

REVIEW ON ANALYTICAL SOFTWARES USED IN PHARMACUETICAL INDUSTRY

Author: Miss.Bobade R.A., Mr. Wasmate D. N., Mr Deshmukh S. U., Dr. Bavage S. B.

ABSTRACT:-

The whole medicinal areas demanded various innovative and scientific results to break the current Problems related to cGMP practices, product, documentation, nonsupervisory body conditions(eg. US FDA, WHO, EU- GMP, snaps), quality of productetc. To overcome analogous problems different computer system Software like LIMS, SABA, JMP Data Analysisetc. Softwares plays an important part by covering and Maintaining the current practices of pharmaindustry. Software development in the pharmaceutical Assiduity allows robotization of process workflows while making the association more effective and Perfecting issues This is achieved across; Pharmacy Services This allows streamlining the medicine Operation processes with the help of an automated tradition allocating system. By installing analogous Software will help pharma assiduity to meliorate their cGMP practices and fulfillment of nonsupervisory Body's conditions. This composition gives overview on different types of software used in pharmaceutical Sedulity. It also covers significance and their need in pharma assiduity. It also covers the meaning of Software used in pharmaceutical assiduity.

Keywords: Computer system software, cGMP practices, LIMS Software,SABA, JMP Data Analysis Software, nonsupervisory body's conditions, quality of product,etc.

INTRODUCTION: Digitization touches every aspect of our lives. Every day, we see a more advanced way of communication where technologies and applications are being launched. This advancement not only facilitates us a better life, but it is now a necessity. In this way, shifts in market trends force the pharmaceutical industry to take the necessary steps to obtain strong technical support that improves drug efficiency and quality of life. The pharmaceutical industry is one of the most challenging industries that always face rapid growth. These changes promote frequent changes in the healthcare market trends and generate global competition with other pharmaceutical companies. Thus, the change forces drug manufacturers and distributors to find solutions to reduce costs, improve efficiency, and streamline operations. A dedicated pharma software is a driving element of the pharmaceutical industry that keeps it in line with market trends and maintains its stability.

Every industry's lifeblood is creativity, the discovery and development of new medicines is carried out with unique challenges, ethical counteraccusations and social liabilities as well as the system feel arcane. Currently, it's only possible to understand the complex processes and effectively and efficiently handle coffers, plutocrat and force due to computer software in the pharmaceutical lores area. Computer software may help relieve medical professionals from diurnal attestation and other pastoral duties, reduce crimes and increase delicacy in data transmission and storehouse, and reduce the use of creatures and chemicals, ameliorate productivity and give results for moment- consuming homemade tasks, develop invariant norms and continue monitoring or deals, and fast and direct access via ever located outstations to the different information. Away from

the fact that nearly 20 times formerly have ratified since the preface by the FDA of crucial electronic confirmation safety norms, the health care industry is still floundering to misbehave with compliance regulations and Acclimatize to new technology while continuing to deliver products in a secure and timely way. In the period of the internet, where software is more charge-critical than ever, it's no longer enough to exceed some of the time for your development systems. You need to constantly deliver excellent software effectiveness, and do it faster than ever. Historically the medicinal and biopharmaceutical sectors haven't been the precursor of revolutionary engineering results and ultramodern chemical engineering generalities. The manufacture of medicine products has been covered for numerous decades through a nonsupervisory Frame which shielded the quality of the final product and checked the specific of batch- grounded operations, raw accoutrements and end products fixed process conditions, and in- process accoutrements. Limitations related to this thickness have been extensively honored by testing thinking for both small patch and biopharmaceutical goods. Numerous fields of product and related artificial lores, one on either hand, have successfully Enforced advanced ways to enhance our current understanding of processes and goods. Throughout the first many decades, indeed so, there has also been growing concern in adding medicine safety and quality it while at the Contemporaneously reducing pharmaceutical product costs by introducing further systematized medicinal development and product strategies.

Role of Information Technology in Pharma Business: The Indian pharma industry is highly fragmented and has grown significantly over the last two-three decades. India is one of the top five pharma emerging markets. Due to its expansion in the rural sector market, it is expected that the Indian pharmaceutical market will grow to 55 billion US dollars by 2020. According to consultancy firm Deloitte by 2019 Global Life Sciences Outlook, "Worldwide prescription drug sales are expected to increase from 900 billion US dollars in 2019 to 1.2 trillion US dollars by 2024.

The IT sector plays an essential role in the development of the pharma industry. The information technology sector grabs various opportunities in the healthcare sector. In the pharma industry, information technology reduces manual work by managing inventory and documentation by pharma software. Also, with the help of pharma software solutions, a pharmacist can prevent a medication error, alert to prevent any kind of damage, and update you about stock/buy/sell data with minimal resource occupancy. In short, the software used in the pharmaceutical industry helps automate the pharma process by increasing productivity, efficiency, and quality of the analysis.

