

MEDTECH CLEANROOM FACILITY SERVICES

TERM SHEET & AGREEMENT (Ver. 01), May 7, 2020

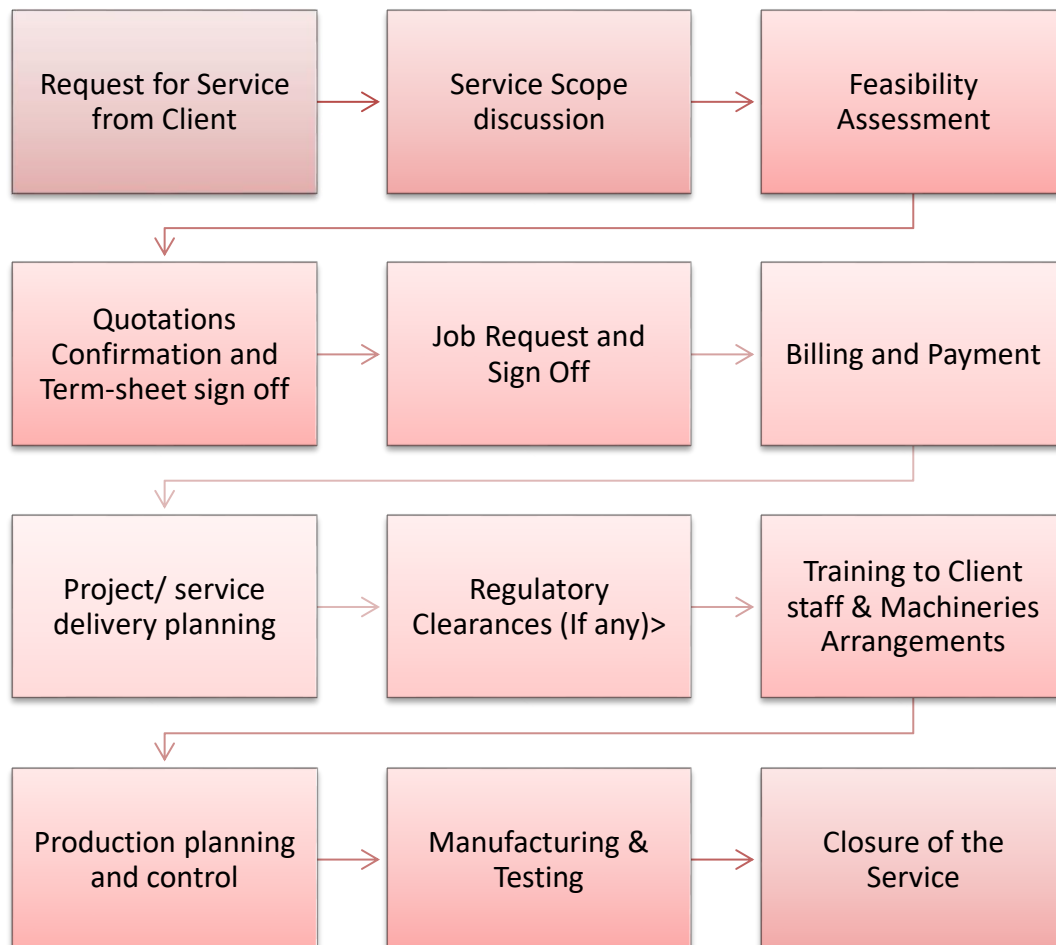
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Engagement Process flow:

Request for Service from Client>> Service Scope discussion>> Feasibility Assessment>> Quotations Confirmation and Term-sheet sign off>>Job Request and Sign Off>> Billing and Payment>> Project/ service delivery planning>>Regulatory Clearances (If any)>> Training to Client staff & Machineries Arrangements>>Production planning and control >>Manufacturing & Testing>> Closure of the Service.



FEATURES

- **MedTech Cleanroom Facility Services relating to:**
 - Cleanroom facility for Manufacturing of Medical Devices for testing purposes.

SERVICES

Service Code	Title	Overview of Activities
EDC-01-CRF	Cleanroom Facility <i>(Active)</i>	<p>Scope: Qualified and functional cleanroom facility.</p> <p>Process: Who will manufacture? – Client’s qualified staff How? – Processes/ methods setting at EDC’s premises Machineries – Client’s control Materials – Client’s control IPQC – Client’s control FGQC – Client’s control</p> <p>Deliverables: Planning manufacturing and BMR preparation Client’s Process Validation documentation support Client’s Equipment Validation and documentation support Qualified and functional cleanroom facility. Environmental monitoring. Cleaning and maintenance.</p>
EDC-02-TLS	Test License Support <i>(Active)</i>	<p>Scope& Deliverables: Qualified and functional cleanroom facility documentation (Site Certificates, Layouts, Site Master File, etc.) for submitting to the regulatory authorities.</p> <p>Clients can manufacture the approved quantity of the devices until the expiry of the test license.</p>
EDC-03-MFG	Manufacturing as a Service <i>(To be launched)</i>	<p>Scope: Manufacturing, packaging, sterilization (dry heat, irradiation, gas) from third party with additional cost, quality control and packaging tests and supply to client or client’s customer.</p>

