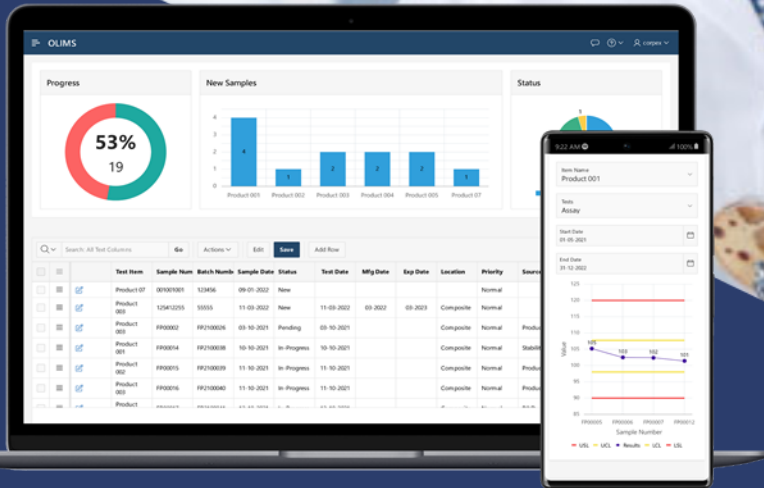# SMART LAB

CORPEX-LIMS is an innovative laboratory information management system that enables manufacturers and quality-based organizations to optimize their operational efficiency while ensuring compliance with internal corporate and external regulatory standards. The system facilitates the manufacturing of high-quality products within regulatory guidelines and is scalable to fit organizations of any size. With its task management and reporting features, CORPEX-LIMS empowers users throughout the facility or organization to access and input data from a centralized system.

www.corpex.info

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ABOUT

CORTEX Informatics is a World class provider of intelligent automation solutions for healthcare, pharmaceutical, food, and chemical industries. Our AI-powered software streamlines critical workflows, reduces errors, and boosts productivity, enabling scientific organizations to focus on what matters most - accelerating drug discovery, enhancing patient care, and driving business growth. We empower scientists with intuitive tools and actionable insights, allowing them to focus on their core objectives while CORTEX takes care of the rest.

CORPEX
INFORMATICS

OUR APPROACH

Fundamental to the Corpex informatics approach is the development of fully functional modules to address specific quality requirements for

- **SilverLIMS**: QC Laboratory System,
- **MicroLIMS**: for Microbiology laboratories,
- **StabLIMS**: Stability Study Management,
- **WaterLIMS**: Water Laboratory solution.
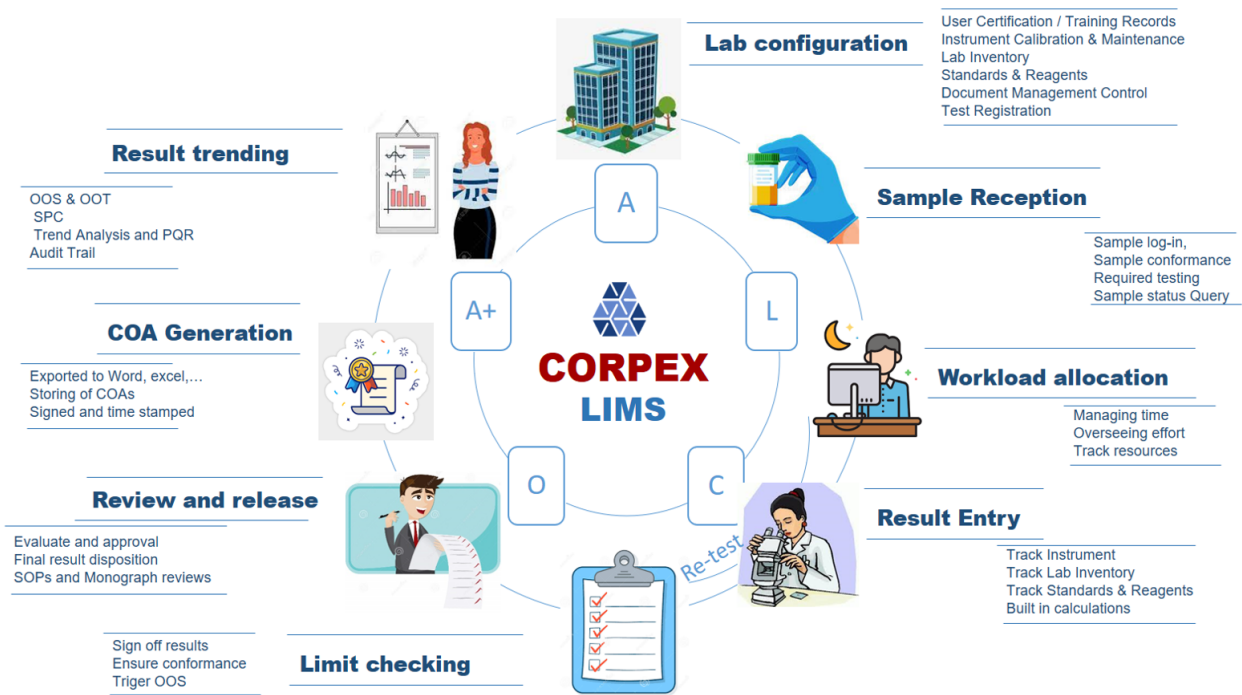- **BioLIMS**: for clinical and bioequivalent laboratories

