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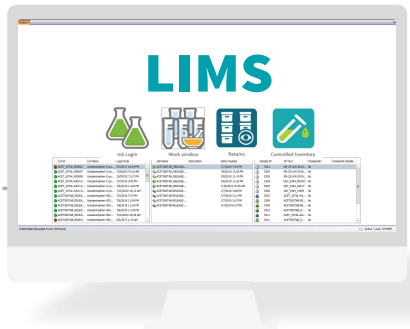
THE ULTIMATE 7 STEP GUIDE

TO SELECTING THE RIGHT LIMS FOR YOUR LAB



01 Choosing the Team

02 Business Process Mapping

03 Requirements Gathering

04 Requirement Traceability Matrix

05 Assimilation of Request for Prposals with Requirements

06 The Demonstration Script

07 Evaluation Criteria, Scoring & Selection of LIMS Vendor

The successful implementation of a LIMS system requires the step-by-step activities outlined below:

01 Choosing the LIMS Team

The composition of the LIMS Team is one of the most important parts of a successful LIMS Project. This Team will be responsible for defining the requirements, assisting with the development of the process maps, and ultimately designing the operation of the new LIMS-based laboratory.

The LIMS Team should consist of:

- Users (Analysts, Supervisors, and Managers)
- Customers (Internal and/or External)
- Support Personnel

02 Business Process Mapping (Laboratory Processes)

Sample management is the basis for all laboratory workflow processes. The laboratory should be mapped on the current sample management processes. Based on discussions with personnel during the process mapping, the requirements for the LIMS system should be recorded at the appropriate steps in the workflow. These will define the "to-be" business workflows and the requirements.

03 Requirements Gathering

Example of Requirements

To-Be Diagram Reference	Functional Area	Requirement
Not Applicable	Admin	Have system maintenance capabilities
		Allow the administrator to add users
		Allow the administrator to change passwords
		Allow the administrator to disable user accounts
		Allow the administrator to define and manage/update roles and security levels
		Allow the administrator all code lists including code lists that support automation based on business rules
		Allow the administrator to restrict users from designated functionality or modules
		Allow users to have remote access - via Tablet/iPad/Windows
		Have data archive and restore capabilities
6.0 Series	Analyses	Have the ability to create templates that facilitate the creation of common analytical configurations, including:
		-Analysis Name
		-Analytes
		-Department (Lab,Ops, BioOps, Pretreatment)
		-Method
		-Matrix
		-Units
		-Limit of Detection (LOD)
		-Limit of Quantitation (LOQ)
		-Indication of whether result is reportable or non-reportable
		-Calculations associated with analysis
		-Comments
		Allow for multiple analytes to be reported for each analysis
		Record analysis template information required by Quality Assurance/Quality Control protocols, regulatory agencies, and accrediting programs, including:
		-The TNI 2016 Standards

User Requirements (URS): The URS are the requirements gathered from the cross section of the laboratory for the business process mapping. These requirements should be developed based on the work flows. These are the requirements from the users and IT for their system. The user requirements should be gathered from onsite meetings and scheduled meetings with the designated LIMS team.

Functional Requirements (FRS): The FRS are the required functions of the system needed in order to meet the user process requirements. All of the functional requirements should be derived from the user manuals and business workflow processes currently in place. These will include instrument integration and interfaces with other systems.

04 **Requirement/Traceability Matrix (RTM):** The Requirement/Traceability Matrix is a summary of all the user and functional requirements. The matrix serves as a guide for the project manager on all requirements and is the basis for the project plan.

Selection Process

05 **Request for Proposal (RFP):** The RFP technical contract should be based on the FRS and URS identified. The RFP should include timeline for the selection, dates in the process, selection/grading criteria, the requirements, and the workflows. The laboratory will add any additional requirements to the proposal (i.e. contract, insurance, and purchasing requirements). It is key that the laboratory define the LIMS budget for the LIMS and implementation.

06 **Demonstration Script:** The demonstration script should be created utilizing laboratory and reporting requirements. In addition, the vendors should be required to show how they configured the items to demonstrate ease of use. The script should be designed for a 4 to 6 hour demonstration allowing time for questions. The vendors chosen from the initial evaluation, based on cost and meeting the RFP requirements, should be sent the demo script 14 days prior to their demo date. Timing of the demos should be monitored to ensure a fair representation from all vendors chosen for the second evaluation.

07 **Evaluation Criteria and Scoring:** There are three facets of the evaluation process.

- Meeting the RFP Requirements
- Cost
- Demonstration

The LIMS Team will utilize the demo script and evaluate the vendors chosen in the initial evaluation. Once the evaluation is complete, the team will summarize the results and present all data to the laboratory. The laboratory will be able to make an objective data driven decision and select the vendor/LIMS.

