



LabPlus Technologies

Implementation Project - LabPlus v3
Replacement of a current LIMS

Table of Contents

1	Project Introduction	4
2	Specifications Conventions	5
3	System Objectives	6
4	Configuration Requirements and Specifications	7
4.1	Overview of Client's analysis workflow	7
4.2	Sample Login	7
4.3	Sample Receipt	8
4.4	Test Assignment	9
4.5	Worksheets	10
4.6	Result Entry	11
4.7	Analytical Instruments	14
4.8	Certificates of Analysis (COA)	15
4.9	Lab Management	17
4.10	Sample Management	18
4.11	Grade Management	19
4.12	Results Queries and Communication	20
4.13	Security	21
4.14	External Systems	22

Abstract

This document partially describes the specifications required for a typical configuration, which follows the analysis of workflows and data requirements, for a laboratory operating assurance quality in a production plant, and considering the implementation of LabPlus v3. These specifications summarize existing workflows and requirements, and propose the required configuration to attain the Client's objectives. This document also details some modifications to existing workflows, as well as configuration decisions which have an effect on the final result and on the resources needed to achieve the implementation of LabPlus v3.

The beta version of LabPlus v3 is available since March 2007, and the Client's implementation must be completed by November 2007.









1 Project Introduction

The Client has elected LabPlus v3 to replace its current LIMS. This document is made up of extracts from the analysis of the system configuration and existing workflows.

LabPlus v3 proposes major architectural changes, in comparison with the Client's actual system. Consequently, it is very important to schedule enough time for system stabilization and testing, throughout the implementation cycle. We will also have to be flexible, as the Client will have to adapt to a new LIMS with a new architecture, which will require of LabPlus Technologies to change their usual implementation processes. In order to improve knowledge transfers and implementation delays, a joint team composed of LabPlus development resources and the Client's will work out a partnership, directly involved in the implementation cycle.

2 Specifications Conventions

In order to simplify the comprehension of this document, it is presented on a “by case” basis, i.e. “Requirements/Solution” for each case. The specifications use the following graphical conventions:

 Attention: Identifies a risk element or compromise.
 Note: Indicates a comment to consider.
 To determine: Indicates an element for which there is not enough information to propose a detailed solution to suit the requirement. Possible causes are limited data from the other Client's systems, the development or implementation stage of the functionality, or analysis development step. Some solution leads will be proposed, and an ulterior date will be set by the project managers for a final solution.
 To decide: Indicates an element requiring a decision that is outside the scope of the business analyst. The outcome is often related to laboratory management, enterprise management, or to the business nature of the settlement.
 Improvement: Identifies improvements to the actual work cycle or data cycle, at laboratory or enterprise level.
 LT Responsibility: Identifies an element which LT is taking full responsibility of.
 Project/team Responsibility: Identifies an element which the Client and LT are sharing the responsibility.
 Client Responsibility: Identifies an element which the Client is taking full responsibility of.