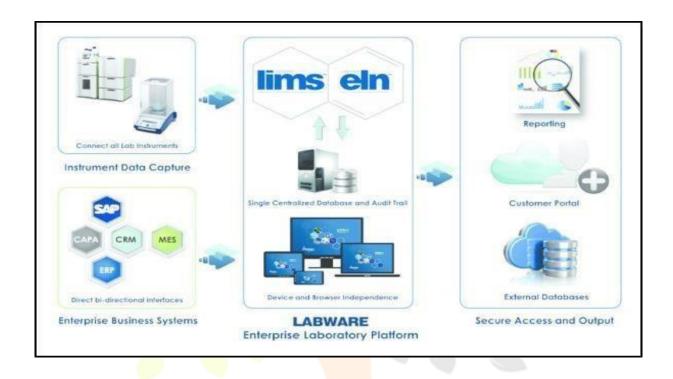
• LIMS Software :-

Dealing with adding volumes of data, laboratories can no longer feasibly manage trials by adhering published results into a paper tablet. With a Laboratory Information Management System, researchers can now link trials to specific samples or lines, as well as easily share information with other lab members and associations involved.

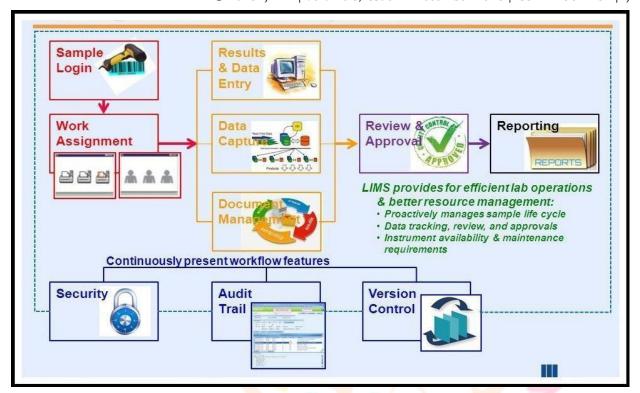
A laboratory information operation system (LIMS), occasionally appertained to as a laboratory information system (LIS) or laboratory operation system (LMS), is a software- grounded result with features that support a ultramodern laboratory's operations. Crucial features include but aren't limited to — workflow and data tracking support, flexible armature, and data exchange interfaces, which completely" support its use in regulated surroundings".

In 1982 the first generation of LIMS was introduced in the form of a centralized minicomputer, which offered automated reporting tools. As the interest in these early LIMS grew, assiduity leaders like Gerst Gibbon of the Federal Energy Technology Center in Pittsburgh began planting the seeds through LIMS- related conferences. By 1988 the alternate-generation marketable immolations were tapping into relational databases to expand LIMS into further operation-specific home, and International LIMS Conferences were in full swing. As particular computers came more important and prominent, a third generation of LIMS surfaced in the early 1990s. These new LIMS took advantage of customer/ garçon armature,

allowing laboratories to apply better data processing and exchanges. By 1995 the customer/ garçon tools allowed the processing of data anywhere on the network. Web- enabled LIMS were introduced the ensuing time, enabling experimenters to extend operations outside the laboratory. From 1996 to 2002 fresh functionality was included, from wireless networking and georeferencing of samples, to the relinquishment of XML norms and Internet purchasing. As of 2012, some LIMS have added fresh characteristics similar as clinical functionality, electronic laboratory tablet (ELN) functionality, as well a rise in the software as a service (SaaS) distribution model.



The features and uses of a LIMS have evolved over the times from simple sample shadowing to an enterprise resource planning tool that manages multiple aspects of laboratory informatics. Lab orders in the LIMS module of the GNU Health design. There's no useful description of the term" LIMS" as it's used to encompass a number of different laboratory informatics factors. The spread and depth of these factors is largely dependent on the LIMS perpetration itself. All LIMSs have a workflow element and some summary data operation installations but beyond that there are significant differences in Historically the LIMS, LIS, and process development prosecution system (PDES) have all performed functionality. analogous functions. The term" LIMS" has tended to relate to informatics systems targeted for environmental, exploration, or marketable analysis similar as medicinal or petrochemical work." LIS" has tended to relate to laboratory informatics systems in the forensics and clinical requests, which frequently needed special case operation tools." PDES" has generally applied to a wider compass, including, for illustration, virtual manufacturing ways, while not inescapably integrating with laboratory outfit. In recent times LIMS functionality has spread indeed further beyond its original purpose of sample operation. Assay data operation, data mining, data analysis, and electronic laboratory tablet (ELN) integration have been added to numerous LIMS, enabling the consummation of translational drug fully within a single software result. also, the distinction between LIMS and LIS has blurred, as numerous LIMS now also completely support comprehensive case-centric clinical data.



There are various LIMS solutions depending on the industry: food and beverage testing, water and wastewater, agriculture and farming, etc. But in this article,

we'll be talking primarily about LIMS in healthcare. Patient-centric LIMS is software designed to automate data processing operations within a laboratory and facilitate its integration with other systems involved in data exchange. Using standardization, a LIMS improves the efficiency of data reporting and its further analysis while maintaining data on a high-quality level. In addition, a LIMS allows laboratories to stay compliant with multiple quality and security regulations

coming from the Food and Drug Administration (FDA), International Organization for Standardization (ISO), etc. Though LIMS keeps expanding its functionality, which in turn changes how the system is defined, we can identify its basic functions focusing on the core function – effective sample management. This process includes six phases:

International Research Journal

- 1. Receiving a sample and registering it along with the related customer data 2. Monitoring: scheduling and tracking the sample
- 3. Sample processing: managing the utilized equipment, inventory, and the corresponding analytical workload
- 4. Quality control: inspecting and approving the results
- 5. Compiling the sample data for reporting
- 6. Storing the sample analysis data.

