OasisLIMS - Labmaster for Windows

Some salient features at a glance

A. Master data planning and entry

(Oasis Infotech offers services for 1, 2, and 4)

1. Product master / Material master (pre-shipped with OasisLIMS)
Entry of relevant details of different

- raw materials
- finished products
- packaging materials
- intermediates
- bulk etc.

in product master

Multi plant option
for handling of data at different organizational levels or user groups

2. Test master (pre-shipped with OasisLIMS)
Defining 'n' number of tests which are performed on a sample

3. Reports: Material master, Vendor master, Test master

4. Product - test - test method links (pre-shipped with OasisLIMS)
Establishing link among product, its tests (as per the monograph) and the test methods required to carry out the tests

Product re-gradation and customer specification
Facility to maintain corporate quality standards as per in-house requirements

Provision to analyse a sample as per customer specification (without additional expansion)

Limits
Defining different types of limits, trend values and tolerance for test(s), product wise

5. Concurrency control on master data updation

6. Report: Product composition details

7. Approved manufacturers and vendors linking (RMs / PMs)
Checking whether the material has been received from an approved vendor, or not

Checking whether the material is from a "marked" manufacturer (as linked with the vendor)

8. Report: Specifications - RMs / FPs / PMs / Intermediates / Bulk etc.

9. Documents maintenance
Finished Products Specifications, Raw Materials Specifications, Standard Operating Procedures, Standard Testing Procedures, Calibration procedures

Provision for SOP aging and versioning with tracking for revisions

Facility to import SOPs from stored files (maintained under standard word processor like MS Word, Ascii text etc.)

B. Transaction processing

10. Sample registration and login
for various sample categories: Regular / retest / OOS / R & D / pre-shipment etc

Bi-directional interface with ERP to ensure data integrity
Transfer of information - Item code and description, Vendor code and name, Manufacturer code and name, Batch number, Receipt date, Challan number, date, MRN / GRN number, date, Manufacturing date and Expiry date, No. of containers received, quantity in each container

Automatic AR number generation
for different types of samples categories

Entry of quantity received in multiple pack sizes / containers

Entry under sampling plan, for multi lot / multi assay and mean result calculation on the certificate of analysis

11. Samples pending for sampling

12. Report: Sampling sheet printing - RMs / FPs / PMs

13. Label printing - Under test, Sampled labels, Laboratory sample

14. Work flow management
Individual test allocation to analyst

15. Protocol sheet / work sheet / analytical work record generation
Concise / exhaustive - indicating all tests to be performed as per the pharmacopoeia, the in-house specifications; the regulatory requirements / Drugs and Cosmetics Act and the Rules and user defined formats for entering readings / observations

16. Lab resources management
Entry of pre-requisites for each characteristic / test of a sample (equipment, volumetric solution, working standard, column etc.) before commencing analysis.

Alerts / messages for necessary action if any of the pre-requisites does not satisfy

Maintenance of instrument log

17. Samples pending for analysis
Samples under analysis

18. Analytical readings / observations entry
Selection of tests for entry of readings / observations

Entry of **only** the readings and observations

Automatic calculation of the results (without giving any external formula for calculations)

Checks and denial for use of un-calibrated equipment for testing

On-line trending with tolerance values
Out of trend indication at the time of reading entry

Toll samples
Sending sample to an outside lab (in case of break down of an equipment during analysis, non-availability of requisite materials, validation etc.)

Operational / validity checks at all possible levels to avoid wrong data entry

Default (pre-defined) values for constants like wavelength, dilutions etc. to save time during data entry

19. Generation of certificate of analysis (COA)

Automatic cross-checking of the results with both official as well as in-house specifications

Automatic decision about conformance or non-conformance of the sample

Automatic generation of certificate of analysis as per the pharmacopoeial requirements and schedule V of the drugs and cosmetics rules (Old COA with old specifications and current COA with current specifications)

Automatic incorporation of opinion in the COA, giving reference to rejection parameters, in case the material is rejected

Generation of calculation sheet (hard copy of the analytical / raw data entered in the system)

Finished product release COA

Finished product pack release COA

20. Bi-directional interface with ERP to ensure data integrity

Transfer of sample disposition information -
Reference number (analytical report number)
Updated batch status in LIMS
Approval date and Retest date
Value of Assay
Value of Loss on drying