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		<p>Who will manufacture? – EDC’s qualified staff. How? – Processes/ methods set by client* Materials – Supplied by client (Raw and Packaging) IPQC –In process quality control tests set by client* FGQC –Finished goods process quality control tests set by client*</p> <p>Deliverables: Sterile, Packed, and Finished goods. Planning manufacturing and BMR preparation Client’s Process Validation documentation support Client’s Equipment Validation and documentation support Certificate of Conformity</p> <p>(*Process validation at EDC’s premises required)</p>
EDC-04-PKG	Packaging as a Service (To be launched)	<p>Scope: Primary and Secondary Packaging of devices in cleanroom and sterilization (dry heat, irradiation, gas) from third party with additional cost, quality control and packaging tests and supply to client or client’s customer.</p> <p>Who will manufacture? – EDC’s qualified staff How? – Processes/ methods set by client* Materials – Supplied by client (RM&PM) IPQC – Processes set by client* FGQC – Processes set by client*</p> <p>Process: Cleaning and packaging.</p> <p>Deliverables: Sterile, Packed, and Finished goods. Planning manufacturing and BMR preparation Client’s Process Validation documentation support Client’s Equipment Validation and documentation support</p> <p>(*Process validation at EDC’s premises required)</p>

ELIGIBILITY

- The Services shall be available for bio-entrepreneurs/incubatees/start-ups/ventures related to medical devices for manufacturing and packaging in the cleanroom facility.
- The management of the EDC shall exercise judgment in making available the services requested.

TERMS

General

- This agreement shall prevent misinterpretation of communications and avoid potential contract disputes and litigation.
- Clarity in business relationships, agreements, authorities, responsibilities, limitations of EDC and Client.
- Better management of commercial relationships between (“EDC”), and (“Client”), as of (the “date of this agreement”).
- EDC may engage third- party consultants or advisors as part of a 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.
- 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 Pune.
- The parties shall endeavor to resolve any dispute relating to the services offered by EDC firstly by mutual discussion and in the event of any persistent disagreement; the same shall be referred to for arbitration to arbitrator tribunal. The arbitral tribunal shall consist of 3 arbitrators, each party shall appoint 1 arbitrator, and the 2 arbitrators so appointed shall appoint the third arbitrator, who will be the presiding officer of the arbitral tribunal. The arbitration will be conducted by such arbitrator(s) in accordance with the provisions of Arbitration and Conciliation Act-1996.
- This agreement remains valid till the expiry of the licenses or completion of the service deliverables agreed in the “Job Request and Sign Off form”.
- This Agreement does not establish a partnership or joint venture between the parties.
- Client and its employees shall at all times (i) observe all EDC rules and regulations while on NCL Innovation Park, including but not limited to rules and regulations designed to protect the safety of persons and property, and (ii) follow the directions and instructions of EDC personnel with respect to the Client’s use of the Equipment and the Facility, and otherwise with respect to Client’s activities.
- The term of this agreement will begin on the date of signing of this Term Sheet and will remain in full force and effect until the completion of service.

Damage or Destruction

- Client shall immediately inform EDC & reimburse EDC for the full cost of repair or replacement of any Equipment, or any other EDC property, which is damaged, destroyed or stolen by Client or its client Personnel. EDC shall use its reasonable judgment in determining whether damaged Equipment or other property should be repaired or replaced.
- Clients/ he/she accept that EDC shall not be held responsible for any injury, harm, or cost incurred by the clients with regard to cleanroom services.

QUALITY MANAGEMENT SYSTEM

Documentation requirements

- Any document/record generated, created during this agreement period shall be retained by EDC/ Client as an original/ duplicate copy.
- Client shall provide the details of the product as per EDC's medical device file format or his/ her own format.

Management Responsibility

EDC's Commitment:

EDC is committed to the highest level of quality in the provision of clean room facility services for the manufacturing and packaging of non-active medical devices, active (non-implantable) medical devices, implantable medical devices, in vitro diagnostic medical devices, devices incorporating/utilizing specific substances/technologies. Infrastructure quality and compliance to all the regulatory requirements and to maintain the effectiveness of the Quality Management System, continuous improvement and customer satisfaction shall bear all of our effects in supporting and catering to the client's needs.

EDC agrees that it will not disclose, divulge or reveal the confidential information authorized by Client. The obligations of confidentiality will apply during the term and will survive till six months upon termination of this agreement.

