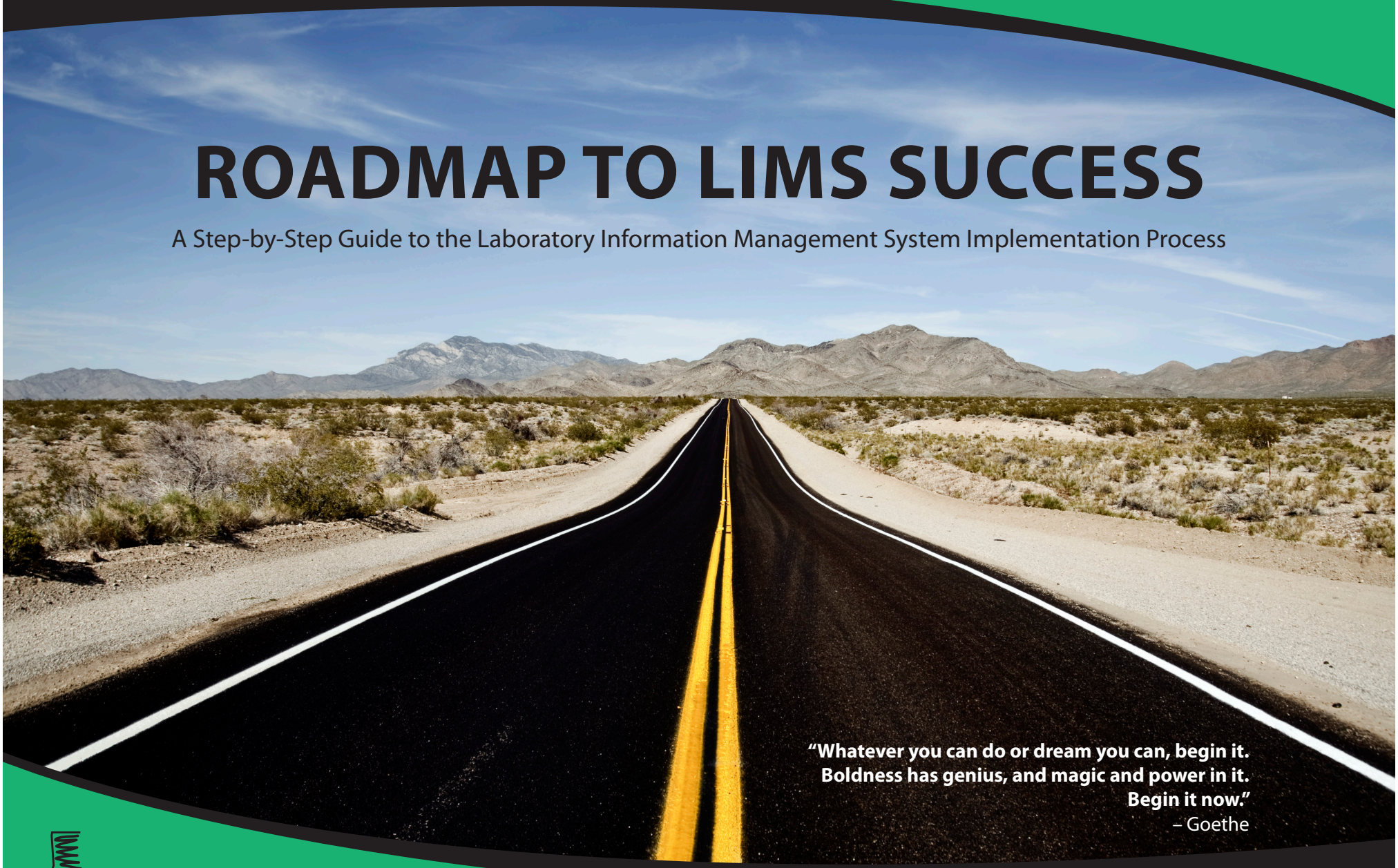
ROADMAP TO LIMS SUCCESS

A Step-by-Step Guide to the Laboratory Information Management System Implementation Process



**"Whatever you can do or dream you can, begin it.
Boldness has genius, and magic and power in it.
Begin it now."**
– Goethe

Accelerated Technology LABORATORIES INC.

Microsoft GOLD CERTIFIED Partner

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ATL's Implementation Process

Purpose

ATL's process for implementing our LIMS software and solutions is the culmination of two decades' experience working with clients of various sizes in numerous markets and industries. Over the course, we've leveraged guidance from our ISO Certified Quality Management System and worked to continuously perfect this process and maintain best practices. We invite you to benefit from our experience.

"Alone we can do so little; together we can do so much."
— Helen Keller

This guide is intended to be used alongside various ATL implementation tools:
- **Templates**
- **Checklists**
- **Gantt Chart**
- **Dashboard**
- **Training Materials**

Implementing a new LIMS is a team project: it is important that partners, participants and engineers work closely together in order to successfully accomplish the mission. This guide is designed as a workbook: it is broken down into **four main sections with eight subsections** that walk step-by-step through the process — from defining project scope through final deployment, including planning, configuration and training. There are places to take notes and document action items throughout.

Think of this guide as a road map that will prepare you for the various stages of LIMS implementation. If you have any questions, please contact your ATL representative.

Let's get started!

—The Accelerated Technology Laboratories Implementation Team

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- Conduct a Needs Assessment (NA)
- Analyze survey results
- Conduct workflow analysis
- Interviews team members
- Conduct laboratory tour
- Review NA results and report
- Final review of requirements

PLANNING TOOLS:
Checklists, Gantt chart, dashboard and survey*
** if Needs Assessment purchased*

SPECIFY CORE SYSTEM FEATURES

REQUIREMENT SPECIFICATIONS

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- Requirements list
- Historical data migration
- Static data migration
- Instrument integration
- Reporting needs and EDDs
- Third party software integration
- Define configuration & customizations

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- Define custom captions
- Set up users and permissions
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PLANNING TOOLS:
Template, Functional Requirement Specifications

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- On the job training
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DEPLOYMENT "GO LIVE"

SUPPORT

- Live technical assistance
- Explanation of functionality
- Knowledgebase
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UPGRADES

- New features and functions
- Regulated environment
- Re-validation required?
- New documentation
- Training on new features
- Training webinars
- Automation improvements
- Suggestion box for new features

PLANNING TOOLS:
www.atlab.com > Support

DEFINE PROJECT SCOPE

Scope definition is the first and most important phase of a LIMS implementation project because it defines the time required as well as total project cost. Project managers must commit to and protect the original scope in order to avoid the dangers associated with creep. There are two places scope is defined: high level (laboratory needs), and low level (business requirements). Together these define the overall project.