All the applications have been jointly developed with Pharmaceutical Companies.

The Corpex informatics modules can be either interfaced with third party or customers' in house applications (LIMS, ERP, Data Archives etc), or integrated within the Corpex informatics' LIMS applications.

CORPEX
INFORMATICS

WHAT IS CORPEX-LIMS?

Efficiently Manage Your Organization's Processes with CORPEX-LIMS CORPEX-LIMS is a comprehensive module that streamlines the management of incoming raw materials, in-process materials, and finished goods. From initial registration to final product, this platform provides an integrated solution for all your business needs.

Lab configuration
User Certification / Training Records
Instrument Calibration & Maintenance
Lab Inventory
Standards & Reagents
Document Management Control
Test Registration

Sample Reception
Sample log-in,
Sample conformance
Required testing
Sample status Query

Workload allocation
Managing time
Overseeing effort
Track resources

Result Entry
Track Instrument
Track Lab Inventory
Track Standards & Reagents
Built in calculations

Limit checking
Sign off results
Ensure conformance
Triger OOS

Review and release
Evaluate and approval
Final result disposition
SOPs and Monograph reviews

COA Generation
Exported to Word, excel,...
Storing of COAs
Signed and time stamped

Result trending
OOS & OOT
SPC
Trend Analysis and PQR
Audit Trail

WHAT CORPEX-LIMS DOES?

CORPEX-LIMS is a cutting-edge solution that empowers manufacturers to optimize operational efficiency while ensuring adherence to both internal corporate and external regulatory standards. This robust system facilitates the seamless production of high-quality products for successful market entry. With its fully scalable design, CORPEX-LIMS caters to organizations of any size. The integrated task management and reporting features provide users across the facility or organization with streamlined access to input and retrieve data from a centralized system, enhancing overall operational effectiveness.

COMPLIANCE

CORPEX Informatics is pioneering in 21 CFR Part 11 compliant solutions for the entire product life cycle of pharmaceutical, and other regulated process manufacturers' quality control operations.

- System validation
- Audit trail
- Restricted access
- Essential training
- Record generation
- Quality procedures
- Digital signature

Corpex informatics products are designed and developed with respect to the latest guidelines from the FDA, ICH and EU.

FDA
21 CFR Part 11

Key Features

CORPEX-LIMS helps organizations streamline the management of their incoming raw materials, in-process materials, and finished goods, from the initial registration of the material to the final product. It encompasses all necessary quality control activities, such as infrastructure lab design, facility management, asset management, consumables management, and sample management.

- Ensure compliance with GxP, GAMP5, GALP & FDA CFR Part 11 requirements.
- Adhere to multiple sets of regulations and guidelines stipulated by global regulatory agencies like FDA, EMEA, EPA, TGA, EudraLex, ISO.
- Integrate Microsoft Windows, Office, and SharePoint into desktop, mobile, and web platforms.
- Our solution provides electronic worksheets, which expedite data entry, enhance efficiency, and minimize manual errors. The added benefit of complete tracking eliminates the need for printing.

