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 72 Students are enrolled in AY 2023-24**

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

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Inaugural function of Skill Development program

દિવ્ય ભાસ્કર બારડોલી-વ્યારા ભાસ્કર 13-10-2023

કીમની ધન્વંતરિ કોલેજમાં સ્કિલ ડેવલોપમેન્ટ સેન્ટર ખુલ્લું મૂક્યું

બારડોલી। સુરતના કીમ ખાતે આવેલી ધન્વંતરિ ફાર્મસી કોલેજ ખાતે સ્કીલ ડેવલોપમેન્ટ સેન્ટરનો લોકાર્પણ કાર્યક્રમ યોજાયો હતો. સાઉથ ઝોનના વિદ્યાર્થીઓ,ફાર્મસીસ તેમજ ઈન્ડસ્ટ્રીઝ માટે સ્કીલ ડેવલોપમેન્ટ સેન્ટર બનશે આશીર્વાદરૂપ. સમગ્ર સુરતમાં સૌ પ્રથમ પહેલું સ્કીલ ડેવલોપમેન્ટ સેન્ટર ધન્વંતરિ ફાર્મસી કોલેજમાં કાર્યરત છે. ત્યારે તેનું લોકાર્પણ ફાર્મસી કાઉન્સિલ ઓફ ઈન્ડિયાના પ્રમુખ ડો મોન્ટુ પટેલના હસ્તે કરવામાં આવ્યું હતું. સમગ્ર સુરતમાં ટેસ્ટિંગ સુવિધામાં એક માત્ર ધન્વંતરિ ફાર્મસી કોલેજ પહેલી છે, જ્યાં MSME પ્લાન્ટ,JBI પ્લાન્ટ,નવી શરૂઆત થવા જઈ રહેલી મેડિકલ ડીવાઈસ ઈન્ડસ્ટ્રીઝ તમામને ધન્વંતરિ ફાર્મસી કોલેજ દ્વારા લાભ મળશે સાથે જ લોકોને સસ્તા ભાવે અને સારી રીતે ટેસ્ટિંગ ની સુવિધાનો લાભ પણ મળશે.

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Guest Lectures

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

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

Date:02/09/2023

Time: 11.00 am to 1.00 pm

Participated Students: 62

Introduction

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This report outlines the key aspects of Good Laboratory Practice (GLP) and Schedule L-1, which are essential for maintaining the quality, integrity, and reliability of laboratory data in the context of pharmaceutical and chemical industries. These guidelines ensure that laboratories conduct experiments, studies, and tests in a systematic and controlled manner to generate accurate and reproducible results.

Good Laboratory Practice (GLP)

Definition

GLP is a set of quality assurance principles and guidelines for the conduct of non-clinical safety studies on pharmaceuticals, chemicals, and other products that have the potential to impact human health and the environment. GLP ensures the reliability, integrity, and consistency of laboratory data generated for regulatory submissions.

Key Principles

1. **Quality System Management**: Establishing and maintaining a comprehensive quality system that covers all aspects of laboratory operations.
2. **Personnel Training**: Ensuring that all laboratory personnel are adequately trained and competent to perform their assigned tasks.
3. **Standard Operating Procedures (SOPs)**: Developing and implementing written procedures for all laboratory activities, ensuring consistency and repeatability.
4. **Facilities and Equipment**: Maintaining suitable laboratory facilities and equipment to support the conduct of studies.

5. **Study Documentation**: Accurate and complete documentation of all study-related activities, observations, and results.
6. **Sample Handling**: Proper handling, storage, and disposal of test substances and samples.
7. **Quality Control**: Regularly conducting quality control checks to monitor the integrity of the data generated.
8. **Archiving**: Proper archiving of study-related records and data for future reference and regulatory inspections.

Benefits of GLP

- Ensures the safety and efficacy of pharmaceuticals and chemicals.
- Enhances data reliability and credibility.
- Facilitates regulatory compliance and market access.
- Reduces the risk of product recalls and regulatory sanctions.

Schedule L-1

Definition

Schedule L-1 is a part of the Drugs and Cosmetics Rules in India, which lays down the requirements for the licensing of manufacturing and sale of drugs and cosmetics. It encompasses various aspects related to the manufacture, testing, and distribution of pharmaceutical products.

Key Provisions

1. **Premises and Equipment**: Specifies requirements for the design, construction, and maintenance of manufacturing and testing facilities. It also outlines guidelines for equipment validation.
2. **Personnel**: Defines the qualifications and responsibilities of personnel involved in manufacturing and quality control activities.
3. **Quality Control**: Describes the procedures for sampling, testing, and release of raw materials, intermediates, and finished products.
4. **Documentation**: Emphasizes the importance of accurate and comprehensive record-keeping, including batch records, analytical data, and stability studies.

