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Good Lab Practices for Developing Countries -- CDL Experience

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GOOD LAB PRACTICES FOR DEVELOPING COUNTRIES -- CDL EXPERIENCE

by

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INTRODUCTION OF CDL

CDL (Chaudhry Dairies Limited) was incorporated in 1984 as public limited company and commercial production started in 1986. Its plant is situated at 62 KM Multan Road, near Bhai Pheru, and Head Office is located at 135 Ferozepur Road Lahore. The Company also operates as a franchise of Candia Cedilac of France.

CDL is the first Food Company and so far the only Dairy Company in Pakistan to get ISO 9002 Certification in 1997. Due to diversification into non-dairy food products, the name of the company was changed from Chaudhry Dairies Limited to CDL Foods Limited to clearly define the scope of the company.

Management of CDL is always moving towards development of Quality Systems within the Organization and also has a vision beyond ISO Certification. Keeping in view this concept, CDL has also started work towards Food Safety System and Good Laboratory Practices Systems. This paper is focusing only to the implementation of Good Laboratory Practices in CDL.

INTRODUCTION OF GLP (GOOD LABORATORY PRACTICES)

GLP are defined as “Rules, Operating procedures and practices implemented to attain the minimum requirement for quality and integrity of the work and data generated by laboratory” GLP standards specify the general requirements for the competence to carry out tests and/or calibrate the lab equipments, and it covers all aspects of lab from layout of lab to waste disposal of lab. In general GLP means applying “common sense with artistic touch to laboratory”.

WHY CDL NEEDED GLP

CDL needed GLP to develop precision and accuracy in analytical work to generate high quality and reliable data of tests related to safety and quality of products to generate technically valid results, to develops trust of other department in analytical results generated by labs and also to develop confidence in lab’s staff.
ELEMENTS OF GLP

Following are the elements of GLP:

1. **LAB LAYOUT** – The purpose of this element is to ensure that any change in the laboratory layout will not effect the GLP rules and accuracy in lab’s analytical results.
2. **ORGANIZATION OF STAFF** – This element defines the authority of analysis to ensure that only trained and competent lab staff can perform the critical jobs.
3. **TRAINING** – This element identifies not only on-job training needs but also make arrangements for induction as well as training of new comers, and after completion of training, ensures that whether the candidate is suitable to perform job independently or not.
4. **HYGIENE & HOUSE KEEPING** – The purpose of this element is to maintain good hygiene and housekeeping standards in labs.
5. **SAMPLE HANDLING** – This element defines some rules for proper handling of samples so as the results produced from the sample are representative of hole lot.
6. **INTERNAL ASSURANCE PROGRAM** – This element ensures the implementation of all the GLP elements.
7. **METHODS** – This element identifies the critical control points (CCP) of each method with control implementation to ensure accuracy in results.
8. **EQUIPMENTS** – The purpose of this element is to ensure that all equipment being used in laboratory is properly calibrated and maintained.
9. **CHEMICAL REAGENTS** – This element ensure that all chemicals and reagents are properly prepared and standardized where necessary.
10. **REPRODUCIBILITY AND REPEATABILITY** – This element ensures accuracy amongst the analysts.
11. **SAFETY** – This element ensures that a safety system is defined for lab as per requirements.
12. **WASTE DISPOSAL** – This element defines the ways to dispose-off various waste of labs, such as broken glassware, biological waste, solvents, toxic chemicals and corrosive chemicals.
13. **DATA MANAGEMENT** – This element defines the analysis and Interpretation of Lab data and also used for proper tracebality.

