Report on

Industrial Visit to GLOGEN Clinical Research Pvt. Ltd., Hyderabad

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(Sponsored by Exhibition Society, Nampally)

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Participants:

M.Pharmacy I semesters Students from

Department of Quality Assurance

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3. Tahimeem begum
4. M.Sai vennela
5. G.Sowmya
6. Gambo Nikitha
7. Bhavani singh
8. K.Nikitha

Department of Pharmacology

1. Bathula Jayasri
2. Bommu Vaishnavi
3. Gade Indu Vimala Devi
4. Hajera Begum
5. Kukkali Sneha
6. Kummari Swathi
7. Mahadev Anitha
8. Nabila Kulsum
9. Nomula Pavani
10. Savanth Swetha
11. Syeda Sumaiya
12. Udutha Bharathi

Accompanied by Faculty Members:

Dr. Anuradha Bhai, Professor & HoD, department of Quality Assurance

Dr. K.R.V.S. Chaitanya, Associate professor, Dept. of Pharmacology

An industrial visit to GLOGEN Clinical Research Pvt. Ltd., Hyderabad, was organized for the students of Quality Assurance and Pharmacology specialization on the 25th of November 2024. The visit aimed to provide students with practical insights into the operations of a clinical research organization, emphasizing the application of theoretical knowledge to real-world scenarios.

INTRODUCTION

GLOGEN Clinical Research Pvt. Ltd. is a globally recognized Clinical Research Organization (CRO) committed to advancing healthcare through its robust clinical research capabilities. By integrating drug safety and regulatory advisory services, GLOGEN provides comprehensive support to its clients, ensuring their clinical initiatives achieve success. The organization's primary objective is to craft effective strategies and deliver impactful solutions, establishing itself as a reliable partner in the clinical research domain.

Dedicated to accelerating product launches through clinical development, GLOGEN combines scientific expertise with a client-centric approach. The company actively collaborates with clients to enhance healthcare management and bring innovative therapies to market.

Core Services

GLOGEN offers a broad range of services tailored to meet the diverse needs of the pharmaceutical and biotechnology sectors, including:

- Bioavailability/Bioequivalence (BA/BE) Studies
- Pharmacokinetic (PK) Bioanalysis
- Biostatistics and Data Management
- Comprehensive Clinical Trial Services

State-of-the-Art Facilities

GLOGEN is equipped with cutting-edge infrastructure designed to uphold the highest standards of clinical research:

- A 100-bed facility to accommodate large-scale clinical trials.
- A dedicated 5-bedded ICU for managing adverse events (AEs) with advanced life-support systems.
- A fully equipped on-site pharmacy with controlled access.
- Advanced AB-Sciex API 4000 LC MS/MS systems for high-precision bioanalytical studies.

- Automated temperature monitoring systems for freezers and refrigerators, ensuring sample integrity.
- Facilities for volunteer registration and screening, supporting smooth trial execution.
- A dedicated archival facility for secure storage of essential trial documentation.

THE VISIT:

The visit began with a warm and cordial welcome by Dr. Rambabu, setting a positive tone for the event. This was followed by an introductory session delivered by Mr. Sridhar Reddy, the Head of Clinical at GLOGEN Clinical Research Pvt. Ltd., who provided an insightful and comprehensive overview of the company's operations and contributions to the field of clinical research.

Session by Mr. Sridhar Reddy:

Mr. Sridhar Reddy's session was pivotal in educating the attendees on key aspects of clinical research, with a focus on GLOGEN's role in advancing medical science. He began by introducing **GLOGEN Clinical Research Pvt. Ltd.**, a company known for its state-of-the-art infrastructure and global contributions to clinical research. He emphasized the company's commitment to delivering high-quality research that aligns with international standards, offering a broad spectrum of clinical services for drug development and trials.

