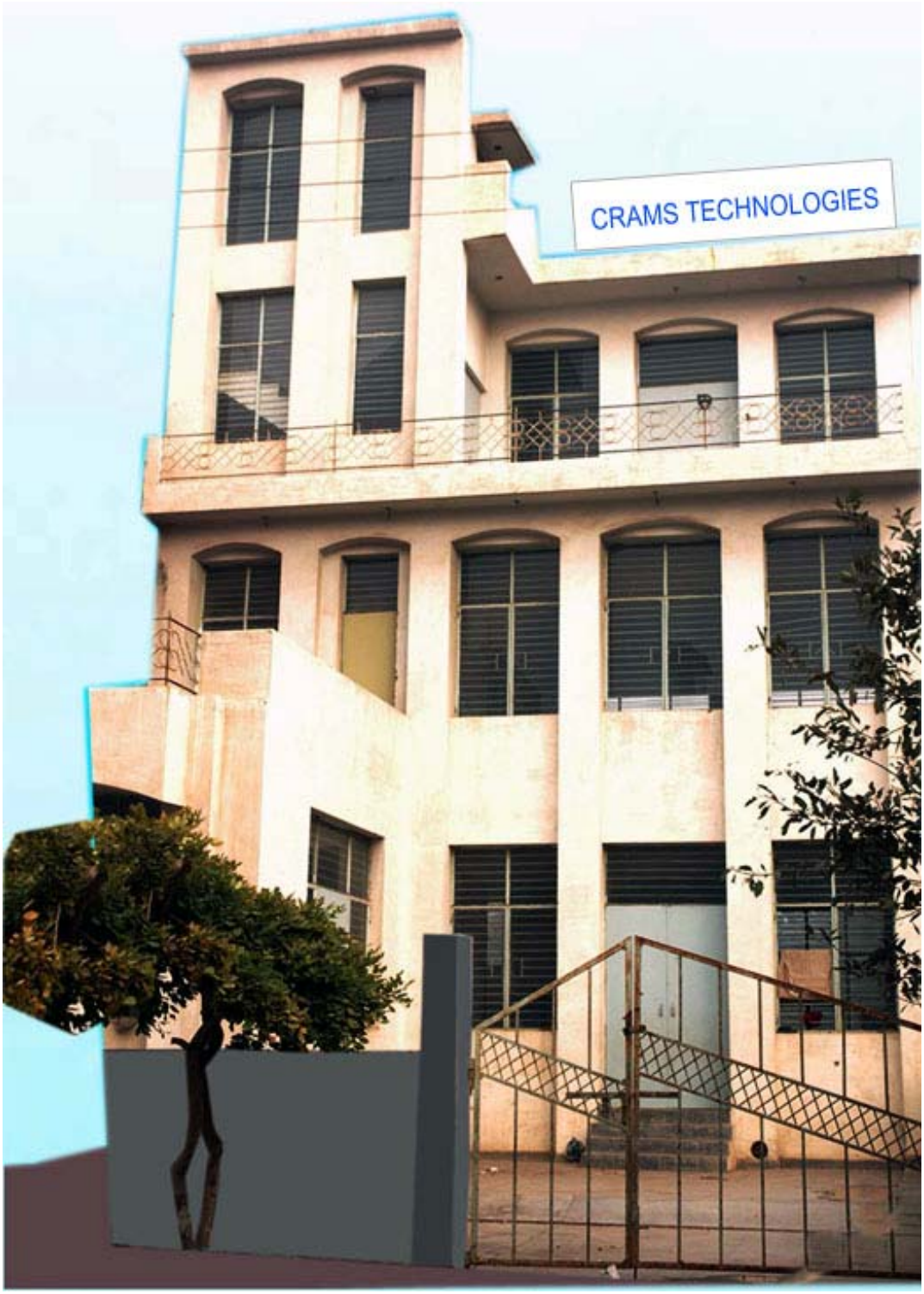
CRAMS TECHNOLOGIES

Solving Chemistry Puzzles Globally



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Solving Chemistry Puzzles Globally

Crams Technologies, a start up CRO, as name spells, are in the business of Contract Research And Manufacturing Services (CRAMS), A CRO for outsourcing of pharmaceutical research. We have just planned our set up as a full fledged CRO in a very short span.