3 System Objectives

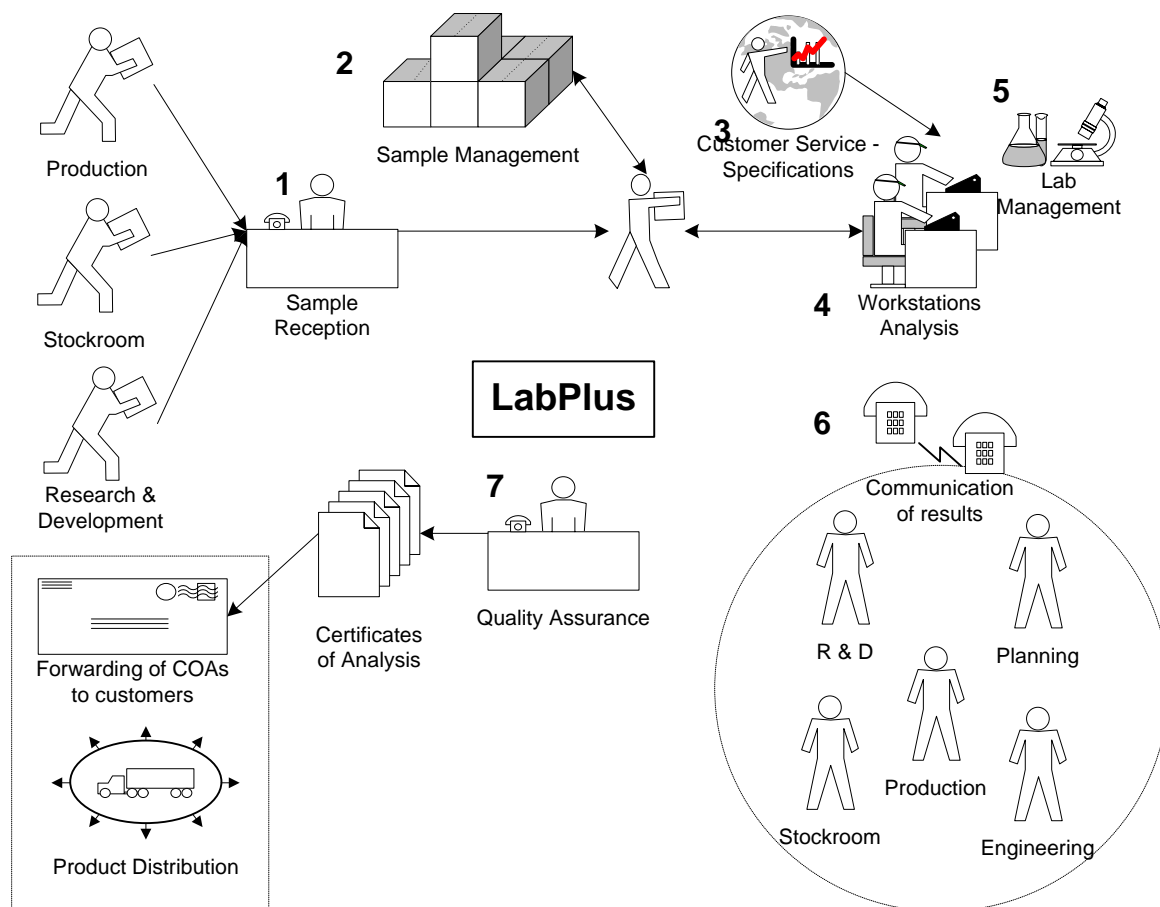
As declared in the Client's specifications, the main objective of the "LIMS Replacement" project is to provide their laboratory operations with a reliable system, powerful enough to answer the enterprise's technological prerequisites. With their new LIMS, the enterprise will benefit from the following advantages:

- Optimization of sample reception and management processes, without adding personnel;
- Improvement of laboratory work management;
- Data transmission between laboratory and production performed in due time, as prescribed by the operation workstation;
- Improvement of the analysis cycle;
- Support for integration or external systems with LabPlus and for production planning;
- Ad hoc query functionality;
- Reduced impact at LabPlus implementation time, both for Client's laboratory and operations;
- Follow-up on additives analyses and for other products analyses, performed by the R&D department of the enterprise;
- Integration of data input from analytical instruments;
- Calibration of analytical instruments is included.

4 Configuration Requirements and Specifications

4.1 Overview of Client's analysis workflow

The following diagram illustrates the workflow for analyses related to production. The analysis of production samples represents about 95% of the laboratory's workload.



4.2 Sample Login

4.2.1 Production Sample

Production sample login is done through a file transmitted from the ERP system. The file is handled by LabPlus XML Login Interface. Production samples are prelogged before they are received by the laboratory. It is possible for analysts to modify prelogged sample attributes, or to log a sample manually in LabPlus.

4.2.2 Other sample types

All other sample types, which are not related to production, are logged manually in LabPlus.

4.2.3 Specific Business Rules

Sample identification is generated using a mask, which is a combination of sample attributes in a predefined sequence [Section][Product][Origin][LotNb]-[Sequence].

4.2.4 Improvements



Improvements:

Each sample will be qualified with a status. The status will change according to the sample's life cycle in the system. Hence, it will be possible to know whether a sample is prelogged, received in lab, analysed, completed, deleted, stored, etc.

It will be possible to assign a set of specifications to a sample, so that it is not necessary to log multiple samples for every specification and duplicate the analysis.



Client decision: It is uncertain at this time whether the laboratory would benefit from the use of bar codes. The actual reference system, identification conventions (envelopes and labels) used in the laboratory and the plants, as well as test login rules, are effective ways to identify samples.

4.2.5 Activities

Identification	Activity	Responsibility
4.2.5.1	Creation of required entities for sample login.	
4.2.5.2	Transfer (migration) or entry of static and semi-dynamic data for sample login.	
4.2.5.3	Interface configuration for XML file exports for sample login from the ERP system.	
4.2.5.4	Interface configuration for XML file import for sample login in LIMS.	
4.2.5.5	Configuration of specific business rules.	
4.2.5.6 (Optional)	Configuration of templates for LIMS reports containing samples identified with bar codes.	

4.3 Sample Receipt

4.3.1 Sample Receipt Cycle

Sample receipt in LabPlus consists in changing the status of a prelogged sample to "Received". This applies only to production samples prelogged from the ERP system.