Key Topics Covered:

1. **Company Overview:**
    - Mr. Reddy highlighted GLOGEN's capabilities in clinical trials, underscoring its cutting-edge facilities that facilitate the execution of complex clinical research projects.
    - The company's contributions were showcased, detailing its impact on improving healthcare outcomes globally, from drug development to regulatory approval.
2. **Clinical Trials Protocols:**
    - He provided an extensive breakdown of the procedures involved in clinical trials, which are critical for evaluating the safety and efficacy of new drugs. He elaborated on the **different phases** of clinical trials, from preclinical to Phase I-IV trials, explaining their significance in gathering data for regulatory approval.
    - He also touched upon the importance of clinical trial design, recruitment strategies, and data collection methods in ensuring trial integrity.
3. **Regulatory Submissions:**

- Mr. Reddy gave a detailed explanation of regulatory submissions required for drug approval. He delved into the processes for **Abbreviated New Drug Application (ANDA)**, **New Drug Application (NDA)**, and **Investigational New Drug Application (INDA)**, outlining the procedural steps involved and their importance in the drug approval process.
- This segment emphasized the intricate regulatory landscape that clinical researchers must navigate to bring new treatments to market.

4. **Generic Drug Studies:**
    - The presentation highlighted the significance of **bioequivalence** and **therapeutic equivalence** in the development of generic drugs. Mr. Reddy discussed how these studies ensure that generic drugs are as effective and safe as their brand-name counterparts, making healthcare more accessible and affordable.
    - He also covered how generic drug studies play a critical role in reducing healthcare costs while maintaining high treatment standards.
5. **Clinical Approvals:**
    - Mr. Reddy concluded his session by explaining the regulatory and ethical requirements for clinical research, which are essential to ensure the safety of participants and the validity of research outcomes. He discussed the importance of adhering to **Good Clinical Practice (GCP)** guidelines and regulatory frameworks.

Session by Mr. Ramanuja Reddy:

After Mr. Sridhar Reddy's presentation, the session was handed over to **Mr. Ramanuja Reddy**, Head of QA and Bioanalytical at GLOGEN. He delivered a detailed lecture on **Quality Assurance (QA)** and **Bioanalysis**, covering critical aspects of maintaining high standards in clinical research.

Key Topics Covered:

1. **Role of Quality Assurance (QA):**
    - Mr. Ramanuja Reddy emphasized the importance of **Quality Assurance (QA)** in clinical research. He explained how QA ensures the accuracy, reliability, and integrity of research data and clinical outcomes, which are crucial for the credibility of clinical trials.

- He also outlined how QA processes help maintain compliance with industry standards and regulatory requirements, which ultimately ensures the safety and efficacy of new drugs.

2. **Extraction Methods:**
    - The session included a technical discussion on various **molecule extraction methods** used in clinical research, particularly in bioanalysis. These methods are essential for isolating and purifying specific compounds from biological samples, which is critical for analyzing the pharmacokinetics of drugs.
    - Mr. Ramanuja Reddy detailed several advanced techniques employed to ensure high extraction efficiency and purity, which are vital for obtaining accurate research results.
3. **Analytical Techniques:**
    - The discussion then moved to **analytical techniques** used in clinical research, with a focus on **LC-MS (Liquid Chromatography-Mass Spectrometry)** and **HPLC (High-Performance Liquid Chromatography)**. Both of these techniques are integral to bioanalysis and drug testing.
        - **LC-MS** is a powerful tool for identifying and quantifying molecules in complex samples, offering sensitivity and specificity.
        - **HPLC** was discussed as a widely used technique for separating, identifying, and quantifying compounds, particularly useful in pharmacokinetic studies to measure drug concentrations in biological matrices.
    - Mr. Reddy also discussed how these methods are employed to study the absorption, distribution, metabolism, and excretion (ADME) of drugs, which is essential for understanding their therapeutic potential.

The sessions provided attendees with valuable insights into the clinical research landscape, the processes behind drug approval, and the technical methods used in bioanalysis. The presentations highlighted the importance of rigorous standards and cutting-edge technologies in ensuring the safety and effectiveness of new treatments. GLOGEN's commitment to maintaining high-quality research standards was clearly evident throughout the discussions.

The site visit, a significant part of the industrial tour to GLOGEN Clinical Research Pvt. Ltd., provided students with hands-on exposure to the functioning and infrastructure of a clinical research organization. Guided by Mr. Sridhar Reddy and Mr. Ramanuja Reddy, the tour

covered various departments integral to clinical trials, Bio-analysis, and quality assurance. Below is a detailed breakdown of the areas visited:

1**. Clinical Operations Section**

This segment of the tour introduced students to the initial and crucial stages of clinical trials and volunteer management.

