

Comprehensive Technical Architecture and Operational Documentation of the CIELA Laboratory Information Management System

The Centralized and Integrated Elogbook for Laboratory Analysis, hereafter referred to as CIELA, constitutes a sophisticated Laboratory Information Management System (LIMS) specifically engineered for the high-precision environment of the Quality Assurance Analytical Center (QAAC) at Kalbe Nutritionals. In the contemporary landscape of pharmaceutical and nutritional manufacturing, the transition from manual, paper-based recording to a robust, digitalized ecosystem is not merely a matter of convenience but a critical mandate for maintaining data integrity and regulatory compliance. CIELA serves as the primary digital nexus for laboratory operations, providing a unified platform for sample lifecycle management, from initial intake via the OSIR interface to final report generation and archival. The system is built upon a modular architecture that segregates laboratory functions into specialized domains—Microbiological, Chemical, and Physical—ensuring that analysts operate within a tailored environment that reflects the specific technical requirements of their discipline. By integrating real-time data visualization, automated calculation engines for complex microbial enumeration, and standardized communication protocols for suspect results, CIELA optimizes laboratory throughput while minimizing the risk of human error.

Core System Philosophy and Architectural Foundation

The architectural design of CIELA is rooted in the principles of centralization and integration, aiming to eliminate the data silos that frequently characterize large-scale laboratory environments. At its core, the system functions as a digital repository that captures every action within the laboratory, creating a comprehensive audit trail that satisfies the requirements of international standards such as ISO/IEC 17025 and FDA 21 CFR Part 11. The philosophy of the system is to provide a "single source of truth" for all analytical data, ensuring that results are attributable, legible, contemporaneous, original, and accurate—a framework known as ALCOA+.

CIELA utilizes a multi-tiered architecture that separates the presentation layer, business logic, and database management. The presentation layer is delivered through a web-based interface, facilitating access across various workstations within the facility without the need for localized software installations. This accessibility is governed by a secure authentication layer that integrates with existing corporate identity providers through an API for employee data. This integration ensures that user accounts are synchronized with the central human resources database, allowing for automated permission management and enhancing the security posture of the laboratory.

Component	Technical Specification	Functional Purpose
User Interface	Responsive Web-Based GUI	Cross-departmental accessibility and workflow navigation.
Authentication	API-based Employee Integration	Secure credentialing and role-based access control.

Component	Technical Specification	Functional Purpose
Data Layer	Centralized Relational Database	Secure storage of sample metadata, results, and audit logs.
Integration	OSIR Real-time Data Feed	Automated sample intake and pooling from external systems.

Security Protocols and User Authentication Framework

The security architecture of CIELA is designed to protect sensitive intellectual property and maintain the sanctity of analytical data. Access to the system is restricted through a login portal that requires a valid username and password, verified against the KALBE Nutritionals corporate database. This ensures that only authorized personnel from the Analytical Center can interact with the system's modules.

Beyond initial authentication, CIELA employs a robust Role-Based Access Control (RBAC) model. Within this framework, users are assigned specific roles such as Analyst, Head of Unit (Kepala Unit/KU), or System Administrator. Each role carries a granular set of permissions that dictate which actions a user can perform. For example, while an Analyst may input results and perform calculations, only a Head of Unit possesses the authority to verify those results and transition a sample to a "Closed" status. This separation of duties is essential for fulfilling the "four-eyes principle," a cornerstone of laboratory quality assurance.

The system also maintains a comprehensive audit trail, recording every transaction, modification, and approval. This digital footprint includes the identity of the user, the timestamp of the action, and the nature of the change. In the event of a data discrepancy or a regulatory audit, this audit trail allows for the reconstruction of the entire analytical process, from sample receipt to final reporting.

Operational Dashboard and Real-time Data Visualization

The CIELA dashboard serves as the central command center for laboratory management, offering a high-level visualization of the facility's operational health. The dashboard is engineered to provide immediate insights into workload, efficiency, and quality metrics, allowing managers to make data-driven decisions regarding resource allocation and throughput.

