SKILL DEVELOPMENT PROGRAM

Ribosome Research Centre

and

Shree Dhanvantary Pharmacy College, Kim

The **Skill Development Program (SDP)** on Industrial Training (Skill Development Module), is launched in 15th August 2022, was aimed at enhancing workforce employability by aligning skills with industry needs. The Program Director is Dr. C.D Shelat sir (Former Deputy Commissioner, FDCA Gujarat), Program Convener is Dr. M.N Noolvi (Principal of Shree Dhanvantary Pharmacy College, Kim) and Co-Ordinator is Dr. Dhara Vashi (Associate Professor, Head of the Department of Pharmaceutical Quality Assurance). These programs were part of various governmental efforts to bridge the skill gap, particularly in developing countries, and improve economic growth through a more skilled workforce. **Total 45 Students are enrolled in AY 2024-25**

Key Objectives:

1. **Bridging the Skill Gap**: The primary aim was to align the education system and workforce training with the practical needs of industries.
2. **Enhancing Employability**: By offering practical, hands-on training in industrial environments, the programs aimed to enhance job readiness among participants.
3. **Improving Productivity**: Increasing the overall productivity of industries through a workforce that is skilled, efficient, and capable of using modern technology.
4. **Youth Empowerment**: Focused on empowering the youth by providing them with relevant skills and training for employment in sectors like manufacturing, IT, healthcare, and services.
5. **Promoting Entrepreneurship**: Encouraging self-employment and entrepreneurial ventures by equipping participants with business and management skills.
6. **Fostering Innovation**: Encouraging creativity and innovation through exposure to modern tools and technologies.

Key Outcomes:

1. **Employment Generation**: The programs led to increased employment opportunities as individuals were trained in skills that were in demand in various sectors.
2. **Skill Enhancement**: Graduates of the programs gained practical skills and certifications, making them more competitive in the job market.

3. **Industry-Academia Collaboration**: Strengthened partnerships between educational institutions and industries, creating pathways for students to transition smoothly into the workforce.

4. **Increased Productivity**: Industries benefited from a workforce that was better trained and more productive, contributing to economic growth.

5. **Global Competitiveness**: The programs also focused on making the workforce globally competitive, especially in sectors such as IT, manufacturing, and services.

6. **Social Inclusion**: Efforts were made to ensure that marginalized groups, including women and rural populations, could participate and benefit from the programs

Committee Members

1. **Dr. C.D Shelat sir**
   Director, Skill Development Program
   Former deputy Commissioner FDCA Gujarat
2. **Dr. M.N.Noolvi**
   Convener, Skill Development Program
   Principal, Shree Dhanvantary Pharmacy College,Kim
3. **Dr. Dhara Vashi**
   Co-ordinator, Skill Development Program
   Associate Professor, Shree Dhanvantary Pharmacy College, Kim
4. **Mr. Abhinandan Sahi**
   Co- Coordinator, Skill Development Program
   Assistant Professor, Shree Dhanvantary Pharmacy College, Kim