A project can be thought of as a box. High level scope defines the walls of the box and separates what is relevant and related to the project from everything that is not relevant.

HIGH LEVEL SCOPE

Define deliverables: often presented in Excel, this helps define the overall project scope.

Define boundaries: helps separate what is in scope vs. what is not. *i.e. This project will affect US operations only, all other operations are out of scope;' or 'This software will be deployed in manufacturing and laboratory divisions, all other divisions are out of scope.*

Once the project starts, there generally aren't many requests to change boundaries and deliverables. Instead, most changes are within business requirements, which help define the details of the project.

LOW LEVEL SCOPE

Product requirements (features): define the characteristics of the deliverables *i.e. If building a house, most of the requirements would be product based like 2x4s, sheetrock, nails, rooms, doors, windows, etc.* When implementing a LIMS, requirements may include unique, automatically-generated numbers, electronic signatures, QC charting, full audit trail, and much more.

Process requirements (functions): define how people interact with the LIMS and how the LIMS interacts with other software such as a Supervisory Control and Data Acquisition (SCADA) system. *For example, discussing how data is moved and transactions flow from one point to another describes process requirements. Describing transaction requirements is more process-oriented, such as how billing moves from orders to invoicing to accounts receivable, or how to look up a status, manually update an invoice and print a report on demand.*

Although the project manager will be intimately familiar with the project, it is also important for key stakeholders to understand overall project scope and how the key pieces fit together.

For additional information on implementing a LIMS, see the article, "Effectively Defining LIMS System Requirements: Launching a Successful Laboratory Automation Project" published in 2006 in Scientific Computing Journal. This paper discusses the relationship between performance, cost and time as they relate to the scope of the LIMS project.

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HIGH LEVEL SCOPE

LOW LEVEL SCOPE

DEFINE PROJECT SCOPE: INITIATION

Determine need for a LIMS and commit to project

The first step in this process is to identify the reasons a LIMS is needed. Once the preliminary due diligence has been completed and it is determined that with an investment in a new LIMS, the business will remain competitive and grow with a fast return on investment (ROI), key stakeholders will move forward on the project.

Once the original scope is identified, only then should new requirements be considered. Within the ATL project management plan, these items are collected and documented for Phase II consideration; this is just one way to manage the risk of scope creep.

It is critical that top management is brought in at this point to support the effort and the team 100 percent. Management must allocate time to the team to complete the project, be prepared to provide additional resources required for unanticipated reasons, and carefully monitor the project to avoid scope creep. If scope increases, time and cost to complete the project will likely also increase.

Assemble team

The LIMS team is typically a multifunctional group of stakeholders that consists of several disciplines, including Scientists, Information Technology, and Management.

It is important to include key system users for several reasons:

- Everyone has different needs, and compromises will need to be made: not everyone will get all he or she wants, but each person should have major needs met by the new system.
- It is much easier to implement a system in which there is user buy-in, rather than a system selected by a purchasing agent because it was offered at a lower cost.

In selecting team members, the following are typically included:
- **Quality Assurance Manager**
- **Laboratory or Plant Manager**
- **IT resource**
- **Key end users from departments (chemistry, microbiology, toxicology, etc.)**

- The Quality Assurance Manager is usually familiar with the organization's most critical needs, as well as regulatory requirements for their industry/customers.
- The LIMS project manager, (PM) typically a person with the most project management experience, will serve as point of contact with the ATL PM.
- Management will have very specific requirements in terms of tools such as specific reports, i.e. Chain of Custody, TAT (Turn Around Time), production and workload reports, etc. The management team may also be concerned with tracking costs, also if there is a need to integrate the LIMS with an accounting package.

ATL's LIMS products can be integrated with most common software packages such as QuickBooks and Peachtree, JD Edwards, Great Plains, and more

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WHY DO WE NEED A LIMS?

TEAM MEMBERS

DEFINE PROJECT SCOPE: INITIATION

Ensure resources are available

Various phases of the project will require dedicated time from various team members. The ATL Gantt chart breaks down resource requirements along with typical time estimates. ATL engineers will also have dedicated times to complete project tasks; therefore, it is critical the entire team shares a close working relationship. There will be many instances where a client team member is asked to complete a task so that an ATL team member can complete another task. *ie Completion of the pre-installation checklist and static table data template is important so the ATL engineers can import the data, including tests, methods, parameters, SOPs, sites, clients, contact information and related data.*

ATL engineers have found that these tasks typically require two weeks to complete and are divided among key LIMS project team stakeholders (fill in the pre-install checklist and static table template). This does not include any result data that may be migrated from a historical LIMS or Excel sheet, which requires a detailed technical review, plus time and cost analysis.

Document needs

Each person on the team may have a slightly different vision for, and expectations of, the LIMS, so it is vital for the project manager to gather all high-level needs or requirements up front to ensure any conflicts are addressed early and quickly. During this task, needs should be discussed at a very high level. *For example, one issue may be the need for improved organization of the laboratory samples to reduce the number lost. This need could be met by implementing a barcoded labeling and scanning solution, or it may require additional refrigerator space.* However, the project manager must simply gather needs, but not jump to potential solutions; this will come during the analysis/planning phase.

Prioritize needs

The project manager must monitor and manage the project to ensure adherence to initial needs, requirements or prioritization. Often requirements can be broken into three categories: must have, nice to have, and eventually needed or wanted. Other teams evaluate the financial returns (ROI) to determine how much time and money a feature would save, and if the savings are not above a dollar threshold those items are dropped. ATL has created a number of tools to assist in this process: a ROI calculator, a project Gantt chart that outlines resources and time commitments, and a project dashboard that lists all key deliverables along with their status. The dashboard is regularly updated (usually bi-weekly) and emailed to the team following progress meetings.