How LIMS automates laboratory operations:-

A LIMS provides one location for all laboratory processes along with the methodology of how data is stored and managed. The system performs sample handling steps in line with instructions for each operation.

Sample registering: On receiving a sample, a lab worker logs it in along with the customer data.

The registration process involves marking the sample with a unique barcode necessary for further tracking.

The LIMS generates a barcode containing data points for reading and extracting. Having a chain of custody (CoC) procedure in place, a lab also assigns roles and groups dictating access to specific data records and their management.

CoC ensures the accuracy of testing results by tracking and documenting each step in the testing process and each entity involved. The CoC procedure involves such measures as securing a private collection station, confirming a photographic ID of a donor, completing a detailed CoC form, linking the sample to the corresponding paperwork by placing a unique barcode both on a container and the CoC form. At this stage, the LIMS generates a series of ad hoc reports including login reports and sample conditions, sample tracking reports. A lab worker also scans supporting documentation or attaches needed files to the electronic document of the sample.

Documentation :- In terms of sample documentation, an Electronic Laboratory Notebook (ELN) allows for going totally paperless. At the same time, an ELN secures electronic data collection while it can limit access to the data based on profiles and permissions. As a software system for digital documenting of research work, an ELN is composed of protocol templates, project management tools, lab inventory management tools, electronic signatures support, etc. Some LIMS solutions offer ELN functionality, while others offer seamless integration with an industry-relevant ELN.

Sample monitoring :- Labs don't want to miss sampling events. So, they use a LIMS to automatically schedule samples on a daily, weekly, monthly, quarterly, semi-annual, or annual basis. LIMS alerts lab workers about the need to prepare a sample collection kit before the test.

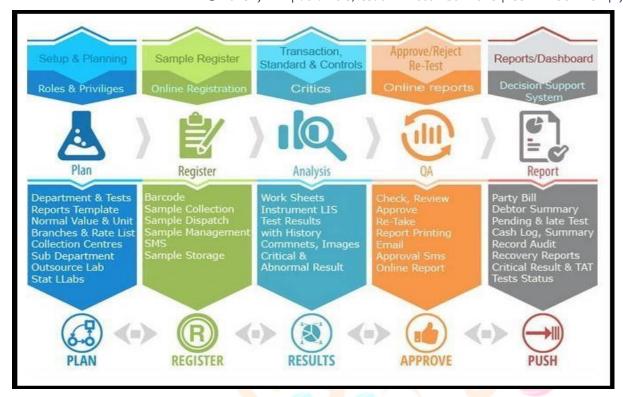
Using a GIS (Geographic Information System) function and sample identifiers, a LIMS is able to track sample status and location. A sample is kept in the freezer it's been assigned to. That's why in some cases it's also required to track the freeze and thaw cycles that a sample undergoes. Location specification can go down to a certain shelf, rack, box, row, and column. The dashboard of the Lab Information System used at the Kasih Ibu Hospital

Sample processing: Tracking a sample through its lifecycle, a LIMS keeps a record of its audit trail while calculating and maintaining its processing and handling times on chemical reactions. Integrating with laboratory instruments, a LIMS is able to feed control files into them directing their operation on a sample. In addition, a LIMS monitors instrument health, scheduling their maintenance, calibration, or repair while keeping detailed records of such activities. A LIMS won't permit a specific task until making sure the instrument is within control and the executing personnel has a renewed certificate.

Sample results quality control: After the analysis is carried out, a LIMS extracts the output files from the instrument and parses it in the required input format to perform a quality control assessment of the operation. Access to the instrument data can sometimes be regulated based on chain of custody assignments or other security features. A LIMS gauges test result values by graphing the results and creating control charts for the selected data. The system configures tests to include QC, matrix spikes, blanks, duplicates, surrogates, matrix spike duplicates, etc. Lab workers can enter control limits manually or use the LIMS to derive them from historical limits.

Sample results reporting: A LIMS integrates auditing and reporting capabilities into a lab satisfying the requirements of health service agencies e.g. the hospital accreditation agency, HIPAA in the US, or other clinical medical practitioners. The LIMS compiles the results according to the data entry standards, drags and drops them into a report template, and then distributes them to designated parties.

Sample data storage and exchange: The successful transfer of data files is a pivotal aspect of the modern LIMS. Transition from proprietary to standardized database management systems has made one of the biggest impacts on how data is managed and exchanged in laboratories. In addition to mobile and database electronic data exchange, many LIMS support real-time data exchange with Electronic Health Records systems utilized by hospitals and clinics.



Additional LIMS features :-

Apart from the backbone sample management functionality, LIMS are often enriched with the following business and administration nice-to-haves, or a lab may integrate these functionalities from other systems.

Accounting:- Having a billing module in place, the LIMS creates quotes, converts to orders, and generates invoices for further export to numerous accounting packages.