- The CORPEX-LIMS application caters to the majority of customer requirements while still allowing for 20% customization to meet specific needs.
- The system administrator can manage user authentications, security levels, authority roles, and user permissions.
- Unlimited users can be registered with different authority levels, and up to 250 users can log in simultaneously. Each user has a unique username and secure password that has a validity period. User logs are automatically archived, and any activity or changes are linked to the relevant user until logout.
- User profiles include calendars, tasks, documents, and purchasing requisitions. Traceability data are secure and non-editable by unauthorized users.
- The application has built-in functions such as daily workload, audit trail, working hours, cost estimate, change control requests, and inventory control.
- Investigations of out-of-specification (OOS) results and corrective and preventive actions (CAPA) can be monitored. The investigation master list holds all investigations until the corrective and/or preventive action is recorded.
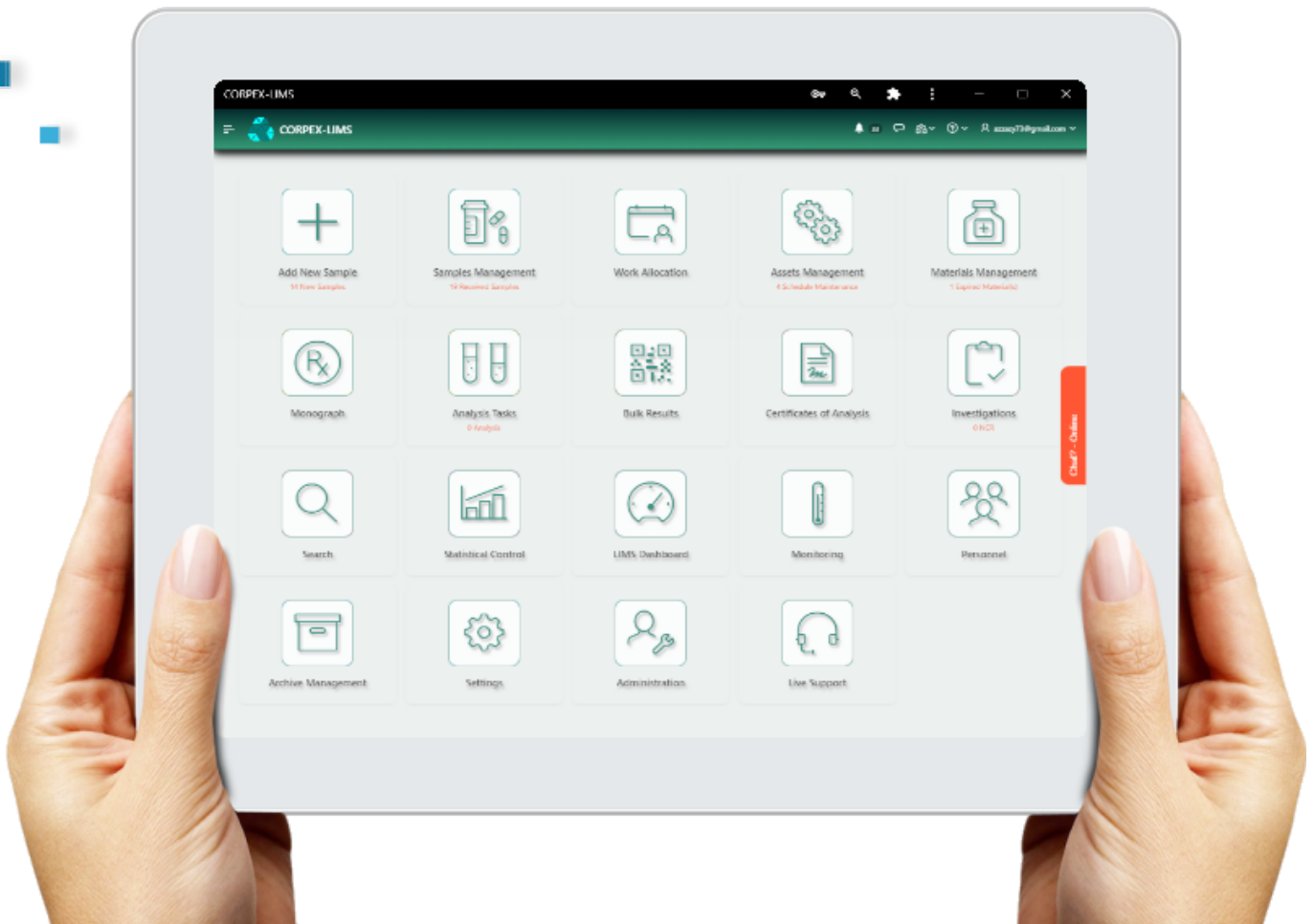
Here are some of the key features and benefits of CORPEX-LIMS:

- Comprehensive Statistical Package: CORPEX-LIMS offers a range of statistical tools including summary views on screen and printable materials, and the ability to perform detailed calculations through statistical analysis, ANOVA, ANACOVA, and trending studies either together or separately.
- Live Synchronization: This system ensures that data is consistent across all sources and targets through continuous harmonization.
- Custom Reports: All data is provided in printed, write-protected materials, and can be exported to various applications, including Microsoft Word, Excel, and Acrobat Reader format.
- Familiar GUI and User-Friendly Interface: CORPEX-LIMS has a graphical user interface that is user-friendly and easy to navigate.
- Immediate and Repeatable Implementation: CORPEX-LIMS can be implemented rapidly, and validation is provided via IQ/OQ/PQ, which can be defended during regulatory audits/reviews.
- Compliance with cGMP: CORPEX-LIMS is in compliance with Current Good Automated Manufacturing Practices (cGMP) and follows the life cycle approach.