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LIST RESOURCES REQUIRED

LIST AND PRIORITIZE NEEDS

DEFINE PROJECT SCOPE: INITIATION

Categorize needs

It is often easier to break into sections the requirements that deal with various high-level business functions. This also allows the project manager to view the costs for each section, as funds often come from different pools of resources that must be tracked.

Break needs into high-level functions, for example:

- **IT requirements may include a new server, software or increased bandwidth**
- **The laboratory may need barcode scanners and new label printers**
- **Accounting may need to integrate the LIMS with accounting software**
- **Specific reporting requirements need to be documented and shared with the ATL project manager**

Complete risk analysis

One of the project manager's responsibilities is to examine all the things that could potentially derail a project, including scope creep and jumping ahead to future phases before completing requirements for previous phases. It is helpful to list these items and document potential solutions, a process known as risk mitigation.

To reduce scope creep, the project manager may need to push new items to future phases because they don't fit within the original project scope and would increase cost and time. Often these additional needs are sound ideas or important requirements, so they should be documented and re-evaluated after initial system implementation.

Working on phases out of sequence usually results in additional costs, time, resources and delays. For example, many people recognize that reports are critical and want to work on them first. However, until the database is fully configured, any work on reports would most likely require re-work later in response to changes within the database.

Budget and timing

Once scope is clearly defined, the time and budget requirements to complete a project should be established. If there is confusion regarding laboratory needs versus wants, or if the team doesn't share a united vision, it is a good idea to conduct a Needs Assessment (NA). This can be done internally or with an external consultant, and the end goal is a clear understanding of where a laboratory needs to be in order to meet regulatory compliance goals and maintain a competitive advantage.

ATL offers on-site Needs Assessment, utilizing a powerful toolset and subject matter experts to understand the current state of a laboratory. Surveys, interviews, and observations are output in a final Needs Assessment report.

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HIGH LEVEL FUNCTION NEEDS

POTENTIAL RISK

BUDGET AND TIMING

DEFINE PROJECT SCOPE: ANALYSIS & PLANNING

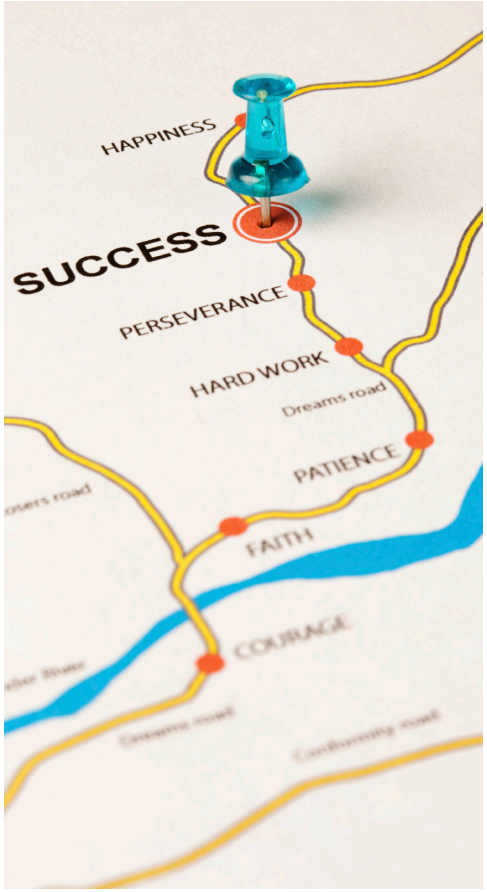
Distribute Needs Assessment (NA) survey

A Needs Assessment — a systematic process for determining and addressing needs or gaps between an organization's current condition versus its desired state — is an important part of the planning process. ATL has created a series of NA surveys specific to various industry segments, which include universal questions and questions specific to the needs and regulations in that industry. This a valuable tool to provide a better understanding of the organization's current state and set of perceptions. A copy of the completed survey is included in the final NA report, and this document is sent to clients electronically in advance of an on site assessment.

"By failing to prepare, you are preparing to fail."
— Benjamin Franklin

Conduct Needs Assessment

The discrepancy between current and aspirational states must be measured in order to appropriately define the need, which can be: a desire to improve current performance, efficiency or accuracy; correct a deficiency; or in response to a regulatory requirement. Gathering appropriate and sufficient data ensures that the solution developed will address the group's needs and wants. By clearly identifying challenges, finite resources can be directed towards developing and implementing a feasible solution.



Analyze survey results

Once the NA survey is completed, it is important to review the results as a group to ensure the responses reflect shared goals. This session is conducted on site and often triggers more questions and feedback on processes and business practices, which leads to a more complete understanding of current and potential challenges.

Conduct workflow analysis

An ATL subject matter expert will take notes as the LIMS project manager details "a day in the life of a sample," as it moves through the laboratory. These notes are transformed into a flow diagram(s) for later review and discussion. During the needs assessment and implementation, an organization has multiple opportunities to examine how business is conducted and determine if ways that are more effective exist to achieve goals.

DEFINE PROJECT SCOPE: ANALYSIS & PLANNING

Interview team members

In any project, it is critical that goals and expectations are clear to all members. In this step, an ATL subject matter expert (an individual with five or more years of laboratory automation or hands-on experience) interviews key stakeholders to understand needs, daily challenges and concerns. This is a critical step in the needs assessment, and information gathered will be included in the final report.

Conduct laboratory tour

ATL team members tour a facility and leverage hands-on experience and an understanding of laboratories and automation in order to identify improvements that can be made based on what has been successfully implemented in similar laboratories. An additional advantage of on site observation is the ability to identify potential project risks that may not be apparent from the outside.

"Planning without action is futile, action without planning is fatal."
— Cornelius Fitchner

Review NA results and final report

Once an ATL subject matter expert has completed the evaluation and collected survey responses and notes, several days are spent condensing and summarizing findings. Those findings are then shared with an ATL needs assessment team for review and comments. The team reviews the data and adds any pertinent comments or recommendations to the final report, which is then presented to the client.

Final review of requirements

The assessment is a tool to validate the high-level needs previously identified by the team. Once the project manager and team have reviewed the report, a meeting is scheduled with the ATL project manager to address questions and ideas resulting from the assessment. In many cases, LIMS needs and project scope are adjusted.