Client's Commitment:

Client is committed to accept and honors the policies and quality management system processes defined by the EDC.

Communication:

Sr. No.	Topic	Communication Method
1.	Training	Verbal/ Classroom/ on job/ Instructions/ Displays
2.	Complaints and Feedback	Verbal/ e-mail/ written

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Management Review

- EDC and Client shall review the activities/ operations carried out at the premises for the permitted use.
- Inputs
- Number of batches manufactured or packed.
- Documentation review; records generated.
- Actions taken on complaints and feedbacks, etc.

RESOURCE MANAGEMENT**Use of Premises**

- The premises shall be used and occupied only for the permitted use. Client shall not use or permit the use of the premises, the property or any part thereof, in a manner that conflict with or is prohibited by the terms and conditions of this agreement.
- Proper assessment of risks caused by odors, smoke, dust, gas, noise, or vibrations during client operations will be done prior to the start of cleanroom operations and will be monitored during cleanroom operations by EDC. The management reserves the right to stop usage prior to or during cleanroom operations if it believes that the client's work will endanger, annoy or interfere with other operations or otherwise cause undue damage to EDC property.
- Client shall obtain, at its sole expense, any permit or other governmental authorization required by it to carry out its work using EDC services.
- In the event of an excess of trash or scrap in or outside the premises, the client shall be informed or notified of the removal of such scrap or trash within a specified period of time. If the client fails to dispose of the scrap or trash within a specified time, EDC shall have the right to remove such excess trash or scrap and shall charge all costs and expenses attributable to its removal from the client.
- Client shall not cause, maintain or permit any outside storage inside the premises without prior consent from EDC. Client shall not carry materials contributing to or generating viable & non-viable particulate matter.
- Client shall provide the details of the resources required for using the premises.
- The client must provide a health certificate and a qualification record of all personnel working in the premises. The health certificate shall be obtained prior to working in the premises. The health certificate shall be considered to be valid for a period of 12 months.
- The Client should refrain from any activity that may adversely affect the quality management system and infrastructure.
- Client must specify the details of work environment and controls required for the activities to be carried out at the premise.
- EDC shall determine and provide the resources needed to implement the quality management system and meet applicable regulatory and customer requirements.

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- Planned and unplanned repair and maintenance of equipment owned by Client shall be performed with prior permission records to be submitted to EDC's concerned department.
- Client will not cause or permit any Hazardous Materials to be brought upon, kept, stored, discharged, and released without the written consent of EDC.
- A maximum of six qualified personnel shall be allowed to work within the controlled area at a time. (Clean zone ISO Class 7: Not more than 3 & ISO Class 8: Not more than 3). Only one client shall work inside the cleanroom at a time.
- The maximum length of time that a gown can be worn is eight hours. As people perspire, the integrity of the gown will weaken. Complicating factors are the temperature and humidity of the cleanroom and the variations between people. Gowns shall be worn only for the length of the shift (normally eight-hour periods to enable operators to take breaks). In ISO Class 8 cleanroom, a gown might be worn for several sessions during the course of the working day.

Utilities and Services

- Client shall take prior permission before using or installing additional utilities.
- Client shall arrange for, and to pay directly all costs of, additional utility services supplied to the premises.

Waiver of Claims; Indemnification

- Client waives all claims against EDC for any damage to any property in or about the Property, for any loss of business or income, and for injury to or death of any persons, regardless of the cause of any such loss or event (including negligence) or time of occurrence.
- Client will indemnify, protect, defend and hold harmless EDC and the EDC Related Parties from and against all claims, losses, damages, causes of action, costs, expenses and liabilities, including reasonable legal fees, arising out of Client's occupancy of the Premises or presence on the Property.
- Client will indemnify and hold EDC and its affiliates, employees, consultants, agents harmless from and against any and all third-party claims (including, but not limited to, reasonable attorneys' fees and litigation costs), disputes, judgments for injury to persons, including death, or damage to tangible property occurring while its employees are on EDC's premises.
- A prompt notice of any claim and the opportunity to control the defense and settlement of the claim shall be given to EDC by the client.
- Without limiting the generality of the foregoing, EDC shall have no liability under any circumstance for breach of this Agreement in any amount which exceeds the total of all service Fees and Training Fees which EDC has received from Client hereunder.

EDC's Access

- EDC, its agents, contractors, consultants and employees, will have the right to enter the premises at any time in the case of an emergency, and otherwise at reasonable times following

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notice to Client (which notice may be given orally) to examine the premises, perform work in the premises, inspect any alterations and/or any improvements, show the premises, exercise any right or remedy, or for any other purposes.