Registration Area:

The students observed the systematic process for volunteer registration, emphasizing compliance with ethical and regulatory guidelines. Key aspects included maintaining data confidentiality, ensuring informed consent, and verifying eligibility criteria for volunteers.

Screening of Volunteers:

Students learned about medical evaluations conducted to assess volunteer suitability for participation in clinical trials. Procedures such as physical examinations, laboratory tests, and medical history reviews were demonstrated.

Clinical Pharmacology Departments:

This section showcased how clinical pharmacology principles are applied to trial design and execution. The students observed setups for dose administration and monitoring.

Four-Bedded ICU:

A state-of-the-art ICU facility designed to manage emergencies during trials was introduced. Students were briefed on the equipment and protocols used to ensure volunteer safety, including continuous monitoring systems.

100-Bedded Wards:

Students visited the well-equipped wards where volunteers stay during trials. The wards were designed to provide a comfortable and controlled environment, crucial for generating reliable clinical data.

Recreation hall for Volunteers:

The students were shown the dining area where standardized meals are provided to volunteers, ensuring dietary control essential for clinical studies.

Sample Collection Room:

The students observed the procedures for collecting blood and other biological samples, including the importance of aseptic techniques and proper labelling.

Nursing Rooms:

The nursing staff demonstrated their role in assisting with sample collection, monitoring volunteers, and administering trial medications.

2. Bioanalytical Department

This phase of the tour emphasized the pivotal role of Bio-analysis in evaluating drug performance.

BA/BE Studies:

The bioanalytical team explained the significance of Bioavailability (BA) and Bioequivalence (BE) studies in drug development, particularly for generic drugs.

Advanced Analytical Instruments:

Students were introduced to cutting-edge instruments used in bioanalytical testing:

- LC-MS/MS (Liquid Chromatography-Mass Spectrometry): Demonstrated as a tool for quantifying drug concentration in biological samples with high accuracy and sensitivity.
- HPLC (High-Performance Liquid Chromatography): Highlighted for its role in separating, identifying, and quantifying components in a mixture.
- Storage Facilities:
- The group inspected specialized deep freezers maintaining temperatures of -70°C and -20°C, used to store biological samples under stable conditions.

Humidity Chambers:

The students were shown chambers used to study the stability of drugs under controlled temperature and humidity conditions.

Laminar Air Flow:

This section focused on maintaining sterile environments for handling samples to prevent contamination, a critical requirement in Bioanalysis.

Nitrogen Generator:

An explanation was provided about the use of nitrogen generators in creating inert environments for sample analysis and storage.

3. **Pharmacokinetics and Biostatistics Department**

Students explored the departments responsible for analysing and interpreting clinical trial data.

Pharmacokinetics:

This area focused on studying the absorption, distribution, metabolism, and excretion (ADME) of drugs. Students learned how pharmacokinetic data is critical for determining dosing regimens.

Biostatistics:

Experts demonstrated how statistical methods are applied to evaluate trial outcomes, ensuring accuracy and reliability in clinical findings.

4. Archives

The visit concluded with a tour of the Archives, where essential documents and data related to clinical trials are securely stored. Students were briefed on the importance of maintaining records for audits, regulatory submissions, and research continuity.

