LIMS | R&D
QMS | ERP

Custom Designed Quality Management Platform for Industries

Integration with SAP/ERP and Lab Instruments

Software Solutions to Drive Productivity and Compliance in Lab

Oasis Infotech

Empowering Laboratories through Automation

VISION

To provide prompt, consistent, reliable and cost-effective quality services to various sectors worldwide, maintaining confidentiality and integrity

Oasis Infotech is a leading application software company, with many industry specific products under its flagship.

Oasis Infotech has been instrumental in developing a wide range of software products to computerize the whole range of manufacturing, analytical and other activities.

Oasis Infotech has been pioneer in Laboratory Information Management System and was the first to introduce LIMS concept in India in the year 1988.

It has successfully undertaken various assignments of software development, implementation and consultation for various industries including many multinationals in India and abroad.

Verticals / Industries / Segments

- Pharmaceutical industry
- Chemicals industry
- Bulk drugs industry
- Consumer health care units
- Cosmetics industry
- Contract research organizations
- R&D laboratories
- Commercial testing laboratories
- QA, QC laboratories
- Textile industry
- Petrochemicals industry
- Food testing, environmental laboratories

- MNCs, SMEs
- Large scale companies
- Govt. of India Drugs Testing Laboratory
- Public Sector Undertakings (PSUs)

Strengths

- The right software solution for automation of analytical, R&D, QA, QC, manufacturing and other activities
- Industry specific software solutions
- Business ready software solutions with Regulatory Compliance
- Cost effective solutions vis-a-vis any other company providing such solutions
- Proven capabilities and commitment for on-going services, future support
- Over 100 implementations in LIMS space, largest clientele in this segment
- Highly reliable, consistent services
- 100% success rate of implementation
- Implementations keeping in view the regulations as well as the practices
- Strong team of QA, QC experts and IT experts: backing for last over 20 years
- Backed with 35 years pharma industry experience and knowledge

Technology Partners

Oasis has formed technology partnerships with premier hardware platform, software, and service organizations to optimise the value of its LIMS solutions and improve its customer's productivity and efficiency.

SAP AG, Integration Partner

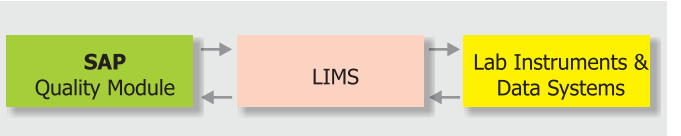
OasisLIMS® is certified for Integration with SAP PI 7.1 NW-XI-CNT 7.1 "Powered by Net Weaver"

SAP Certified Integration
POWERED BY SAP NetWeaver

Intel, Software partner

Intel® Software Partner Program provides a framework for collaborative solutions development around Intel architecture.

intel Software Partner



Integration setup : LIMS, SAP/ERP & Instruments

Creating new dimensions in Automation, with Software Services

Software solutions range

Laboratory Information Management System (LIMS)

OasisLIMS® Professional
- For small enterprises
- MS Access based, limited edition

OasisLIMS® EL
- Enterprise version for medium scale enterprises
- MS SQL server, client server based

OasisLIMS® Web based
- For large enterprises, multi plants roll out
- For compliance with US FDA 21 CFR Part 11
- Integrated with SAP ECC 6.0/7.0 and above
- Built on ASP.Net with the option of MS SQL Server/Oracle database, central server deployment, scale-able up to 250 users

LIMZ-RD™
- For R&D centers/labs, for automation of R&D activities in pharma research specially in FD division and ADL (analytical development lab)
- Web based, built on ASP.Net with the option of MS SQL Server/Oracle Database, central server deployment, scale-able up to 250 users

EnviroLIMS EWM
- For environment, water monitoring

True-LIMZ CTL™
- For commercial/public testing laboratory
- MS Access client server based (with integrated billing)

Optional modules with LIMS
- Trend analysis
- Vendor rating
- Stability studies management
- Equipment calibration management
- Reference and working standards management
- Control/reserve samples management
- Training records management
- Chemicals, glassware inventory management
- Microbial Media management
- Column management
- Quality cost analysis
- Market complaints management
- Projects management
- Formulation development trials management/recipe management
- Dissolution profiling
- Analyst qualification
- Analytical method validation

Other software packages

Stabi-M™
- For large enterprises, multi plants
- For stability studies management and compliance with US FDA 21 CFR Part 11
- Integrated with SAP ECC 6.0/7.0 and above
- Built on ASP.Net with the option of MS SQL Server/Oracle database, central server deployment, scale-able up to 70 users

CrisCon® ERP (Enterprise Resource Planning)
- Pharma ERP - Enterprise version: Specially designed to automate various activities of manufacturing units

Oasis-QMS (Integrated Quality Management System)
- Deviation Management, Change Control Management, Lab Incident Management, CAPA – Corrective and Preventive Action), OOS (out of specifications), OOT (out of trend), Auditing management

Oasis-eBMR (Electronic Batch Manufacturing Records)
- Software for batch records maintenance with BMR issuance and electronic instructions

Oasis APQR
- Annual Product Quality Review and records of batches produced

Oasis EMS
- Equipment Management system for calibration and maintenance

O-LINK™
- Equipment connectivity, to efficiently transfer analytical data between instruments and OasisLIMS

