



Regulatory Information and Facilitation Center [RIFC]

100, NCL Innovation Park, Dr Homi Bhabha Road, Pashan, Pune : 411008, India

RIFC Membership Program

Term sheet & Agreement (Ver. 01)

Effective date: October 1, 2025

The Regulatory Information and Facilitation Center (RIFC) is joint initiative of the Venture Center and BIRAC under the BIRAC Regional Bio-Innovation Center (BRBC) program.

Website: <https://www.venturecenter.co.in/services/advisory-and-consulting/regulatory-information-and-facilitation>

FEATURES

- **Regulatory Advisory Services relating to:**
 - General Regulatory Advisory (India, US, EU)
 - Regulatory Roadmap & Strategy for Startups
 - Standards & Classification Guidance
 - Documentation Templates & Review (GSPR, Risk Files, Technical File)
 - Clinical/Performance Study Guidance
 - QMS (ISO 13485, ISO 14971) Support
 - MDR/IVDR, FDA, CDSCO Pathway Planning
- **Scope of Services**
 - Medical Devices (all classes)
 - In-Vitro Diagnostics (IVDs)
 - Digital Health / SaMD
 - Preventives & Therapeutics (select scope)
- **Highlights**
 - Subscription model designed for startups needing ongoing support.
 - Predictable costs with tiered plans.
 - Independent, unbiased & practical advice from regulatory experts.

SERVICES

Plan Code	Plan Title	Overview	Deliverables/Outcome
RIFC-MBR-01	Starter	2 call/month, 2 document reviews, templates, email Q&A	Written feedback, templates, 1-hour call summary
RIFC-MBR-02	Growth	3 calls/month, 4 reviews, regulatory roadmap, 1 training session	Reports, roadmap, training slides
RIFC-MBR-03	Pro Launch	Weekly calls, unlimited Q&A, CE/FDA/CDSCO strategy, submission planning	Regulatory strategy document, submission readiness checklist
RIFC-MBR-04	Enterprise	Custom plan for accelerators, CROs, VC-backed portfolios (dedicated expert + workshops)	Engagement plan, dedicated reporting, training sessions

Add-ons (optional):

- Technical File/DMF/DHF Review – ₹ 10,000/file
- Regulatory Training Session – ₹ 2,500/session

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ELIGIBILITY

- The Advisory Services shall be available for medical device manufacturers, suppliers of the medical device manufacturers, bio-entrepreneurs/ventures related to scientific products seeking regulatory information & assistance.
- The management of the RIFC shall exercise judgment in making available the services requested.
- The RIFC aims to assist bio-entrepreneurs in planning, seeking and securing regulatory approvals.

PAYMENT TERMS

- **Introductory advisory for the first time and for one hour duration would be free.**
- **Second meeting onwards meetings shall be charged as ₹ 2000 per hour until client signs for all services.**
- Advisory services will be charged either on task basis or on hourly payment basis depending upon the service requested. An estimate of charge on task basis or advisory hours would be given at the introductory free meeting.
- The estimated payment is to be made in advance of each paid advisory engagement.
- The duration of each engagement will be mutually agreed upon by RIFC and Applicant and the corresponding payment shall be made in advance by the Applicant.
- Final payment would be invoiced at the time of end of the advisory service, which needs to be paid before completion and delivery of deliverables.
- Payment is acceptable by DD or cheque payable in Pune or at Par or could be deposited directly into the RIFC / BRBC's bank account.
- Any fees charged by the concerned Government office, authorities for any action required to be taken shall be in addition to the fees charged by the RIFC.

TERMS

- Applicant shall not (intentionally or otherwise) do anything to suggest that the RIFC, BRBC, Venture Center (VC) or BIRAC Government of India as being party to the venture/activity for which RIFC's advisory services were engaged.
- Applicant shall not hold RIFC/Venture Center/BRBC/BIRAC responsible for any liabilities directly or indirectly related to RIFC's advisory services, including any referrals provided by the RIFC.
- Applicant acknowledges that RIFC has no control whatsoever over the activities of any of the parties to which it provides referrals to, and thus shall not be held responsible for any issues, costs, damages, liabilities, etc. related to Applicant's engagement with those parties.
- Applicant shall not indemnify and hold harmless RIFC its members, directors, officers, employees, agents contractors and authorized representatives from all costs expenses including attorney's fees liabilities, obligations, damages and claims including any claims related to free and paid advisory services offered by the RIFC.
- RIFC does not offer any guarantees related to the effectiveness of its advisory services including, but not limited to, regulatory approval & certifications. Applicant understands and accepts that

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RIFC will offer its advisory services on a 'best effort' basis without any guarantees on the outcome of such advisory services.

