

All-In-One LIMS with a difference



Qualis  
LIMS



Comprehensive LIMS for QC/QA & Anal R&D

Multi-site, multi-section

Caters to any Laboratory

Complete Specifications Management

Raw, In-process, Finished & Environmental samples

Barcode labeling of samples

Job allocation for analysts and Instruments

Electronic TDS based Results Entry

Interfacing of PC-based & non-PC based instruments

OOS & OOT Investigations, Training records,

Deviations recording, Document management

Audit trail & 21CFR Part 11 Compliance

COA and MIS reports

## Designed for QA/QC

QualIS® is designed for use in any industrial analytical Laboratory and commercial labs testing such samples. QualIS helps in streamlining the process with respect to laboratory investigations starting from tests and specifications management, ordering of tests, registration of samples, job allocation, results entry, approval, report generation, OOS, deviations recording and document management

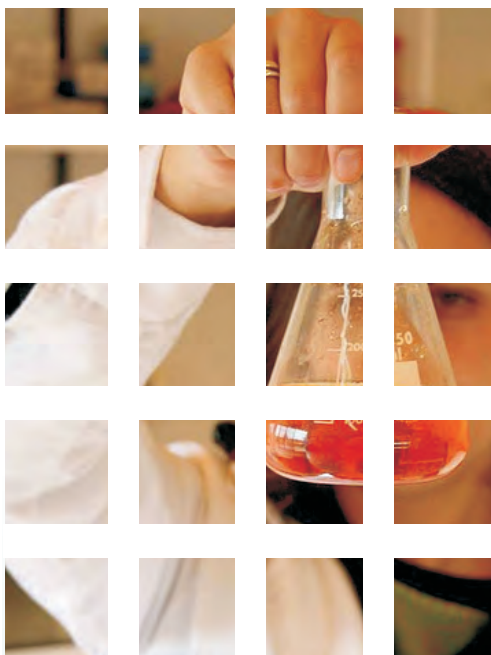
## Quick and easy access through browser

The system is fully scalable flexible multi tiered enterprise system designed to streamline the laboratory business process from sample receipt to final report and beyond. QualIS was built from ground up as a web based system architecture with little or no legacy behind it.

## Tests and Specifications Management

Test masters with relevant attributes and switches can be maintained based on test category and sections that will handle tests. Tests can have one or multiple parameters. Parameters can be numeric, character, pre-defined values, attachments etc. Tests can be linked to instruments, rounding rules, analysis techniques which is in turn linked to personnel and their training records.

Specifications can be managed for multiple material with several layers for quick access and easy maintenance. Material > Group > Sub-Group > Profile > Specification version > Tests > Parameters > Limits. Specification document can be uploaded for each of the specs and at the same time material required for performing tests can be linked to specs.



## Sample registration & Test ordering

Samples [Raw material, In-process & Finished product] received are pre-registered with a unique sample number or ARNumber [Analytical Request Number] with appropriate batch#, lot# and AR Number and sent to respective testing sections like RM, FP& Micro. It is possible to perform complete specification based testing by selecting the appropriate profile and specification [USP, BP, IP] for each sample. Testing priorities can also be set for samples.

## Bar Code Labeling

QualIS supports barcode label generation. Labels will be generated after completion of registration. Barcode labels can be used to quickly identify result records, jobs etc within the system and chain of custody can be recorded very easily.

## Job Allocation

Job allocation module enables allocation of tests, instruments and personnel for samples. The section head can allocate analyst to perform a specific test. More than one person can be allocated per test with split jobs.

Jobs can be scheduled based on calendar days, the scheduler will display already allocated samples/tests for a specific analyst and workload of each instrument in the lab. Job allocation is linked to personnel training records and certified persons can be allocated for jobs.

Section heads can have total control over the instrument usage and jobs allocated to personnel. A graphical chart showing the amount of workload given to personnel gives a very clear picture of the lab and workload. Re-scheduling of jobs are also possible.





# QualIS<sup>®</sup> Integrated LIMS



## Electronic Test Data

### Sheets

Typically QC perform very complex tasks while performing a test and each of the steps involving the preparation, analysis of standards and the sample are normally recorded in lab notebooks or controlled sheets.

Normally LIMS systems record only the final results of such tests and notebook data are maintained as paper records. With QualIS it is possible to design templates of test data sheets [WYSIWYG] and also perform complex calculations similar to excel and release such sheets for analysis data capture.

## Manual or Instrument

### Data Capture

It is possible to manually enter data in the electronic test data sheets while calculations are getting done in real time. It is also possible to interface any analytical instrument with the electronic test data sheets. Users can interface any analytical Instrument without having to perform any coding or vendor dependency.