Software services
- Interfacing of equipment with LIMS using Olink
- Interfacing of ERP with LIMS
- Interfacing of LIMS with SAP
- Software validation services
- LIMS consulting and implementation services

Custom designed software services

Web based/client-server custom designed software development (System analysis, design, development, testing, implementation, Go Live) on all platforms with expertise in a variety of frameworks and programming languages

OasisLIMS®

The most comprehensive LIMS software that helps you comply with Schedule L-1 of Drugs and Cosmetics Rules (GLP), US FDA 21 CFR Part 11 norms, PIC/S and EU Annexure 11 guidelines

- OasisLIMS®
- OasisLIMS® EL
- OasisLIMS® Web based

OasisLIMS®

- Covers about 70% of the activities/requirements laid down in GLP; remaining about 30% requirements are relating to premises, infrastructure, manual working etc.
- Documentation - better organized and maintained, always up-to-date for auditing/inspections
- Regularly updated: with amendments in pharma-copoeias/D&C Act and the Rules/in-house
- Customizable, flexible and functionally rich, ready to accommodate any type of requirement, as per your needs

OasisLIMS® saves

- Cost in QA, QC operations
- Valuable man-hours of technical staff
- Time spent on calculations
- Time spent in writing and checking reports

The time saved – utilized for other important/productive tasks in the lab

Key features

Test Methods/Calculations

- Automatic on-line calculations for more than 175 test methods as per IP/BP/USP/in-house including titrations, dissolution, weight variation, content uniformity, UV, GC/HPLC etc.
- Eliminates possibilities of calculation mistakes
- No time is consumed in calculations: saves significant time of chemists
- Pre-defined values for dilutions, titration factors, wavelengths, other constants
- No need to define external formula for calculations
- One test method can be used for 'n' no. of products
- No need to maintain notebooks for calculations
- Validated test methods, no-need to verify/check results
- Validity checks at all possible levels

Specification Maintenance

- Specifications for raw materials / packing materials / intermediates/bulk/finished products easily maintained, with facility of revisions history
- No need to refer to specifications repeatedly at the time of analysis
- Facility to maintain SOPs, STPs, calibration procedures, with revision history

Sample login/Registration

- On GRN/production intimation, sample login takes place in the software with minimum parameters
- Allows many types of logins such as normal sample, retest, pre-shipment/pre-purchase, OOS, R&D etc.
- Automatic, unique AR No. (analytical report number) generation for different categories of samples
- Facility to enter sampling plan for every product/material
- Sampling details and sampling observation entry
- Option of partial/reduced analysis
- Tests automatically allocated to the sample

Work sheets/protocol sheets

- Automatic generation of worksheets dynamically, for raw materials/packing materials/intermediates/bulk/finished products, indicating all the tests to be performed as per pharmacopoeia (IP/BP/USP etc. and/or in-house specifications)
- User defined formats for entry of readings/observations, as per drugs and cosmetic act and the rules
- Work sheet may also incorporate method of analysis
- Calculation sheet (raw data sheet) automatically generated

Generation of CoA - Certificate of Analysis

- Printing as per pharmacopoeial, regulatory requirements
- Integrity pre-established; no need to check individual report
- Automatic cross verification of results with the specification limits
- Automatic decision of approval/conformance or rejection/non-conformance of sample
- Opinion includes rejection parameters/tests also
- System itself is designed to take decision independently
- Eliminates possibility of biased opinion
- Saves lot of time of senior chemists, senior chemists can focus on value added tasks

MIS and other reports

- Work sheet, CoA, Specifications, SOPs, STPs
- Sampling sheet, Sample register (category wise), Rejection register
- Labels (under test, approved, rejected, sampled, quarantined etc.)
- QC productivity report
- Analyst performance report
- Samples pending for sampling
- Samples pending for analysis
- Samples pending for entry of readings/observations
- COA pending for review
- COA pending for printing
- Lab performance report on various parameters
- Sample approval status
- Samples for retest
- Products (control samples) for destruction

Interactive Dash Boards/
Key Performance Indicators (KPIs)

OasisLIMS has dashboard capabilities to address many challenges managers face, a powerful business tool that optimizes decision making by turning LIMS valuable data into graphical information.