Interactive Insights during the Visit

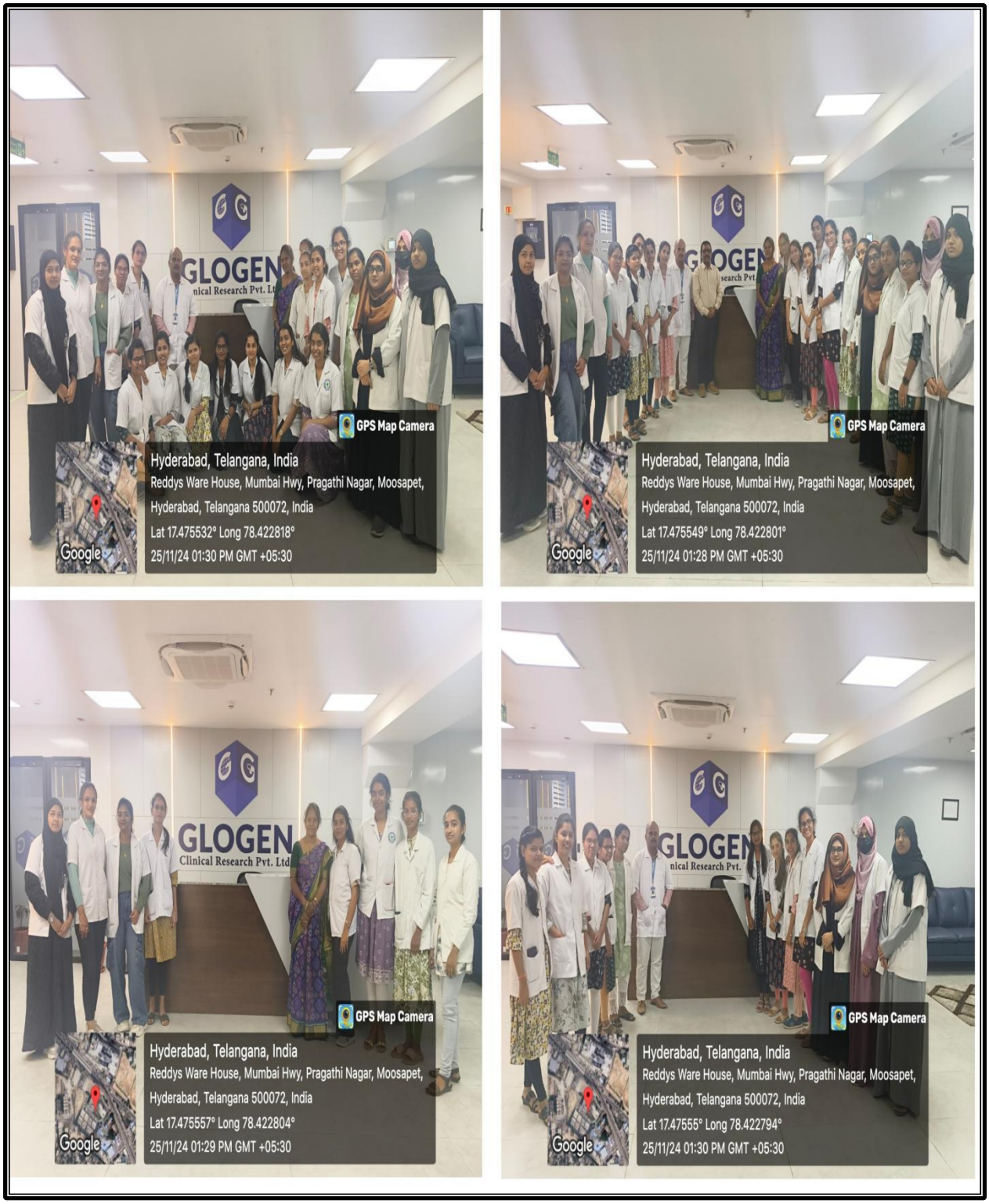
The faculty members, Dr. Anuradha Bhai and Dr. KRVS Chaitanya, expressed their gratitude to the hosts for their exceptional efforts in delivering a detailed, interactive, and insightful experience. They appreciated the meticulous planning and execution of the visit, which provided students with a comprehensive understanding of clinical research processes.

The industrial visit to GLOGEN Clinical Research Pvt. Ltd. proved to be an invaluable learning experience for the students. It bridged the gap between academic learning and practical application, providing exposure to cutting-edge technologies and methodologies in the field of clinical research.

The students returned with a greater appreciation of the role of clinical research in healthcare innovation, equipped with knowledge that will contribute significantly to their professional growth.

Throughout the site visit, students had the opportunity to engage in discussions with the staff. Queries about practical challenges, regulatory compliance, and technological advancements in clinical research were addressed, enriching their understanding of the field.

This immersive exposure to real-world clinical research operations significantly enhanced the students' academic knowledge and inspired them to explore new dimensions in Quality Assurance and Pharmacology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