5. **Labeling and Packaging**: Specifies requirements for labeling, packaging, and storage of pharmaceutical products.
6. **Complaints and Recalls**: Addresses procedures for handling complaints and recalls of pharmaceutical products.
7. **Batch Release**: Outlines the responsibilities and requirements for batch release by the authorized person.

Significance of Schedule L-1

- Ensures the quality, safety, and efficacy of pharmaceutical products in the Indian market.
- Establishes a regulatory framework for drug manufacturing and distribution.
- Facilitates compliance with international quality standards, promoting export opportunities for Indian pharmaceutical companies.

Conclusion

In conclusion, Good Laboratory Practice (GLP) and Schedule L-1 are crucial components of quality assurance and regulatory compliance in the pharmaceutical and chemical industries. GLP sets the standards for laboratory conduct, data integrity, and documentation, while Schedule L-1 governs the manufacturing and distribution of pharmaceutical products in India. Adherence to these guidelines is essential to ensure the safety and efficacy of products and to meet regulatory requirements.

2. Name of Speaker: Mr. Parth Kava, CEO, Medlera Healthcare,Surat

Topic: Futuristic Scope of Biotechnology

Date: 22/09/2023

Time: 11.00 am to 1.00 pm

Participated Students: 67

Introduction:

Biotechnology is the application of biological systems, organisms, or derivatives to develop or create products or processes that improve our lives. It leverages the understanding of genetics, molecular biology, and cellular processes to manipulate living organisms or biological systems for practical purposes.

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Futuristic Scope of Biotechnology

1. Precision Medicine

Precision medicine is a paradigm shift in healthcare. It involves tailoring medical treatments to an individual's genetic makeup, allowing for personalized therapies. Key components of this futuristic application include:

- **Genomic Medicine**: Analyzing an individual's entire genome to predict disease susceptibility and customize treatments.
- **Targeted Therapies**: Developing drugs that specifically target the genetic mutations driving diseases, leading to more effective treatments with fewer side effects.

2. Gene Editing and CRISPR-Cas9

Gene editing technologies, especially **CRISPR-Cas9**, have opened doors to manipulate genes with unprecedented precision. This has profound implications:

- **Curing Genetic Diseases**: Potential to cure genetic disorders like sickle cell anemia and cystic fibrosis at the genetic level.
- **Enhancing Agriculture**: Improving crop yields and making plants more resistant to pests and diseases.
- **Ethical Considerations**: Ethical debates regarding the use of gene editing in humans, including germline editing.

3. Synthetic Biology

Synthetic biology is an interdisciplinary field that combines biology, engineering, and computer science to design and construct new biological parts, devices, and systems. The futuristic applications are vast:

- **Biofuel Production**: Engineering microorganisms to produce sustainable biofuels, reducing reliance on fossil fuels.
- **Bio-Computing**: Creating biological computers for data storage and processing.
- **Biological Sensors**: Developing biological sensors for environmental monitoring and disease detection.

4. Regenerative Medicine

Regenerative medicine holds the promise of replacing or regenerating damaged tissues and organs:

- **Stem Cell Therapy**: Using stem cells to repair damaged tissues and treat conditions such as spinal cord injuries and heart disease.
- **3D Bioprinting**: Printing functional organs, like kidneys or hearts, using a patient's own cells, reducing the need for organ transplantation.

5. Bioinformatics and Big Data

The integration of biotechnology with **bioinformatics** and **big data** analytics is transforming research and healthcare:

- **Drug Discovery**: Accelerating drug discovery by analyzing massive datasets of molecular interactions and drug responses.
- **Personalized Medicine**: Leveraging patient data for tailored treatment plans and early disease detection.

6. Environmental Biotechnology

Biotechnology can contribute significantly to solving environmental challenges:

- **Bioremediation**: Using microorganisms to clean up pollutants in soil and water.
- **Biofuels and Green Chemistry**: Developing environmentally friendly alternatives to traditional industrial processes.

7. Nanobiotechnology

Nanobiotechnology involves the integration of nanotechnology and biotechnology for novel applications:

- **Drug Delivery**: Precise drug delivery systems using nanoparticles to target specific cells or tissues.
- **Diagnostic Tools**: Highly sensitive nanosensors for early disease detection.