Sample-life-cycle at a glance: Manual vs. Software mode

Sample-life-cycle-activity	Manual working in Lab	Automation of activities after deploying OasisLIMS
Sample registration (on sample receipt)	Details entered manually in sample register	Sample login/registered from SAP-ERP
In-process samples scheduling	Manual (hourly, twice a day, once a shift etc.)	Automatic login in OasisLIMS through in-built sample scheduler
Preparation of under test labels, sampled labels	Manually prepared using Word processor etc.	Automatic generation of labels with bar code
Analysis work allocation	Manual	By OasisLIMS to an analyst qualified to conduct test(s), based on work load
Referring test procedures/MOA	Manual	Available on-line
Analysis of sample	By analyst	By analyst
Recording test readings/observations at the time of analysis	Entered in note books	Entered in work-sheet generated by OasisLIMS
Recording test results during analysis	Entered in note books	Captured automatically from instruments through instrument interfacing
Data entry from filled work sheet	—	Test readings/observations entry in OasisLIMS
Calculation of results	Manual	Built-in automatic on-line calculations; Built-in excel interface for user defined calculations
Comparison of results with standard specifications	By analyst	Automatic cross checking with the standards, limits
Decision about sample disposition	By analyst	Automatic decision about conformance or non-conformance
Preparation of Certificate of analysis	Prepared using Word processor etc.	Automatically prepared and printed by OasisLIMS
Checking of CoA	By senior analyst for completeness and correctness of CoA	Integrity of OasisLIMS pre-established, no need to check individual CoA
Re-checking and signing/authorization of CoA	By manager after ensuring completeness and correctness of CoA	On-line review with electronic signatures
Preparation of approved/rejected/under hold labels	Prepared using Word processor etc.	Automatic generation with bar code
Recording of final result and CoA details in sample register	Manual	Automatically generated by OasisLIMS
Documentation	Manual, prepared using Word processor etc.	Better organized and maintained, always up-to-date for auditing/inspections
Preparing status reports, data trending reports etc.	Manual or by using excel etc.	Dashboards, MIS tools and data trends automatically available

LIMZ-RD™

For R&D centers/labs, for automation of R&D activities in pharma research specially in FD division (formulation development) and ADL (analytical development lab)

Web based, built on ASP.Net with the option of MS SQL Server/Oracle Database, central server deployment, scale-able up to 250 users

LIMZ-RD enables collaborative research efforts across far-ranging in-depth R&D activities such as

- Projects Management
- Dynamic Recipe management/formulation development
- Inventory Control and recording of trial batches
- Sample Lifecycle Execution/Samples Management
- Stability Studies management as per ICH guidelines
- Dissolution Profiling with similarity factor/comparison
- Analytical Method validation (linearity, robustness, precision, specificity, ruggedness etc.)

EnviroLIMS EWM

For environment, water monitoring

Web based, built on ASP.Net (also available in VB 6.0 Client/Server for small/mid enterprises)

Superior data trending features, graphical and tabular representation of resultant data and behavioral trend of a particular sample point in an area/site over a period of time

OOS (out of specifications) investigation

Alerts and reminders for due tasks such as pending for sampling

Entry of readings/observations or test results from the filled work sheet for each sampling point, limits appear online

Environment Monitoring

• Environment monitoring of manufacturing premises, warehouses • Airborne particulate count • Settle plate exposure • Surface monitoring • Personnel monitoring

Provision to enter relevant parameters of analysis such as report date, compliance status, temperature, humidity, time of exposure, media details etc.

Water sample monitoring

• Analysis of water samples: process implementation through LIMS
• Sample points and sample pull schedules

True-LIMZ CTL™

For small/mid public testing labs engaged in sample processing of Pharma, Food, Water, Environment etc.

Built on VB 6.0 Client/Server, specifically designed

Besides Core LIMS functions, True-LIMZ has

• Integrated billing/FA modules for maintenance of customer groups, rate definitions, group product test rate, group test rate, test rates

• Preparation of invoices/bills • Payment receipts recording • Credit notes/debit notes • Statement of accounts • Party ledgers, outstanding reports, sales reports, accounts summaries etc

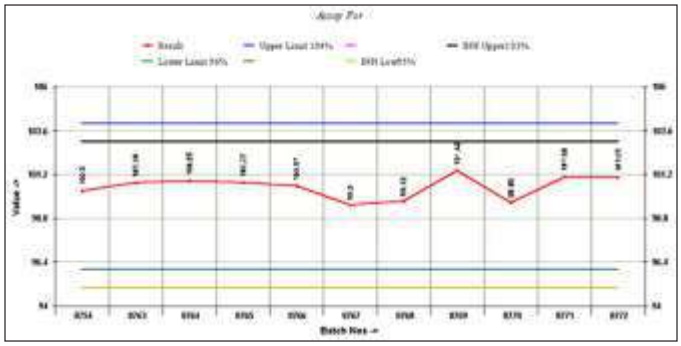
Modules with LIMS

LIMS may be integrated with "plug-in and use" add-on modules to cover various quality assurance activities.

These include:

Trend Analysis

For graphical and tabular representation of resultant data of different batches to study the behavioral trend of a product over a period of time



- Comprehensive report generation as per the user's choice of parameters
- Comparative analysis of batches on user-defined parameters along with the specification details in a standard spreadsheet format
- Extrapolation of trending data along with mean, median and mode; linear line graph/logarithmic curve

Vendor rating

For selection of vendors for approval based on analytical data and sample data as well

Summary reports on sample disposition/condition/status for the material received from vendor for its subsequent approval

Stability studies management

For scheduling of stability samples for analysis at different time intervals maintained at various experimental conditions such as temperature and humidity, for selected parameters

• Stability sample pre-registration (including pack type, experimental conditions, chambers, pack size, orientation etc.) • Scheduling of analysis at different time intervals under various experimental conditions, for selected parameters • Stability testing schedule/pulls printing (date wise, product wise) • Stability sample login • Partial/reduced analysis • Stability work sheet • Stability labels • Analytical readings/observations/results entry • On-line result calculations • Stability COA review/approval • Protocol sheet generation • Stability graph - period wise/experimental condition wise • Stock report of each walk-in chamber • Stability sample bin card printing • Stability samples stock tracking including consumption records • Samples pending for stability login • Samples pending for analysis • Stability COA pending for review • Stability samples status report • Alerts and reminders