Customer relationship management :- A CRM module in the LIMS stores and retrieves all the lab's contacts and demographic patient information.

Personnel and workload management: Some LIMS functionality includes work schedules organization, workload assignments, employee demographic information, training, and financial information. This module tracks time expended on laboratory tasks and calculates billable hours through project completion.

Analytics: Using historical data, a LIMS can create a trend analysis chart by test, department, client, site, or a variety of other criteria. Analyzing all the lab data, a LIMS helps better understand your lab turnaround time and identify performance issues leading to critical business decisions.

LIMS visualized analytics, Source :- STARLIMS

Supplies management :- A LIMS measures and records inventories of all vital supplies and laboratory equipment. It alerts when the expiration date is approaching or supplies are running out so they can be re-ordered. There is even laboratory software like Quartzy supply marketplace dedicated solely to handling procurement. It helps labs make better purchasing decisions. Patient portal. Having access to a patient portal, lab clients can view their status and results, check limits, view or print reports, etc. What's particularly relevant today – patients can remotely log in samples via the portal and then ship them to the laboratory.

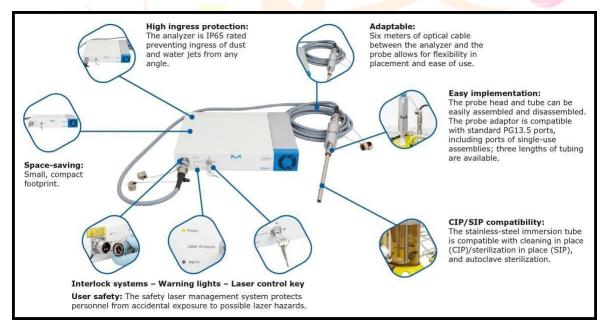
Benefits of a LIMS System :-

- 1. Automates repetitive laboratory administration tasks
- 2.Integrates your lab's instruments and systems intuitively
- 3.Improves the capacity and profitability of your laboratory

- 4.ncreases reliability by reducing the risk of errors occurring
- 5.nables faster, better, informed decisions from real-time reporting
- 6.Increases efficiency by streamlining process and data management
- 7.rovides information when and where you need it, locally or in the cloud
- 8.llows access to the right information quickly at any stage of any process
- 9.nsures all work meets regulatory requirements and current best practice
- 10.Enhances data integrity with automatic audit logging and revision control

ProCellics™ Raman Analyzer with Bio4C™ PAT Raman Software:-

ProCellicsTM Raman Analyzer with Bio4CTM PAT Raman Software is a PAT platform for in-line and real-time monitoring of cell culture critical process parameters (CPP) and critical quality attributes (CQA) for upstream mAb and vaccine process development and data scientists, and MSAT managers, who want to implement PAT from process development to manufacturing, to get real-time insights into their processes with in-line monitoring and to simultaneously measure multiple parameters without grabbing samples to provide insights on what is going on inside their bioreactor. Our Raman PAT Platform is GMP-ready with small footprint analyzer and user intuitive software solution that facilitates 21CFR part11 compliance and providing chemometric modeling guidance to build robust models. Raman PAT Platform enables process improvement capabilities, time savings and flexibility, improved yield and quality. It also helps implement a nutrient control loop strategy, a first step towards automation and bioprocessing.



. ProCellicsTM Raman Analyzer with Bio4CTM PAT Raman Software an Easy-to-Use GMP Process Analytical Technology (PAT) Platform to Monitor Cell Cultures In-Line and in Real-Time, from Process Development to Manufacturing Cell culture processes are complex and highly variable in nature and yet only a handful of key parameters such as temperature, pH, and dissolved oxygen (DO) are typically controlled in realtime.

While the measurement and control of these parameters is necessary for successful bioprocess monitoring, they do not provide a direct indication of the culture's content itself, but only rough assumptions on the culture's true state and limited process and cell growth understanding. Critical process parameters (CPP) such as glucose, lactate, or ammonium and key performance indicators (KPI) such as total cell density (TCD) and viable cell density (VCD) provide a direct indication of the culture's content and state but are generally measured off-line and therefore, not in real-time. Similarly, mammalian cell culture feeding strategies lack real-time measurement and rely on daily manual sampling which increases the risk of contamination and batch failures.

ProCellicsTM Raman Analyzer :-

The analyzer is available in two configurations, fully adaptable to manufacturing requirements, to address a range of monitoring needs, from process development to manufacturing.

ProCellicsTM Raman Analyzer single channel

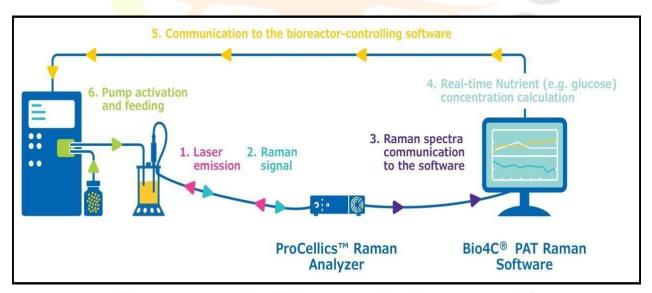
The single channel enables monitoring of cultures with a single probe. The package includes a base unit with a 785 nm laser, one probe, accessories and an all-in-one computer





ProCellics™ Raman Analyzer multi-channel

The multi-channel unit enables monitoring of up to four cultures in parallel within the same system footprint. This package includes a base unit with a 785 nm laser, a multi-channel unit with four probes, accessories and an all-in-one computer.



