TERMSHEET & AGREEMENT (Ver.04) Effective date: Apr 01, 2026

FEATURES

- **Regulatory Advisory Services relating to-**
  - General Advisory & Planning Regulatory Pathway
  - US FDA Application
  - Standards Identification
  - ISO 13485 Implementation
  - ISO 13485 Document Review
  - ISO 14971 Risk Management Implementation
  - HIPAA General Advisory
- **Scope of Services-**
  - Medical Devices **(Current focus & Active)**
  - Diagnostics, Therapeutics, Preventives **(Current focus & Active)**
  - Software as Medical Devices (SaMDs) **(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-US-01-ADV	**General Advisory& Planning Regulatory Pathway**	**Includes:** Covers expert recommendations on the US FDA regulatory requirements for your device, from idea, to design a prototype, to market, to post-market. Understand and realize applicable standards like ISO, IEC and ASTM, Etc. 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:** Estimate timelines, cost, resources and controls required at the various stages of device development and sale. **Outcome:** Reports and in person explanation.
RIFC-US-02-FDA	**US FDA Application**	**Includes**: Covers provision of application templates, preparation of regulatory application forms, establishing connection with Authorized Representative and end-to-end support for submission to FDA, including query resolution, pre-sub meeting, 510(K) submission, PMA, Denovo, Breakthrough device designation, Humanitarian device exemption, etc. **Benefits:** Kickoff the approval process for US. **Outcome:** eSTAR submission, Application process, In person explanation, and successful US FDA Approval.

RIFC-US-03-STD	**Standards Identification**	**Includes:** Covers applicability of device-specific standards, the rationale behind using the standard, establishing connections with CDSCO/NABL Approved testing laboratories for execution of testing as per the identified standards 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 and save time & money on selecting the appropriate scientific techniques in the boundaries of regulations. **Outcome**: Reports and in person explanation. ***Note: Get reference access to licensed ISO, IEC, and ASTM standards and essential regulatory guidance through Regulatory Compass at Venture Center Library.**
RIFC-US-04-QMS	**ISO 13485 Implementation**	**Includes**: Covers sharing the templates of the SOPs per ISO 13485 and 21 CFR 820 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. Includes training on ISO 13485 clauses for team members, along with support during ISO certification audits (Stage 1 and Stage 2) and resolution of non-conformities (NCs) raised by certification bodies. **Benefits:** Learn the do's and don'ts of a perfect document. Learn to prepare and maintain quality documents. **Outcome**: Templates, Training and in person explanation. ISO 13485 Certification Readiness
RIFC-US-05-DOR	**ISO 13485 Document Review**	**Includes:** Covers review of important and mandatory documentation like standard operating procedures, validation protocols & reports, quality manual, Device Master File (DMF), Design History File (DHF), Site or plant master file, package inserts (IFU), primary and secondary packaging material symbols and text, etc against the ISO 13485 and 21 CFR 820 requirements. **Benefits:** Know the structure, contents, and control of documentation. Identification of inadequacies in the prepared documents along with the suggestions to remove inadequacies if there are any. **Outcome:** In-person explanation of suggestions to be compliant with ISO 13485 and 21 CFR 820 compliant documents.
RIFC-US-06-RMP	**ISO 14971 Risk Management Implementation**	**Includes**: Identification of the probability of occurrence of harm and severity of that harm of the device to patients or users. Application of techniques, 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 one. Reduce risk to the patient. Reduce risk to the business. **Outcome**: Reports and in person explanation. Risk management plan, Risk report & matrix
RIFC-HP-01-ADV	**General Advisory**	**Includes:** Covers advise on the applicability of the US FDA Health Insurance Portability and Accountability Act (HIPAA) for your device. Understand the implementation steps to comply with the HIPAA. Understand and realize applicable standards like ISO, IEC and ASTM, Etc. **Benefits:** Estimate resources and controls required for HIPAA compliance at the various stages of device development and sale. **Outcome:** Reports and in person explanation.

ELIGIBILITY

- The Advisory Services shall be available for 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.

PAYMENTTERMS:

- ***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 any mentioned services***
- Advisory services will be charged either on task basis or on hourly payment basis depending upon the service requested. Hourly rate would be Rs. 1200 per hour subject to a minimum of Rs. 3000 for two hours.
- 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.

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/VentureCenter/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 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.

PRICING

Service Code	Title of Service	Price in INR
RIFC-US-01-PAT	General Advisory& Planning Regulatory Pathway	₹ 2000 per hour
RIFC-US-02-FDA	US FDA Application	₹ 2000 per hour
RIFC-US-03-STD	Standards Identification	₹ 2000 per hour
RIFC-US-04-QMS	ISO 13485 Implementation	₹ 2000 per hour
RIFC-US-05-DOR	ISO 13485 Document Review	₹ 2000 per hour
RIFC-US-06-RMP	ISO 14971 Risk Management Implementation	₹ 2000 per hour
RIFC-HP-01-ADV	HIPAA General Advisory	₹ 2000 per hour

DISCOUNT CATEGORY

A. Current resident of VentureCenter	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 II	Class III
1	RIFC-US-01-PAT (General Advisory& Planning Regulatory Pathway)	10	10	15
2	RIFC-US-02-FDA (US FDA Application)	15	20	20
3	RIFC-US-03-STD (Standards Identification)	15	20	20
4	RIFC-US-04-QMS (ISO 13485 Implementation)	60	90	120
5	RIFC-US-05-DOR (ISO 13485 Document Review)	45	75	90
6	RIFC-US-06-RMP (ISO 14971 Risk Management Implementation)	45	60	90
7	RIFC-HP-01-ADV (HIPAA General Advisory)	10	10	15

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.

* 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 where in 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 Authorized Signatory	For Applicant Authorized Signatory
Seal	Seal
Date	Date