Sample receipt workflow will consist in submitting a query to get all samples with a prelogged status, select the samples received, and then click a button to change their status.

Alternately, bar codes could be used to select samples, as soon as production is equipped to

generate bar codes to identify samples.


Sample receipt and login are done in one step for manually logged samples that are not production samples.

4.3.2 Improvements



Improvement: Sample receipt is declared in LabPlus. It will be possible to submit a query to check if all prelogged samples were received by the laboratory.

4.3.3 Activities

Identification	Activity	Responsibility
4.3.3.1	Creation of the required query to find prelogged samples.	

4.4 Test Assignment

4.4.1 Test Assignment Cycle

There are two ways to assign tests, in relation to the nature of samples. For production samples, tests are assigned automatically, according to specific sample attributes (product, <grade-spec>, origin, grade, etc.). For samples related to other operations, tests are assigned manually at login time.

Two analytical profiles will be available in LabPlus V3: a “product” profile for production samples, and a “standard” profile, for other types of samples. This way, it will be easier to assign tests to samples, while minimizing interactions with the technician.



Notes:

In LabPlus v3, authorized users may add ad hoc tests to any samples, including production samples, so there may be additional analyses, if necessary. It is also possible to cancel a method, if it is not required anymore.

Tests assignment is done at the login stage, whether manual or automatic (XML file from ERP).

Additional tests for special finished products are inserted at the assignment stage. This step consists in verifying, for specific <grade-spec>, if analysis results obtained for the original batch justify the addition of a step to test finished products, in order to comply with the customer’s specifications.



Attention:

Sequence numbers actually used to identify samples created in the laboratory (for tests on finished products) will be replaced by “subsamples”. In LabPlus v3, it is possible to assign a method to the same sample many times, by using different analysis numbers. The strategy is the same for “re-analysis”. However, sequence numbers used for production will not be replaced.

4.4.2 Specific Business Rules

A distinct workflow will be configured for the “product” analytical profile. This profile will take into account sample attributes such as product, origin, etc., in order to determine the method to assign to samples.

4.4.3 Improvements



Improvements:

It will be possible to add sets of ad hoc tests, and to cancel methods when they are no longer required.

It will be possible to view the methods required for a sample, and also the status for each method.

Analysis results for methods will be saved in one table in the database. That will cut down on the effort and time required to access and search data.

It will be possible to assign multiple <grade-spec> to a sample. Methods will be determined for each <grade-spec>. This will avoid analysis duplicates.






To determine:

The Client wants to add a business rule in the "product" analytical profile, in order to determine the analysis frequency. The field "frequency" will be inserted in the table of analyses.

The Client wants to add a business rule that automatically copies the analysis results from one batch to another one, when they share the same original batch. This represents a customized business rule.

4.4.4 Activities

Identification	Activity	Responsibility
4.4.4.1	Creation of required entities for test management and assignment.	
4.4.4.2	Transfer (migration) or entry of static and semi-dynamic data for test assignment.	
4.4.4.3	Configuration of specific business rules.	

4.5 Worksheets

4.5.1 Worksheet Cycle

Actually, technicians perform analyses as stated in their worksheets. Worksheets are virtual documents displayed on screen. Each workstation is dedicated to a specific task and has its own worklist, which acts as a workload filter for specific methods.

In LabPlus v3, security is built in system functions, and manages access to screens. The concept of accreditation is used to give access to specific methods to a selection of technicians and contractors.


In LabPlus v3, worksheets will not be used to give access to all system functions. Worksheets will rather be used to access functionalities in line with laboratory work only.

In the "worksheet" screen, the first step is the selection of the worksheet to display. The technician will then view all samples to analyze by priority. As in all screens using a grid to display data, it will be possible to change the sort field and sort order by clicking in the column header.

The Client wants to display records in input order, for all worksheets with production samples. This is

“first in, first out (FIFO)” processing and it corresponds to the reality of production laboratory, where response time is crucial.

Worksheets for packed batch samples will be sorted by shipping date, so that products with priority delivery are analyzed as soon as possible, in order to prepare the certificates of analysis (COA) and ship products quickly.

 **Note:**
In LabPlus v3, it is possible to configure worksheets as an attribute in a method. It is then possible to use the attribute as a filter in methods and get the required data with minimum changes to sample search.

4.5.2 Improvements





Improvements:

The separation of system functionalities and analytical work, in regard to access rights.

The modification of the sort order for dynamic records.

4.5.3 Activities

Identification	Activity	Responsibility
4.5.3.1	Creation of required entities for worksheets.	
4.5.3.2	Creation of required queries.	