Suggested Reading:

1. Christine Paszko, 2006.
Effectively Defining LIMS System Requirements: Launching a Successful Laboratory Automation Project. *Scientific Computing pp 3-5.*

2. Christine Paszko, 2009.
How Can a LIMS Needs Assessment Save the Laboratory Money. *Scientific Computing pp 1-4.*

3. Alan Serrero, Ted Paczek and Christine Paszko, 2007.
Laboratory Needs Assessment benefits LIMS Implementation. *Waterworld pp18-20.*

NOTES

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PLANNING TOOLS:
www.atlab.com > Support

CORE SYSTEM FEATURES: REQUIREMENT SPECIFICATIONS

The second major phase of implementation deals with ensuring all aspects of the project have been discussed, considered, documented, planned and reviewed so that configuration can commence. This is the most challenging phase because decisions must be made regarding features, functions, workflows, etc., and some may conflict — in which case the project manager must assign priority.

Phase two is often the toughest for perfectionists who want everything flawless at each project stage, and before they feel ready to go live.

Identifying special requirements (instrument import, custom EDDs (Electronic Data Deliverables), reports, third party integration, etc.) is required at project initiation, in defining scope. Actually defining requirements occurs during this phase, whereas finalization of the requirements occurs during the implementation phase.

The reality is that, as the business continues to evolve, unique requests crop up. The best strategy is to configure the database as soon as possible in order for parallel testing to begin so that the laboratory can take full advantage of key requirements, while tweaking additional business processes to meet the required functionality. A LIMS is dynamic; there will constantly be new requirements and features that will evolve with the business.

Review defined scope

The initial phase of defining project scope will have produced a high level requirements/needs document. At this stage, it is very important to review and further refine the scope so it can be locked down and effectively communicated with all team members.

Requirements list

During this stage, requirements — a major part of project scope and core system functionality — are further defined. Many laboratories will begin with a list of common LIMS features and add or remove features and functions required to meet specific operational needs. The American Society for Testing and Materials (ASTM) offers a comprehensive yet generic list developed to cover different types of laboratories that utilize LIMS.

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IDENTIFY SPECIAL REQUIREMENTS

SCOPE REFINEMENTS

CORE SYSTEM FEATURES: REQUIREMENT SPECIFICATIONS

Historical data migration

In some cases, laboratories may wish to import historical data from a previous system, or Excel sheets, into the new LIMS in order to review historical data and trends, or because they are required to import QC data.

Because data migration can be costly, often laboratories choose to leave old data in the historical system to access only as needed.

Data migration often requires the creation of queries and field mapping because of terminology variance. For example, in the previous system a field could be called "parameter," and in the new database it may be referred to as "analyte," so it is important that the data field be mapped one to another.

Static data migration

Importing data (often a combination of Excel and paper forms) from a previous LIMS or data management system is known as static data migration. Data is typically comprised of site information, matrices, tests, methods, parameters, SOPs, clients, contact information, employee information, etc. This is a good opportunity for the laboratory manager and IT team members to work together and correct errors or purge incorrect or obsolete static data.

Instrument integration

When implementing a new LIMS, one of the biggest time savings and quality improvements results from instrument integration. Importing data electronically rather than manually eliminates transcription errors, and data can come straight from the instrument in many output formats, i.e. .XLS, .CSV, .TXT, XML, etc. Because the output from instruments can vary greatly, each instrument output file requires configuration. ATL team members work with the client to document integration requirements with respect to naming convention, output file formats and integration configuration, along with any automated or scheduled imports following data review.

Reporting needs & EDDs (Electronic Data Deliverables)

One major benefit of ATL's LIMS is ease of reporting. In addition to several canned reports that come standard with the system, users have the ability to modify canned reports as well as add their own custom reports. Several canned EDDs in multiple output formats (i.e. XML and XLS) are included, and users can create additional EDDs as desired.

ATL offers courses on Report Writing to train users on best practices as well as how to create additional types. Visit our website to learn more.

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HISTORICAL AND STATIC DATABASE/FILE LOCATIONS

INSTRUMENT INTEGRATION REQUIREMENTS

PREFERRED EDD FORMATS

CORE SYSTEM FEATURES: REQUIREMENT SPECIFICATIONS

Third party software integration (SAP, SCADA, etc.)

If there is a need to share data with other enterprise systems, integration should be discussed in terms of what data is needed from which system. *For example, does LIMS data need to be exported to an ERP system or SAP or does data from another enterprise system need to be imported into the LIMS?*

Next, users must determine the frequency of data transfer, and whether it will be uni- or bi-directional.

Another consideration is whether data imported is validated or requires users to validate and approve upon import. ATL's LIMS products allow users to configure the system to import or export data at configurable times such as hourly, daily, etc. Other options for integration include metrology data, i.e. incubators, refrigerators, autoclaves, freezers, and other types of environmental and instrument measurements.

Define configuration and customizations

System configurations differ from customizations in that they do not involve any programming, i.e. data grid configuration, custom form or field captioning, and altering screen colors. Customizations are usually a competitive advantage of enterprise LIMS solutions because most businesses have unique features or proprietary processes that are not available in a commercial off the shelf (COTS) LIMS. Customizations are typically limited to less than 10% of the system, because most common features are already included.

The first step is to complete the ATL Customization Request Form, which is a non-technical form used to document and define needed requirements. The ATL technical team uses this document to create the Functional Requirements Specification (FRS), which serves as a blueprint for the engineer who will develop the new feature.

Because ATL is an ISO certified firm, our quality assurance team must verify any customization. After the customization passes verification testing, it is documented and delivered to the client. Customizations are typically addressed in further detail following initial system configuration: static table data must be configured first to provide the subject matter expert with information needed to complete the requirements document. *For example, if instrument integration is going to be performed, it will be critical to have all static table data configured so that the requirements document can indicate to which field the instrument data will be imported.*

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THIRD PARTY INTEGRATION NEEDS

FREQUENCY OF DATA TRANSFER

CORE SYSTEM FEATURES: CONFIGURATION

Populate static table data and confirm install

The first major step in the configuration phase is populating static table data. This will serve as the foundation for all future configuration steps, from creating functional requirement specifications (FRSs) for instrument integration to reporting. This frequently involves extracting data from a historical LIMS or Excel sheets, or even a paper-based system. This is an excellent time for the laboratory team to clean up data such as test names, customer contacts, and other static table data information.