Key performance indicators (KPIs) are presented through a series of dynamic widgets and graphs. These visualizations include:

1. **Sample Status Tracking:** A real-time count of samples categorized as "Open" (awaiting action), "On Progress" (currently being analyzed), and "Closed" (fully verified and approved).
2. **Trend Analysis Graphs:** Longitudinal data showing the volume of samples processed over time, allowing for the identification of seasonal peaks or operational bottlenecks.

3. **Efficiency Metrics:** Tracking of First Time Quality (FTQ), On-Time Analysis (OTA), and potentially Freedom to Operate (FTO) targets.

The OTA metric is particularly critical, as it measures the laboratory's ability to deliver results within the timeframe promised to the client. High OTA scores indicate a well-optimized workflow, while a high pending sample count might signal a need for additional staffing or equipment calibration. The dashboard's visual clarity ensures that these critical metrics are accessible at a glance, facilitating proactive management of the laboratory's commitments.

Navigation Hierarchy and Temporal Data Organization

CIELA employs a logical and intuitive navigation structure that mirrors the organizational flow of the QAAC laboratory. The sidebar provides immediate access to the primary sub-laboratories: MICRO, CHEMICAL, and PHYSICAL. This segregation ensures that analysts are presented with the specific tests and parameters relevant to their discipline, reducing cognitive load and the potential for misdirected data entry.

The organization of historical data is handled through a hierarchical folder system based on time. Users navigate through a three-tier structure:

- **Folder Year:** Selecting the specific calendar year of the analysis.
- **Folder Month:** Drilling down into the specific month.
- **Folder Day:** Accessing the records for a specific date.

A key technical feature of this system is its dynamic population logic. The system only generates a date folder if at least one Analytical Request Form (ARF) has been entered for that day. This prevents the interface from becoming cluttered with empty records. Furthermore, CIELA utilizes a color-coded status indicator for the date folders to provide immediate visual feedback on the progress of work:

- **Green Visualization:** Indicates that all data for that specific date has been closed, verified by the Head of Unit, and approved.
- **Yellow Visualization:** Signals that there are still open or pending items for that date, requiring further action before the daily log can be finalized.

Sample Management and the ARF OSIR Interface

The lifecycle of a sample within CIELA begins at the "Main ARF" interface, which manages the intake of Analytical Request Forms from the OSIR system. This interface acts as the gateway for all incoming work, providing a real-time feed of samples received at the laboratory. The system is designed to handle "pooling," where multiple unique samples are grouped together for administrative or analytical efficiency.

In the "Received ARF" tab, users are presented with a detailed grid of incoming requests. Each entry includes:

- **Pooling ID:** A unique identifier for the grouped samples.
- **Receive Date:** The timestamp marking the official arrival of the sample.
- **Promise Date:** The target completion date based on agreed turnaround times.

- **Total Samples:** The count of individual specimens within the pooling group.
- **Action Buttons:** Options to "Add ARF" (show modal for specific data entry) and "Download" the pooling record.

This phase of the process is critical for establishing the chain of custody. By assigning a unique identifier at the point of receipt—a process known as accessioning—the system ensures that the sample can be tracked through every subsequent stage of preparation, analysis, and disposal.

Intelligent Pooling Logic and Master ARF Configuration

When a user selects the "Add ARF" action, a popup modal appears to facilitate the configuration of the specific samples within the pooling group. This modal displays a granular list of individual sample numbers, sampling points, and the required parameters for each.

The system incorporates intelligent business logic at this stage to guide the analyst. For example, parameters containing strings such as "longum," "infantis," "breve," or "bifido" trigger a mandatory selection for "analysis dilution". This proactive validation ensures that specialized microbiological protocols are followed from the outset, preventing the loss of samples due to improper preparation.