Equipment calibration management

For management and calibration of equipment that are used for analysing samples

• Registration of equipment/equipment master maintenance • Defining calibration limits for various applicable tests • Equipment test master • Equipment test link • Equipment calibration login • Equipment calibration sheet/Work sheet • Calibration reading/observation entry • Certificate of calibration/Equipment calibration report • Calibration labels • Annual equipment calibration calendar • Equipment calibration status • Equipment pending for calibration • Equipment due for AMC • Equipment breakdown record • Equipment maintenance record • Alerts and reminders • Equipment log

Reference and working standards management

For keeping track of inventory and usage of Reference Standards/Working Standards in analytical laboratory

• Effective maintenance of reference standards/working standards on the basis of procurement details, source, assay, standardization, usage etc. • Reference/working standards master • Login • Reference/working standards issue • Reference/working standards bin card • Reference/working standards usage • Reference/working standards - use before • Reference standards register • Working standards register • Working standards due for standardization • Alerts and reminders • Management of standardization due dates

Control/reserve samples management

For efficient handling of control/reserve samples that includes quantity, packaging, and storage location with relevant batch details

• Inspection schedule : Provision for regular check/review of control samples at pre-defined intervals • Generation of control sample register, issue register, destruction register • Entry of issue, destruction details • Box slip generation (Control Sample) • Periodic visual inspection sheet • Control samples due for destruction (based on the expiry date and as per the FDA requirements)

Training records management

For maintenance of training records (internal as well as external) for all personnel

All executives may be granted qualifications on the basis of training undertaken; it may be on any product, process, equipment or test procedures for which they have been trained.

• Department, trainees, trainers, training type master • Registration of employees (qualification, experience, designation, date of appointment etc.). • Entry of plans for training of staff in various departments on a subject (product, process, equipment, test procedures etc.) • Conduction of training and evaluation with grading facility to suffice GLP requirements • Maintaining details of training (in-house as well as external) • Training evaluation • Granting qualifications on the basis of training courses attended • Training schedules pulling • Training calendar

Chemicals, glassware inventory management

For maintenance of inventory of chemicals/glassware used in laboratory

There is a facility to track receipt and consumption of chemicals; a comprehensive reporting systems is available to produce useful reports.

- Entry of chemicals, glassware as masters with respective pack size, grade, rate, MSL, ABC analysis, storage requirements, safety instructions and unit of measurement
- Date wise login/registration of chemicals, glassware on receipt at stores
- Recording issues of chemicals against requisitions
- Stock positions of chemicals etc. including total receipts, total issues, balance etc.

Microbial Media management

For maintenance of records of microbiological media including stocks, usage etc

• Master information maintenance as standard formula/composition, storage requirements, method of preparation, MSL, unit of measurement etc. • Date wise entry

of receipt with respect to vendor, mfg. date, exp. date, batch no., qty. received, cost, pH etc. • Media preparation and sterilization record with all relevant parameters • Media usage record • Stock positions of media

Column management

For management of records of columns used and keeping track of their performance

- Provision to maintain master information with respect to date of purchase, column ID no., dimensions, packing, column serial no., manufacturer, vendor etc.
- Provision to maintain column usage record with respect to product/material for which used during analysis, flow rate etc.
- Product wise, column wise number of injections record; column log
- Maintenance of column log book

Quality cost analysis

For monitoring and controlling the cost on quality

- Registration of standard cost of chemicals/regents
- Test wise consumption details necessary for every product analysis
- Planning of consumption of chemicals/reagents aligned with production batches
- Provision for recording of consumption of chemicals/reagents on the event of analysis
- Reports on chemicals/reagents registered with the system
- Reports on consumptions and stocks positioning

Market Complaints management

For effective handling of market complaints and recalls

Different types of market complaints can be entered and their records can be maintained.

- Market complaint registration
- On the screen comparison between the original test results (at the time of manufacture) and the results of analysis of the complaint sample
- Provision to assign a complaint as per the SOP and tracking of the action taken
- Action taken, when and by whom
- Complaints on which action is pending
- Recording of the action taken including the packing condition, physical appearance, opinion, the tests desired to be performed on the complaint sample
- Frequency of occurrence of a particular complaint (color change, microbial contamination, empty pocket etc.)
- Area wise (region) analysis of complaints
- Analyzing market complaints information, complaint type wise/product wise, for a particular duration

Projects management

For efficient management, recording and tracking of various projects received from clients across the Globe

• Project Master - Pre-information • Project Master – Introduction • Project Master – Information • Project Activities • Project Commercials • Documents/Procedures • Project View • Certificate of Analysis • Project Reports • Project Activity View • Project Activity Graph •Project Component Master

Formulation development trials management/recipe management

For efficient management of different trial batches while developing a formulation and subsequent optimisation, scale-up

• Material receipt entry • Product Formula • Summary of Trial Details • Review Stock Status • Material Issue • Material receipt register • Stock in hand • Issue Register • Direct Consumption Register • Material Bin Card • Production Trial Batch Summary

Dissolution profiling

For management of entire data of dissolution test of a product and innovator's product including F1, F2 analysis