It is also important to ensure that a back-up and recovery system is in place and the system has been tested before the LIMS is put into production.

The second step, more of a system administrator task, is to ensure that installation was properly executed on a dedicated, secure server with adequate processing power, network connectivity, bandwidth and hard disk space — particularly if historical data will be imported. In addition, the latest service packs of the database engine (SQL Server or Oracle) and LIMS software must also have been applied.

Define custom captions

ATL's system allows the utilization of terminology meaningful to a laboratory's environment. This is accomplished by allowing re-captioning of the form and field names. *For example, if the laboratory calls a group of samples an Order, then the caption can be modified to reflect that.* The LIMS administrator has access and permissions to make caption changes.

Set up users and permissions

Often accomplished through creating groups, the project manager sets up users, and provides system access as well as permissions to sections within the LIMS. *For example, a bench chemist may be given privileges to enter and validate but not to approve data.*

Set up workflows

Generally straightforward, workflows should mimic how samples move through the various stages in the laboratory. A typical flow may be sample login to preparation (if required) to analysis to QC, reporting, and final disposition. Many laboratories have unique workflows for processing samples: by documenting the desired workflow, the ATL team can configure the LIMS to match the process.

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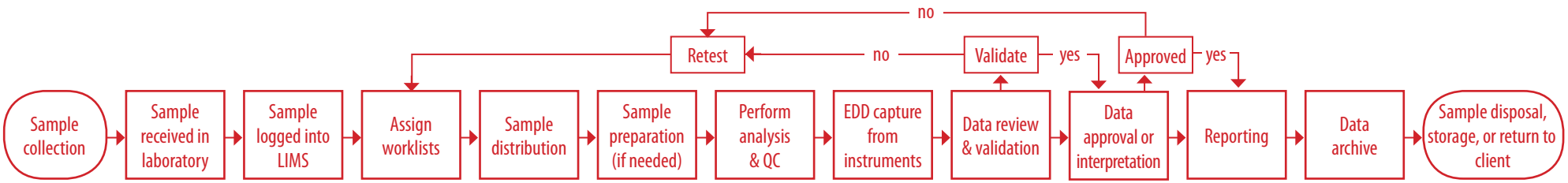
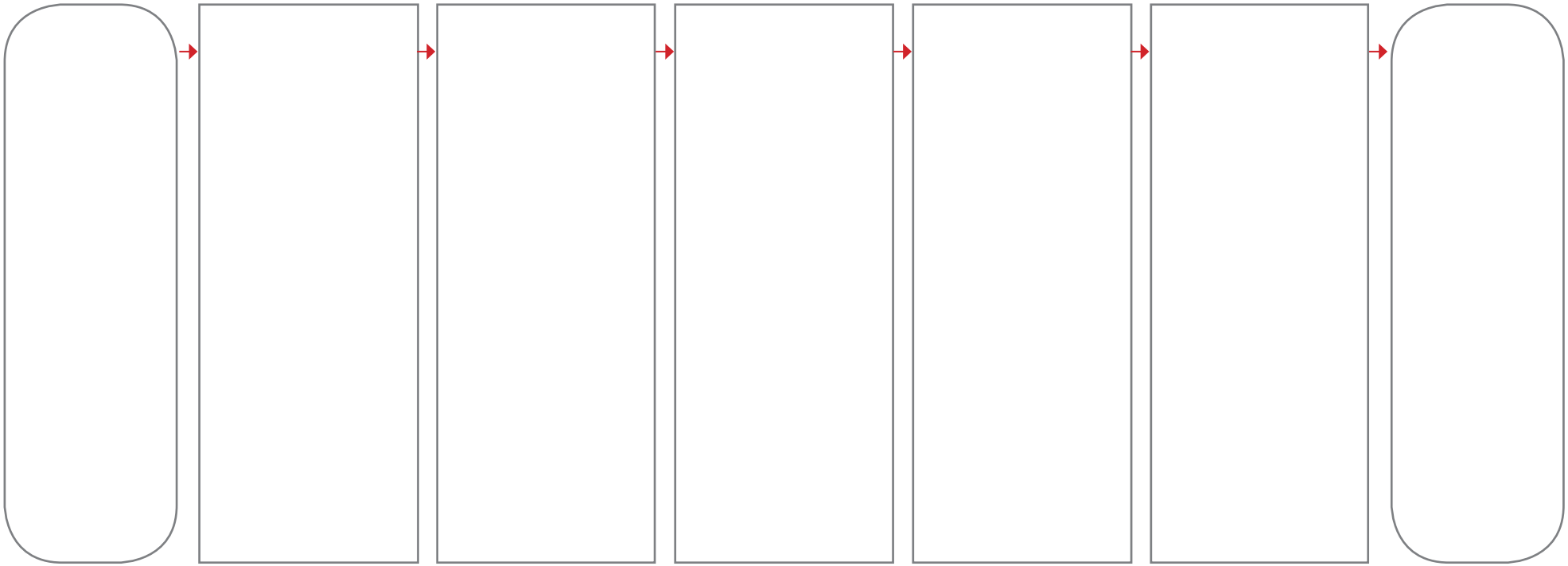
IDENTIFY HISTORICAL STATIC DATA SOURCES

USERS AND PERMISSIONS

CORE SYSTEM FEATURES: CONFIGURATION

In the space provided, create a typical workflow for your laboratory using the example as a guide to the required level of detail.
For the creation of additional workflows, please feel free to use additional paper.





CORE SYSTEM FEATURES: CONFIGURATION

Set up electronic signatures

Commonly in regulated environments, key steps in a workflow may require an e-signature (the logged-in user must enter username/password) for verification at a particular stage in the process.

Set up control limits

Control limits describe what a process is capable of producing, while tolerances and specifications describe how the product should perform to meet customer expectations. Control limits are horizontal lines drawn on a statistical process control chart, typically at a distance of +/- 3 standard deviations of the plotted statistic from the statistical mean, and can be set up to alert users when results are outside predefined limits. Some laboratories offer multiple methods for a single test, or different quality control limits for different methods.