Data Field	Source/Type	Description
Pooling No	System Generated	Unique identifier for the batch of samples.
Sample Number	Client Provided	Unique identifier for the individual specimen.
Sampling Point	Master Data	The specific location or stage from which the sample was taken.
Parameters	Test Catalog	The list of analytical tests required for the sample.
Dilution Check	Logic Condition	Automated prompt for dilution if specific microbial strings are detected.

Pre-Analysis Module and Sequential Identity Generation

Once samples are added from the pooling modal, they transition to the "Prep Analysis" module. This module is designed to prepare the samples for the actual analytical phase, focusing on organization and the establishment of unique daily identifiers.

A sophisticated feature of this module is the generation of a sequential unique number for each sample on a daily basis. This number resets every day, providing a clean and organized way to

track the volume of work processed within a single shift. Furthermore, CIELA utilizes parameter concatenation logic. If a single sample number requires multiple tests, the system merges these parameters into a single string (e.g., "EB, Sal, YM"), allowing the analyst to see the full scope of work for that sample in a consolidated view.

The preparation module also supports the marking of samples with visual badges to indicate specific conditions:

- **Note Badge:** Triggered when the analyst adds a custom note or special instruction to a sample.
- **Duplo Badge:** Applied when a sample is selected for duplicate analysis to ensure measurement precision. The marking of parameters for "Duplo" is a critical quality control step. Parameters selected for duplication are automatically diverted to the specialized "eLogbook Duplo" for result entry, ensuring that the necessary replication is performed and documented correctly.

Decomposition of RTS Sampling Points and Parameters

In environmental monitoring and cleaning verification, CIELA manages a specialized data type known as RTS (Rapid Toxic Screen or similar monitoring protocol). The system includes logic to handle complex, concatenated codes that represent both a parameter and a physical location within the production facility.

For example, a code like YM.G1.1.1 is automatically parsed by the system into its constituent parts. The "YM" is recognized as the parameter (Yeast and Mold), while "G1.1.1" is assigned as the sampling point (e.g., Line 1, Stage 1, Point 1). This decomposition allows for sophisticated trend analysis, where managers can track contamination levels at specific points on a production line over time, rather than just seeing an aggregate result for a sample.

The system logic for RTS includes:

1. **Parsing:** Splitting the original string into Parameter and Sampling Point.
2. **Grouping:** Aggregating multiple parameters that share the same sampling point.
3. **Concatenation:** Creating a unified list of parameters for each unique point.
4. **Sequencing:** Assigning a sequential number to each unique sampling point for organized tracking during the prep phase.

Analytical Execution and the Start Analysis Protocol

The transition from the preparation phase to the active analytical phase is governed by the "Start Analysis" module. This module serves as the official timestamping mechanism for the laboratory's work. When an analyst is ready to begin testing, they must select the relevant samples and trigger the "Start Analysis" action.

This action performs several critical functions in the background:

- **Timestamping:** Capturing the exact date and time the analysis commenced (start_analysis_timestamp).

- **Status Transition:** Moving the sample from the preparation queue to the active analytical queue.
- **Visibility Management:** Removing the sample from the "Start Analysis" tab and populating it in the "Input Result" tab.

This state-based workflow ensures that the system always accurately reflects the current status of every sample in the lab. It also provides the necessary data for calculating actual turnaround times, which are essential for laboratory performance reviews and for ensuring that tests are performed within validated stability windows.

The Result Entry Ecosystem: Manual vs. Automated Assistance

The "Input Result" module is where the primary data acquisition occurs within CIELA. The system is designed to accommodate different styles of result entry, recognizing that different tests require different levels of interaction.

One of the standout professional features is the "Counting Assistance" tool. This tool is specifically designed for microbiological analysts who need to process large volumes of plates. By entering the unique analysis number found on a petri dish, the system automatically retrieves all associated sample metadata. The analyst then inputs the observed count or result, and the system "passes" this data directly into the input table below. This minimizes the risk of transcription errors and ensures that results are correctly associated with the appropriate sample record.