Conclusion

In conclusion, the futuristic scope of biotechnology is awe-inspiring. It promises to reshape healthcare, agriculture, industry, and the environment. However, as with any powerful technology, ethical and regulatory considerations must accompany these advancements. The collaboration of scientists, policymakers, and society is vital to ensure that biotechnology continues to be a force for positive change, addressing global challenges while respecting ethical boundaries. The future of biotechnology is bright, and it holds the potential to address some of humanity's most pressing issues.

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

Topic: Overview of Pharmaceutical Industry

Date: 16/09/2023

Time: 11.00 am to 1.00 pm

Participated Students: 64

Description:

1. Research and Development (R&D)

The Research and Development department is the heart of any pharmaceutical company. Its responsibilities include:

- Drug Discovery: Identifying potential drug candidates through extensive research, often targeting specific diseases or conditions.
- Preclinical Testing: Conducting rigorous testing in laboratories and animal models to assess safety and effectiveness.
- Clinical Trials: Overseeing the progression of drugs through phases of human clinical trials to evaluate safety, dosages, and efficacy.
- Regulatory Affairs: Preparing and submitting applications for regulatory approvals.

2. Manufacturing

The Manufacturing department ensures the efficient and consistent production of pharmaceuticals:

- Drug Formulation: Developing the processes to create the final drug product, including determining the appropriate dosage form (tablets, capsules, injections, etc.).
- Quality Control: Monitoring the quality of raw materials and finished products through rigorous testing to meet regulatory standards.
- Scale-up Production: Transitioning from laboratory-scale production to large-scale manufacturing.

3. Regulatory Affairs

Regulatory Affairs plays a crucial role in ensuring that pharmaceutical products meet legal and regulatory requirements:

- Regulatory Submissions: Preparing and submitting applications for drug approvals to regulatory agencies like the FDA (U.S.) or EMA (Europe).
- Compliance: Ensuring that the company adheres to all applicable regulations, including labeling and advertising.

4. Marketing and Sales

The Marketing and Sales department focuses on promoting and distributing pharmaceutical products:

- Market Research: Analyzing market trends, competition, and customer needs.
- Advertising and Promotion: Developing marketing campaigns and promotional strategies.
- Sales: Managing relationships with healthcare providers, pharmacies, and distributors.

5. Medical Affairs

Medical Affairs is responsible for providing medical and scientific expertise:

- Medical Information: Responding to inquiries from healthcare professionals and patients about the company's products.
- Clinical Trials: Designing and managing post-marketing clinical trials to gather additional data on product safety and efficacy.
- Key Opinion Leader Engagement: Collaborating with healthcare experts to ensure the company's products are used effectively.

6. Quality Assurance and Compliance

Quality Assurance and Compliance oversee the company's adherence to quality standards and regulatory requirements:

- Quality Assurance: Implementing quality control measures, conducting audits, and ensuring that manufacturing processes meet quality standards.
- Compliance: Ensuring that the company follows all relevant regulations and guidelines.

7. Supply Chain and Logistics

Supply Chain and Logistics manage the flow of materials, information, and products:

- Procurement: Sourcing raw materials and components required for manufacturing.
- Distribution: Managing the distribution network to ensure timely delivery to customers and markets.

8. Finance and Administration

The Finance and Administration department is responsible for the financial health of the company:

- Budgeting: Managing budgets and financial planning for R&D, manufacturing, and other operations.
- Administration: Handling administrative functions, including human resources and legal affairs.

9. IT and Technology

Information Technology and Technology departments play a critical role in data management, cybersecurity, and digital transformation:

- Data Management: Handling vast amounts of data generated during research, clinical trials, and operations.
- Cybersecurity: Protecting sensitive information from cyber threats.
- Digital Transformation: Leveraging technology for process optimization and innovation.

Conclusion

In conclusion, the pharmaceutical industry relies on a multitude of departments, each with its specific responsibilities. Collaboration between these departments is essential to bring life-saving medications to patients while adhering to stringent regulatory requirements. Understanding the inner workings of the pharmaceutical industry provides valuable insights into how it contributes to global healthcare and innovation.

