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Yokogawa Eyes Global Industrial Opportunities with OpreX LIMS V5 Laboratory Information Management System

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Keywords

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Summary

The ongoing COVID-19 crisis has turned a rare spotlight onto laboratories that must now deliver rapid and accurate results on thousands of daily tests that are vital for decision making at the highest levels of government. This, in turn,

Leveraging on deep industry knowledge across the main LIMS markets, its global network of resources, and a newly developed partner program, Yokogawa looks to expand the domestic success of its OpreX LIMS V5 solution across global markets.

requires those laboratories to operate at high levels of productivity and efficiency. And much as the adoption of technology to replace cumbersome manual processes and connect and analyze information raises productivity and efficiency in manufacturing, deploying technology in labs in the form of laboratory information management systems (LIMS) is essential for effective laboratory performance and to establish the all-important single source of truth.

While medical labs have only recently begun to grab headlines, laboratories have been playing a key role in industries for decades, notably in sectors running complex processes like oil refining and chemical manufacturing or those operating under tight regulations such as pharmaceutical and food & beverage. This is where industrial automation supplier Yokogawa is focusing efforts with its OpreX LIMS V5 offering for laboratories.

As detailed in a recent briefing for ARC Advisory Group by Japan-based Yokogawa executives, the OpreX LIMS product has a close to 30-year heritage in its domestic market with deployment at over 160 customer sites and regular additions of new functions and capabilities. By leveraging the company's deep

industry knowledge across the main LIMS markets, its global network of offices and resources, and a newly developed partner program, Yokogawa is now looking to replicate its domestic success through a major internationalization initiative for OpreX LIMS V5.

LIMS for Industry

The word “laboratory” usually brings to mind white-suited medical research scientists working in brightly lit rooms replete with test tubes, centrifuges, and microscopes, and investigating samples of blood, viruses, and other biological material. Less heralded are industrial laboratories, located either directly on



Laboratories Play a Key Role in a Variety of Process Industries (Photo Courtesy of Shell)

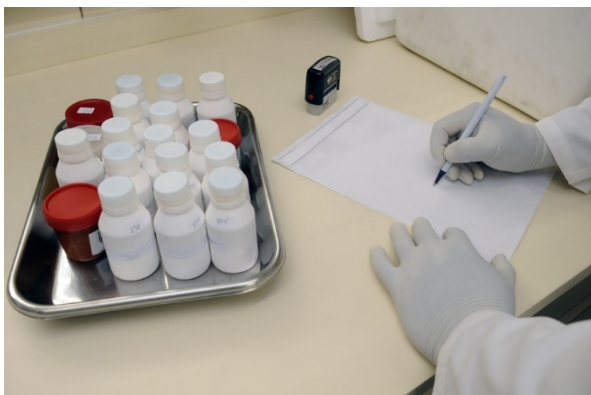
the manufacturing/process site or operating as contract services. These serve the needs of industrial enterprises in production quality control, environmental testing to assure sustainable manufacturing, adherence to regulatory requirements, research and development, and other areas.

In the downstream oil refining sector, for example, laboratories commonly perform functions such as crude oil feedstock testing, production quality control, and final product certification. The Euro 5 emissions regulations also require testing of sulphur content in diesel fuel using lab equipment such as ultraviolet fluorescence analyzers as well as tests for parameters including kinematic viscos-

ity and fuel density. Similarly, industries like chemical, food & beverage, pharmaceutical & biotech, and waste & wastewater all have specific lab testing needs.

Just as automation and information technology improve operational efficiency on the plant floor and enhance decision making on the top floor, laboratory operations need technology to help drive efficiencies across key functions such as sample tracking, inventory management, labor and equipment scheduling, and report generation and archiving. Doing so helps ensure that the business imperatives on laboratories to be productive, safe, and to offer (internal or external) customer service characterized by fast turnaround time and adherence to high quality standards are met.

Enter laboratory information management systems, more commonly referred to by the “LIMS” acronym. ARC Advisory Group defines LIMS as a software-



LIMS Can Help Overcome Many Information Problems Common to Manual Processes

based laboratory management system with features that effectively support a modern laboratory's operations. LIMS functionality is structured to follow and facilitate the key laboratory processing phases, from receiving and registering a sample and its associated customer data right through to inspecting, approving, and compiling the sample data for reporting and analysis.

Without LIMS, a laboratory will experience issues and problems all too familiar to those in manufacturing environments that still rely extensively on paper forms and manual data entry. These issues include human error in transcription causing missing or incorrect data; more ad-hoc work practices and duplication of effort; poor item and inventory tracking; slow report preparation with weak analysis; and inadequate record keeping, making tracing and auditing difficult.

Market Growth Drivers

The clear benefits of LIMS in eliminating blocks to operational efficiency make the technology essential to the effective running of industrial laboratories and market demand is set to continue to grow over the next decade.