For samples not using the assistance tool, analysts can input results directly into the data grid. The interface supports different input types based on the parameter:

- **Textbox Inputs:** Used for quantitative results (e.g., numeric counts).
- **Dropdown Menus:** Used for qualitative results, allowing the selection of categorical outcomes like "Positive," "Negative," or "Suspect".

The module also includes a "Bulk" processing feature, where analysts can select multiple samples with identical results (such as a batch of negative routine screens) and submit them with a single action. This significantly enhances efficiency without compromising the audit trail, as the system records individual results for each sample within the batch.

eLogbook Duplo: Mathematical Logic for Precision Replicates

Quality control within CIELA is reinforced through the "eLogbook Duplo," a specialized module for managing replicate analyses. This module ensures that duplicate results are handled with the mathematical rigor required by modern laboratory standards.

When a sample is marked for duplication during the prep phase, its result entry must be performed within this specific eLogbook. The system requires the entry of two separate results: Result 1 (\$R_1\$) and Result 2 (\$R_2\$). The system then utilizes a built-in calculation engine to determine the final result.

The mathematical logic for the final result is as follows:

$$R_{final} = (R_1 + R_2)/2$$

By forcing the entry of both raw values and automating the calculation, CIELA ensures data integrity. Analysts cannot simply input a pre-calculated average; they must provide the raw data for both replicates, creating a transparent record that is easily verifiable during internal or external quality audits. Once the final result is calculated and saved as a draft, it is passed back to the main result input module for final submission.

eLogbook Bifidobacterium: Automated Dilution and Enumeration Modeling

For the specialized analysis of *Bifidobacterium*, CIELA provides a dedicated "eLogbook Bifidobacterium". Microbiological enumeration of this organism often requires a series of dilutions to achieve a countable range of colonies, and manual calculations of these dilutions are a common source of error.

The CIELA module automates this process through a structured input interface that mirrors the serial dilution process. The analyst selects the specific dilutions performed (e.g., 10^1 through 10^9) and then inputs the observed colony counts for each. The system then automatically calculates the "Actual" concentration for each dilution based on the following scientific notation:

$$C_{actual} = n \times 10^d$$

Where:

- C_{actual} is the calculated bacterial concentration.
- n is the number of colonies observed in a specific dilution.
- d is the exponent of the dilution factor.

The system then calculates the "Bifido Final" result by averaging the actual concentrations across the valid countable plates. This automated approach not only saves time but ensures that the resulting data is calculated with absolute consistency, adhering to the mathematical requirements of microbiological enumeration.

Dilution Factor	Colony Count (n)	Actual Concentration (Cactual)
10^1	[Input]	$n \times 10^1$
10^5	5	500,000
10^6	[Input]	$n \times 10^6$

Dilution Factor	Colony Count (n)	Actual Concentration (Cactual)
Final Result	Average ($\\$C_{\{actual\}}\\$)	Bifido Final

Exception Management: The Suspect Result Workflow

In the event of a suspect positive result or a result that requires a re-check, CIELA provides a structured communication and documentation workflow. This "Suspect Result" module is critical for ensuring that manufacturing and quality assurance stakeholders are notified immediately of potential issues.

When an analyst identifies a suspect result, they click a dedicated "Suspect" button, which opens an "Email Helper" interface. This interface pre-populates an email template with the relevant sample details, including the sample number, pooling number, parameter, and the initial suspect result. The system also automatically calculates an "Estimation Confirmation Date," typically set as \$H+2\$ (two days from the current date), which is included in the email as the due date for the final re-check result.

The email is targeted to specific customer groups based on the sample's origin (e.g., SHP samples are directed to customer A, while KNS samples go to customer C). By automating this notification process, CIELA ensures that the communication is both rapid and standardized. Furthermore, once the email is sent, the sample is diverted to a specialized confirmation elogbook, where the results of the re-check are documented before the sample can be officially closed.