LABLET X4

SilverLIMS

REVOLUTIONIZING DIGITAL CONTROL

SilverLIMS offers a seamless, swift implementation process, with straightforward upgrades and support, simplifying the validation process. It enables better monitoring and enhances supplier product quality. The platform's statistical functionality allows for early detection of manufacturing quality deviations and reduces the time required to handle Out Of Specification products. Ultimately, this leads to a boost in operational efficiency.

SilverLIMS represents the future of Laboratory Management Systems for quality control laboratories in the pharmaceutical, chemical, and food industries. It provides an integrated solution to manage laboratory samples, lab instruments, resource allocation, and document control, all through a modern and user-friendly interface.

StabLIMS

Stability Studies Management System

STABLIMS™ provides support for various stability studies across diverse climatic zones. To ensure optimal results, it's imperative to establish the incubation temperature and relative humidity, and determine testing frequency, acceptance criteria, and pull dates. Additionally, defining the infrastructure and sample location of the inventory is crucial.

STABLIMS™ is a comprehensive system designed to manage the day-to-day activities of stability departments, whether it be in the quality or research and development sectors. The platform adheres to medicinal product regulations, including FDA, WHO, CDER, ICH, ISO, and CFR 21 Part 11 guidelines to manage and automate diverse drug products. STABLIMS™ features electronic worksheets for speedy data entry, enhancing efficiency while minimizing manual errors. You can track your progress effortlessly without the need for printed documents. Our software satisfies up to 95% of customer requirements, with the remaining 5% completely customizable to meet specific demands.

BioLIMS

Biotechnology laboratory Management system

Biotech labs use biotechnological laboratory information management systems (LIMS) to automate tasks, increase accuracy, and ensure compliance. LIMS can be used to track samples, reagents, experiments, and results, and are used in pharmaceutical, clinical, research, clinical trials labs. Benefits include increased efficiency and accuracy, enhanced compliance, and improved communication and collaboration. When choosing a LIMS system, it is important to consider the lab's specific needs.

BioLIMS systems can be customized to meet the unique needs of each laboratory. For example, a pharmaceutical lab may require a LIMS system that is compliant with FDA regulations, while a food and beverage lab may require a system that can track ingredients and ensure quality control. Additionally, some labs may require a BioLIMS system that can integrate with other laboratory equipment, such as chromatography systems or mass spectrometers.

Implementing a BioLIMS system can also help labs to streamline their workflows and reduce the amount of manual data entry required. This can lead to faster turnaround times for experiments and results, which can be particularly important in clinical and pharmaceutical labs where time is of the essence.

MicroLIMS

Automate Microbiology Lab

Media Preparation · **Microbial Limits Test** · **Sterility & LAL Testing** · **Water Examination** · **Environmental Monitoring** · **Antimicrobial bioassay** · **Disinfectant Efficacy** · **Preservative Effectiveness** · **Trend Analysis** · **OOS Investigation** · **Data Visualization** · **Audit Trail**

TRANSFORMING MICROBIOLOGICAL CONTROL

MicroLIMS is a software specifically designed to boost the efficiency and productivity of microbiology labs. It is capable of monitoring data associated with experiments, laboratory workflows, instruments, and documentation activities, ensuring accuracy and reducing the potential for errors.

MicroLIMS simplifies the management and organization of laboratory data, allowing microbiologists to seamlessly integrate the software into their existing workflows. The user-friendly interface facilitates ease of use, while real-time data analysis and reporting capabilities provide timely insights for informed decision-making. Any microbiology lab looking to enhance productivity and efficiency while maintaining high standards of accuracy and quality control must consider utilizing MicroLIMS.
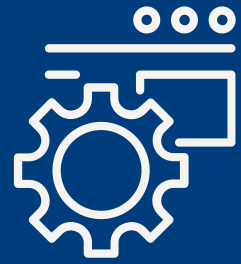
WaterLIMS

Water Laboratory Information System

The Water Laboratory system is an all-encompassing solution that simplifies and speeds up the testing process of water samples. It is designed to manage daily sample testing across diverse locations, presenting the results in graphical form through various dynamic functions. The system also streamlines sample reception and management, laboratory infrastructure, and user management. This is made possible through multiple user profiles equipped with different permission levels, security protocols, and authorizations. The system comprises electronic worksheets, built-in features for cost estimates and inventory control, and advanced statistical analysis.

One of the most impressive aspects of the Water Laboratory system is its ability to offer provisions for investigations and corrective actions. This feature enables the system to quickly identify any issues with sample testing and allows for corrective measures to be taken promptly. Furthermore, the system is equipped with live synchronization, which ensures that all data across different platforms is updated in real-time. Lastly, the system has a report generation feature that allows for easy and efficient analysis of data. Its user-friendly interface is integrated with Microsoft Windows, Office, and SharePoint, and is accessible across desktop, mobile, and web platforms. The Water Laboratory system is the perfect solution for anyone who wants to streamline their water sample testing process while maintaining accuracy and efficiency.