Custom captions facilitate faster acceptance and utilization of a new LIMS, so it is important that these be discussed as a group in order to define captions that are accurate and meaningful.

Define calculations

This step typically involves reviewing current processes, determining what calculations are currently performed, and documenting them with exact formulas. This may or may not include any dilution factors that are used. The LIMS will perform a calculation, which should match the exact value from the previous system and the exact value obtained using a calculator. Often instruments will export the calculated value, and in these cases it is best to import the value from the instrument, as the instrument calculation has been validated by the instrument manufacturer.

""If everything seems under control, you're not going fast enough."
— Mario Andretti

NOTES

DEFINE CUSTOM CAPTIONS: DEFAULT VS. NEW

DEFINE CALCULATIONS

CORE SYSTEM FEATURES: CONFIGURATION

Confirm Functional Requirement Specifications (FRSs)

FRS is the final stage before a customization can be developed: typically they include custom reports, instrument integration, and new features or functions.

As an ISO certified firm, the steps ATL follows to create a customization are:

- The customer complete a Customization Request Form and sends it to ATL
- The ATL account manager reviews the request and enters it into the tracking system
- An ATL engineer provides a ballpark time/cost estimate, if the customization is not part of a proposal where cost has previously been determined, and provides the cost estimate to the customer
- If a PO is issued, along with a 50% deposit, the process moves forward and a formal FRS will be generated (if the customization is part of a proposal, this step is skipped)
- If for any reason the customer has changes to the FRS prior to going into development, the history file on the FRS is updated and approved
- If the requested change results in an increase/decrease in cost or time to complete, an updated quote is provided along with a new estimated delivery date for the customization
- Once the FRS is signed by the customer and returned to ATL it is sent to development and testing (QC), then prepared for delivery and installation
- Once delivered, the FRS is closed and if any additional changes are required, a new FRS is created

Note: the static tables in the LIMS must be populated before the FRSs or any workflows can be completed.

References:

Customization Request Form

EPA GALP (Good Automated Laboratory Practices)

NOTES

DEFINE FRSs

ATL ADVANTAGE PLAN: A ROADMAP TO SUCCESS

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ANALYSIS/ PLANNING

- Distribute Needs Assessment (NA) survey
- Conduct a Needs Assessment (NA)
- Analyze survey results
- Conduct workflow analysis
- Interviews team members
- Conduct laboratory tour
- Review NA results and report
- Final review of requirements

PLANNING TOOLS:
Checklists, Gantt chart, dashboard and survey*
** if Needs Assessment purchased*

SPECIFY CORE SYSTEM FEATURES

REQUIREMENT SPECIFICATIONS

- Review defined project scope
- Requirements list
- Historical data migration
- Static data migration
- Instrument integration
- Reporting needs and EDDs
- Third party software integration
- Define configuration & customizations

CONFIGURATION

- Populate static table data and confirm install
- Define custom captions
- Set up users and permissions
- Set up workflows
- Set up e-signatures
- Set up control limits
- Define calculations
- Confirm FRSs (Functional Requirement Specifications)

PLANNING TOOLS:
Template, Functional Requirement Specifications

IMPLEMENTATION

VERIFICATION TESTING

- Quality control checks
- Static data
- Check accuracy
- Check spelling
- Validate set up
- Workflows & e-signatures
- Calculations, limits & charting
- Reports, parsers & SOPs

TRAINING

- On-site training classroom
- On the job; one on one
- Web-based resource DVD
- Training manuals
- Video tutorials
- Quickstart Guide
- LIMS Boot Camp
- Parallel testing

PLANNING TOOLS:
Admin and end user training manuals, resource DVD

DEPLOYMENT "GO LIVE"

SUPPORT

- Live technical assistance
- Explanation of functionality
- Knowledgebase
- White papers
- FAQs
- User forum
- Electronically submit an incident
- Webinar schedule

UPGRADES

- New features and functions
- Regulated environment
- Re-validation required?
- New documentation
- Training on new features
- Training webinars
- Automation improvements
- Suggestions for new features

PLANNING TOOLS:
www.atlab.com > Support

IMPLEMENTATION: TESTING

Input and feedback during initial setup defines how the LIMS is configured, implemented and utilized to correspond with operational requirements and business policies.

Implementation is the realization or execution of a plan. One of the most time-intensive portions of LIMS implementation, testing requires verification for correctness of previously-imported test methods as well as a review of processes to ensure workflows are properly configured. In addition, customer projects are defined, plus collection schedules, QC limits, tests and reports are set up for each project.

System implementation benefits from high levels of user involvement and management support. If users are heavily involved in configuration, they leverage opportunities to mold the system according to operational priorities and business requirements, and they react more positively to the change process. Incorporating user knowledge and expertise leads to better solutions.

Despite reviews, some errors aren't caught until end-user training — but can be addressed prior to going live. Because LIMS support evolving laboratory operations, changes will also need to be made.

Quality Control checks

Quality Control checks are critical in successfully implementing an enterprise LIMS. Typically, many different groups or departments involve multiple individuals to verify static table data, calculations, and captioning for their individual sections.

Static data

Static data usually changes little over time, therefore the majority of information can be configured prior to deployment. *For a utility, this may be the list of sampling sites, tests, methods, etc. For a manufacturing firm, it may be a list of products, specifications, vendors, etc.*

One thing to consider: the way data appears in tables in the LIMS is typically the way it will appear on the final report to the customer, so it is important to enter test and site names consistently and as you wish them to read. It is also important to be consistent with naming conventions across the organization, i.e. if one group has test names in capital letters and another does not, and tests from both groups are requested by a single customer, the final report will not be consistent.

It is important that the LIMS administrator and a designated backup person are responsible for updating and maintaining static table data, and that there is a process in place to coordinate and track any changes made after system deployment.

NOTES

QUALITY CONTROL TEAM MEMBERS

IMPLEMENTATION: TESTING

Check accuracy

It is much easier to ensure static table data is accurate before it goes into the system. During this testing phase, users can become familiar with the application while checking dropdown lists and units to ensure all is complete and nothing duplicated. Often this is a cross check performed by another team.