4.6 Result Entry

4.6.1 Result Entry Cycle

The actual Client’s LIMS employs many database tables for result entry. The tables are used to store data and implement the functionality for result entry that fits the Client’s requirements.

Tests required for production samples are automatically set up at login. Result entry is done through worksheets. As mentioned in section 4.5, some worksheets differ from others, in particular for tests on blends and finished products. Business rules will be different from what is actually implemented in the database schema, as additional data will be stored in satellite tables for those worksheets.


Here are the functionalities implemented in the result entry screen, when it is accessed from a worklist:

- Validation of limits;
- Validation of specifications;
- Inter/Intra samples calculations, combined/total test types calculations;
- Value formatting;
- Application of correction factors;
- Display of default values, formulations and methods;
- Average values from previous analyses;
- Interface with analytical instruments.

Each of these functionalities is designed within its own entity, with fields to store data and business rules derived from default ones. The set of operations required to achieve result entry will be configured in a customized work cycle, also derived from a built-in cycle.

Customized business rules will be used to display specific messages at result entry if the value is out of spec, for example.

In order to attribute results to analysts, the Client wants to capture the digital signature of the technician who performed the analysis in a worksheet before saving it.

 **Note:** In LabPlus v3, results are stored in three fields: raw value, formatted value, and calculated value. Technicians and instruments use raw values. Formatted values and calculated values are computed by the system, according to business rules.

4.6.2 *Limits*

In LabPlus v3, limits are validated for tests that are associated with methods. There are two types of limits:

- Detection limits use < and > symbols in the formatted value when it is out of limit. Ex: < 15 ppm;
- Control limits display messages to indicate when a value is improbable. The system can be configured to accept or reject the value. Ex: pH of 17.

4.6.3 *Specifications*

The Client uses multiple specifications (3 types) for one product. Specifications can be set up according to product, origin, grade, and a <grade-spec> set.

Out of spec results must generate warning messages for the technician. He can then decide to edit a result, redo an analysis, or continue without any change.

4.6.4 *Calculations*

The actual Client's LIMS links calculations to tests. The same approach will be used in LabPlus v3, where calculations will also be associated with tests, and tests coupled with methods.

4.6.5 *Value Formatting*

In LabPlus v3, numerical values can be formatted (ex XXX.XX). The format is stored within the test record. The value is stored in the "formatted value" field in the result record.

4.6.6 *Correction Factors*

Correction factors are special calculations using predefined constants for specific tests. Correction factors can be adding or multiplying (ex. $y=mx+b$).

In LabPlus v3, correction factors are configured in methods, as any other calculations. The function "REFCST ()" is used to read and return the constant value for a test/instrument.

4.6.7 *Default Values and Formulations*

For some product, grade, <grade-spec> and origin combinations, the system displays the default value in the result entry screen. Those values are especially useful for blends and finished products (ex. Matrix values). In the actual Client's LIMS, those values are defined as tests with default values, or linked to another table (for matrix searches, for instance).

In LabPlus v3, it will be possible to declare a default value for each test in a method. As mentioned previously, it will be possible to use the function "REFCST ()" to return the constant value for a test/instrument. Instead of using a different table for matrixes, the same mechanism will be used for correction factors and calculations.



Note:

In LabPlus v3, it is possible to view a method while in the result entry screen. In some cases, it could guide the technician, without having to use default values.

4.6.8 *Average Values from Previous Analyses*

For some types of analyses, the Client wants the system to show the technician the average value from 15 previous analyses that used the same tests. This could help the technician to see if the value he entered is within the average, and make corrections if necessary.

4.6.9 *Specific Cases*

As mentioned previously, some worksheets are different, as they require side-by-side sample analysis, for instance (tabular result entry). Also, as there is a high level of cohesion and dependency between blends and finished products worksheets, it could be necessary to configure a macro work cycle for these analyses.

4.6.9.1 Sample Preparation

In the actual Client's LIMS, the technician can add sequence numbers in sample preparation worksheets, for subsamples created in the laboratory. Afterwards, he can enter results for samples and their subsamples in a grid where they are displayed side by side. The system automatically calculates which subsamples to use for tests on finished products.

In LabPlus v3, subsamples will be used when generating sample preparation worksheets.

4.6.9.2 Tests on Finished Products

Worksheets for finished products contain all subsamples the system selected for multiple samples (up to 4), coming from different batches. The system determines the position of each subsample in the analysis and automatically inserts quality control samples. Results are entered in a tabular grid, where the samples are in the x-axis. The system automatically performs calculations. The analyses are sequentially numbered.

LabPlus v3 uses numbered worksheets for this type of analysis. The worksheet contains the analysis for a set of samples and quality controls, both coming from different batches, and sorts samples according to a specific order.