Automated Features

The following features are included with your subscription

Enhanced Collaboration
Emails are distributed to users as they get assigned to records.

Automated Reminders
Automatic notifications remind users of assignments approaching due date ahead of time and
continues to notify them after the due date until an appropriate action is taken.

Mobile App
Access Corpex-QMS from any smartphone or tablet wherever you are.

Reporting & Charting Tool
Build real time reports in minutes with our easy-to-use reporting & charting tool.

Visual Drag & Drop Designers
Configure forms and workflows and build reports based on your company's requirements

Data Import Tools
Import historical records by mapping data to fields in Corpex-QMS.

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Enhancement and New Applications:

We strive to ensure our product is best in-class, so we roll out enhancements, bug fixes, and new applications on a regular basis.

Initial Training:

After onboarding, we will conduct training sessions that cover:

- Administrators' Training: In this training, we train the users that will be administrating
- Corpex-QMS on skills they need such as creating user profiles, controlling access, adding users to groups, and resetting users' passwords.
- Train the Trainer: During these sessions, we will train selected employees from your side on using all the Modules as decided by the customer.
- Additional training can be arranged based on your needs for an additional fee.

Multi-Location Structure

This feature allows you to segregate documents by geographical/organizational divisions called locations enabling one system to be deployed for different divisions. This feature ties up users to locations so that any record that a user creates will also be connected to the location of that user. Also, access to documents/records can be restricted based on locations.

E-signature

This feature allows you to force users to re-authenticate using their username and password whenever they save documents or move them across the workflows.

Audit Trail (Field History)

This additional feature allows you to track changes to Corpex-QMS records whenever a record is changed by any user. Tracked changes include previous value, new value, date changed and name of the user that did the change.

Key Benefits

- Rapid material release
- Risk-based Approaches
- Creates inter-departmental visibility & enhance planning
- Minimizes inventory investments & expedite material turnover
- Instills efficiency in all activities
- Shifting annual product review to live review
- Centralizes inventory & material management data

Onsite Training

CORPEX Informatics offers comprehensive onsite training programs catering to all levels, with certification provided for users and administrators, as well as a training matrix. Our training package includes supported documents such as user manuals, training materials, handouts, and sample SOPs. We also provide a validation protocol (IQ/OQ/PQ) with a separate order.

Live Support

CORPEX Informatics provides businesses with a comprehensive live support system, available during business hours via live chatbot, social communication, and phone calls.
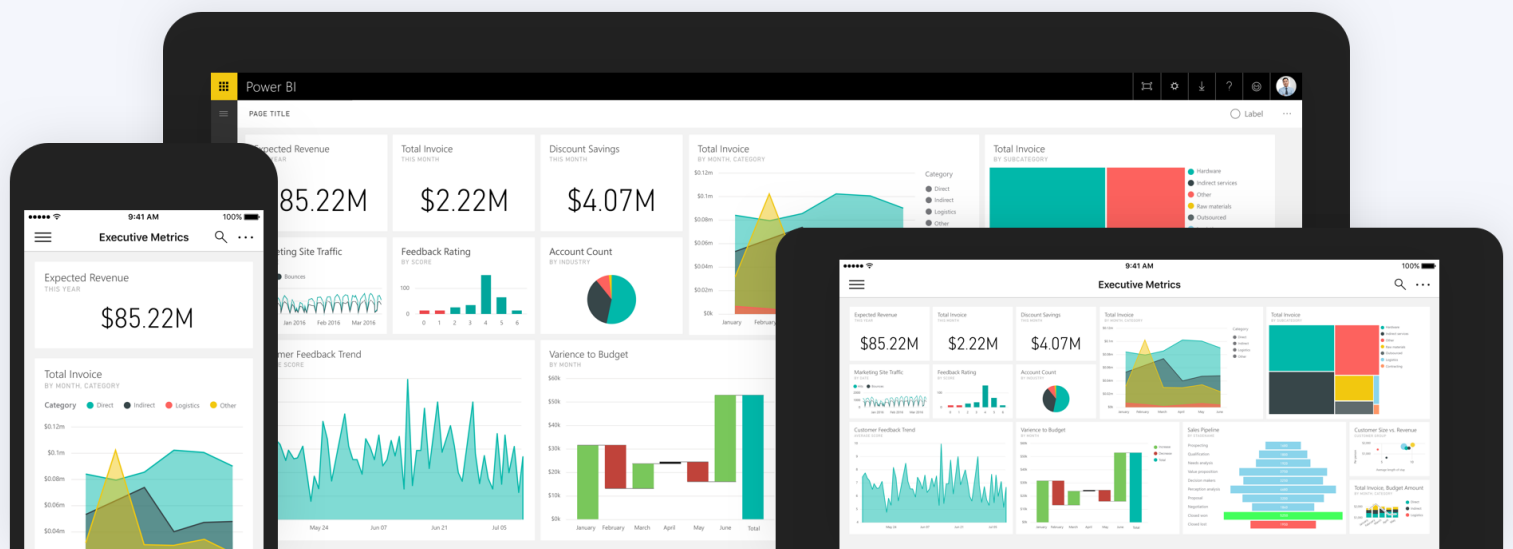
Our support team is comprised of knowledgeable and friendly professionals who are dedicated to providing prompt and effective assistance to our clients. Whether you have questions about our products and services or you need help troubleshooting an issue, we are here to help.