Under this umbrella, we plan to support pharma industry in the fields of synthetic chemistry, analytical chemistry, regulatory aspects and IPR for Innovator and Generic companies across the world who seeks to have high quality, competitively priced Indian chemistry skills to their advantage. Crams Technology will leverage its strengths in Analytical Chemistry, organic synthesis, process development and regulatory aspects.
Crams Technology will offer following customized products and services:

- Creating Intellectual Property through filing of patents
- Starting materials, intermediates, and final products
- Drug intermediates synthesis
- Scale up, process optimization
- Third party audits
- Due Diligence
- Dossiers preparations
- Analytical Method Developments
- Analytical Validatons
- Isolations and purification of compounds
- IPR Strategeies

This is the brain child of a highly experience & known person in Indian pharma industry.

We are situated very near to Delhi at Faridabad, which is about an hour journey from Airport. We have a total built up area of about 6000 sqft divided in to Analytical Laboratry, Synthetic laboratories, Natural Product Isolation area, conference room and sitting area for regulator & IPR scientists.

Crams (contract research and manufacturing services) Technologies, a CRO with multidisciplinary skills in chemistry, Analytical, regulatory and IPR. We provide customised services to pharmaceutical on a strong platform of confidentiality and intellectual property protection.

About Us

Ours is a team of highly experienced personnel from best of Research Centers in India.
We have total experience of about 4 decades in pharmaceutical research.
Our Team capabilities include organic synthesis, analytical strength including stability & impurity profiling, natural products extractions, isolation & purification, regulatory compliance and IPR.
In our team we have experience scientists from Ranbaxy, Dabur and Jubilant etc.
In total we have several research publications to our credit.
One of our team member was an expert committee member of USP from 2000-2005.
Our team members were awarded for their best work from Industry as well from Indian Drugs Manufacturers associations.
We are members of Indian Pharmaceutical Associations, Indian Analytical Society.

Services

- Synthetic Chemistry
- Route selections
- Process development, optimizations & validations
- Multi step synthesis
- Library Synthesis
- Reference material development
- Custom synthesis from mg to gram level
- Analytical Chemistry
- Method Development
- Method Validation
- Isolation and purification of Reference standards of main synthetic compounds and Impurities.
- Isolation and purification of Reference standards of natural compounds and Impurities.
- Regulatory Support
- Dossier preparation
- DMF compilations
- ANDA compilations
- Due Diligence
- Third Party audits
- IPR
- Strategies for Pharma organisations
- Patent Search and litrature Back-up
- Infringement analysis support
- Patent Drafting

Analytical Chemistry

To develop and optimize methods, scientists at Crams Technologies cGMP compliant analytical facilities are equipped with an array of tools and techniques, including HPLC, GC and TLC etc.
Crams Technologies develops analytical methods for all the analytical applications such as:

- Potency
- Impurities
- Residual solvents
- Physical and chemical tests
- Cleaning assessment
- Chiral purity

After a successful method development, Crams Technologies has the capabilities to validate analytical method as per ICH guidelines. Our scientists perform methods validation activities using a practical approach coupled with outstanding quality and sound scientific expertise.

We will perform validations for chromatographic as well non chromatographic methods as per regulatory requirements and mutually agreed protocols.

At Crams Technologies, stability studies are a part of its analytical services.

Modes Operendi

On receiving a request for any project, Initial customer discussions regarding potential projects are carried out by CRAMS TECHNOLOGIES Sales & Business Development staff. These specialists are trained to provide information about CRAMS TECHNOLOGIES services and capabilities and to obtain an overview of the customer's requirements in order to find the best fit between the customer's needs and CRAMS TECHNOLOGIES capabilities.

Afterwards we would submit a propoasal depending upon the type of possible arrangment.

Fee-for-Service/Purchase Order: Proposal would be submitted with at least following component:-

- Time Required
- Man power required
- Cost Estimate
- Reporting Details
- Mile Stones
- Deliverables

Upon acceptance of this proposal, work will be initiated. Though we have mentiond few controls of project however every parameter can be tailor-made based on customers' needs.

FTE (Full Time Equivalent) arrangement- Under this type of arrangement, we will dedicate agreed number of scientists (FTE's) to work for the customer in our laboratories. An FTE arrangement allows our customer to seamlessly interface with the bench scientists and prioritize projects based on requirements.

Flexible FTE- Under this arrangement, We provides the option to vary the number of FTE's our customers wish to deploy during the course of the project subject to the customer meeting the minimum agreed annual FTE deployment.

Through such flexibility, our customers are able to scale-up or scale-down FTE count on the project rapidly thereby allowing them to address the project requirement/end goals without compromising on the timelines.

Once project is ordred to us the product management process is as follows.

A full-time project manager will be assigned to the project. Progress of the work is communicated at regular intervals, typically in written weekly or monthly reports as per agreement. The complete project details are known only to the project leader and he shares the part with his team members on a need to know basis. This is done to provide utmost confidentiality. Samples of intermediate compounds are available on request at any stage of the synthesis. The project can be stopped at any time.