4.6.10 *Specific Business Rules*

Customized business rules will be designed to fit the requirements regarding result entry, sample preparation, and sample sort order in the worksheet. For instance, some of these requirements are:

- Average value from previous analyses;
- Subsamples order in worksheets;
- Selection of samples based on best results (for calculations) and automatic assignment of methods according to results;
- Automatic generation of subsamples;

- Calculations between and within samples;
- Correction factors.

Even though those business rules are already in LabPlus v3, they have to be configured and customized to get the required level of automation.




4.6.11 Improvements



Improvement:

During the implementation process of LabPlus v3, we will review how data is stored in the worksheets. For instance, when we talked with the technicians, we realized how helpful it would be to store certain results in the database to follow up on them.

4.6.12 Activities

Identification	Activity	Responsibility
4.6.12.1	Creation of required entities for result entry.	
4.6.12.2	Transfer (migration) or entry of static and semi-dynamic data for result entry.	
4.6.12.3	Configuration of specific business rules and customized workflows.	

4.7 Analytical Instruments

4.7.1 Instruments

The Client uses analytical instruments for some analyses. Actually, analyses performed by instruments are coupled with a worksheet. Methods are selected according to each set of <grade-spec>. When using instruments, samples are analyzed one at a time, and it is possible to redo an analysis in case there is a problem. In that particular case, previous values are replaced with new ones, as long as the worksheet is not saved (closed) by the technician.

LabPlus v3 will work together with LimsLink to configure the interfaces for all required instruments. The interfaces will break down the output files of the instruments, and use the XML format compatible for LabPlus v3.



Client Decision:

The Client does not want manual entry of sample numbers, to avoid keying errors. It can be implemented in two ways:

- Using bar codes; with this scenario, the technician uses bar codes to identify samples in LimsLink;
- Uploading LabPlus worksheets in LimsLink; with this scenario, the technician prepares a worksheet containing the samples to analyze, and then upload it in LimsLink.

**Note:**

In LabPlus v3, all data entries are kept in audits.

In order to close a worksheet, the system will use treatment statuses.

4.7.2 Specific Business Rules

LimsLink methods are recommended, as LimsLink represents a trusted application between instruments and LabPlus. These methods would also help to configure some specific business rules and contribute in reducing maintenance costs.

4.7.3 Improvements

**Improvement:**

The Client's actual work cycle requires that sample numbers are entered manually in instruments, as well as an occasional entry of results. In LabPlus v3, it is possible to eliminate manual result entry and reduce the copy of sample numbers in instruments, according to the configuration of the selected method.

4.7.4 Activities

Identification	Activity	Responsibility
4.7.4.1	Creation of required entities for instruments.	
4.7.4.2	LimsLink Training.	
4.7.4.3	Configuration of LimsLink methods.	
4.7.4.4	Configuration of LabPlus XML interfaces.	

4.8 Certificates of Analysis (COA)

4.8.1 Certificates of analysis

The Client issues certificates of analysis for every batch shipped to customers. For most grades, with a very few exceptions, a certificate is issued automatically, as soon as the analysis complies with the selected <grade-spec>. This process certifies that the batch being shipped is in compliance with specifications, an important part of the enterprise's conformity certification. In general, the certificates contain analysis results of the packing sample. Occasionally, they may also contain results of the original batch, or of other stages as it is the case, for instance, for special grades.

For diverse reasons, the actual Client's work cycle requires that the quality manager verifies if all necessary analyses were performed, then issues the certificate when results comply with customer's specifications. Actually, the quality manager knows which certificates to issue according to the folders put on his desk by the technicians, when all the analyses are completed.

In LabPlus v3, samples will have a treatment status, and it will be easy to identify for which samples analyses are completed and a certificate may be issued.



Specific Business Rules:

Business rules controlling report production, and operations to determine and evaluate the information displayed in reports, will require customizations. Also, rules to automatically generate reports when all analyses are completed will be customized.

The mechanisms for report production will use information transmitted by Client's interfaces, regarding customer's language and units of measure, to perform necessary translations and data conversions. Also, information about correction factors, used in the Client's reference system will have to be configured in LabPlus v3.

The results approval cycle is a prerequisite to generate reports. Customer data and preferences are stored in external systems and are transmitted to the LIMS, when required, as printing parameters.

4.8.2 Improvements











Improvements:

The use of a "partial" certificate template, to issue certificates even if a sample is out of spec in some tests and/or if some tests are not completed.

A free text section will be available in the report. The text entered in a textbox will appear in the printed report.

Report production history will be stored in the database.


