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SHOBHABEN PRATAPBHAI PATEL SCHOOL OF PHARMACY & TECHNOLOGY MANAGEMENT

REPORT ON INDUSTRY VISIT

RAPTIM RESEARCH LTD.

A CONTRACT RESEARCH ORGANIZATION

FEBRUARY 17, 2024

About the Company

Raptim Research Private Limited (formerly known as Raptim Research Limited), founded in 2005 has been one of the fastest-growing CRO (Contract Research Organization). Raptim is a full-service CRO in early and late phase studies providing multiple research services for pharmaceutical, biotechnology, and generic drug industries. Raptim stands for “Rapid Time” as our primary goal is to provide fast
turnaround quality study results to help in the sponsor’s approval process of regulatory submission and product approvals.

Raptim Research is a full-service provider focused on early and late phase clinical research services with 15 years of experience. Our support services include large and small molecule Bio-analysis, Clinical Pharmacology, In-vitro Studies, Feeding Tube Studies, BCS Biowaiver studies, Data Management, Biostatistics, Regulatory Support, and Project Management.

Raptim has operational facilities in Mumbai (Maharashtra) and Gandhinagar (Gujarat) in India, and a marketing office in New Jersey, USA.

Services

Raptim Research Private Limited (formerly known as Raptim Research Limited) provides comprehensive end-to-end clinical development and laboratory services with a full suite of integrated solutions, method validation and other analytical services to the pharmaceutical and biotechnology industries. We are a CRO who firmly believes in the philosophy of “Extended Enterprise” work hand in hand with the sponsor’s product development team of their own. Our management team’s technical leadership experience in the dermatological field that ranges from concept to complete development cycle which brings added value to our customers.

Unlike any CRO, Raptim brings new solution to your product approvals and our team knows we can be most effective and pursue perfection in those specializations with everything we do. Our services span early development, clinical development and post-approval and include comprehensive CRO capabilities. We are focused on helping our customers optimize their development programs using our innovations and maximize value and outcomes for their products through strong and trustworthy governance at Raptim.

Mumbai Facility

- Facility having more than 20,000 sq. ft. of carpet area
- 3 clinical units with 170 beds facilitating simultaneous conduction of multiple studies resulting in quick turnaround time
- Ease of conducting mix population studies with separate housing areas for Male and Female Subjects
- Clinical pathology lab accredited by the College of American Pathologists (CAP) and National Accreditation Board for Testing and Calibration Laboratories (NABL) equipped to carry out tests for biochemistry, haematology, urine chemistry and serology as per study requirements
- The clinical facility has been approved by DCGI (INDIA) and it is fully compliant with ICH GCP and other International Regulations like USFDA, WHO, UK MHRA, TGA (Australia), Canada, etc

Company Address

A-226 / A-242, TTC Industrial Area, Mahape MIDC, Navi Mumbai 400 710

HIGHLIGHTS OF THE VISIT

On February 17, 2024, first-year M. Pharm (Regulatory Affairs & Pharmacology) students had the opportunity to visit Raptim Research Pvt. Ltd. in Navi Mumbai. This educational visit aimed to provide with firsthand insights about different clinical research processes, the work flow and regulations required.

Key Learnings:

1. Clinical Department:

In the clinical department during pre-study the volunteers were recruited followed by their registration, screening, selection as per the inclusion and exclusion criteria. The volunteers are provide with informed consent form for ensuring their consent for participating in the study. During study housing of volunteers as per the protocol and study design is done. At defined time intervals vitals and blood collection from volunteers is taken and transferred to deep freezer and later for analysis. Also 24/7 medical practitioner including MBBS MD doctor were available for immediate care. Two bed of ICU were also available for any serious condition during study. The staff, including side staff, was readily available to attend to any concerns or needs, creating an environment of support and reassurance.
Students witnessed the clinical site with an ongoing study on a batch of 50 volunteers. They were separate rooms for dosing and housing areas. The facility was well organized with all the necessary care taken and fully equipped with:

- Housing area
- Dosing area -Investigation Product
- Blood collection area- Timely withdrawal of samples from patients
- Sample Separation area
- Analytical department

They have reserved 2 beds for Adverse Drug Reactions and have a collaboration with SSD Hospital. They have maintained a space for the information regarding the activities scheduled with regarding of the sample withdrawal.

2. Analytical Department:

The analytical department focused on gathering, analyzing, and interpreting data to provide insights and support decision-making processes. This department typically utilized various tools and techniques to analyze samples. The technological adaptation with electronic tools has improved data integrity, cycles times, risk management, cost and patient recruitment.

Bio analytical capabilities:

- 43 LCMS/MS (LC MS/MS: API 6500/5500/4500/4000/3500/2000)
- 3 HPLC
- 2 ICP
- 1 ICP MS

In Raptim different methods used are:

- 250+ Validated Methods
- Developed Sensitive and Complex Methods
- 50+ Well-Trained and Experienced Scientists
- Laboratory Information Management System (LIMS)
- Deep Freezers (-20oC and -70oC)
- GLP Compliant Lab

3. Permeation Study Department:

The focus of our visit was to gain insights into permeation studies, particularly through the examination of the Franz diffusion cell, a vital apparatus in pharmaceutical research for understanding drug permeability across membranes. We observed a range of equipment, including permeation cells, spectrophotometers, HPLC systems, and temperature-controlled chambers.
Permeation cells are specialized chambers where the membrane (e.g., skin, synthetic membrane) is placed between two compartments to measure the diffusion or permeation of substances.