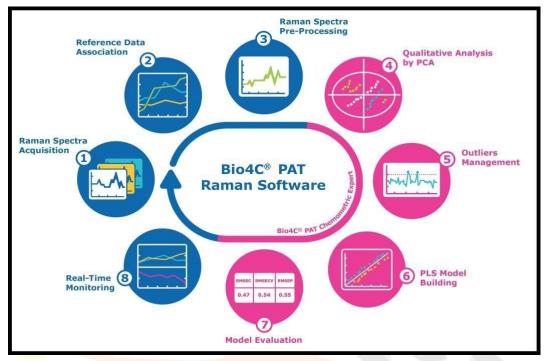
3)Bio4CTM PAT Raman Software:-

Bio4CTM PAT Raman Software – including its additional module Bio4CTM PAT Chemometric Expert – was developed by bioprocess experts specifically for bio-process monitoring. The software provides end-toend functionalities for spectral acquisition, reference data association, spectral pre-processing, chemometric model building, and real time monitoring. The Bio4CTM PAT Raman Software interface is divided into four distinct modules for easy operation.

Instrument Calibration – guides the user on periodic verification of the analyzer and probe. It helps users through a partial recalibration to ensure the best quality spectral acquisition for model building and monitoring.

• Model Building – utilizing Bio4CTM PAT Chemometric Expert, the user can build chemometric models for measurement of various process parameters and quality attributes. The software offers a complete solution to manage, preprocess, and analyze data from different calibration batches.

- Monitoring allows the user to monitor process parameters and quality attributes in real-time and displays graphs showing their progress. Sending data through an OPC protocol, this module enables the configuration of a feedback process control loop.
- Maintenance and Settings enables user management and houses all software settings. Through this module, you can manage user access, electronic signatures, and access a complete audit trail.



4) Chromeleon Software:-

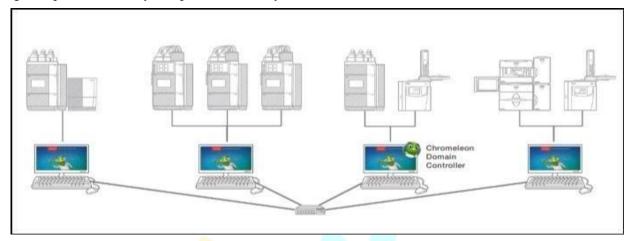
For laboratories currently operating with multiple standalone Thermo ScientificTM ChromeleonTM Chromatography Data System(CDS) instances, Workstation Connect allows you to unlock the power of your existing software by simply connecting them together. By extending Chromeleon CDS beyond the workstation, you can deliver many enterprise-level capabilities to your software with minimal effort and cost. With the addition of a Support and Maintenance Agreement (SMA) you can further secure and future-proof your software.

The Workstation Connect solution provides the ability to connect multiple workstations, with costs and efforts minimized since no additional hardware, such as servers, is needed. Benefit from a more efficient workflow and greater productivity with remote access to data and instruments, even from outside the laboratory. Built with flexible architecture that can adapt to your infrastructure, Workstation Connect can be your first step into a network deployment. As your requirements change, you can seamlessly evolve to a full enterprise system ensuring your CDS grows with your laboratory, while maintaining a consistent user experience. Maximize the benefits of your standalone Chromeleon software with a Workstation Connect deployment and SMA, enabling regulatory compliance, remote working, and dedicated support to deliver value beyond the workstation.

Extend your capabilities :-

For those laboratories currently operating with multiple standalone Chromeleon CDS instances, simply connecting them together enables a range of advanced capabilities, including improved data security and efficiency—we call this Workstation Connect. This allows you to get the most out of your data, while offering full compliance capabilities and providing a way for you to gain many advantages of a full network deployment but without the associated effort, cost and IT infrastructure. Simply assign one computer as the Chromeleon Domain Controller and immediately all instruments and data can be accessed from any instance. Remote working is enabled, system and user administration is centralized, and data availability and exchange is improved. This increases collaboration while delivering enhanced security with compliance capabilities. With Workstation

Connect, enterprise-level support is added to provide fast resolution of issues, with access to upgrades and security updates, maximizing the uptime, reliability and performance of your business-critical software.



Expand your network :-

Growing laboratories, whether running Workstation Connect or multiple standalone software instances, can move to an enterprise-level CDS by simply adding a server to the installation to provide central data storage and administration with consolidation of all software under one vendor. An enterprise installation offers not just greater capacity and performance, but also enhanced security for your data. With centralized data storage, backup and archiving procedures can be put in place and you can utilize Network Failure Protection to ensure compliant operation independent of the network. So, if the network goes down, unique XVaultTM technology will keep operations running, ensuring 24/7 laboratory uptime. After network recovery, data is automatically uploaded and synchronized to the central server, ensuring data security and integrity. With centralized storage, all your data can be easily compared, searched and trended, offering insights into system usage, user actions, and method robustness.

