Regulatory Information and Facilitation Center [RIFC]
100, NCL Innovation Park, Dr Homi Bhabha Road, Pashan, Pune : 411008, India

TERM SHEET & AGREEMENT (Ver. 0) Effective date: May 06, 2025

FEATURES

- **Regulatory Advisory Services relating to -**
  - General Advisory
  - Planning Regulatory Pathway
  - Standards Interpretation
  - Document Preparation & Review
  - Risk Management
  - Clinical Trial Study Plan** (to be announced)
  - Clinical Trial Advice** (to be announced)

- **Scope of Services -**
  - Medical Devices **(Current focus & Active)**
  - Diagnostics, Therapeutics, Preventives **(Current focus & Active)**

- **Independent, unbiased, & non-commercial practical advice**
- **Leverages experiences of other senior entrepreneurs, & mentors**

SERVICES

Service Code	Title	Overview Ask us a question and we shall get you an answer!
RIFC-EU-01-ADV	**General Advisory**	**Includes:** Covers expert recommendations on the European regulatory requirements for your device, from idea, to design a prototype, to market, to post-market. Understand and realize applicable like ISO and IEC. **Benefits:** Estimate timelines, costs, resources, and controls required at the various stages of device development and sale. **Outcome:** Report covering the general overview of the regulations and other applicable guidance documents and explanation of the report if required.
RIFC-EU-02-PAT	**Planning the Regulatory Pathway**	**Includes**: Covers the most appropriate path for registration and securing regulatory approvals for your device. Know the exact class of the device, associated risk, documentation, and forms and dossier contents, templates. Know which government officials and offices to approach. **Benefits:** Have an action plan to kick off the approval process for a country of interest. **Outcome:** Report explaining the most appropriate regulatory pathway and in-person explanation of the regulatory process

RIFC-EU-03-STD	**Standards Interpretation**	**Includes:** Covers identifying the applicability of device-specific standards, the rationale behind using the standard and scientific methods of investigation during device design and packaging development to support the device safety, efficacy, effectiveness, and risk. **Benefits**: Avail Subject Matter Expert's (SMEs) opinion to save time & money to select the appropriate scientific techniques to test the device for its safety and effectiveness within the boundaries of regulation. **Outcome**: Report identifying the device-specific standards and in-person explanation of the rationale for choosing the standards.
RIFC-EU-04-DOP	**Document Preparation & Review**	**Includes**: Covers sharing the templates of the SOPs per ISO 13485 requirements and hands-on training on preparation of important and mandatory documentation (based on the shared templates) like standard operating procedures, validation protocols & reports, quality manuals, Device Master Files (DMF), Design History Files (DHF), Site or plant master files, package inserts (IFU), primary and secondary packaging material symbols and text, etc. **Benefits:** Learn the do's and don'ts of a perfect document. Know the structure, contents, and control of documentation. Learn to prepare and maintain quality documents. **Outcome**: Training manual and in-person explanation.
RIFC-EU-05-RMP	**Risk Management**	**Includes**: Identification of the probability of occurrence of harm and severity of that harm of the device to patients or users. Application of techniques, and procedures to assess, control, communicate and review the risk associated with the device. **Benefits**: Risk management attempts to identify and measure or mitigate the harm and gives you an opportunity to protect the public from harm/ injury arising from new medical devices or changes in the existing ones. Reduce risk to the patient. Reduce risk to the business. **Outcome**: Reports and in-person explanation. The risk management plan, report & matrix

ELIGIBILITY

- The Advisory Services shall be available for medical device manufacturers, suppliers of the medical device manufacturers and 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 half hour duration would be free.
- Advisory services will be charged either on a task basis or on an hourly payment basis depending upon the service requested.
- An estimate of charge on a 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.

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, 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 and 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 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 Google meetings and 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 unused 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 the contrary.
- The parties shall endeavour 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 the arbitrator(s) to be appointed by RIFC. The arbitration will be conducted by such arbitrator(s) in accordance with the provisions of the Arbitration and Conciliation Act-1996.
- This Agreement and the party's rights and obligations under it shall be governed by and interpreted in accordance with the laws of India. The jurisdiction will be the courts of Mumbai.

PRICING

Service Code	Title	Price in INR
RIFC-EU-01-ADV	General Advisory	₹ 2,000 per hour
RIFC-EU-02-PAT	Planning the Regulatory Pathway	₹ 2,000 per hour
RIFC-EU-03-STD	Standards Interpretation	₹ 2,000 per hour
RIFC-EU-04-DOC	Document Preparation & Review	₹ 2,000 per hour
RIFC-EU-05-RMP	Risk Management	₹ 2,000 per hour

DISCOUNT CATEGORY

A. Current resident of Venture Center	10%
B. Current portfolio company of Venture center	10%

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

Sr. No.	Service Code	Estimated Hours			
		Class I	Class IIa	Class IIb	Class III
1	RIFC-EU-01-ADV (General Advisory)	05	05	10	10
2	RIFC-EU-02-PAT (Planning the Regulatory Pathway)	15	15	20	20
3	RIFC-EU-03-STD (Standards Interpretation)	15	15	20	20
4	RIFC-EU-04-DOP (Document Preparation & Review)	90	90	120	120
5	RIFC-EU-05-RMP (Risk Management)	60	60	90	90

Note:

1) The number of hour's estimation is based on judgments and information based on similar previous services. Consider a 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 be in addition to the above (if any).
3) Only one discount will be applicable at a time.

* All the charges mentioned herein above in the Pricing Table are applicable for services to individuals, entrepreneurs, and 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.

The 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