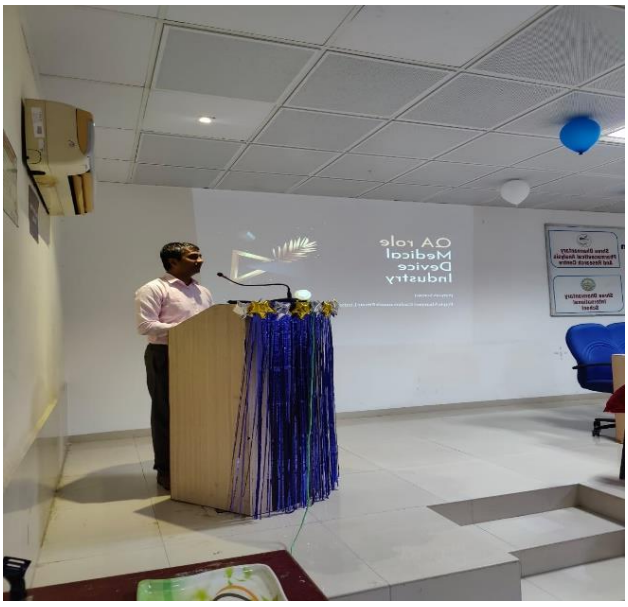
4. **Name of Speaker:** Dr. Pratyush Somani, Manager QA/RA, Purple Microport Cardiovascular Pvt. Ltd. Sachin, Surat

Topic: Quality Assurance in medical device Industry

Date: 19/08/2023

Time: 11.00 am to 1.00 pm

Participated Students: 63



Description:

The lecture commenced with a comprehensive overview of Quality Assurance in the medical device industry. The lecturer emphasized that QA is not merely a process, but a commitment to ensuring patient safety, product reliability, and adherence to regulations.

Quality Assurance Components:

The lecture delved into the core components of QA, highlighting design control, risk management, regulatory compliance, supplier management, process validation, and post-market surveillance. Each component was explained with real-world examples to illustrate its significance.

Regulatory Landscape:

The guest lecturer provided an in-depth analysis of the complex regulatory landscape governing the medical device industry. They emphasized the importance of staying updated with regional and international regulations, such as FDA guidelines in the United States and EU MDR in Europe.

Balancing Innovation and Safety:

A crucial theme of the lecture was striking the balance between innovation and safety. The lecturer elaborated on the challenges of introducing new features while maintaining the utmost safety and effectiveness of medical devices.

Challenges in Quality Assurance:

The lecture addressed challenges that QA professionals encounter, including evolving regulatory requirements, rapid technological advancements, globalization of supply chains, and the intricate task of managing risk.

Post-Market Surveillance:

The guest lecturer stressed the importance of post-market surveillance in QA. They discussed how continuous monitoring and data gathering after a device is on the market help identify potential issues and enable prompt interventions.

Discussion and Q&A:

Following the lecture, an engaging discussion and question-and-answer session allowed attendees to delve deeper into specific aspects of QA in the medical device industry. Attendees

sought clarification on topics such as risk assessment methodologies, the impact of globalization on QA processes, and strategies for managing regulatory changes.

Conclusion:

The guest lecture on "Quality Assurance Role in the Medical Device Industry" offered a profound insight into the critical role QA plays in ensuring the quality, safety, and compliance of medical devices. Attendees gained a comprehensive understanding of the multifaceted nature of QA and its significance in advancing healthcare technology while safeguarding patient well-being.

This report serves as a testimony to the knowledge shared during the lecture and provides a glimpse into the evolving landscape of Quality Assurance within the medical device industry. It is our hope that this lecture will continue to inspire a commitment to excellence and innovation while upholding the highest standards of patient care.

Industrial Visit

Name of Company: Alphard Pharma

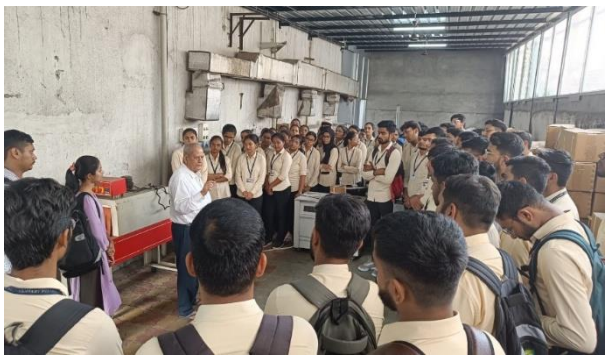
Address: Plot No. C-1/433, Ankleshwar GIDC, Ankleshwar, Gujarat 393001

Date: 06/10/2023

Time: 9.30 am to 3.00 pm

Participated Year: 4th Year B.Pharm

Participated Students: 72



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Name of Company: Ribosome research Centre

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

Date: 26/08/2023

Time: 9.30 am to 3.00 pm

Participated Year: 4th Year B.Pharm

Participated Students: 63

Name of Company: Zydus life science Ltd.

Address: Ankleshwar GIDC, Ankleshwar, Gujarat 393001

Date: 21/10/2023

Time: 9.30 am to 3.00 pm

Participated Year: 4th Year B.Pharm

Participated Students: 68

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