## Result Entry, Raw Data, Traceability

Results entry module allows users to enter results for tests based on Sample No. and Test. Final results along with Instruments used with ID, usage time, their calibration status



while recording results can be linked while at the same time raw data and reports can be attached for each test, also working standards used with batch#, reagents, volumetric solutions used with their respective expiry dates can be recorded to maintain complete traceability of results. While every re-test, re-entry of results are also maintained as history with reason for changes are recorded. This system of recording of all relevant details with respect to a specific sample, test leads to complete traceability of results from a single point and at the same time enables regulated labs to face audits much more efficiently.

## Approval

QualIS approval workflow steps can be configured to achieve multiple levels of approvals and actions to be performed on such approvals. First level of approval after results entry completion is done by a "Checker" who can check all the results, calculations, raw-data etc the checker can mark samples and tests as "checked". The checker can even recommend re-test/re-calculation to the next level. After checker the sample moved to a "Verifier" typically a section head who can verify all the data and if necessary can order for a re-test or re-calculation. The sample moves through the department head and QA where the final release/reject disposition is made.

## Reports

QualIS has been designed to quickly launch such reports from a dedicated reporting module. The reporting module is quite powerful, based on the nature of the report the query type can be dynamically varied. Like to create a COA for an already released material can be done by simply typing the Sample No. or by searching through the database based on dates and material released during those dates and also by number.

The reporting tool is quite useful in generating logs like instrument usage logs, column usage logs, training and certification competency cross tab reports. Several MIS reports are also generated to help manage the lab.



## OOS Investigations

The moment a result is published by an analyst it is a OOS, immediately an OOS # is generated with details such as Sample No. test failed etc. OOS investigation module allows the user with appropriate role to take actions on OOS Sample No. OOS alerts can be triggered with unique OOS number for the results entered and are printed. Time frame can be fixed by the section head for each OOS. OOS investigations can be categorized for both chemical and micro with their respective work flows.

## Material Inventory

### Management

Material inventory management module manages the complete inventory of the laboratory. A material category master helps in creating masters for all types of standards [reference standards, working standards, outside party standards], volumetric solutions, reagents, chemicals, glassware etc along with the details such as Ref.Std No, Batch#, Lot#, Qty, Unit, Expiry date, Storage condition, Purity, ROL, Open expiry days etc.

## Standards and Volumetric Solutions

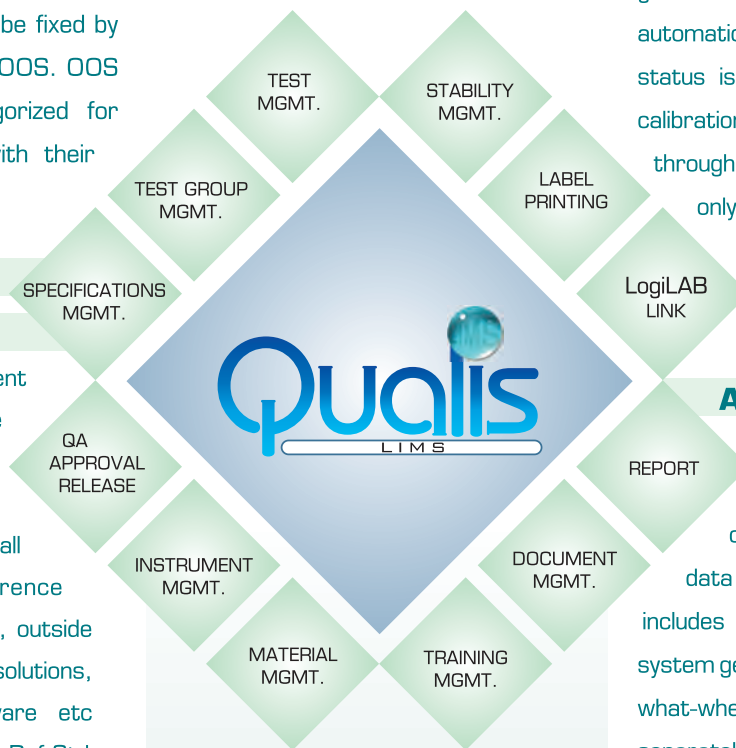
Standard details such as purity on "as is basis" and dry basis is captured which can be reflected for calculations for tests. Volumetric solution details such as molarity factor are maintained along with re-standardization history.



## Materials requiring

### validation

Materials such as microbiology media, kits can be entered in the inventory with a re-validation date. This means these material need to be tested and released and only upon release these material will be made available for analysts to consume for normal tests.