• Dissolution Login • Dissolution Work-Sheet Printing • Dissolution Reading Observations • Dissolution Profile Report • Dissolution Profile Data Sheet • Dissolution Profile Compare • Dissolution Profile Status Report

Analyst qualification

For maintenance of records of qualifying all the analysts about their expertise on analysis of product or use of equipment through a system of qualifying tests and comparing results with benchmark/reference values

Sample allocation based on analyst qualification

Analytical method validation

For efficient management of Analytical Method validation activities including linearity, robustness, precision, specificity, ruggedness etc

Stabi-M™

Stability Studies Management System

True web based enterprise software system

- Recording and managing stability studies data with the capability of pulling schedules, analysis data with stability life cycle execution from registration to certification
- Various summary and trending reports with protocol sheets as per ICH guidelines and regulatory requirements

(refer Stability Studies Management module features for details, page 4-5)

CrisCon® ERP

Pharma Enterprise Resource Planning (ERP) software package to integrate all business areas in SMEs and mid-cap pharmaceutical manufacturing units

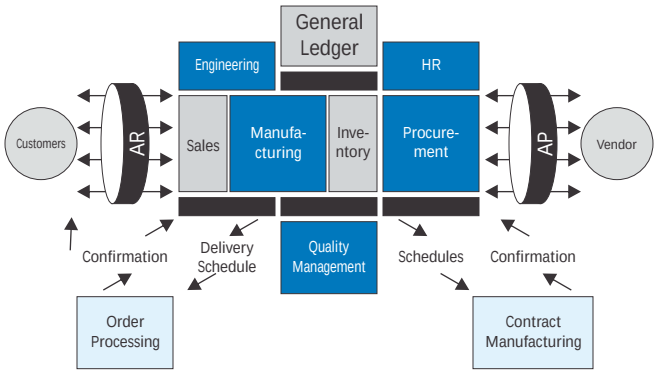
Built on VB 6.0 Client/Server, MS SQL Server

CrisCon forces users to maintain entire documents/records correctly, completely and timely, as per the regulatory requirements. It thus helps in easy implementation of cGMP, WHO GMP, Schedule M guidelines etc.

CrisCon offers a unique blend of operational knowledge, industry expertise and best practices to ensure that your goals are achieved on-time and on-budget.

CrisCon increases operational efficiencies across the enterprise and includes the activities: Inventory management, Procurement management, Production Planning & Control, Material requirement planning (MRP), Production, Sales, Warehouse management, Financial accounting, Quality management, Human resource management, Payroll management

Enterprise Resource Planning : Modules Integration



Oasis-QMS

Integrated Quality Management System

Deviation Management, Change Control Management, Lab Incident Management, CAPA – Corrective and Preventive Action), OOS (out of specifications), OOT (out of trend), Auditing management

Oasis-eBMR

Electronic Batch Manufacturing Records

Software for maintenance of batch manufacturing and packaging records, electronically: Efficient and safe recording, reporting, storing and retrieval of batch records

Built on VB 6.0 Client/Server

Microsoft Client/Sever based VBA application built for secure document management

On-line manufacturing records through electronic batch records (eBR) and electronic work instructions (EWI)

For easy compliance with cGMP Regulations: Standard and most appropriate tool that is specifically designed to assist in compliance with the principles of cGMP

Maintenance of BMR/BPR with electronic instructions and recording of production process data

Approvals through electronic signatures by QA at every stage of production process

Easy interface with ERP and LIMS

- Streamlines work practices/manufacturing procedures through standardization
- Assures quality of product on-line, embedded BPR audit checks at every stage
- Automatic tracking
- Reduces complexity of handling paper batch records and their printing
- Adopted rapidly by the users
- Saves cost (reduced paper handling, reviews, and long-term storage)

Oasis APQR

Annual product quality review for all the batches of a finished product manufactured during the year/period

- Decreases the risk of out-of-specification results
- Minimizes the risk of rework/reprocessing
- Decreases downtime, Increases productivity
- Decreases the risk of product recalls
- Meets all regulatory commitments/requirements
- Improves communication between production, engineering, quality and regulatory functions
- Recording of process/raw data on various stages; graphical representation of processing parameters
- Generation of trend on yield
- Generation of reports from LIMS on various quality attributes of finished product
- Storage, maintenance and generation of exhaustive reports on stability studies at different experimental conditions, time points and packaging conditions
- Data trending of selected tests and graphical representation of analytical data
- Provision to record and maintain summary and discussion of quality attributes
- Provision to maintain market complaints data, product recall data, CAPA
- Deviations and OOS results handling, Change control

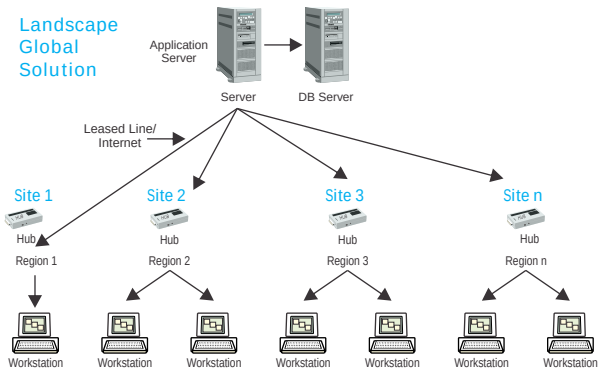
Oasis EMS

Equipment Management System

Encompasses all the features of Equipment calibration management as an independent software (refer page 5)

Multiple Sites Operations

OasisLIMS web based enterprise version has capabilities to support multiple sites lab data management using centralized data storage and application. Information is accessed and immediately available enterprise wide.