THE WAY CDL IMPLEMENTED GLP

CDL started implementing GLP in following way:

1. CDL established a team comprising of following members within Laboratory to establish and implement GLP.
   - Manager Quality Systems (MQS) – Team Leader
   - Quality Control Executive
   - Shift Chemist
   - Food Safety Officer
   - Senior Lab. Technicians

2. Training package was finalized by MQS in coordination with Sectional Heads to train the members and other lab staff focusing on the following points:
   - Analytical skills
   - Preparation and standardization of Solution
   - Proper equipment handling
   - Calibration of equipment and glassware
   - GLP rules
   - Housekeeping, personal and equipment hygiene, chemicals handling & safety
3. MQS arranged training as per schedule and also performed proper evaluation after training, where possible, and keep record of evaluation.
4. A collaborative testing schedule was formed and implemented to check the competency of lab staff in their analytical skills.
5. GLP team conducted Gap Analysis within due limits to rectify the issues and to finalize the GLP implementation process.
6. GLP manual was prepared by team. The manual comprised of introduction, scope, policy, rules and elements of GLP and finally the GLP Manual was got approved from the top management with its practical implementation.

Note: Project Phases are attached in Annexure 1

BENEFITS OF GLP

As a result of implementing GLP, CDL Foods Limited has drawn following benefits:

- Precision and accuracy of analysis is improved.
- Lab staff has become more confident in analytical work and in handling of equipments.
- Overall equipment hygiene is improved in lab, which has enhanced Lab beauty.
- Time for conducting analysis is reduced due to increase work efficiency.
- A team of experts has been prepared for trouble shooting of various lab issues.
- Results generated by lab are more reliable.
- Overall quality of product has improved.
- Product and customers safety has improved.
- Lab activities become more organized in every aspect.
- Work efficiency of lab staff is increased.
ANNEXURE 1

Project Phases

GLP Project consists of five phases

Phase 1: Gap Analysis

- Gap analysis of existing system against GLP requirements, prepare report and action plan for implementation and follow up
- GLP team development

Phase 2: Planning and Implementation

- Training of GLP for Laboratory Analysts
- Develop a detailed system for calibration of lab equipments by focusing on
  - Master equipments for calibration
  - Stock level of calibrated equipments for daily use
  - Review of existing calibration procedures
  - Verification system / frequency for calibrated equipments
  - Maintenance schedule for lab equipments

Phase 3: Develop Internal Assurance Process

Internal assurance process (IAP) is backbone of GLP. IAP consists of main five areas. Each area will be developed as follows:

1. IAP FOR TEST METHODS:
   - Develop critical control points for each test methods in progress.
   - Give training to staff to enhance their competencies

2. IAP FOR CHEMICALS:
   - Define stock solutions
   - Standardization system for solution
   - Storage and expiry of solutions
   - Frequency of check of solution
   - Proper labeling with usage instructions

3. IAP FOR EQUIPMENTS
   - Availability of manufacturer manuals for each equipments
   - Maintenance schedule for laboratory equipments
   - Calibration of lab equipments
   - Proper labeling of equipments

4. IAP FOR REPRODUCABILITY
   - Duplicate sampling
   - Use of reference sampling for accuracy
   - Cross checks
   - Collaborative testing

5. IAP FOR SAFETY
   - Availability of First Aid Kit
   - Availability of Material Safety Data Sheet for each Chemicals and solutions
   - Availability of eye showers
   - Availability of Personal Protective Equipment
Phase 4: Develop Manual
GLP Manual will be prepared including all requirements of GLP.

Phase 5: Implementation
- Print IAP Cards
- Implementation as per manual

MILK PROCUREMENT:
GLP in milk procurement Laboratories will be implemented during visits for milk hygiene program.

AUTHOR’S SYNOPSIS

Ariq Qamar is presently working as Manager Quality System & Milk Hygiene in CDL Foods Limited, Lahore. He did MBA in Marketing from Punjab University Lahore, M Sc.(Hons.) in Food Technology, from Agriculture University Faisalabad and B Sc. (Hons.) in Food Technology, from Agriculture University Faisalabad. He is Certified Quality Professional from Pakistan Institute of Quality Control. He has Auditor /Lead Auditor Certificate for ISO 9000 & HACCP. He is Member of Pakistan Society of Food Technologist. He taught more than 30 in-house courses and Guest Speaker in Lahore Chamber of Commerce and different colleges.