Final Reporting, Traceability, and Audit Trail Finalization

The final stage of the CIELA workflow is the generation of the "ARF Final Report". This tab provides a comprehensive view of all "Closed" data—samples that have undergone the full analytical process and have been officially verified by the Head of Unit.

The report interface displays a robust data grid that includes every relevant data point from the sample's lifecycle:

- **Traceability Data:** No. Analisa, Pooling No, Titik Sampling, and Sample Number.
- **Temporal Data:** Receive Date, Start Date, and Promise Date.
- **Methodological Data:** Test Method, Test Unit, and Item Description.
- **Results Data:** Final analytical results, including any notes or Duplo averages.

This report serves as the official digital logbook of the laboratory, fulfilling the requirements for long-term record-keeping and auditability. Because every entry is linked to an authenticated user and a specific timestamp, the laboratory can provide a complete and unalterable history of any sample to internal auditors or external regulatory bodies.

Strategic Implications for Laboratory Management and KPIs

The implementation of CIELA extends beyond operational efficiency into the realm of strategic management. By capturing granular data on every aspect of the laboratory's work, the system provides management with the tools to optimize the entire analytical ecosystem.

The tracking of First Time Quality (FTQ) and On-Time Analysis (OTA) allows for the identification of systemic issues. For example, a high rework rate (low FTQ) for a specific parameter might indicate a need for analyst retraining or instrument maintenance. Similarly, tracking the "Analyst Occupancy" and throughput ensures that work is distributed evenly across the team, preventing burnout and reducing the risk of fatigue-related errors.

Furthermore, the integration of metrics such as "Freedom to Operate" (FTO) within the broader corporate dashboard ensures that the laboratory's activities are aligned with the company's legal and commercial goals. By providing a centralized, transparent, and accurate view of the laboratory's output, CIELA allows the QAAC to move from a reactive testing model to a proactive quality management model.

Regulatory Compliance and the ALCOA+ Standard

In the highly regulated world of nutritional and pharmaceuticals, compliance is not optional. CIELA is engineered to support adherence to international standards such as ISO/IEC 17025 (general requirements for the competence of testing and calibration laboratories) and FDA 21 CFR Part 11 (regulations on electronic records and electronic signatures).

The system achieves this by enforcing the ALCOA+ standards for data integrity :

- **Attributable:** Every action is linked to a specific, authenticated user.
- **Legible:** All data is stored in a clean, machine-readable digital format.
- **Contemporaneous:** Results and timestamps are captured at the moment of action.
- **Original:** CIELA functions as the primary electronic logbook, capturing raw data directly.
- **Accurate:** Built-in calculation engines for Duplo and Bifidobacterium minimize manual errors.

By satisfying these requirements, CIELA ensures that the laboratory remains audit-ready at all times. The system's ability to generate comprehensive final reports with a full audit trail significantly reduces the time and effort required to demonstrate compliance during regulatory inspections.

Future Roadmap and System Integration



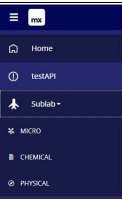



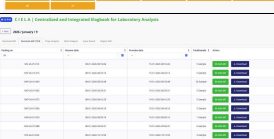

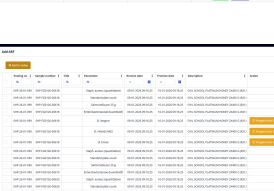
While CIELA currently provides a comprehensive solution for laboratory management at Kalbe Nutritionals, the system is designed with scalability and future integration in mind. The modular nature of the software allows for the addition of new sub-laboratories or the integration of new types of analytical instruments.