O-LINK™

Equipment integrator

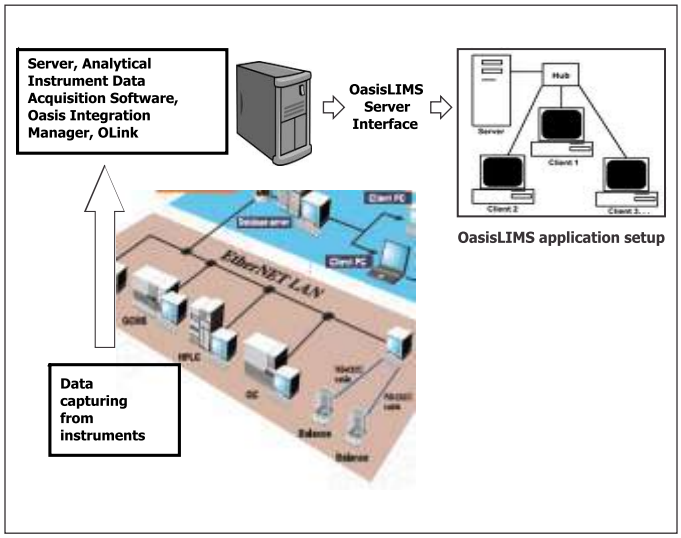
Olink GUI collects data from instruments (RS232, TCP/IP, ASCII file based) and instrument-software generated files or any ASCII file: Readily interfaces with any instrument that produces a text file

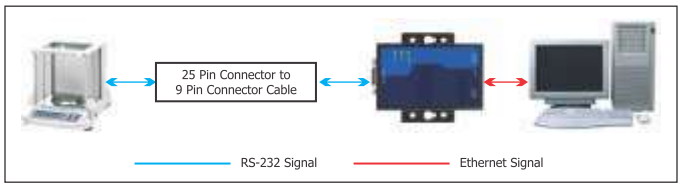
Data parsing, storing of raw data and other relevant meta data

Communicates results to LIMS in a secure central server database environment

Provision to select and store chromatograms/text/result files which are accessible from the software for their review/report for future reference