We were guided through the components and functioning of the Franz diffusion cell, which consisted of donor and receptor compartments separated by a membrane. The researchers explained how substances are applied to the donor compartment and monitored as they permeate through the membrane into the receptor compartment. Sampling ports allowed for the collection of permeated substances at designated time intervals for analysis.

Different types of activities carried out in this lab included:-

- Bioequivalence Studies: Comparing the permeation behavior of generic and brand-name drug formulations to assess their equivalence.
- Dermatokinetic studies: refers to the study of the kinetics or movement of drugs or other substances across the skin.
- Safety and Toxicology: Dermatokinetic studies also play a crucial role in assessing the safety and potential toxicity of topical formulations. Researchers investigate factors such as skin irritation, sensitization, and systemic exposure to ensure the safe use of dermatological products.
- Permeation Studies: Dermatokinetic studies involve evaluating the permeability of drugs across the skin using techniques such as Franz diffusion cells, tape stripping, and in vitro skin penetration assays. These studies help determine the rate and extent of drug absorption into the systemic circulation and local tissues.

4. Regulatory Department:

Raptim Regulatory Services Included But Not Limited To:

- To achieve the regulatory goal, we can suggest a concrete regulatory strategy to give you a competitive advantage

- Provide detailed feasibility before study execution to get real-time information and expected timelines.
- Preparation & submission of regulatory documents for obtaining:
- Approval to conduct a clinical trial in India
- Approval to import Investigational Products
- Liaising and Obtaining registration documents in the interest of clients
- Safety reporting
- Preparation of regulatory submissions in CTD and eCTD format
- Preparation of summaries required for generic submission
- Executing regulatory submission
- Responding to the health authorities' queries during the approval phases of the product
- Regulatory offerings in Raptim have successfully completed over 30+ regulatory inspections from Indian & International Regulatory agencies and 70+ sponsor audits from Indian and International clients. All the services are executed in strict compliance with regulatory and ICH

Company Walkthrough:

Students had an informative conversation with Dr. Milind Bagul, Head of Analytical Services. He took us through the history of the organization and how beautiful their journey has been. He also addressed us how well prepared they were in terms of audits they had witnessed a number of inspections from various regulatory authorities and few of them also being unannounced audits.

Question and Answer Discussion

1. Is there an independent Pharmacovigilance division within your organization or structure?

Answer –The organization does not possess a standalone and dedicated Pharmacovigilance department.

2. How does regulatory affairs contribute to auditing processes regarding conformity with legal standards?

Answer –There is not a unique function attributed specifically to the regulatory department during audits pertaining to adherence with legislative norms. Instead, regulatory affairs collaborates with various departments across the organization to maintain compliance throughout all stages of drug development, production, and marketing. This collaboration ensures that regulatory requirements are met and potential risks are identified and addressed proactively. However, it should be noted that while regulatory affairs may not have a singular role during audits, their expertise remains crucial in maintaining overall compliance and managing risk associated with regulatory matters.

3. How are protocol deviations managed and addressed within a clinical research organization?

Answer –Protocol violations occurring within a clinical research organization are communicated to the study's sponsoring entity. These reports include detailed descriptions of the nature of the deviations, allowing the sponsors to assess the severity and implications of the departures and take appropriate actions accordingly.

4. Are there any ongoing Chrono pharmacology studies being conducted at your clinical research facility?
Answer –At present, the clinical research facility is not conducting any Chrono pharmacology studies.

5. How do you find volunteers for the clinical studies?
Answer – Raptim Research has a database of 35000+ Volunteers for clinical studies. They are informed about the whole process of the study involving about the advantages and risks of this.

6. How to make them patients compliant to the studies?
Answer – Dr. Milind shared an experience when they were studying on Ergocalciferol, (22 Days). They had a protocol that no patient should be exposed to sunlight and due to this they had to keep patients in a dark room with zero exposure to sunlight. To make patients feel comfortable and adhere to the protocol they used to arrange a bus and them once or twice for a night ride. Such efforts are really appreciated.

7. On a scale of 10, how difficult are biosimilars to study on?
Answer –They are indeed difficult to work on due to the acceptability criteria and much more of complexity, but maybe with technology it will be convenient to work on.

8. How do you manage to be so well prepared with the inspections?
Answer – From day 1 we have tried our best to keep all the studies well documented and they have been using technology so well that they go paperless they just need a laptop and they have all the documentations in a click. Dr. Milind also said he has witnessed all the unannounced inspections and they used to be calm as very thing was well documented.

CONCLUSION

During our visit, we acquired insights into the workflow of clinical research, diving into various intricate processes such as volunteer recruitment, housing, sampling, analysis, quality assurance, data management, and regulatory compliance.
Interacting with professionals from different departments provided us with a comprehensive understanding of their perspectives on clinical research. Transitioning from theoretical learning to practically experiencing operational dynamics of a CRO made our visit profoundly informative.

GALLERY


GPS Map Camera
Navi Mumbai, Maharashtra, India
268, Mahape Midc Rd, MIDC Industrial Area, Mahape, Navi Mumbai, Maharashtra 400701, India
Lat 19.114284°
Long 73.023129°
17/02/24 04:56 PM GMT +05:30
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