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

TERM SHEET & AGREEMENT (Ver. 12) Effective date: December 31, 2025

FEATURES

- **Regulatory Advisory Services relating to:**
  - General Advisory
  - Planning Regulatory Pathway
  - Standards Interpretation
  - ISO 13485 Document Preparation& Review
  - ISO 13485 Document Review
  - Risk Management
  - Clinical Trial Study Plan
  - Clinical Trial Advice
  - ISO 13485 Internal Audit
  - ISO 9001 Document Review
  - ISO 27001 Document Preparation & Review
  - Digital Personal Data Protection (DPDP) Act, 2023 advisory

- **Scope of Services**
  - Medical Devices and In-vitro diagnostic medical devices (IVDs)
  - Software as Medical Devices (SaMDs)

- **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-01-ADV	**General Advisory**	**Includes**: Covers expert recommendations on the global regulatory requirements for your device, from idea, to design a prototype, to market, to post-market. Understand and realize applicable standards like BIS, ISO, ASTM, ANSI, and IEC. Know about the relevant laws, rules and statutory requirement of a county of interest. **Benefits:** Estimate timelines, cost, resources and controls required at the various stages of device development and sale. **Outcome:** Reports and in person explanation.

Service Code	Title	Overview Ask us a question and we shall get you an answer!
RIFC-02-PAT	**Planning the Regulatory Pathway**	**Includes:** Covers 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:** Reports, application processand in person explanation.
RIFC-03-STD	**Standards Interpretation**	**Includes:** Covers 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 and save time & money on selecting the appropriate scientific techniques in the boundaries of regulations. **Outcome:** Reports and in person explanation.
RIFC-04-DOP	**ISO 13485 Document Preparation & Review**	**Includes:** Covers sharing the templates of the SOPs as per ISO 13485 requirements and hands-on training on preparation of mandatory documentationlike SOPs, 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. **Benefits:** Learn do's and don'ts of a perfect document. Know the structure, contents, and control of documentation. Learn to prepare and to maintain quality documents. **Outcome:** Training manual and in person explanation.
RIFC-05-DOR	**ISO 13485 Document Review**	**Includes:** Covers hands-on training of important and mandatory documentation like SOPs, validation protocols& reports, quality manual, Device Master File (DMF), Design History File (DHF), Plant master file, package inserts (IFU), primary and secondary packaging material symbols and text, etc.against the ISO 13485 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.

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RIFC-06-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, procedures, policies to assess, controlling, communicating and reviewing 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-07-CTP	**Clinical Trial Study Plan**	**Includes:** Designing of the clinical investigation plan of medical devices and clinical performance evaluation of new In-Vitro diagnostic medical devices. **Benefits:** Negotiations with the trial sites. Guidance on preparation of documents like Investigator's Brochure (IB), Clinical Investigation Plan, Case Report Form (CRF), Informed Consent Form, Undertaking by the Investigator, Clinical Investigation Report, Periodic Safety Update Reports (PSURs). **Outcomes:** Study design and roadmap.
RIFC-08-CTA	**Clinical Trial Advice**	**Includes:** Referrals and guidance for identifying suitable partners/ clinical trial sites (hospitals). Review of the data before submitting to the licensing the authorities. **Benefits:** Understand the types of studies required to conduct for your devices as per the regulatory requirements. Get the complementary pathway and documentation review support. **Outcome:** Advice. Guidance. Referrals.
RIFC-09-INT	**ISO 13485 Internal Audit**	**Includes:** Covers training and conducting internal audit of mandatory documentation like SOPs, quality manual, Device Master File (DMF), Design History File (DHF), etc. against the ISO 13485 requirements. **Benefits:** Identification of inadequacies and readiness to face external audits. **Outcome:** Internal audit report ***Note*-** *Travel, Accommodation, Transport and Food arrangement shall be made by the client*

