



# LIMS Service Offerings

AppLabs understands the rigor and effort in bringing a drug from discovery to market. This could take as much as 15 years or sometimes even more. The management of information during this phase can be one of a pharmaceutical

company's biggest assets. Hence Laboratory Information Management Systems/ Software (LIMS) forms the kernel of drug development as far as data management is concerned.



### Challenges facing the HCLS industry in the above context are multi pronged:

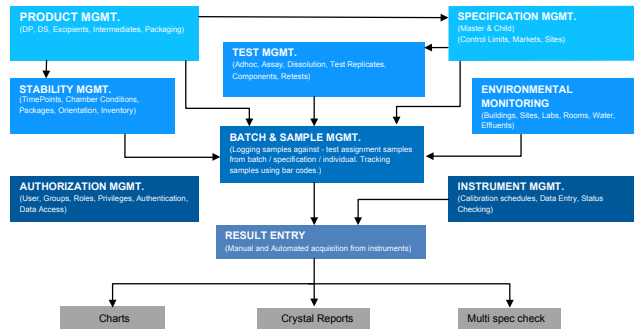
- ▶ Lengthy, costly customization projects for the generic LIMS
- ▶ Continuous pressure to control costs, increase efficiency, and build pipeline
- ▶ Regulatory compliance, dynamic sample testing, and complex batch-centric (non-continuous) manufacturing processes
- ▶ Need for extensive out-of-the-box pharmaceutical functionality
- ▶ Reduce the time it takes to implement and validate a LIMS
- ▶ Increase user acceptance and simplify future system upgrades

AppLabs' proven expertise in testing of LIMS applications helps HCLS organizations build software that delivers extensive out-of-the-box pharmaceutical functionality, significantly reducing the time it takes to implement and validate a LIMS. Our solutions also help increase user acceptance and simplify future system upgrades.

### Key Features

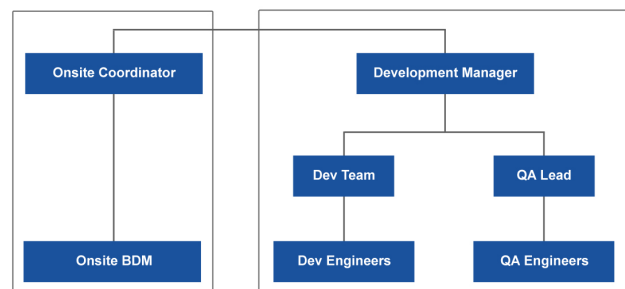
- ▶ Product Management: Versioned entities like drug products, excipients, intermediates, packages
- ▶ Test Management: Adhoc (appearance related), Assay (formulation and composition), Dissolution(dual media, single medium behavior), test regimens, test groups
- ▶ Specification Management: Market and site driven, multiple limits
- ▶ Batch and Sample Management: Logging samples, scheduling sample creation, sample tracking
- ▶ Result Entry: Manual and acquisition, color coding for limits, live graphs for sample comparison while checking against multiple specs
- ▶ Reporting: Tabular and graphical reports
- ▶ Environmental Monitoring: Scheduling EM verifications
- ▶ Stability and Inventory Management: Across timepoints and storage conditions, auto sample pull based on timepoints, scheduling tests, automatic inventory calculations

- ▶ Sampling Plans: For QA and QC at manufacturing stage
- ▶ Lifecycle management: Custom lifecycles for review and approval
- ▶ Auditing : 21 CFR part 11 compliance, multiple levels of compliance



### AppLabs' Delivery Model

#### Onsite-Offshore



### Test Methodology

The test strategy followed by AppLabs results in 100% test effectiveness and high customer satisfaction on deliverables:

- ▶ Step by step detailed scripts that cover functional flow of entire use case
- ▶ Using QC to track the script execution
- ▶ Exploratory testing
- ▶ Individual issue testing
- ▶ Script execution
- ▶ Test results captured as per FDA guidelines
- ▶ Peer review
- ▶ Random testing of 10% of total scripts executed
- ▶ Compatibility testing