Data
Visualization

The Significance of Data Visualization in BI Dashboards and how Oracle Apex can helpTo make complex data more understandable, BI dashboards rely heavily on data visualization through charts, graphs, and other visual components. Oracle Apex provides developers with a wide range of interactive and customizable visual components to meet specific requirements. These include charts, gauges, calendars, and maps, each with its unique benefits.

Charts are a widely used component for data representation in BI dashboards. They allow for the representation of trends, comparisons, and distributions. Gauges, on the other hand, are ideal for displaying critical metrics and key performance indicators (KPIs). Corpex-QMS offers a variety of gauge types, such as speedometers, progress bars, and circular gauges, to meet your needs.

Calendars and maps are also important components for data representation. They enable the display of data geographically or temporally. Corpex-QMS ensures easy integration with Google Maps, making it simple to visualize data on the map. The calendar component is useful for displaying data over time, such as appointments or events.
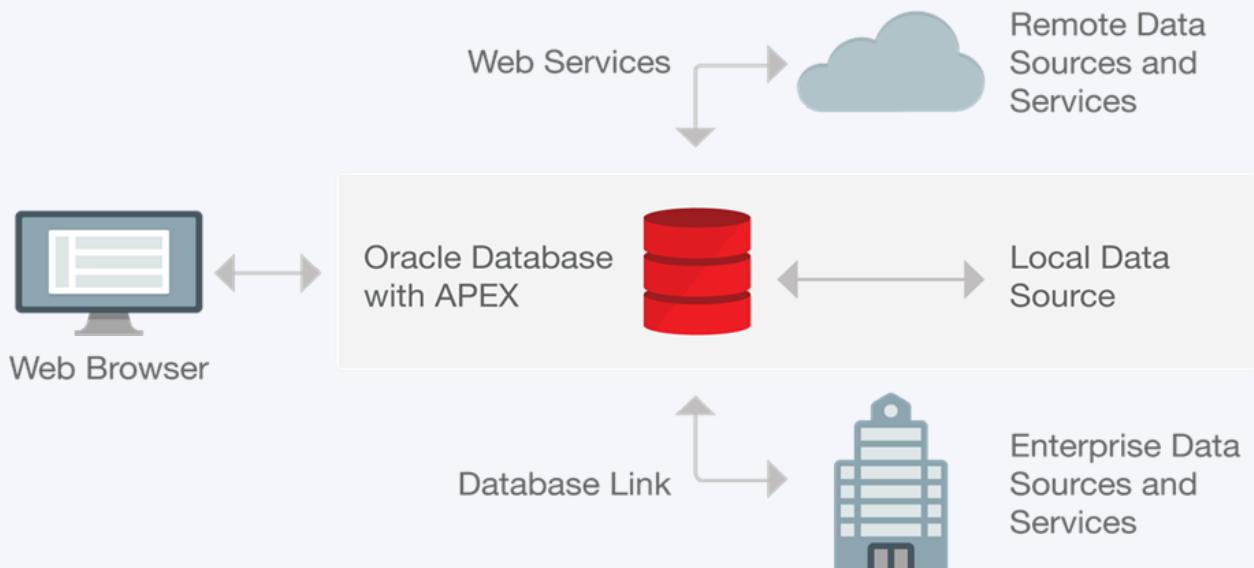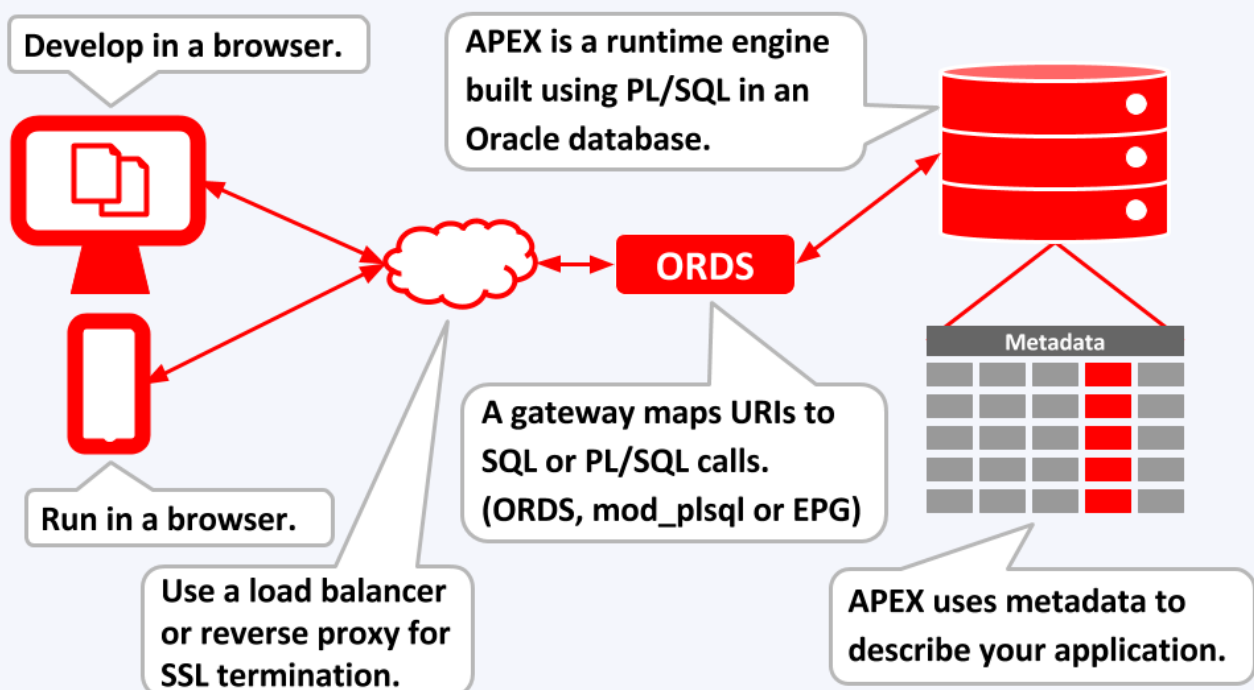
Development
Platform