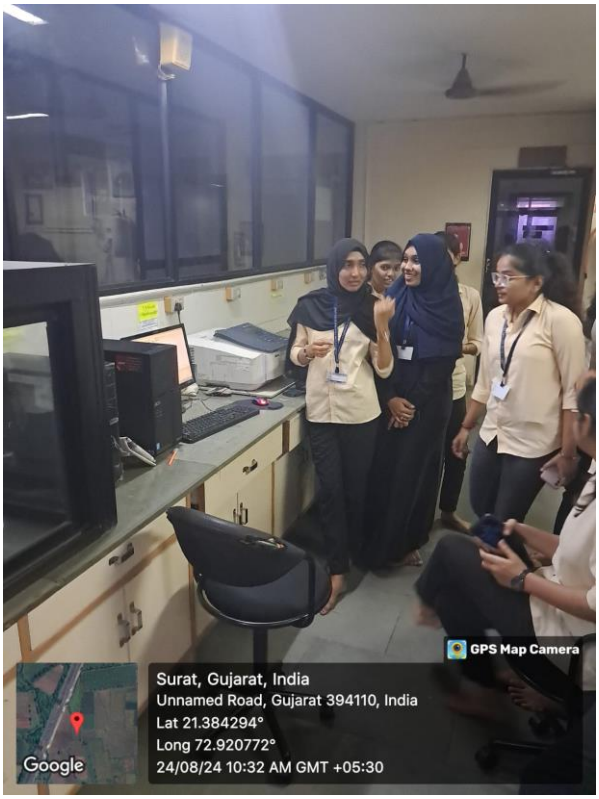
SKILL DEVELOPMENT PROGRAM

Ribosome Research Centre

and

Shree Dhanvantary Pharmacy College, Kim

Hands on Training on Sophisticated Instruments



SKILL DEVELOPMENT PROGRAM

Ribosome Research Centre

and

Shree Dhanvantary Pharmacy College, Kim

Guest Lectures

1. Name of Speaker: Mr. Anand Pande, DGM Quality Control, Zydus Life Science

Topic: Good Laboratory Practice (GLP) & Schedule L-1

Date: 20/09/2024

Time: 11.00 am to 1.00 pm

Participated Students: 32

Introduction

Good Laboratory Practice (GLP) and Schedule L-1 play crucial roles in maintaining high-quality standards in the pharmaceutical and chemical industries. These guidelines ensure that the research and manufacturing processes are safe, reliable, and compliant with regulatory norms. This report provides an overview of both GLP and Schedule L-1, their importance, and their impact on laboratory practices.

Objective

The objective of the seminar was to discuss the principles of Good Laboratory Practice (GLP) and the specific requirements of Schedule L-1 under the Drugs and Cosmetics Act, focusing on how these standards contribute to ensuring accuracy, consistency, and compliance in laboratory environments.

Good Laboratory Practice (GLP)

GLP is a set of principles intended to assure the quality, integrity, and reliability of non-clinical laboratory studies, especially those related to the safety testing of chemicals and pharmaceuticals. GLP standards are globally recognized and enforced by regulatory authorities like the U.S. Food and Drug Administration (FDA) and the Organisation for Economic Co-operation and Development (OECD).

Key Principles of GLP:

1. **Organization and Personnel**: GLP emphasizes clear organizational structures, defined roles, and responsibilities for personnel to ensure the proper conduct of laboratory studies.
2. **Facilities**: Laboratories must have appropriate infrastructure, equipment, and controlled environmental conditions.
3. **Equipment**: All equipment must be regularly calibrated, validated, and maintained to ensure accuracy.
4. **Standard Operating Procedures (SOPs)**: Laboratories should maintain SOPs for all processes and ensure that personnel are well-trained in following them.

5. **Study Planning and Documentation**: Every study must be well-documented, from the study plan to the final report, to maintain transparency and traceability.
6. **Quality Assurance**: Independent quality assurance units should monitor study activities and report deviations.

Importance of GLP:

- Ensures the integrity and reliability of data.
- Facilitates international acceptance of test results.
- Promotes ethical laboratory practices.
- Minimizes errors, fraud, and duplication of efforts.

Schedule L-1

Schedule L-1 is part of the Drugs and Cosmetics Rules, 1945, under the Drugs and Cosmetics Act, 1940, specifically focused on pharmaceutical laboratories. It provides detailed guidelines for the construction, maintenance, and operations of pharmaceutical laboratories, ensuring compliance with Good Manufacturing Practices (GMP).

Key Requirements of Schedule L-1:

1. **Personnel**: Laboratories must employ qualified and experienced staff to conduct testing and maintain quality standards.
2. **Infrastructure**: The laboratory layout must prevent contamination and cross-contamination, with separate areas for different activities like microbiological testing, chemical analysis, and sterility testing.
3. **Equipment**: Laboratories should have adequate, validated equipment to ensure the accuracy of results.
4. **Documentation**: Laboratories must maintain records for all tests performed, including raw data, test results, and reports, for a specified period.
5. **Environment**: The environment must be controlled to avoid any interference with test results (e.g., temperature, humidity, cleanliness).