## Training Record

### Management

Training records module allows scheduling of trainings, invite participants and record each participants training records. Training can be linked to analytical technique which in turn is linked with instrument category. This means whenever a person is trained on a specific subject the training can be linked to a specific technique and individuals can be marked as "Competent" and "Certified". Only competent persons can be allocated jobs to perform certain activity related to a technique. All training record documents can be uploaded for each individual and can be made available at any time.

## Instrument & Equip

### Management

Instrument management module manages all the instruments and equipment available across the lab. A scheduler is available for calibration and maintenance of instruments. The scheduler provides alerts and also generates calibration samples automatically. Also the instrument status is maintained. Each and every calibration is recorded and will go through normal workflow for approval, only approved or calibration passed instruments will be allowed for allocation.

## Audit Trail

Audit trail module records every action that involves creation, deletion, editing of data within the LIMS system. This includes recording user actions and system generated audit trails of who-did-what-when-and-why. A log is maintained separately for system generated entries and user generated entries.

## Change control

### Management

Change control management allows recording of changes that need to be done on procedures and policies. Unique id's are maintained for each requests and are approved by QA/QC.



## Deviations Recording

Deviations recording module allows recording of any deviation from normal procedure that was planned or unplanned with unique ID. Deviations can be categorized as major or minor with time periods and CAPA records can be maintained and approved by QA/QC.

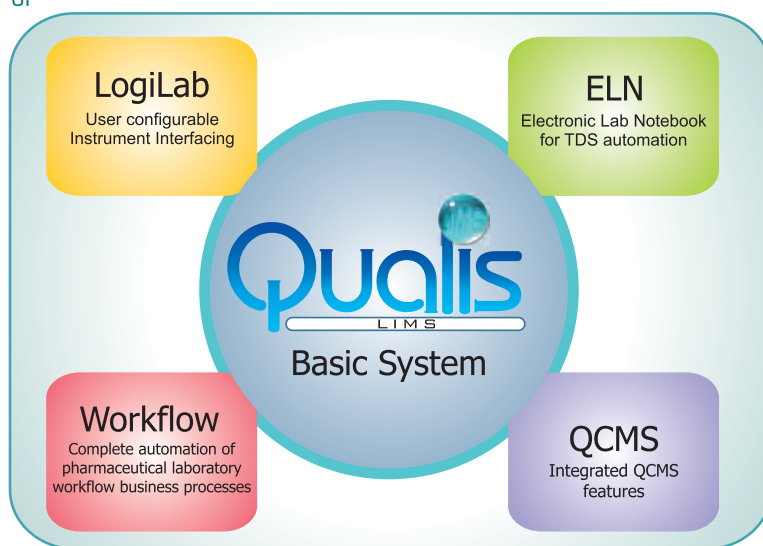
## Document Management

Document management module allows management of various categories of documents with versioning and release capabilities. Documents can be uploaded, categorized with version control, description & unique ID with release workflow control and controlled access.

A powerful audit trailing module records any action that creates, edits, deletes records and a complete result history is maintained. Even the electronic test data sheet has a complete version control on a cell-to-cell basis this Feature gives any auditor complete confidence in the lab that is using the system, as the entire process is transparent to any auditor. Prove to your auditors that your data is authentic and cannot be tampered by anyone.

## Instrument Interfacing

Even today instrument interfacing is considered as a myth within the LIMS users world, the reason being every LIMS vendor will promise instrument interfacing but how? By writing custom scripts? If that is what you are imagining well you are looking at something old and here is our next generation interfacing solution which even end-users can interface any new instrument at any point and time without the help of the LIMS expert!



## SDMS / ECM

A comprehensive LIMS should also have raw and meta data management capability. Qualis SDMS module has a powerful scheduler for file capturing along with tagging of such files with respect to the samples for which those files were generated, this is one of the biggest pitfalls of traditional SDMS systems which merely capture and archive data without any relationship to the actual processes within the lab.

## 21 CFR Part 11

### Compliance

Qualis has built in user management module that comprises roles and rights management. The roles and rights is quite deep which allows control of each and every control within a application form. The system has necessary policy management with respect to users, passwords.

## Electronic Lab Note Book

Built-in electronic lab notebook brings the difference within the LIMS. So far ELNs have been used only as standalone systems and that too only for research purpose. Qualis built-in ELN gives the lab the power to design their own data capture sheets in a powerful and easy to use spreadsheet front end. Also creating formula and calculations is a breeze.

Qualis SDMS module also has a very innovative solution called as "CFRGateWay". This solution addresses the 21 CFR Part 11 gaps with respect to software used by laboratories that are not having features to comply with the regulation.





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