Service Code	Title	Overview Ask us a question and we shall get you an answer!
RIFC-10-DOC	**ISO 9001 Document Review**	**Includes:** Covers hands-on training of important and mandatory documentation like SOPs, validation protocols & reports, quality manual, Product Master File, Plant master file, primary and secondary packaging material symbols and text, etc. against the ISO 9001 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 9001.
RIFC-11-INF	**ISO 27001 Document Preparation & Review**	**Includes:** Access to standardized SOP templates tailored to ISO 27001 requirements. Guidance on establishing and implementing an effective Information Security Management System (ISMS). Hands-on training for creating and managing mandatory documentation, including SOPs, policies, and control records **Benefits:** Learn do's and don'ts of a perfect document. Know the structure, contents, and control of documentation. Learn to prepare and to maintain quality documents aligns with ISO 27001 standards. **Outcome:** Training manual and in person explanation.
RIFC-12-DPA	**DPDP Act Advisory**	**Includes**: Covers expert guidance on the DPDP act, 2023 applicability to the organization. Understand the provisions of the DPDP act and implications on the organizational processes. Advise on roles and responsibilities of the organization under the act, HR requirements for employees and candidates, and Procedural or Documentation requirement to be compliant. **Benefits:** Understand legal accountability and governance structure required for handling sensitive health data, compliance framework related to employee and candidate data, which often includes sensitive financial and medical information and essential documents and procedures required of compliance for the organization. **Outcome:** Advisory Report and in person explanation.

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 except RIFC-07-CTP and RIFC-08-CTA. Clinical Trial Services shall charge as ₹ 5000 per hour.***
- Advisory services will be charged either on task basis or on hourly payment basis depending uponthe service requested. An estimate of charge on task basis or advisory hours would be given at the introductory freemeeting.
- The estimated payment is to be made in advance of each paid advisory engagement.
- Theduration of each engagement will be mutually agreed upon by RIFC and Applicant and thecorresponding 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 paidbefore completion and delivery of deliverables.
- Payment is acceptable by DD or cheque payable in Pune or at Par or could be deposited directlyinto the RIFC / BRBC's bank account.
- Any fees charged by the concerned Government office, authorities for any action required to betaken 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 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-01-ADV	General Advisory	₹ 2000 per hour
RIFC-02-PAT	Planning Regulatory Pathway	₹ 2000 per hour
RIFC-03-STD	Standards Interpretation	₹ 2000 per hour
RIFC-04-DOP	ISO 13485 Document Preparation & Review	₹ 2000 per hour
RIFC-05-DOR	ISO 13485 Document Review	₹ 2000 per hour
RIFC-06-RMP	Risk Management	₹ 2000 per hour
RIFC-07-CTP	Clinical Trial Study Plan	₹ 5000 per hour
RIFC-08-CTA	Clinical Trial Advice	₹ 5000 per hour
RIFC-09-INT	ISO 13485 Internal Audit	₹ 2000 per hour

RIFC-10-DOC	ISO 9001 Document Review	₹ 2000 per hour
RIFC-11-INF	ISO 27001 Document Preparation & Review	₹ 2000 per hour
RIFC-12-DPA	DPDP Act Advisory	₹ 2000 per hour

* 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.

DISCOUNT CATEGORY

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

***Discount categories are applicable for all services except RIFC-07-CTP and RIFC-08-CTA.**

SPECIAL OFFERS

Duration of validity	Applicable services	Special offer/ discounts
31 Dec. 2025 – 31 Jan. 2026 **NEW!**	RIFC-12-DPA	Total 10% Special discount on DPDP Act Advisory service for first 5 signups. (Special offers are not applicable to Category A and B. Only one offer can be selected)

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

Sr. No.	Service Code	Estimated Hours			
		Class A	Class B	Class C	Class D
01	**RIFC-01-ADV (**General Advisory)	10	10	10	10
02	**RIFC-02-PAT (**Planning Regulatory Pathway)	35	35	35	35
03	**RIFC-03-STD**(Standards Interpretation)	10	10	15	15
04	**RIFC-04-DOP** (ISO 13485 Document Preparation & Review)	200	200	200	200
05	**RIFC-05-DOP** (ISO 13485 Document Review)	120	120	120	120
06	**RIFC-06-RMP** (Risk Management)	60	60	90	90
07	**RIFC-07-CTP** (Clinical Trial Study Plan)	100	100	120	150
08	**RIFC-08-CTA (**Clinical Trial Advice)	40	40	40	40
09	**RIFC-09-INT (**ISO 13485 Internal Audit**)**	32	32	32	32

10	**RIFC-10-DOC** (ISO 9001 Document Review)	120	120	120	120
11	**RIFC-11-INF** (ISO 27001 Document Preparation & Review)	120	120	120	120
12	**RIFC-12-DPA** (DPDP Act, 2023 Advisory)	10	10	10	10

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.

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

Seal

Date

For Applicant

Authorized Signatory

Seal

Date