The Benefits of Modern Data Management Systems and the Advantages of Oracle APEX. Conventional systems have been widely used for data recording and enterprise management over the years. However, as data volume increased, these methods became less effective and could not process data as efficiently as modern tools. The high economic cost and environmental impact also made these systems less desirable. With modern data and information management systems, business owners can now manage data and leverage information with ease. These systems allow for seamless information sharing with teams and relevant stakeholders.

One of the most popular modern web application development platforms currently available is Oracle APEX. This tool provides a user-friendly interface suitable for all skill levels, easy scalability and customization, and continuous development and support from Oracle. Oracle APEX is used for various projects, including business applications, data-driven applications and analytics, public web applications, and internal applications.

Infrastructure Configuration

Develop in a browser.

APEX is a runtime engine built using PL/SQL in an Oracle database.

Run in a browser.

A gateway maps URIs to SQL or PL/SQL calls. (ORDS, mod_plsql or EPG)

Use a load balancer or reverse proxy for SSL termination.

ORDS

Metadata

APEX uses metadata to describe your application.

Production Environment Topology

Delivery
Milestone

At CORPEX Informatics, we are committed to being involved in every stage of the CORPEX-LIMS implementation process. The duration of the implementation process varies based on the client's requirements, and we provide an estimated timeframe for the same. Our approach comprises several phases that aim to ensure a smooth transition with minimal disruptions to the client's critical procedures. Additionally, we offer a range of service and support contracts that can be customized to meet our clients' specific needs.
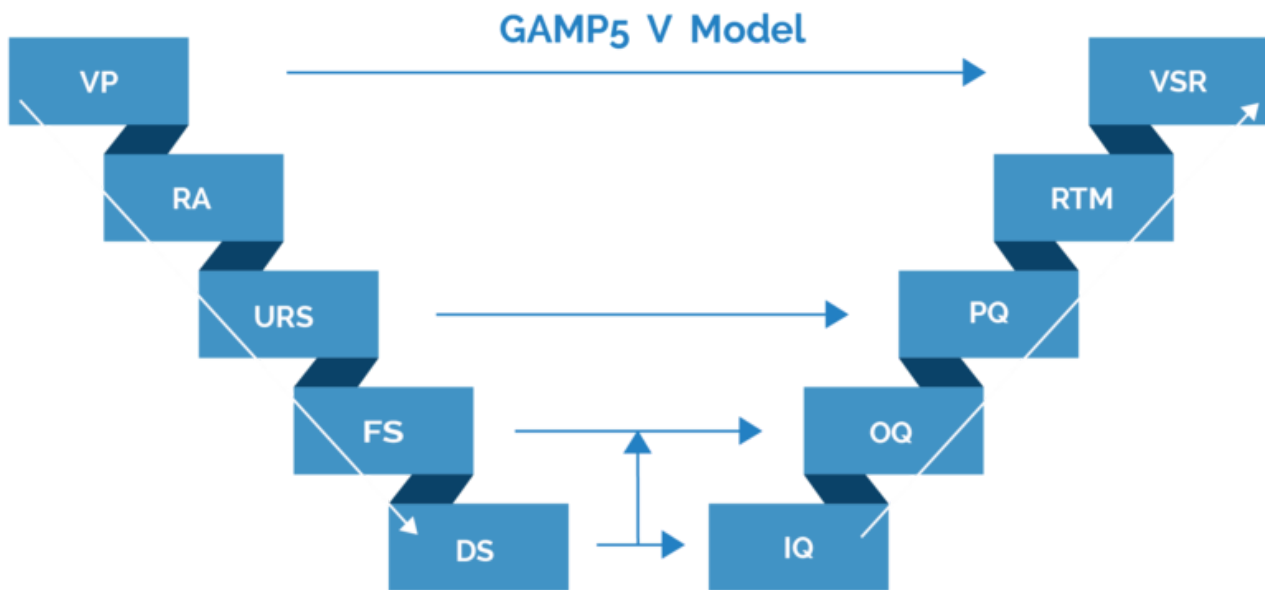
Six Months Roadmap for Business Planning Software Development and Optimization

This slide is 100% editable. Adapt it to your needs and capture your audience's attention.

Month 1	Month 2	Month 3	Month 4	Month 5	Month 6

PLAN		DELIVER		CLOSE	

Phase 1 INITIATE	Phase 1 & 2 ANALYZE	Phase 3 & 4 CONFIGURE	Phase 5 VALIDATE	Phase 6 DEPLOY	Phase 7 OPTIMIZE
Finalizing transition planning Company expectation alignment	Determine resource and architectural requirements Finalize design	Configuration Development Unit testing	Resource validation Readiness for business	Business operation go live with resource implementation	Monitoring continuous operations Plan for future projects

Manage	SCHEDULE – BUDGET – SCOPE – ISSUES – QUALITY – COMMUNICATION – MANAGE RISK