4.8.3 Activities

Identification	Activity	Responsibility
4.8.3.1	Creation of required entities to support Client's business rules.	
4.8.3.2	Transfer (migration) or entry of static and semi-dynamic data for report production.	
4.8.3.3	Creation of a standard report template.	
4.8.3.4	Modification of the standard report template to fit Client's requirements.	
4.8.3.5	Configuration of business rules for automatic report production.	
4.8.3.6	Configuration of XML export (COA file) of report data.	
4.8.3.7	Configuration of the import of printing parameters to the LIMS.	
4.8.3.8	Customization of the header of the report (client info) and forwarding (Printer, FTP, Fax, Email).	

4.9 Lab Management

4.9.1 Lab Management

The Client actually manages the workload with manilla folders stored in a filing cabinet. A cabinet section represents a production stage. In LabPlus v3, it will be possible to get the same information quickly, with the help of predefined queries using sample status and parameters.

 **Note:** A sample logger and an event manager will be included in LabPlus v3. These tools will assist in the planning and the assignment of recurring tasks, like instrument calibrations.

4.9.2 System Configuration


The Client wants to modify the system configuration, such as adding a new test for instance, without having to call for IT services. LabPlus v3 provides great flexibility in the management of entities and data. It will be easy for lab supervisors to create new grades, add new tests, etc.

The following table presents the principal configuration elements and the user profiles to configure them.

Element	Description	Profile
Creation/Modification of Entities	Creation of a new entity or modification of an existing one	LT specialized personnel or technical resources trained as system administrator
Adding/Editing entities data records	Adding or editing data in an entity	Authorised lab user or supervisor
Business rules, interfaces and reports	Adding or editing system rules and data exchange	LT specialized personnel or technical resources with required training

4.9.3 Quality Controls

The Client's quality controls mainly involve instruments calibrations and using standards in analyses. Calibrations produce correction factors used in subsequent calculations. Actually, the documentation for quality controls is kept in ring binders in the laboratory. In LabPlus v3, quality controls and calibrations will be integrated in the system: warnings will be sent out when an instrument needs to be calibrated, and control samples will be logged when they are required.

 **Note:**
In LabPlus v3, quality controls can be associated to a method, a worksheet or an instrument.
Calibrations are always associated to an instrument.

4.9.4 Improvements



Improvements:




Lab management simplified by the use of sample logger and event manager tools.

Lab management improved by the use of treatment statuses.

Lab personnel will be able to manage their data in lab entities. Authorized personnel will be able to create new tests, specifications and grades.

Automated quality control samples and calibrations, so there is no oversight.

4.9.5 Activities

Identification	Activity	Responsibility
4.9.5.1	Creation of required entities for lab management.	
4.9.5.2	Configuration of the sample logger and event manager.	
4.9.5.3	Data entry for the required quality controls.	



4.10 Sample Management

4.10.1 Sample Management

As mentioned previously, the Client points out that it is difficult to search for samples, to modify their status and find out if all analyses are completed. Sample management will be improved in LabPlus v3 with effective ways to manage statuses and storage.

Sample storage is used for customers for whom samples must be kept up to two years after analysis. If there is a complaint, the laboratory can recover a sample and redo the analysis. Samples are put in boxes in a storage room. In LabPlus v3, the box number and storage date will be recorded in a database table. It will be easier this way to perform queries to find a particular box, or even to find all samples stored for more than 2 years.

A single box can contain about 200 samples, so modifying samples one by one is a tedious task. It will be possible to enter starting and ending sample numbers, and the modification will be performed on all samples in the interval in a single step.


<p> Attention: Processing this way may cause inconsistencies, as samples are not verified one by one. The Client agrees to this, as its actual system behaves the same way.</p> <p> Note: Using bar codes would improve this process.</p>

4.10.2 Improvements

 **Improvement:**

Sample storage management is built in the system, in order to speed up queries.

4.10.3 Activities

Identification	Activity	Responsibility
4.10.3.1	Creation of required entities for storage management.	

4.10.3.2	Creation of required queries.	
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4.11 Grade Management

4.11.1 Grade Management

The Client's customer service determines product grades. When new grades are created, or modifications are made on existing grades, information and specifications are passed on to the laboratory, where they are entered in the LIMS.

In LabPlus v3, the following elements are considered at the creation of a new grade:

- Grade registration;
- <grade-spec> information;
- "Internal" and "realistic" grade specifications and for each of its origins;
- "Warning" specifications for each <grade-spec>;
- Creation of required tests for the grade, its <grade-spec> and its origins;
- Report information for grades and <grade-spec>.

 **Note:** In LabPlus v3, specifications are built-in. However, <grade-spec> design will be set up to suit the Client's requirements.

As mentioned in section 4.6, grades, origins and <grade-spec> are used to determine analyses and specifications.