Significance of Schedule L-1:

- Ensures compliance with GMP and GLP requirements.
- Helps in maintaining the safety and efficacy of pharmaceutical products.
- Enhances the quality of laboratory practices in the pharmaceutical industry.

Conclusion

Both GLP and Schedule L-1 are fundamental in promoting best practices in laboratory environments. The seminar highlighted the importance of adhering to these standards for ensuring product safety, maintaining high-quality research, and ensuring regulatory compliance. By implementing GLP and Schedule L-1 guidelines, laboratories can improve operational efficiency and the reliability of their outcomes, which is essential for safeguarding public health and ensuring international acceptance of their products.

Recommendations:

- Continuous training for laboratory staff on GLP and Schedule L-1 requirements.
- Regular internal audits to ensure compliance with standards.
- Upgradation of laboratory facilities and equipment to meet evolving regulatory expectations.

2. **Name of Speaker:** Ms. Richa Patel, Former QA Manager, Alphard Pharma, Surat

Topic: Overview of Pharmaceutical Industry

Date: 12/09/2024

Time: 11.00 am to 1.00 pm

Participated Students: 34

SKILL DEVELOPMENT PROGRAM

Ribosome Research Centre

and

Shree Dhanvantary Pharmacy College, Kim

Introduction:

The pharmaceutical industry is one of the most complex and highly regulated sectors globally, focused on discovering, developing, manufacturing, and distributing drugs to improve patient health. To efficiently execute these functions, the industry is divided into various specialized departments, each contributing to different stages of the drug

lifecycle. Below is an overview of the key departments in the pharmaceutical industry and their respective functions.

---

1. Research and Development (R&D)

The R&D department is the backbone of the pharmaceutical industry, responsible for discovering new drugs and therapies. It is typically divided into:

- **Drug Discovery**: This team identifies new chemical entities or biologic compounds that may have therapeutic potential. Drug discovery often begins with the identification of biological targets (e.g., proteins, genes) associated with specific diseases.
- **Preclinical Development**: Once promising compounds are identified, preclinical testing in laboratories and animal models assesses safety, toxicity, and biological activity.
- **Clinical Research**: The clinical research team conducts human trials to evaluate the safety and efficacy of a drug. These trials are performed in four phases:
    - **Phase I**: Tests drug safety and dosage on a small group of healthy volunteers.
    - **Phase II**: Examines efficacy and side effects in a larger patient population.
    - **Phase III**: Confirms efficacy, monitors adverse effects, and compares the new drug to standard treatments in larger populations.
    - **Phase IV**: Post-marketing studies to gather additional information on long-term effects and safety.

Function:

The primary goal of the R&D department is to bring innovative and effective drugs to the market through a rigorous process of discovery, testing, and clinical validation.

---

2. Regulatory Affairs

The Regulatory Affairs department ensures that all pharmaceutical products comply with local and international regulatory requirements. Each country has its own regulatory body, such as the **FDA** in the U.S. or the **EMA** in the EU, which sets guidelines for drug development, testing, and marketing.

Function:

- **Regulatory Submissions**: This team prepares and submits investigational new drug (IND) applications, new drug applications (NDA), and marketing authorization applications (MAA) to regulatory authorities.
- **Compliance Management**: They ensure that clinical trials, production processes, and marketing strategies comply with regulatory standards.
- **Post-Approval Monitoring**: After a drug is approved, the regulatory team manages ongoing compliance and any necessary reporting of adverse effects or safety concerns.

---

3. Manufacturing and Production

The Manufacturing department is responsible for producing pharmaceutical products at scale. This department ensures that drugs are made consistently and meet required quality standards.

Function:

- **Process Development**: Works with R&D to scale up drug production from laboratory to industrial levels.
- **Active Pharmaceutical Ingredient (API) Production**: This team produces the active ingredients used in the drugs.
- **Formulation**: Involves combining the API with other materials to create a final dosage form, such as tablets, capsules, or injections.
- **Packaging and Labeling**: The final product is packaged and labeled according to regulatory guidelines.