As your laboratory continues to expand, additional servers can be added to distribute the workload between central resources with load-balancing and failover capabilities, ensuring the same performance as local operation and increasing reliability.

✓ Key benefits of Chromeleon 7.3.1 CDS for the laboratory:

- ★ Improved lab productivity helps you do more with less and realize significant productivity gains.
- ★ More "right-first-time" results reduced out-of-specification results, even for non-expert users.- Easier to achieve, maintain, and demonstrate compliance, making it easier than ever to keep up with ever-evolving standards and regulations.

✓ Key benefits of Chromeleon 7.3.1 CDS for IT:-

- * Reduced costs for faster ROI- Enable standardization of your system to reduce costs with no compromise to additional lab efficiency gains
- ★ Seamless scalability from workstation to global enterprise deployment, for central deployment, maintenance, and management of the CDS with local, regional, or cloud data centers
- ★ Efficient, long-term stability for built-in business continuity with industry-leading data security and integrity tools

✓ Capabilities built for the lab in Chromeleon 7.3.1 CDS:-

- ★ Industry-leading multi-vendor control, for support of over 525 different instrument modules from over 20 manufacturers, including all Thermo Scientific chromatography and many Thermo Scientific MS instruments
- ★ Secure, administrator-controlled user access and permissions to ensure data integrity and enable compliance with GxP and 21 CFR Part 11
- ★ Simplified run creation, including sequence, methods, and reports, with universal two-click eWorkflowTM procedures now offering dual system support
- ★ Automated pass/fail decisions during runs, with Intelligent Run Control to get the analysis right the first time

- ★ Quick, accurate peak integration with Cobra Peak Detection and handling of unresolved peaks with SmartPeaksTM Integration Assistant
- ★ Streamlined MS quantitation and support for multiple MS workflows, data processing, elemental composition, and NIST spectral library screening
- ★ Simplified backup, searching, and trending of chromatography and mass spectrometry data
- ★ Integral Report Designer with customizable, spreadsheet-based report templates, with advanced calculations and charting

✓ Chromeleon 7.3.1 CDS capabilities for IT:-

- ★ Support for full virtualization with dongle-free licensing
- ★ Fully tested and documented support for cloud deployment
- ★ Thermo Scientific™ 247 Instrument Controller, eliminating the need for antivirus or operating systemdriven updates
- ★ Central management and scheduled update downloads from within Chromeleon CDS
- ★ Secure storage of all results in relational database (Oracle OR Microsoft SQL Server)
- ★ Chromeleon Data Vault, a domain architecture that enables adding storage and redundancy as the number of users and/or demand for uptime grows
- ★ Performance tested and optimized for 1,000+ users and instruments
- ★ Built-in business continuity in case of network or central resources being unavailable
- ★ Enhanced integration with Thermo ScientificTM WatsonTM LIMS and Thermo ScientificTM SampleManagerTM LIMS, SDMS, and LES to manage the complete laboratory workflow.

5) Lab Solution Software:-

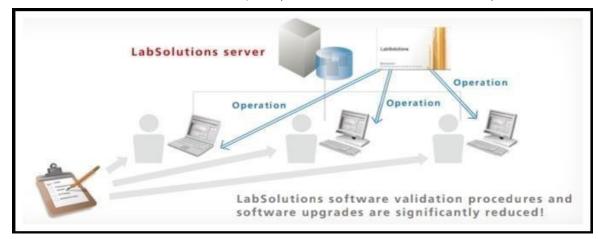
LabSolutions features an innovative operating environment and provides complete data management to ensure secure information in networked laboratories.

LCs and GCs are used extensively in quality control and research and development departments in a wide range of industries, including pharmaceutical, chemical, and food. Recently, an increasing demand for food safety and environmental analysis and measurement has led to a dramatic increase in the number of samples being analyzed which, in turn, has resulted in demands for faster, easier-to-use instruments and software. In the pharmaceutical industry, compliance to regulations and guidelines, such as CSV and PIC/S GMP, U.S. FDA 21 CFR Part 11, Data Integrity and so on, and the proper, efficient management of instruments and analytical data are required. With this background, faster, more efficient management of instruments and data is essential. LabSolutions is a network-compatible analysis data system capable of meeting these needs.

LabSolutions CS:-

Freely Accessible to the Analysis Network:-

Since all analytical data are managed in the database of a server computer, LabSolutions CS can read data from any personal computer on a network. In addition, analysis directions and instrument monitoring and control can be performed from a personal computer (client PC) not connected to the instruments.



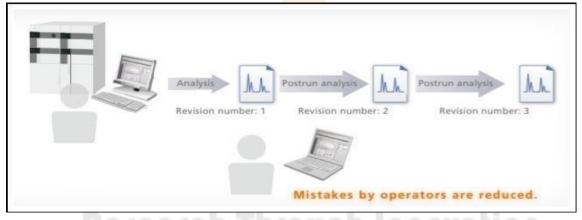
Moreover, client PC functions are performed on a server and client PCs corresponding to a Windows terminal service do not need to install LabSolutions software. Furthermore, LabSolutions CS corresponds to Citrix XenApp and can perform more advanced server management.