4.11.2 Special Grades

Some grades require a different process, such as sieving grades or special product grades. Additional business rules will have to be designed in order to implement those processes:

- In general, only one sample per box is analysed (12-15 samples/batch);
- The first sample goes through the entire analysis process;
- Subsequent samples are analysed according to a partial analysis process;
- The final report must disclose the results of each analysis (12-15 samples) and the average for some analyses;
- Boxes that do not meet with specifications will not be shipped, and therefore excluded from reports and average calculations;
- For some products, there is a need to modify the frequency of analysis, according to the grade and its <grade-spec>;
- A special grade may be shipped before all analyses are performed and a report printed;
- The report for a special product contains results coming from various production stages;
- All products are packed and shipped in boxes, although some grades may not be packed but shipped in a container (bulk), which has an impact on report production.

4.11.2.1 Grades without tests on finished products

In order to cut down on costs, customers can require that some tests do not have to be performed on specified grades when specifications are met for the batch at a given production stage. An additional business rule will be designed, in order to insert tests on finished products when results of the original batch do not comply with the specifications.

4.11.3 Specific Business Rules

Special grades will require customized business rules, listed below:

- Report template including the calculation of the average of displayed results;
- Exclusion of samples that do not comply with specifications, from average calculations and reports;
- Configuration of analysis frequency for certain sample types;
- Report production rule for special product batches;
- Exemption of test assignment conditional on the results and the specifications.

4.11.4 Improvements






Improvements:

Superior integration of special grades with the added functionality of additional grades.

Grade management review, to simplify and centralize the work cycle for grade management.

4.11.5 Activities

Identification	Activity	Responsibility
4.11.5.1	Creation of required entities for grade management.	
4.11.5.2	Transfer (migration) or entry of static and semi-dynamic data for grades and specifications.	
4.11.5.3	Configuration of business rules.	

4.12 Results Queries and Communication

4.12.1 Queries

The Client has mentioned that it is not simple to perform queries with the actual system, and that the IT service has created some queries that can be executed as necessary. Those queries are used for lab management.

In LabPlus v3, customized queries can be created in every screen displaying dynamic data. The Client will be able to easily configure administrative queries. The queries may use any entity field as search criterion.



Note:

In LabPlus v3, queries can be configured by laboratory personnel. In most cases, it will not be necessary to require IT services or know SQL language.

4.12.2 Communication

Laboratory data will be available to external users. LabPlus v3 "Lab Services" domain will manage external users' access to treatment status of their samples, analysis results, and certificates of analysis.

Moreover, interfaces designed to share information with external systems will open up laboratory data to other users in the company who use third party applications.

4.12.3 Improvements



Improvement:

Laboratory personnel will have tools to configure their queries without having to call IT services.

Direct access to laboratory data will be possible for external users.

4.12.4 Activities

Identification	Activity	Responsibility
4.12.4.1	Configuration of customized queries for the laboratory.	
4.12.4.2	Configuration of customized queries for external users.	

4.13 Security

4.13.1 Security Management

Actually, in the Client's LIMS, access is granted through worksheets. As mentioned in a previous section, in LabPlus v3, access to screens and functionalities will be done using roles, and access to worksheets is granted using user certification. Users are assigned one or more roles, which grant them permissions to access the functions needed to do their work.

Because LabPlus v3 is a web application, session duration is limited to 20 minutes; if there is no activity during this lapse of time, the session is automatically terminated. The Client wants to increase the delay to an entire shift, about 8 hours. "Single Sign-On" technology will be implemented and supported by LabPlus v3 to fit this requirement.

LabPlus v3 implements digital signature that is compliant to FDA and CFR 21 Part11 standards. It guarantees user's accountability at result entry, even if he is not the user logged on the system. The digital signature is captured at user's authentication (username (initials) and password) before results are saved.

It will be possible to configure external users in read mode only. They will be able to access laboratory data, without any intervention from laboratory personnel. Because LabPlus v3 is a web application, it will not require any special installation on workstations, although a license to access data will be mandatory.

LabPlus v3 security is configured through dedicated screens in the application.

4.13.2 Improvements





Improvements:

The laboratory may analyze its work cycle in order to implement complete accountability, compliant to GALP, CFR 21 PART11 and ISO17025 standards.

External users can access laboratory data.