4. Quality Control (QC) and Quality Assurance (QA)

These two departments work closely together to ensure that every drug produced meets the highest quality standards and regulatory requirements.

Function:

- **Quality Control (QC)**: Focuses on testing raw materials, in-process products, and final products to ensure they meet safety, potency, and purity standards.
- **Quality Assurance (QA)**: Oversees the implementation of **Good Manufacturing Practices (GMP)**, ensuring that all processes, from production to distribution, are compliant with regulatory and quality standards.

---

5. Supply Chain and Logistics

The Supply Chain department manages the procurement of raw materials, production planning, inventory management, and distribution of the final products.

Function:

- **Procurement**: Ensures the timely and cost-effective sourcing of raw materials and APIs from suppliers.
- **Inventory Management**: Balances supply and demand to avoid shortages or overproduction.
- **Logistics and Distribution**: Coordinates the transportation of finished products to wholesalers, pharmacies, hospitals, and other healthcare providers.

---

6. Sales and Marketing

The Sales and Marketing department is responsible for promoting pharmaceutical products to healthcare professionals and consumers. This department works closely with

Medical Affairs and Regulatory Affairs to ensure that marketing efforts align with legal and ethical standards.

Function:

- **Market Analysis**: Identifies potential markets and customer segments for new drugs.
- **Sales Team**: Provides healthcare professionals with information about new drugs, focusing on their efficacy, safety, and benefits.
- **Promotional Campaigns**: Includes advertising, educational seminars, and digital marketing to raise awareness about new treatments.
- **Post-Market Support**: Collects feedback from healthcare professionals and patients to improve product performance and identify potential safety issues.

---

7. Pharmacovigilance (Drug Safety)

Pharmacovigilance ensures the safety of pharmaceutical products after they are on the market. This department monitors drugs for adverse effects and safety concerns throughout their lifecycle.

Function:

- **Adverse Event Reporting**: Collects and analyzes reports of any adverse reactions from patients, healthcare professionals, or clinical trials.
- **Risk Management**: Develops strategies to mitigate identified risks, such as adjusting dosages or issuing safety warnings.
- **Safety Updates**: Provides periodic safety updates to regulatory authorities, ensuring continued compliance and public safety.

---

8. Legal and Intellectual Property (IP)

The Legal and IP department is responsible for protecting the company's patents, trademarks, and other intellectual property. It also manages legal compliance across all departments.

Function:

- **Patent Filing and Protection**: Secures intellectual property rights for new drugs and formulations, preventing competitors from copying innovations.
- **Contract Management**: Drafts and reviews contracts with suppliers, distributors, and other stakeholders.
- **Litigation Management**: Handles legal disputes, including patent infringement claims and regulatory violations.

Conclusion

The pharmaceutical industry is a complex ecosystem, with each department playing a critical role in ensuring the development, production, and distribution of safe and effective drugs. From the initial stages of drug discovery in R&D to post-market safety monitoring in Pharmacovigilance, these departments must work collaboratively to navigate the challenges of stringent regulations, high production standards, and global health needs. The industry's multi-departmental approach ensures the delivery of life-saving medicines while maintaining the highest standards of safety and compliance.

3. Name of Speaker: Dr. Pratyush Somani

Manager QA/RA, Purple Microport Cardiovascular Pvt. Ltd. Sachin, Surat

Topic: Good Documentation Practice

Date: 27/09/2024

Time: 11.00 am to 1.00 pm

Participated Students: 33

SKILL DEVELOPMENT PROGRAM

Ribosome Research Centre

and

Shree Dhanvantary Pharmacy College, Kim

Introduction

Good Documentation Practice (GDP) is an essential element of regulatory compliance in industries such as pharmaceuticals, biotechnology, and healthcare. It ensures that documents are created, managed, and maintained in a way that ensures data integrity,

accuracy, and traceability. This seminar discussed the key principles of GDP, its importance in maintaining regulatory compliance, and its role in quality assurance.

Objective

The objective of the seminar was to provide an understanding of the principles of Good Documentation Practice, its relevance in maintaining data integrity, and how it supports compliance with regulatory frameworks such as Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP).