The Project manager becomes the customer's key point of contact a **Crams Technologies,** keeping the customer informed abut the progress of the project from initiation to completion. Their primary objective is to ensure delivery of the project, on time, on budget and to the quality standards expected by the customer.

Data Managment

We are in process of developing an in house request to report system. This will be scientist/project specific.

Intellectual Property Protection

Complete confidentiality and protection of client intellectual property is part of the **Crams Technologies** culture. Employees have back-to-back confidentiality agreements with the company to adhere to confidentiality. Within the company we have a firewall concept across the businesses in terms of projects and technologies Clients can trust us completely with their proprietary information. Whether it is a service based partnership or a collaborative research program, sensitivity to client confidentiality permeates all our operations.

At Crams Technologies, we believe the creation and protection of IP is a key differentiator that will profile our intellectual capabilities on a global platform. In line with this business ethic, we afford non-disclosure and confidentiality agreements the utmost importance and priority. In genral all IP rights belong to our clients irrespective of FTE or project business model.

However, we operate on a flexible IPR ownership business model with our customers. This is decided and agreed at the time of drawing the agreement.

Quality Management

- Quality Management System is based on ICH.
- Quality Management System is comprehensive covering all cGMP aspects.
- We will be having regular internal cGMP audits & continuous improvements

Infrastructure and facilities

We are situated very near to Delhi at Faridabad, which is about an hour journey from Airport.

We have a total built up area of about 6000 sqft divided in to Analytical Laboratry, Synthetic laboratories, Natural Product Isolation Area, conference room and sitting area for regulator scientists

We have invested about 200KUS$ for a creating a built up area of 6000 sqft in a facility. We are investing further to creat state of the art research facility.

Lab Facilities:

- Labs are customized as per the project requirements.
- All laboratories contain modular hoods.

Scale-Up Facility

Our CRO, Crams Technologoies has dedicated scale-up labs with analytical and special equipments for scale-up with capacity up to grams scale.

- Glass Assembly 20Lt
- Glass assembly 20 Ly
- Rotavapors
- Columns
- Heating vacuum oven

Analytical support

- A quality functional unit
- Round the clock analytical support
- Validated Analytical Methods Development: covers all aspects from sample and model selection to collaborative trials
- Identification, isolation and characterization of impurities
- Complete range of integrated systems to meet research and discovery purification needs

Analytical facilities and equipments:

- HPLC
- Automated Mass Directed Preparative System
- FTIR
- Polarimeter
- Milli-Q Systems
- Gas Chromatrography
- LC-MS/MS *
- 400 MHz NMR *

*Initialy we have made arrangement with nationalized laboratory for carrying out our job. For the same we have signed a MOU and confidentiality agreements.

All regulatory licenses are already in place.
100% power back up.
Competent Engineering Maintenance Support.

Education

Refresher Course for working candidates

After working in industry it has been realized that new joinees learn a very small portion of the total concept while on job. They just understand what they have been taught during working time. Neither do they try to learn themselves as they do not find time on job nor industry take interest because of the pressures of business deliverables. But on the other hand they expect promotoins and growth as couple of years pass. The outcome is the frustration instead of learning which makes them plan to change.

Whatever energy and time is spent by the first organization that becomes the basic platform for second organization and the candidate feels that they have been upgraded well.

In this whole process candidate learns only small aspect of the whole process and most of the times fails as grows senior in the stream.

In order to support a refresher, a course cum training has been organized with mix of theoretical and practical aspects. In this course we also try to build his presentations/spoken and written English skill. We will try to help candidate in general but course can be very specific and tailor-made as per the need of sponsoring organization. The syllabus and content can be discussed and finalised.

Certificate Course for Freshers

It has been observed that a small course about the need of pharmaceutical research will help fresh students to get entry in pharma world. Though pharma industries have different needs but training will be provided to the candidates as per specific skill/capabilities.

Under this course we will provide followings:-

- Refreshing of theoretical background as per industry needs.
- Practical/ Laboratory based assignments.
- Brief overview of regulatory/quality assurance needs.
- Brief overview of IPR (Intellectual Property Rights/Patents) needs in pharma Industry.
- Training on presentations skills and spoken English.
- Support will be provided to get suitable job.

Career

As we are a start up organistaion so we are in need of candidates at all level in the areas of our services. We have very ambitious plans and are expected to grow very fast. Deserving candidates can grow with us.

You may post your resume.

Contact
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