Assignment and Subletting

- Client will not, voluntarily or by operation of law, assign, sell, convey, sublet or otherwise transfer all or any part of Client's right or interest in this Lease, or allow any other person or entity to occupy or use all or any part of the Premises (collectively called "Transfer") without first obtaining the written consent of EDC, which consent shall not be unreasonably withheld. Any Transfer without the prior written consent of Client shall be void.

PAYMENT TERMS

- Payment is acceptable by DD or cheque payable in Pune or at Par or could be deposited directly into the defined bank account details on the invoice.
- 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 EDC.
- EDC retains the right to cancel existing paid engagements with the Client at its sole discretion. In this case, no refund will be provided.
- No refunds will be provided for the un-used batches/ period or postponed.
- EDC may revise rates charged for services at any point in time, at its sole discretion. This will not affect existing, signed agreements, but will affect any future engagements between the EDC and Client.
- The duration of each engagement will be mutually agreed upon by EDC and Client and the corresponding payment shall be made in advance by the Client as agreed in the "Job Request and Sign Off form".
- Final payment would be invoiced at the time of end of the services, which needs to be paid before completion and delivery of deliverables. This includes the additional usage of the cleanroom than the agreed shifts in "Job Request and Sign Off form", costs of consumables, and any other unforeseen costs incurred to fulfill the services.
- The application form once submitted cannot be cancelled and the applicant is liable to pay the charges towards the services applied for.

Additional Charges

- Unless otherwise specifically stated in this agreement, any charge payable by Client under this agreement other than Base charge is called "Additional Charge."
- The term "Charge" whenever used in this agreement means Base Charge, Additional Charge and/or any other charge, fee or monies payable by Client under the terms of this agreement.
- There will 50% additional charge levied if usage of the premises continues beyond the working hours mentioned in the pricing table below.

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Security Deposit

- Upon Client's execution of this agreement, Client shall deposit Rs 50,000 (Rs Fifty Thousand only) as the fully refundable deposit.
- This deposit will be refunded to the client after one month of expiry of this agreement
- The Security Deposit is not an advance rent payment or a measure of damages under this service.

Use of Names

Client will not under any circumstances advertise or otherwise publicly state or imply that EDC has tested or approved any product or process.

Client shall use name, trademarks of EDC in publicity, advertising or news release subject to prior written approval from EDC.

PRICING
Base Charges^μ

Service code	Title of service	Price in INR
EDC-01-CRF#	Cleanroom Facility* <i>(Active)</i>	₹20,000.00 - 08 Hours ₹10,000.00 - 04 hours
EDC-02-TLS	Test License Support <i>(Active)</i>	₹50,000.00/ year
EDC-03-MFG	Manufacturing as a Service <i>(Yet to be launched)</i>	<i>To be announced</i>
EDC-04-PKG	Packaging as a Service <i>(Yet to be launched)</i>	<i>To be announced</i>

*The service is available on all working days for Entrepreneurship Development Center (Venture Center) between 930 am and 730 pm. The use of cleanroom facilities between 730 pm to 730 am will incur 50% additional charges.

Flat rate (fixed fee) for a service regardless of usage for 32 hours (i.e. ₹80,000.00) will be invoiced as the base charges. Discounts and special offers are applicable after 32 hours of usage.

μ Charges mentioned in Pricing Table above are applicable for services to individuals, startups, micro and small 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 (Medium, Large and Foreign companies) there will be a 100% premium applicable.

DISCOUNT CATEGORY

A. Incubatees (current resident incubates OR portfolio companies of VC)	50 %discount
B. Start-ups (with DIPP registration certificate/Registered under Startup India Mission)	30 %discount

SPECIAL OFFERS

Applicable services	Duration of validity	Discounts
EDC-01-CRF	For first 5 Incubatees, Valid till March 2021 NEW!	Additional 20%
	For first 5 start-ups, Valid till March 2021 NEW!	Additional 20%
EDC-02-TLS	For first 5 Incubatees, Valid till March 2021 NEW!	100% Fee waiver for first year

An illustrative estimate of the number of shifts required for the different services

Sr. No.	Service code	Estimated costs per 1000 products
01	EDC-01-CRF <i>(Active)</i>	<i>(To be announced)</i>
02	EDC-02-TLS <i>(Active)</i>	
03	EDC-03-MFG <i>(Yet to be launched)</i>	
04	EDC-04-PKG <i>(Yet to be launched)</i>	

Cost of use of Personal Protective Equipment (PPE) and consumables are at actuals. Clients may arrange for their own Personal Protective Equipment (PPE) and consumables of cleanroom compatible standards and the same needs to be approved by the quality team at EDC.

Client has read and understood all of the above terms and conditions pertaining to the Cleanroom facility services offered by EDC and agrees to abide by the same.

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SIGN OFF

For and on behalf of EDC

For Client

Authorized Signatory

Authorized Signatory

Seal

Seal

Date

Date