- RIFC will keep a record of the activities undertaken as part of an advisory engagement. These activities may include face-to-face meetings with the Applicant and/or analysis conducted by RIFC staff without the Applicant's presence. In all cases, RIFC will be the sole and final authority as to the duration (number of hours) spent on the paid advisory services.
- RIFC retains the right to cancel existing paid advisory engagements with the Applicant at its sole discretion. In this case, the maximum refund liability for the RIFC will be limited to the un-used amount paid by the Applicant for the cancelled advisory services.
- RIFC may revise rates charged for advisory services at any point in time, at its sole discretion. This will not affect existing, signed advisory agreements, but will affect any future advisory engagements between the Applicant and RIFC.
- RIFC may engage third- party consultants or advisors as part of an advisory service agreement at its sole discretion.
- The terms and conditions of this agreement may be amended only by mutual consent and exchange of written letters and the amendments shall be applicable from the date of such amendments unless agreed to contrary.
- The parties shall endeavor to resolve any dispute relating to the advisory services offered by RIFC firstly by mutual discussion and in the event of any persistent disagreement; the same shall be referred to for arbitration to arbitrator(s) to be appointed by RIFC. The arbitration will be conducted by such arbitrator(s) in accordance with the provisions of Arbitration and Conciliation Act-1996.
- This Agreement and the parties' rights and obligations under it shall be governed by and interpreted in accordance with the laws of India. The jurisdiction will be courts of Mumbai.

PAYMENT TERMS

- Subscription fees payable monthly/quarterly in advance.
- Starter Plan: ₹15,000/month
- Growth Plan: ₹35,000/month
- Pro Launch Plan: ₹60,000/month
- Enterprise Plan: Custom pricing based on engagement.
- Add-on services charged separately.
- Payment by bank transfer / UPI / cheque.
- Fees to government agencies, testing labs, or notified bodies are additional.

SPECIAL OFFERS

Duration of validity	Applicable services	Special offer/ discounts
15 September – 15 October 2025 NEW!	RIFC-MBR-03	Additional templates/Review of the documents for CDSCO/ISO application for first Five (5) members

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An illustrative estimate of the number of hours required for the different jobs

Plan Code	Plan Title	Overview	Time Commitment
RIFC-SUB-01	Starter	2 call/month, 2 document reviews, templates, email Q&A	4-8 Hours
RIFC-SUB-02	Growth	3 calls/month, 4 reviews, regulatory roadmap, 1 training session	10-15 Hours
RIFC-SUB-03	Pro Launch	Weekly calls, unlimited Q&A, CE/FDA/CDSCO strategy, submission planning	25-30 Hours
RIFC-SUB-04	Enterprise	Custom plan for accelerators, CROs, VC-backed portfolios (dedicated expert + workshops)	As per termsheet for respective markets (India, EU and US)

Note:

- 1) The number of hour's estimation is based on judgments and information based on similar previous services. Consider plus or minus of 30% while estimating the budget for the above services.
- 2) Service tax and other taxes applicable at the prevailing rate shall in addition to the above (if any).
- 3) Only one discount will be applicable at a time.
- 4) Travel, Accommodation, Transport and Food arrangement shall be made by the client in case the team needs to travel for service RIFC-09-INT.

* All the charges mentioned herein above in Pricing Table are applicable for services to individuals, entrepreneurs, micro, small and medium enterprises as defined by govt. of India wherein 50% or more ownership is held by Indian Nationals or companies incorporated in India. In other cases (Large and Foreign companies) rates will be double the amount stated therein.

Applicant has read and understood all of the above terms and conditions pertaining to the advisory services offered by RIFC, and agrees to abide by the same.

For and on behalf of RIFC

For Applicant

Authorized Signatory

Authorized Signatory

Seal

Seal

Date

Date

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