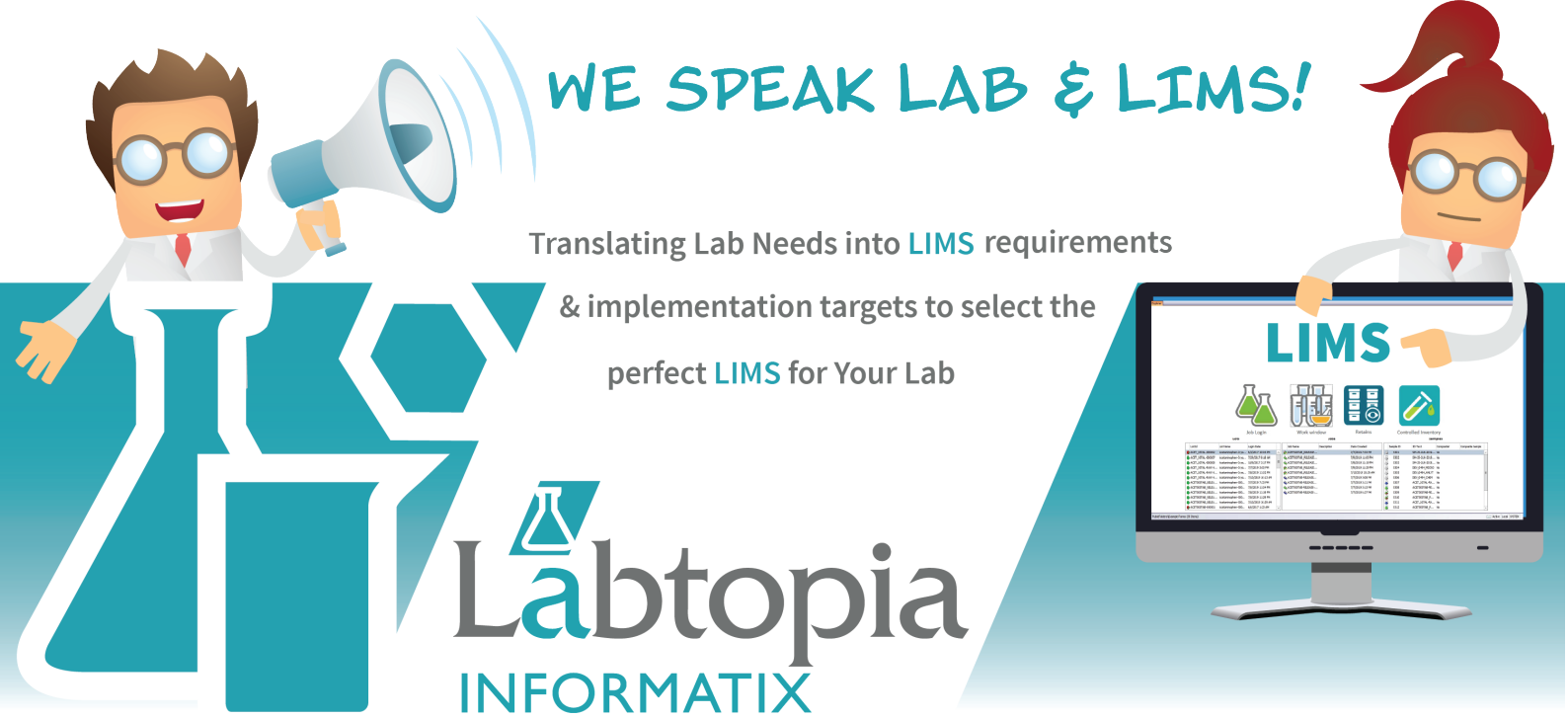
Vender Selection:

The selected vendor should be notified by email and phone. All other vendors should be sent an email thanking them for their time and effort in the selection process.

PROJECT DELIVERABLES

The deliverables described below are listed in the order in which they must occur.

- **Business Process Flowcharts ("as-is" and "to-be")**
- **User and Functional Requirements (URS/FRS)**
- **Creation and Submission of RFP to List of Vendors**
- **Initial Evaluation of Vendor Response (Evaluation 1 – Cost/Requirements)**
- **Creation of Demo Script**
- **Creation of Evaluation Criteria for the LIMS Team**
- **Submission of Demo Script to Top Vendors (Vendors from Evaluation 1)**
- **Management and Evaluation of Demonstrations based on the Demo Script**
- **Scoring for Team Review**
- **Compilation of all Evaluation Data and Costs**
- **Notification of Selected Vendor**



Need help selecting the right LIMS for your Lab?

Let Labtopia help translate your Lab's needs into
LIMS requirements & implementation targets
to select the perfect LIMS for your Lab!

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