Validate set up

In this exercise, each department runs typical samples through the system to verify configuration as well as downstream functions such as workflows, e-signatures, calculations, reports and instrument integration, along with any custom features or functions. Users continue to expand knowledge of the LIMS system while verifying that user access and permissions are properly defined and configured.

Workflows & e-signatures

Those that were previously configured should now be reviewed and verified to confirm proper operation, and that a change in the business has not required a change in workflow.

Calculations, limits, & charting options

Calculations should be set up in the LIMS, verified, executed, and the result recorded. Then the same calculation should be done on a calculator. This verification task of performing each calculation should be documented and saved. Once the calculation has been verified, it is locked so there is no need to re-check the calculation in the LIMS. The LIMS administrator (and their designated backup) should be the only one with permission to modify calculations in the system.

Reports, instrument parsers, customizations & SOPs

Anything integrated into the LIMS should go through verification testing to ensure accuracy before end user training begins. Some projects may have only a few reports and instruments to be integrated while others may have dozens. Time required to deploy the LIMS will vary based on the scope of each project.

NOTES

CHECKLIST

IMPLEMENTATION: TRAINING

On site classroom training is effective for providing an overview of the system as well as a basic understanding of the software. Popular with large groups of users, this format includes a question and answer session.

On the job training features an ATL expert who provides on site training right at the laboratory bench where users perform daily work. This one-on-one approach delivers a richer experience through immediate information from a valuable resource who can not only answer specific questions and address real world scenarios and issues, but who also efficiently reinforces and builds upon previous training.

Web-based or resource DVD-based training provides a convenient way to educate users and administrators who have limited time or are unable to attend on site or on the job training. ATL engineers have developed training videos that are comprehensive and accessible via the internet or DVD, plus ATL offers web-based training quarterly that covers standard topics or subjects that have been requested.

Manuals are always provided — in PDF and printed format — as a hard copy resource to provide specific explanations, often through screenshots and illustrations, of software features and functionality.

Video tutorials are provided for users who like to learn on their own time frame, and serve as an excellent supplement to other training tools.

Quickstart Guide is a laminated visual reference that provides tips and tricks to easily navigate the software.

Boot Camp is a series of in-depth courses that provide intense, concentrated hands on training on personal computer stations. Held near ATL's headquarters or at a location convenient for a client, these intermediate and advanced courses are conducted by certified training experts who utilize in-depth manuals, materials, and daily quizzes to ensure a solid grasp of the information presented.

Parallel testing should be done when a new LIMS is ready to replace an older version of a similar application. This is a technical way to ensure the software has been properly installed and configured, and is yielding outputs identical to the historical application. Also during parallel testing, calculations and all reporting functions should be checked and verified to ensure they contain proper results and limits, and yield the look and feel desired. Items to be checked for any errors include contact information, phone, email, and disclaimers.

"I hated every minute of training, but I said, 'Don't quit. Suffer now and live the rest of your life as a champion.'"
— Muhammad Ali

ATL ADVANTAGE PLAN: A ROADMAP TO SUCCESS

DEFINE PROJECT SCOPE

INITIATION

- Determine need for a LIMS and commit to project
- Assemble team
- Ensure resources are available
- Document needs
- Categorize needs
- Prioritize needs
- Complete risk analysis
- Budget and timing

ANALYSIS/ PLANNING

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UPGRADES

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PLANNING TOOLS:
www.atlab.com > Support

DEPLOYMENT: GO-LIVE

The goal of this phase is to ensure the business is truly ready to utilize the new LIMS. Focus is on preparing production and support systems, and completing cutover activities. Here are some best practices we recommend to ensure a smooth rollout:

"Ability is what you're capable of doing. Motivation determines what you do. Attitude determines how well you do it." — Lou Holtz

• Verify internal and external readiness: use a checklist to identify users, process owners and stakeholders, and cross check the processes for each business work stream against what was purchased (this can be the system requirements documentation).

After training, the project manager should seek signoff from key stakeholders that all users can manage and execute business processes, and that infrastructure stakeholders are ready to support the new LIMS with all necessary hardware, application and system administration support. Confirm that leadership is ready to manage the new LIMS.

• System performance testing in realization will minimize risk of major problems following go-live. Ensure that a dedicated server is available to host the application and that a test/development server are also configured to evaluate any software changes prior to putting into production. Create a checklist of each business process and anticipated transaction volume, and make sure that system performance is capable of handling peak volumes (as defined in the Needs Assessment). This includes performance tests for business processes involving third party software or corporate external systems that will involve interfacing with the LIMS.

• Cutover plan and go-live strategy approval should be completed and signed off by the project manager, as well as reviewed and approved by LIMS department managers. Cutover requirements were defined during needs assessment and include the handling of production issues, enhancements, etc.

• ATL Support Packages exist to provide clients with the tools that they need to be successful. These include live, toll-free technical support, white papers, product upgrades and enhancements, knowledgebase, programming and project management assistance along with a number of other features supplied through an ATL support plan.

NOTES

GO-LIVE CHECKLIST

DEPLOYMENT: SUPPORT

Live technical assistance ATL support engineers provide live help and are able to resolve most incidents the same day. In order to assist clients with cost control, ATL offers four tiers of technical support: Platinum, Gold, Silver, and Bronze. Our most popular package is Gold, and includes a dedicated account manager, free product upgrades, unlimited technical support, and access to a private support area with white papers, user forum, knowledgebase, FAQs, and more.

Explanation of functionality This is the most common call received by ATL's support team. Often a client's business will change and they will want to incorporate a new feature or use an existing feature in a new way, and want to understand how the software can accommodate this new challenge. ATL also provides comprehensive user manuals in hard copy and in electronic pdf form. In addition, ATL also offers video tutorials, and webcasts that cover the various features and functions in ATL's software.

Knowledgebase is a robust feature of ATL's support site that offers users a searchable database for information on the ATL products that our customers are utilizing. This repository allows for information on LIMS to be collected, organized, searched and shared.

White papers can also be found under the secure support site. These papers offer a resource for LIMS administrators who seek additional information on a specific topic.