Vast savings in time and elimination of the potential for error in transcription





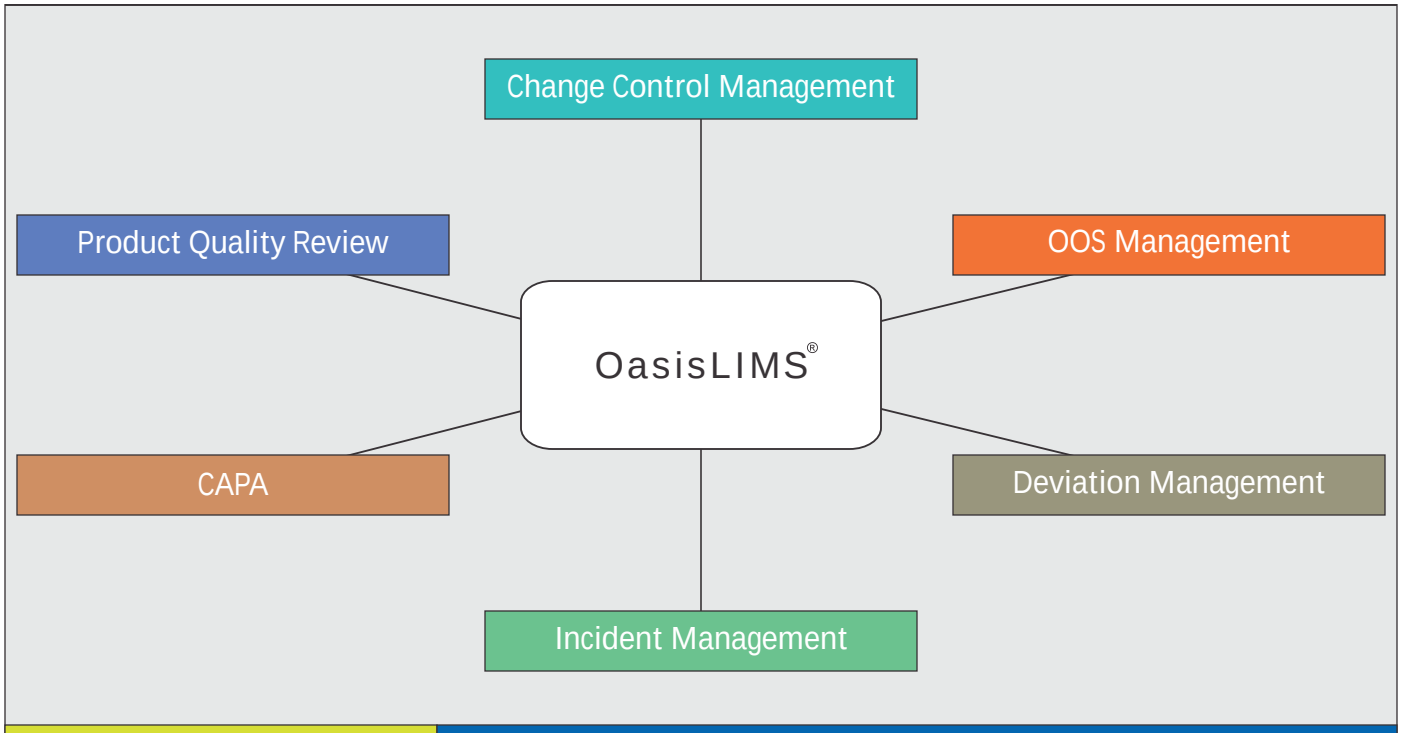
Bar codes Integration

Bar codes integration, uniqly identify sample related data in machine readable form on CoA, labels etc., it provides for quick access, accuracy and efficiency.

RM Code

simplifying QMS

OasisLIMS add-on modules for Quality Assurance



QM Modules

- Change Control Management (CMS)
- Deviation Management
- Non Compliances Management (OOS/OOT)
- Incident Management (Lab/Environment)
- CAPA (Corrective and Preventive Action)

Oasis QMS THAT WORKS FOR YOUR BUSINESS

Make informed compliance decisions

Accelerate delivery of new products

Achieve and prove regulatory compliance across the enterprise

Avoid costly system duplication and ongoing validation costs

Ensure consistency of information and processes

Quickly respond to new regulations and legislative demands without having to rethink the entire approach

21 CFR Part 11 compliance for electronic and audit trail

Electronic forms for automation and processing of regulatory events such as CAPAs and Deviations

Full traceability and accountability – including who viewed, reviewed and approved documents, key decision points and sign-off on compliance processes

Oasis quality management system (QMS) consists of configurable, easy-to-use and connected applications for automating, streamlining and effectively managing change controls, deviation, incidents, complaints, CAPA and pharma based quality processes on a web-based or client/server based platform.

simplifying QMS

OasisLIMS add-on modules for Quality Assurance

Change Control Management (CMS)

A comprehensive module that enables organization to effectively manage changes to processes, documents (STPs / SOPs / Procedures), facilities, hardware, software, engineering, products, equipments, protocols and other areas.

The module comprises of initiation of change from department, assessment and recommendation by head of department, QA-QMS group review/selection of team, forward for impact assessment by associated departments, evaluation for acceptance/rejection of change, change implementation planning and execution and finally closure of summary.

Deviation Management

OasisLIMS deviation management tool helps capture defects and assess their risk. OasisLIMS simple deviation reporting option lets you quickly capture details like part, quantity, failure type, and severity.

With this module, you initiate and document planned and unplanned deviation with supporting documentation, define root-cause of deviation, evaluate and investigate to analyze risk at any point in the process with initial and final risk assessment, resolve problems quickly, keep every department in a loop and optionally integrate and escalate with CAPA Management to manage high risk.

Non Compliances Management (OOS / OOT)

Adherence to the specifications and testing for conformity to the written specifications is required for every component of the product such as pharmaceutical ingredients (API), excipients and other components, in-process materials, and finished products/stability samples, if that fails there's an (OOS) out-of-specification test result, an investigation must be conducted and its results documented.

OasisLIMS-QMS offers the flexibility, functionality to record case of OOS and configurable (user defined) investigations checklists with advanced tracking functions. This module helps users capture data on forms automatically from LIMS. The system offers best-practice features to incorporate all the steps and procedures from initiation to summary/conclusion of OOS incident.

The out of trend (OOT) are those suspected results or sequence of results that are within specifications but are unexpected based on historic information such as Assay, RS, Disso., water/LOD etc. Similar to OOS module, there is a separate comprehensive procedure to handle record and investigate out of trend (OOT) results for campus including stability samples.

CAPA (Corrective and Preventive Action)

CAPA Management helps companies develop a risk-based, streamlined problem resolution process. Oasis-QMS has effective CAPA handling module in the system that improves product quality and safety, increases customer satisfaction and more importantly ensures compliances with the standards such as those set by FDA/ISO or other regulatory authorities.

CAPA Sources: Connected with Deviation management, Market complaints management, OOS results, OOT results, change controls, lab / environment incidents, Equipment calibration / validation failure, Batch failure, Product recall, Stability failure, PQR, Audits etc.

The standard Workflow of CAPA: Initiation / corrective and preventive action plan and execution (major tasks, resources required and deliverable timeline) / implementation verification / effectiveness check / CAPA Closure / CAPA extension approval / CAPA extension (optional) / CAPA logs / CAPA reports.

CAPA Management's reporting capabilities give the tools to identify regulatory threats and areas for improvement, includes departments; Quality assurance/control, Manufacturing, Raw / packing / finished stores, Maintenance, Supply chain, Regulatory affairs, Formulation / analytical research developments, Information technology, Engineering etc.

Product Quality Review (PQR)

The regulations require an annual product quality review (PQR) of all products that are manufactured at a manufacturing facility. OasisLIMS-APQR module helps you meet objective of verifying the consistency of the existing manufacturing process, the appropriateness of current specifications for raw materials and finished products and the ability of your stability data to highlight any trends, and to identify product and process improvements.