21. Out-of-specification (OOS)

Provision for re-sample login (with different AR number) in case the material is rejected (giving reference to its original AR number)

Facility to enter action details and measures (under standard template)

22. Label printing - Approved / rejected / quarantine

23. Report: Certificates pending for printing

24. Sample registers

RMs / FPs / Rejection / PMs etc. for different sample categories

25. Reports: Sample status reports
Laboratory data
QC productivity report
Analyst performance report

26. Reports: Materials Library - Approved vendors, re-certification parameters, packing requirements, RMs used in FPs, sample quantity / reserve sample quantity

27. Trend analysis
Generation of Trend on user-defined critical parameters, for selected batches to study the behavioral trend of a product over a period of time

Extrapolation of trending data along with mean, median and mode

Graphical representation of data, linear / logarithmic / exponential

28. Report: Samples for retest

29. Report: Reserve samples for destruction

30. Stability scheduling
Stability scheduling at different time intervals and various experimental conditions

Sample registration
Stability schedule printing
Analytical readings / observations entry
Automatic calculation of results
Certification and reporting

Stability samples status report
Stability labels

Stability graph - period wise / experimental condition wise
Generation of different types of graphs, bar charts with analysis like regression, co-relation, mean, mode, median, standard deviation

Calculation of degradation rate

Shelf life prediction on the basis of procedure defined in relevant SOP of user company

31. Equipment Calibration management
Registration of equipment
AMC tracking
Equipment calibration - test links including limits, schedules

Calibration and monitoring
Periodic calibration register
Calibration reports and certification
Annual calibration calendar

32. Reference standards / working standards management

Effective maintenance of reference standards /working standards on the basis of procurement details, source, assay, standardization, usage etc.

Stock maintenance of reference and working standards received from different sources

Issuance and consumption of standards

33. Reserve samples management

Reserve samples for destruction (period wise)
Reserve samples details (compartment wise)
Reserve samples register
Inspection and destruction schedule

34. Training records

Entry of plans for training of staff in various departments on a subject
Conduction of training and evaluation
Training schedules
Training calendar

35. Market complaints records and analysis

Effective handling of market complaints and recalls
Market complaints entry and corrective action
Market complaints register, Pending market complaints
Market complaints analysis and review

36. Trade returns analysis

37. Renewal of licences

38. Volumetric solutions management

39. Columns management

40. Chemicals / Glass wares / spares / tools etc. inventory management

41. Analyst qualification

42. 21 CFR Part 11 Compliance

Validation
IQ/OQ/PQ

Audit Trail - Date wise / User wise / Function wise
Computer generated time-stamped, human readable, all operator entries, accurate and complete copies of data, electronic data archiving and ready retrieval.

Security
Controlled system Access - administrative and automatic system control

Current user sessions - monitoring
User profiles maintenance
Password expiry

43. Internal Messaging System

Mail system for the OasisLIMS users to exchange messages among themselves

44. Alerts/Reminders

Upon log on, due tasks such as retest, equipment calibration, stability are automatically flashed and directed to concerned users by issuing alerts and reminders in the logon screen window

45. Idle Session Timeout

Idle session by a user exceeds a stipulated maximum period an automatic timeout takes place and on restoring the session system demands for user name and password

46. Account Lockout

On three (3) successive unsuccessful logins, access to OasisLIMS is denied and attempted account is locked automatically by the system. User is prompted to contact the system administrator to unlock and re-activate the account. System keeps record of the accounts and passwords tried by the suspect for administrative purposes.

47. Email System

OasisLIMS has online emailing facility that enables users to email reports produced by the system amongst themselves in a closed user group (LIMS) or external users, for this it avails the services of existing mail server

48. Backup and restore

49. Year transition system

50. Export Reports

Every report produced by the system can be exported online in various industry standard formats such as Excel, PDF, HTML, RTF, TEXT etc. to meet information exchange requirements of users working with different software systems.

51. Instrument Connectivity

Talks are on with LABINDIA (India), LABLINK (Canada) and CSOLS (UK) for strategic alliance to develop lab interment interfaces for seamless connectivity to capture data directly from instruments in order to eliminate transcription errors and improve sample turn around time with better data security and integrity.