

17-6: Laboratory Information Management System (LIMS)

LIMS is running in SPT's Quality control and Analytical Research units. LIMS system provides sample numbering, labeling and work flow; retest and expiration date management; quality control laboratory equipment calibration and maintenance program; data analysis tools; sample result database; chromatography laboratory interface; analytical procedure archiving and automatic audit trails. LIMS stores and organizes all quality control lab-generated data in a relational database as records identified by unique sample numbers.

LIMS is needed to support the management of large volumes of research and production analytical data, which serve as evidence supporting the validated status and genealogy of each API compound lot produced in cGMP operating environment. Using LIMS, SPT is able to provide validated, traceable, secure and retrievable records of all analytical information within its facility related to the manufacture of API compounds; and with all the benefits from LIMS, SPT speeds both the research and production process cycle times as well as increases the reliability of data by eliminating manual calculation errors.

LIMS contains the following functions:

- * Management of tested materials, their tests and specifications
- * Logging and managing samples in the work centers
- * Evaluating results and assigning disposition decisions to the associated samples
- * Stability Scheduling: Functions to pre-define a stability program for one or more batches in a study, with storage conditions, sampling time points, and tests to be performed at those points. The application then logs samples into LIMS at the appropriate time points.
- * Instrument Calibration
- * Reference Standards Management