4.13.3 Activities

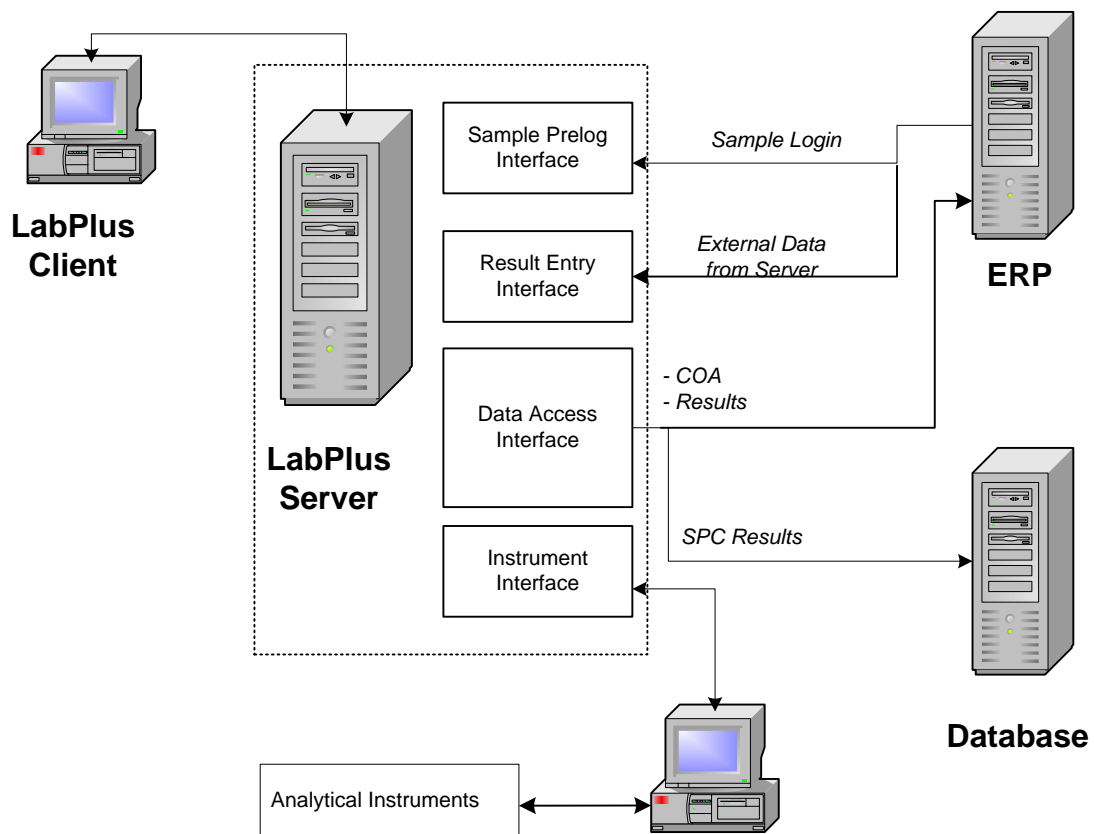
Identification	Activity	Responsibility
4.13.3.1	Creation and configuration of users and roles.	
4.13.3.2	Registration of customized pages to be managed by the system administrator.	

4.14 External Systems

4.14.1 External Systems

LabPlus v3 must integrate with existing systems in the enterprise, such as analytical instruments and ERP, the latter being used to manage the production and the enterprise. Also, there is another third party application, which computes real-time statistics in the laboratory.

The following diagram illustrates LabPlus' integration with other systems in the enterprise.



Interfacing is carried out by XML file exchanges between LabPlus v3 and the external systems. The following interfaces are required:

- ERP → LIMS : Sample login, List update, etc.

- LIMS → Client's systems (ERP, Statistics Module, etc.)

Sample login strategy must find a way to send reports and results to their corresponding request numbers, in order to close the loop.

As mentioned in section 4.2, it is possible to log a sample with more than one <grade-spec>. The ERP system will provide information on the grade, <grade-spec>, origin, and customer. This information will be sufficient to query the production schedule and find the request number. Then, after all analyses are completed, the report will be linked to the request, reducing analysis duplicates.

Results will be exported to external systems using an XML file, generated when the data is saved in the database.

When a report is produced, information in the report is sent to external systems.

As mentioned in section 4.7, interfacing between LabPlus and LimsLink is done using XML files.

It is also possible to add and modify LabPlus v3 entities, both static and semi-dynamic, using XML files.

4.14.2 Specific Business Rules

Business rules will be configured to automatically launch report production and/or results transfer, whenever a sample status is changed to the expected value.

4.14.3 Improvements



Improvement:

External systems in the enterprise will always be up to date, even when results are modified, because LabPlus v3 will automatically exports results as they are entered or when an analysis report is produced.

4.14.4 Activities

Identification	Activity	Responsibility
4.14.4.1	Configuration of export/import XML interfaces from ERP and other systems.	
4.14.4.2	Configuration of import/export XML interfaces from the LIMS.	