	✓		
8	Clinical Trial Advice	✓		
9	ISO 13485 Internal Audit	✓		
10	ISO 9001 Document Review	✓		
11	HIPAA General Advisory			✓
12	ISO 27001 Document Preparation & review	✓		
13	DPDP Act Advisory	✓		



**CONTACT US TODAY AND
SCHEDULE YOUR INTRODUCTORY MEETING**

Connect with us



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