Frequently Asked Questions (FAQs) are posted on the support site to allow users to research whether anyone has previously asked or inquired about the same topic.

User forum This is a place where all customers can go to share information with other users as well as ask questions of the user community.

Electronically submit an incident Users can electronically submit an incident on ATL's support site 24/7 for review and resolution.

Webinar schedule is posted on the support site, and includes past, current and future sessions, both training and user groups. Webinars are typically an hour long and cover key topics of interest. ATL also hosts user group meetings that feature a user and how he/she utilizes ATL's products, or a key feature, in their organization.

NOTES

DEPLOYMENT: UPGRADES

New features and functions resulting from updates in technology, business requirements and regulatory concerns are continually incorporated into ATL products. In addition, focus groups are periodically held to better understand customer needs and document potential improvements. Minor updates are made quarterly, and major updates are released annually.

Clients that operate in regulated environments are subject to a regulatory landscape that is constantly evolving. In response, ATL proactively ensures that the software constantly facilitates compliance through relationships with key partners, user group meetings and focus groups.

Re-validation is sometimes mandatory for customers that operate under GMP or strict regulatory compliance guidelines of CAP/CLIA. ATL has a comprehensive validation solution for proper execution and documentation.

New documentation is required as the software system evolves, and this documentation must be properly managed and organized. ATL's LIMS products offer a number of ways this can be achieved: it is important that evidence of validation is locked and securely stored, plus easily and quickly retrieved in case of audit.

Training on new features is a continuous process. As the LIMS evolves in the organization, there is an on-going need to retrain end-users and system administrators. This can be done informally on the job or in a classroom. Training forms provide evidence that training occurred, and this documentation should be stored in the system for easy retrieval.

Training webinars are offered live throughout the year for clients, and recorded for viewing at a later time. Webinars provide an excellent way to train new users as well as provide refreshers for existing users to ensure they are maximizing the features and functions.

Automation improvements An organization's improvements to the LIMS should be continuous in order for it to remain competitive as the technology and business worlds evolve.

Suggestion box for new features is a one way ATL solicits ongoing ideas from customers, particularly those who face new and unique data automation challenges daily. Input is welcome via the user forum, account managers or by email.

"A person who never made a mistake never tried anything new. "
— Albert Einstein

Sggested Reading:

Christine Paszko. 2007. Ten Keys to Successful LIMS Deployment, Laboratory Equipment: Software: pages 28-30.

GLOSSARY

Account Manager (Sales) the ATL person responsible for managing the relationship with a customer, including notifications about training events, trade shows, user meetings, and all additional benefits under the ATL support plan.

Comma-Separated Values (CSV) file stores tabular data (numbers and text) in plain-text form. The file is a sequence of characters, with no data that has to be interpreted instead, as binary numbers. This is a common instrument output format.

Electronic Data Deliverables (EDDs) a type of electronic report in which data is extracted from the LIMS database in a particular order or output format. Many state and federal agencies require that data be electronically submitted so that they can import the data into their databases.

Electronic Signature, or e-signature, is any electronic means that indicates that a person adopts the contents of an electronic message, or that the person who claims to have written a message is indeed the one who wrote it, and that the message received is indeed the one that was sent.

End-users are managers, chemists, QC officers, and other members of a laboratory operation who will utilize the LIMS. These individuals are assigned credentials that provide the appropriate level of permissions to perform their jobs.

Enterprise Resource Planning (ERP) software systems integrate internal and external management information across an entire organization, including finance/accounting, manufacturing, sales, service, customer relationship management, etc.

Extensible Markup Language (XML) is a markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable.

Gantt chart is a type of bar chart developed by Henry Gantt that illustrates a project schedule, including resources, tasks and estimated completion times.

Key Stakeholders a person, group, or organization with a direct or indirect stake in an organization because it can affect or be affected by the organization's actions, objectives, and policies.

Laboratory Information Management System (LIMS) a software-based laboratory and information management system that offers a set of key features and supports a modern laboratory's operations.

LIMS Administrator primary individual(s) responsible for maintenance and operation of the LIMS. Tasks typically include setting up new users, defining permissions and privileges, adding new tests, ensuring system backed-up, and creating or modifying reports.

Needs Assessment (gap analysis) systematic process for determining and addressing needs or "gaps" between current and desired conditions. The discrepancy between the two must be measured in order to identify the need, which can be a desire to improve current performance or correct a deficiency.

Project Dashboard is the "control panel" created and maintained by the ATL project or account manager to keep everyone up to date on project progress. All deliverables and tasks are listed and shaded: yellow (in progress), red (delayed) or green (completed). Routinely updated and distributed to the team.

Project Scope is work that needs to be accomplished in order to deliver or implement a product, service, or result with specified features and functions. Scope involves gathering information required to start a project, and the features the product needs to meet stakeholder requirements.

Project Manager (PM) a professional in the field of project management, responsible for the planning, execution and closing of any project.

Risk analysis a technique to identify and assess factors that may jeopardize success of a project; helps define preventive measures to reduce the probability of risk factors occurring and identify countermeasures to successfully mitigate constraints.

Return on Investment (ROI) is rate of return, also known as 'rate of profit' or sometimes just 'return', is the ratio of money gained or lost (whether realized or unrealized) on an investment relative to the amount of money invested.

Scope creep refers to the incremental expansion of project scope which may include or introduce additional requirements that weren't part of initial planning, while concurrently failing to adjust schedule (time to completion) and budget.

SOP (Standard Operating Procedure) a written document or instruction detailing all relevant steps and activities of a process or procedure; provides employees with a reference to common business practices, activities, or tasks.

Subject Matter Expert - the person who is an expert in a particular area or topic, i.e. laboratory informatics and automation.

.TXT refers to a computer file (sometimes spelled "textfile," an old alternate name is "flatfile") that is structured as a sequence of lines of electronic text. Some laboratory instruments export their data in this format.

Workflows consist of a sequence of concatenated (connected) steps. Emphasis is on the flow paradigm, where each step follows the precedent without delay or gap and ends just before the subsequent step may begin.

.XLS (Microsoft Excel) an electronic output format that is a common instrument export format used in the laboratory. Excel is a commercial spreadsheet application written and distributed by Microsoft for Windows and Mac OSX.