Potential future developments for CIELA include:

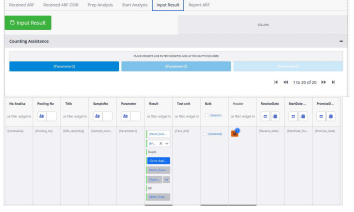
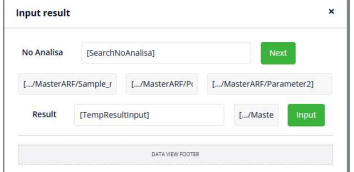
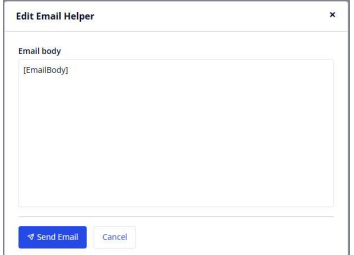
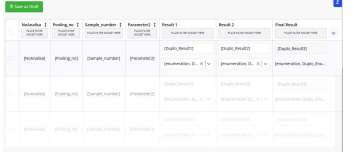
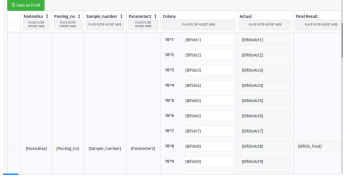
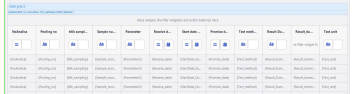
1. **Instrument Interfacing:** Developing direct APIs to transfer data from laboratory equipment (e.g., spectrophotometers, HPLC units) directly into the CIELA database, further eliminating the need for manual data entry.
2. **Advanced Predictive Analytics:** Utilizing the historical data within CIELA to develop predictive models for quality trends, potentially identifying batch failures before they occur.
3. **Expanded Mobile Connectivity:** Enhancing the dashboard's mobile capabilities to allow managers to view real-time laboratory status and approve urgent results from any location.

By continuing to evolve and integrate with the broader digital ecosystem of the company, CIELA will remain at the forefront of laboratory informatics, ensuring that the KALBE Nutritionals QAAC continues to deliver the highest standards of analytical excellence.

Screenshot Documentation

No	Page	Visual	Microflow	Logic summary
1	Login page		-	API prpoint employee data or SSO login
2	Visualization dashboard		-	open/close/onprog data analysis, Sample Data trend, FTQ/OTA
3	Navigation Bar		-	<ol style="list-style-type: none"> 1. Sublab MICRO, CHEMICAL, PHYSICAL, CHEM INSTRUMENT 2. E-logbook
4	Nav Year		-	Year
5	Nav Month		-	Month
6	Nav Day		-	Day
7	Main ARF			Get realtime sample data pooling unique from API OSIR based on selected day by user
8	Popup Pooling ARF			Get all sampel data from selected pooling number, trigger "Add ARF"

9	Popup Pengenceran BIF			Selected pengenceran w will trigger logarithmic counting in the BIF e-logbook.
10	Button Add ARF for pendingan			Button will be visible if sample as Pendingan
11	Button Add ARF for today			Button will be visible if sample received date is today
12	Preparation Analysis Menu			Convert multiple-row parameters into a single-row concatenated string
13	Button for color highlight specific parameter			The button will highlight parameters containing specific strings.
14	Popup for setting sampel (take a note, Mark as duplo analysis)			Add note or set duplo if necessary
15	Popup for take a note			Add a note to communicate with other analysts.
16	Popup for choose duplo parameter			Set duplo for parameter will trigger for generate duplo e-logbook
17	Visual for sampel has note or duplo analysis			Visual for sampel has note or duplo analysis
18	Visual popup for sampel has note or duplo analysis			Visual popup for sampel has note or duplo analysis
19	Start analysis menu			Starting the analysis will enable result input in the next module.

20	Input Result menu : <ol style="list-style-type: none"> Counting assistance Data input table 			
21	Popup Counting assistance with unique parameter			Show detail data from data mark as suspect positif
22	Popup for email need to be confirm to customer,			automatically generate email template
23	Logbook duplo for input result sampel with marked as duplo on preparation menu			Input duplo analysis for average result and passing data to input result page
24	Logbook bifidobacterium for input result sampel with set as pengenceran BIF on popup Add ARF			Input bifidobacterium analysis for average result and passing data to input result page
25	ARF final report for traceability			ARF final report with detail data