With LabSolutions, both LC and GC systems are operated from the same software, enabling simultaneous control of multiple instruments from a single PC. The LC and GC instruments connected can be used in a flexible manner by switching between them. The shared LC and GC analysis operating environment, which inherits the operability of LCsolution and GCsolution, lessens the training time for workstation operations.

Safe and Secure Data Management :-

✓ Database Management Prevents Mistakes :-

With LabSolutions DB and CS, the analysis data is managed securely by the database. Overwriting, deletion and other mistakes typical of data file management do not occur. In addition, when postrun analysis is performed using the acquired data, postrun analysis data revision numbers are automatically assigned, preventing the accidental overwriting of raw data. It is easy to display earlier data.



LabSolutions CS Network :-

√Total Laboratory Data Management:-

- One stop solution for Shimadzu UV, FTIR, GC, HPLC, LCMS, ICPMS and Thermal Systems
- Seamless integration for Agilent and Thermo GC and HPLC Connectivity to Shimadzu GCMS, TQMS, AAS, TOC through MID
- Electronic Record / Electronic Signature.

✓ Complete IQ/OQ Documentation Available :- ✓ Centralized,

Safe and Secure Data Management:

- Complete data stored on server
- Data base structure with safe and secure data
- Centralized control for user groups management, policy settings and projects
- Transfer of method, batch and report to server.

✓ Complete Audit Trails for System, Applications and User Management :-

- Logs are directly stored on server for complete security
- Instrument longs are also stored on server directly

✓ User-Friendly Operating Environment :-

- Complete operating status on single screen
- Powerful search engine
- Uninterrupted chromatography analysis even when server is down
- Customized spreadsheet reports through optional multi data report
- Powerful tool of "Create Report Set" to compile data from various instruments in one report with their logs.

LabSolutions i-Package :-

- Cost effective solution
- Incorporates all LabSolutions CS capabilities
- Connects unlimited Shimadzu spectro systems
- Connects up to 15 chromatography systems
- Minimum investment on server hardware
- Can be upgraded for more chromatography system.

6) ProcessPro's Comprehensive Analytics and Reporting Software:

The app ProcessPro offers dynamic views' on- the- cover' with measureless reporting openings. druggies are suitable to record, checkup, sludge and query as applicable, gaining easy access to the data and manipulating and imaging the information. Pre determined and customizable dashboards offer crucial business details, enhancing out- of- the- box operation capabilities. It's an advanced logical tool; featuring a robust data reporting storehouse, Advanced Analytics enables interactive visualization, reporting and analysis of your data from any device(desktop or mobile) anywhere in your business. In any case, graphing, sorting and digging into your critical business details, combined with detailedpre-constructed reports, criteria and KPIs, scheduling and warnings give an essential tool for your business analysis. Predefined links and the data association also give the capability to extend the study to otherpre-constructed business coffers.

7) BatchMaster ERP Software:-

BatchMaster Software focuses 100 per cent on designing and furnishing software results for the food, chemical, nutraceutical and pharmaceutical diligence. It's a formula grounded, process manufacturing operation that supports R&D, expression, packaging, going, product, QC, QA, force, compliance, and traceability. Sample operation, medication (MRP), scheduling (MPS), warehousing, alarm operation, and sharing of EDIs are voluntary modules. similar technologies allow businesses to streamline and grow their operations fleetly, cut costs and fluently misbehave with moment's decreasingly strict nonsupervisory authorizations.

8) S2K Enterprise Software:-

VAI's technology roadmap, (VAI's) collective strategy with IBM, offers businesses with a business that relies on stylish practices in the assiduity that exploits technology to develop quality and boost performance. The S2 K product family includes distribution, manufacturing, retail, mileage, and leasing results; with assiduity-specific features for Durable Goods, Apparel, and Pharmaceutical companies.

9) MasterControl Quality Management System(QMS):-

MasterControl Quality Excellence(a QMS Software Solution) is an intertwined quality operation system that eliminates the need to paper- grounded quality processes. It helps life- wisdom companies cleave more efficiently to the ever- changing FDA and ISO quality norms. It also helps you automate all databasebased systems for program operation, timetabling, read- up, monitoring, escalation, review, and blessing. The crucial frame in the MasterControl suite combines all quality processes including control of advancements, feedback from consumers, corrective/ preventative action(CAPA) and checkups. MasterControl also offers a manufacturing result called MasterControl Manufacturing Excellence. It's a suite of proven technologies that optimizes the side- to- end lifecycle of manufacturing and fluently integrates with other enterprise software similar as MRP, MES, ERP, mama and product schedules.

CONCLUSION:-

This article will review the challenges facing pharmaceutical laboratories, and examine the three most common alternatives available to pharmaceutical companies evaluating laboratory informatics systems in the context of the above-mentioned challenges.

Also in this review article we introduced various computer system software useful for regular cGMP practices like manufacturing, documentation, etc. were followed in the pharmaceutical industry. This article also covers the current and future need of pharmaceutical industry for software. There are some common softwares which has been used in organization, quality control area, research and development, storage, resource and generation, in all disciplines of engineering and architect, management, pharmacy and agriculture. The listed softwares are specially used in pharma sectors and most useful for problem solving, data integrity issue, creating tamperproof audit trial, data backup and restoration.