Deliverables

Computerized Software Validation (CSV)

GAMP5 V Model

VP — RA — URS — FS — DS — IQ — OQ — PQ — RTM — VSR

Computer Systems Validation (CSV) is a rigorous methodology utilized to examine, verify and document that a regulated computer-based system performs its intended functions accurately, securely and consistently, while ensuring traceability and reliability.

CORPEX-LIMS bundle encompasses a comprehensive CSV full validation package, which comprises:

- Validation Plan (VP)
- Risk Assessment (RA)
- User Requirement Specification (URS)
- Functional Specification (FS)
- Design Specification (DS)
- Validation Summary Report (VSR)
- Requirements Trace Matrix (RTM)
- Performance Qualification (PQ)
- Operational Qualification (OQ)
- Installation Qualification (IQ)

Annual Maintenance Contract (AMC)

The AMC will includefollowing scope. All AMC is provided remotelyfrom CORPEX Informatics Office or onsite according to the business need :

Service Plan options	Inclusions
Silver package (10%)	• 9 hours / 5 days Email and Telephone support • Guarantied 10% discount on future purchases • Free remote end user support for 10 hours per month • Fixed onsite support
Golden package (20%)	• 9 hours / 5 days Email and Telephone support • Patches and fixes • Minor version updates • All required change controls • Guarantied 20% discount on future purchases • Free remote end user supportfor 20 hours per month • 1 Free upgradeper year • Fixed onsite support • Regulatory Audit support once required
Platinum package (30%)	• 24 hrs. Email and Telephone support • Patches and fixes • Minor version updates and validation scripts • All required change controls. • Guarantied 30% discount on future purchases • 1 Free upgrade per year • Free remote end user support for 30 hours per month • Unlimited Name user with concurrent Users up to 100 Users

Return On Investment (ROI)

Return on Investment (ROI) is a fundamental performance metric employed to assess investment efficiency and profitability. It is also useful in comparing the efficiency of different investment options. The ROI calculation endeavors to determine the return on an investment relative to its cost.

To calculate ROI, one should consider the following parameters to reducing costs and increasing productivity through more efficient working

:

Reduce clerical work by skilled Lab Personnel

Enforce SOPs for more productive output

Improved Management control of resources

Monitor Resource Performance at all levels

Cut Down Resources Load by > 30%

Fast and accurate calculations of KPIs

Scheduled PM of equipment allowing to save a lot of Money

Thank
You

Let's work
Together

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2023