What is Good Documentation Practice (GDP)?

GDP refers to standardized practices required to ensure documents, whether paper-based or electronic, are consistently created and maintained to provide evidence of activities performed. These practices guarantee that documents are accurate, complete, and reliable, ensuring that they meet regulatory requirements for audit trails and quality control.

Key Principles of GDP:

1. **ALCOA Principle**:
    - **Attributable**: All entries in documents must be traceable to the individual who created or modified the record.
    - **Legible**: Documentation must be clear and easy to read, both at the time of creation and during its retention period.
    - **Contemporaneous**: Data should be recorded at the time the activity is performed.
    - **Original**: The document or record should be the first capture of the information or a verified copy.
    - **Accurate**: Documentation must reflect the truth of the action taken, with corrections made following defined procedures.
2. **Complete**: Documentation should be thorough and contain all necessary details, ensuring that no critical information is omitted.

3. **Consistent**: Documentation should be done in a uniform format, following standard operating procedures (SOPs) and ensuring consistency throughout the organization.
4. **Enduring**: Documents must be maintained in a way that ensures their long-term retention and accessibility.
5. **Available**: Documents should be easily accessible when required for review, inspection, or audit.

Importance of Good Documentation Practice

- **Regulatory Compliance**: GDP is required to meet regulatory standards set by bodies such as the U.S. FDA, European Medicines Agency (EMA), and the World Health Organization (WHO).
- **Data Integrity**: Ensures the accuracy, reliability, and completeness of data, which is crucial for regulatory audits and inspections.
- **Traceability**: GDP ensures that all actions are traceable, providing a clear audit trail for quality assurance and regulatory review.
- **Risk Management**: Poor documentation can lead to errors, product recalls, or non-compliance penalties. GDP helps mitigate these risks by ensuring proper data handling.
- **Quality Control**: Documentation is key to maintaining high-quality standards in processes, testing, and manufacturing, ensuring that any issues are identified and rectified promptly.

Best Practices for Implementing GDP

1. **Training and Awareness**: Regular training sessions for all personnel involved in documentation processes to ensure awareness of GDP requirements.
2. **Standard Operating Procedures (SOPs)**: Well-documented and standardized procedures should be established for creating, revising, and archiving documents.
3. **Document Control System**: Implementation of a robust document control system to manage document creation, approval, revision, and retrieval.

4. **Error Handling**: Proper methods for correcting errors (e.g., using single-line cross-outs, adding initials and dates) to ensure transparency.
5. **Record Retention and Security**: Secure and organized storage of records, ensuring that they are protected from loss, damage, or unauthorized access.

Conclusion

The seminar emphasized that Good Documentation Practice is an integral part of regulatory compliance and quality assurance in industries dealing with sensitive data and products. By adhering to the principles of GDP, organizations can ensure data integrity, reduce the risk of errors, and enhance regulatory compliance. The implementation of a strong GDP framework not only ensures product quality but also boosts the credibility and reputation of an organization.

Recommendations:

- Continuous GDP training for all relevant staff.
- Regular audits of documentation practices to identify and rectify gaps.
- Use of electronic documentation systems to streamline processes and enhance data accuracy.

SKILL DEVELOPMENT PROGRAM

Ribosome Research Centre

and

Shree Dhanvantary Pharmacy College, Kim

Industrial Visit

Name of Company: Believe International Ltd

Address: Block No. 497, At, Tal, Mahuvej, Mangrol, Gujarat 394125

Date: 10/09/2024

Time: 9.30 am to 3.00 pm

Participated Year: 4th Year B.Pharm

Participated Students: 43

SKILL DEVELOPMENT PROGRAM

Ribosome Research Centre

and

Shree Dhanvantary Pharmacy College, Kim

Name of Company: Ribosome research Centre

Address: Sr No.261/1, Block No. 271, near Shri Dhanvantary Pharmacy College, Kim, Gujarat 394110

Date: 11/09/2024

Time: 9.30 am to 3.00 pm

Participated Year: 4th Year B.Pharm

Participated Students: 37