The analytical data is captured from OasisLIMS for all the stages the product goes through including in-process and finished stage with batch tracking. Annual product quality review for all the batches of a finished product manufactured during the year / period:

Decreases the risk of OOS results / minimizes the risk of rework-reprocessing / decreases downtime

Increases productivity / decreases the risk of product recalls / meets all regulatory commitments / requirements

Improves communication between production, engineering, quality and regulatory functions; recording of process / raw data on various stages

Graphical representation / histograms of processing parameters / generation of trend on yield data

Generation of reports from OasisLIMS on various quality attributes of finished product / storage, maintenance of stability studies records / data trending of selected tests, graphical representation of analytical data and summaries, provision to maintain complaints data, product recall data / deviations, Failures and OOS results handling / change controls etc.

O-Link™ Server 2.0

Software for Instruments/CDS integration

Connects instruments ... Integrated laboratory

O-Link™ 2.0

Built on ASP.Net technology | Client/Server based | Integration Ready with Instruments and CDS

O-Link is fully configurable integration solution that maximizes your investments in lab data systems and instruments by ensuring that resultant data gets transferred to LIMS / ELN on-line and in real-time manner. It also maintains data integrity for major compliance requirements where businesses and operations are pharma/ chemicals / R&D centric.

Paperless lab initiative

Integrated LIMS and CDS

Data security and integrity

For compliance with 21 CFR Part 11

Work flow optimization

Option for integrated sample management module

Centralized chromatograms and instrument data

Instant results data visualization tool

- Benefits
- Directly captures data/results from analytical instruments through RS 232 port (serial comm)/TCP-IP at the time of reading/observation entry
- Ensures Data Integrity
- Automatically maintains instruments logs and raw data in electronic form
- Captures the CDS output results as a package of both results and sample and test data
- Direct database access from CDS server for capturing results
- User defined test methods for further calculations on intermediate results
- Maintains all raw data information in O-Link server for future reference during auditing/inspections
- File based output

Standard Execution

- Registers the sample in Core O-Link sample management module
- Marks specific tests in O-Link in an integrated manner to collect data from Instruments with serial port (RS 232) or Ethernet TCP-IP and instrument-software generated files
- Parses the data
- Displays it in user designed lab sheets (spreadsheets)
- Incorporates MoA/SOP in-line
- Stores raw data and other relevant meta data
- Performs test-driven calculations
- Finally, transfers results to O-Link database in a secure environment

Advantages

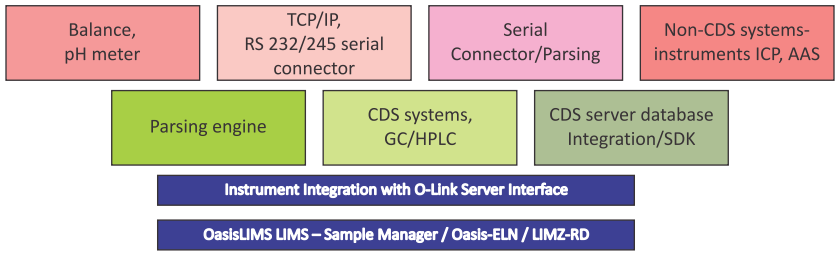
- Enhances the overall efficiency of the laboratory and the entire enterprise
- Improves standardization in Lab processes
- Improves sample turn-around time
- Eliminates Manual entry errors
- Gives faster and authentic results
- Meets Compliance requirements

Integration with analytical equipments using O-Link Server

Instruments Integration

O-Link Server/ELN

- Fully Integrated Application with Sample Management Workflow
- Robust Data Integrity and Compliance
- Robust Interface for managing the external data coming into O-Link database



Connected Informatics System features

User defined color themes	Panels for fast shortcuts	Notifications, alerts, reminders – Integration with email/sms	Word processor/ Spreadsheet capabilities like MS Word
Provision for incorporation of tables, shapes and images in documents	Integration with Oasis-QMS, ERP, MES system	On-line access to ELN/EWS	Sample tracking system helps users to quickly view sample details
Barcode integration to print on labels	Report Designer for User defined reports	Excel like User defined test methods / calculations	Instruments Integration

Other Software Solutions

OasisLIMS Professional: LIMS Professional for small enterprises

OasisLIMS EL: LIMS Enterprise for medium scale enterprises

OasisLIMS IL: Web based, Integrated LIMS for large enterprises

LIMZ-RD: LIMS for R & D centers/F&D Labs/AD Labs/API Labs

EnviroLIMS EWM: LIMS for environment, water monitoring labs

True-LIMZ CTL: LIMS for commercial testing/Public testing laboratories/Food labs/Environment labs

Stabi-M: Stability Studies Management for large enterprises, multi plants roll out

Oasis QMS: Quality Management System for large enterprises, multi plants roll out

Oasis eBR: Electronic Batch Records management for large enterprises, multi plants roll out

The Group

Contract Research & Analytical services

- Oasis Test House Limited, Jaipur
- Oasis Test House, Ahmedabad

Pharmaceutical Production, Contract Manufacturing Services

- Jaipur Pharmaceutical Works, Jaipur
- Cris Pharma (India) Limited, Dehradun

Software Development and Services

- Oasis Infotech, Jaipur
- Oasis i-Tech Private Limited, Jaipur

Valued Group Clientele

... many more

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