REFERENCES:-

- 1.Mannam A, Mubeen H "Review Article Digitalisation And Automation In Pharmaceuticals From Drug Discovery To Drug Administration" international Journal of Pharmacy and Pharmaceutical Science 10(6), 2018 May 8, 1-10.
- 2.Mali P Y, Panchal S J "A review on worldwide essential software resources in Pharmacy" Chronicles of Young Scientists 2(1), 2011, 11-20.
- 3.Victor DeCouto, Singh S. "Electronic Validation in the Pharmaceutical Industry" (2016). Mathematics and Computer Science Capstones. 28. La Salle University La Salle University Digital Commons. http://digitalcommons.lasalle.edu/mathcompcapstones/28.
- 4. Upadhyay P. The Role of "Verification and Validation in System Development Life Cycle" IOSR Journal of Computer Engineering 5(1), sep-oct 2012, 17-20.
- 5. Jukka R, Johannes K "Review The Future of Pharmaceutical Manufacturing Sciences" Journal Of Pharmaceutical Sciences 104:3612–3638, 2015 Published online 2015 August 17 in Wiley Online Library (wileyonlinelibrary.com)..
- 6.Hoffmann A, IGihny-Simonius J, Marcel Plattner, Vanja Schmidli-Vckovski, Kronseder e C "Computer system validation: An overview of official requirements and standards" Pharmaceutics Acta Helvetiae, 72, 1998, 317-325.
- 7.GAMP 5 Good Automated Manufacturing Practices, Version 5, Guideline document for automated systems from International Society of Pharmaceutical Engineering.
- 8.https://softwareconnect.com/manufacturing/virtual-office/
- 9.https://www.softwareadvice.com/manufacturing/pharmaceutical-manufacturingsoftwarecomparison/
- 10.https://www.softwareadvice.com/manufacturing/pharmaceutical-manufacturingsoftwarecomparison/
- 11. https://www.pharmtech.com/view/overview-lims-pharmaceutical-industry

- 12.JMP is a suite of computer programs for statistical analysis developed by JMP, a subsidiary of SAS Institute.

 .Wikipedia ·https://www.jmp.com/en_hk/industries/data-analysis-software-for-thepharmaceutical-industry.html.
- 13.softwaresuggest.com.https://www.softwaresuggest.com/pharmaceutical-industry-software.
- 14.Software Advice is a company that provides advisory services, research, and user reviews on software applications for categories including medical, CRM, HR, construction, business intelligence and marketing automation. Wikipedia https://www.softwareadvice.com/manufacturing/pharmaceutical-manufacturingsoftwarecomparison/.
- 15.https://www.pharmtech.com/view/overview-lims-pharmaceutical-industry.
- 16.https://www.pharmaguideline.com/2022/01/laboratory-information-managementsystemlims.html?m=1.
- 17.https://www.pharmasoftsol.com/laboratory-information-management-system.php
- 18..https://sapac.illumina.com/informatics/infrastructure-pipeline-setup/lims.html.
- https://solution4labs.com/en/laboratory-information-management-software-lims-101.
- 19.https://www.softwareadvice.com/manufacturing/pharmaceutical-manufacturing-software- comparison/
- 20.https://www.slideshare.net/JYOTIRMOYROY11/laboratory-information-management-systemlims76379668
- 21https://www.slideshare.net/mariam1020/laboratory-information-management-system-lims
- 22..https://www.slideshare.net/PRAGADEESHSURESH2/criteria-to-choose-best-laboratoryinformationmanagement-system
- 23.T. Dingsøyr, S. Nerur, V. Balijepally, and N. Moe, "A decade of agile methodologies: Towards explaining agile software development," The Journal of Systems and Software, vol. 85, no. 6, pp. 1213-1221, 2012.
- 24.M. McHugh, F. McCaffery, B. Fitzgerald, K. Stol, V. Casey, and G. Coady, "Balancing agility and discipline in a medical device software organisation," Software Process Improvement and Capability Determination, pp. 199-210, 2013.
- 25.M. McHugh, O. Cawley, F. McCaffery, I. Richardson, and X. Wang, "An agile v-model for medical device software development to overcome the challenges with plan-driven software development lifecycles," in Proc. 5th International Workshop on Software Engineering in Health Care, 2013, pp. 12-19.
- 26.B. Fitzgerald, K. Stol, R. O'Sullivan, and D. O'Brien, "Scaling agile methods to regulated environments: An industry case study," in Proc. the 2013 International Conference on Software Engineering, pp. 863872, San Francisco: IEEE Press, 2013.
- 27.L. Heeager and P. Nielsen, "Agile software development and its compatibility with a documentdriven approach? A case study," in Proc. 20th Australasian Conference on Information Systems, pp. 205-214, Melbourne, 2009.
- 28. EudraLex Volume 4 GMP Annex 11: Computerized Systems, European Commission 2011
- 29.GAMP5, A Risk-Based Approach to Compliant GxP Computerized Systems, ISPE, Tampa, FL, 2008.