ARC research indicates that over a third of that market demand comes from the pharmaceutical & biotech sector. The four other primary markets of food & beverage, chemical, oil refining, and water & wastewater account for an additional one-half of the overall market. Globally, the LIMS market is dominated by North America and Europe, with Asia and Latin America currently some way behind. However, Asia is the fastest growing market and is positioned to become a much more significant industrial LIMS market in the decade ahead.

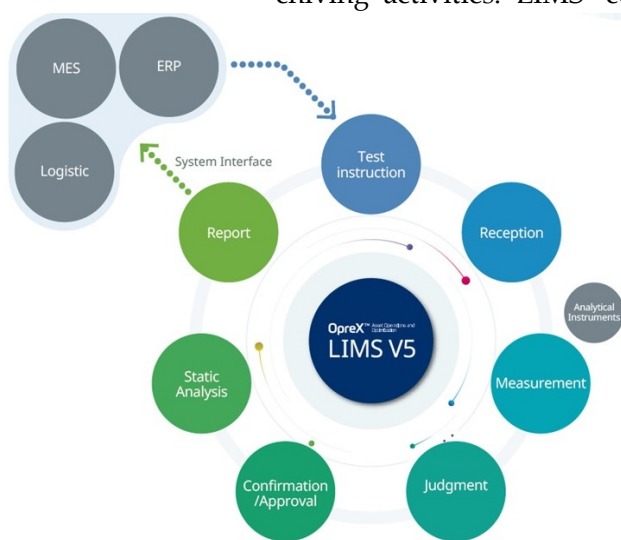
Urbanization and increasing populations, especially a rising middle class, are key factors set to drive that growth in Asia. The rising levels of affluence in Asia is driving establishment and expansion of the chemical, food & beverage, oil refining and pharmaceutical industries, all key LIMS markets, as more people desire brand-name personal and household care items, prefer convenience foods, drive cars and take air travel and are able to afford modern medicines.

And many parts of Asia still require investments in water & wastewater infrastructure to bring water access and effectively treat wastewater.

Within those industries, increasing regulatory requirements translate to the need for laboratories to undertake the requisite tests and ensure production output is compliant. Given the potential health hazards that can arise with off-spec drugs or falsified data, pharmaceutical and food & beverage industries are strictly regulated and hence are the two leading markets for LIMS.

In pharmaceutical & biotech, GxP guidelines, originally developed by the US Food & Drug Administration (FDA), are used by regulatory authorities in many countries to ensure the safety and efficacy of drugs by specifying “good practices” in laboratories (GLP), manufacturing (GMP), and distribution (GDP). Good laboratory practice promotes the development of quality test data and requires those tests to be performed, monitored, reported, and archived under proper conditions; and LIMS is an appropriate tool for companies looking to achieve GLP compliance.

In the food & beverage industry, Hazard Analysis and Critical Control Point (HACCP) methodology provides a systematic approach for identifying, evaluating, and controlling food safety hazards. It is used as the basis to comply with industry regulations, notably ISO 22000. HACCP is data intensive, as it involves setting critical limits plus monitoring, and record-keeping and archiving activities. LIMS’ core capabilities of data collection and analysis facilitate HACCP implementation and hence manufacturers’ compliance with regulatory requirements.



OpreX LIMS V5 Serves as the Single System for all Data- and Information-related Activities in the Laboratory

Inside OpreX LIMS V5

Now branded as OpreX LIMS V5, Yokogawa’s laboratory information management systems’ product has an almost 30-year history in its home market of Japan. New releases in that time have catered for new PC operating systems and added functionality to meet industrial market needs such as stability test planning (2011) and reagent batch registration (2019). Yokogawa’s customer base for its LIMS solution comprises more than 120

Japanese companies, primarily in the four industrial markets of pharmaceutical, chemical, food & beverage, and oil & gas.

In the laboratory, OpreX LIMS V5 acts as the single system for all data- and information-related activities that may have previously been performed using multiple systems. From test request to reception to test instructions to measurement/analysis to confirmation/approval and finally to reporting, OpreX LIMS V5 becomes the nerve center of lab operations for Yokogawa's customers.

In addition to interfacing with PC screens for configuration, data entry, approvals (e-signatures), and reports/analysis, at the equivalent of the "plant floor" level; OpreX LIMS V5 connects to lab instruments (spectrophotometers, gas chromatographs, viscometers, etc.) from a variety of different vendors. These interface directly for PC-compatible instruments or through protocol converters for others. At the upper level, it connects to PIMS (plant information management system), MES and ERP systems to facilitate functions such as data storage, information visualization, and operations scheduling.

Creating Customer Value

As ARC learned, several features of OpreX LIMS V5 cater to lab customers' needs for usability, productivity, and security. For example, users can modify GUI screen formats and configure and format generated reports according to their operational roles and needs. To meet increasing customer demands for cloud-based systems, the software can be accessed and updated via secure web service using either Amazon's AWS or Microsoft Azure. This facilitates maintenance and reduces in-house infrastructure and resource requirements. To maintain confidentiality of a company's lab operations and test results, OpreX LIMS V5 implements various security mechanisms. These include a hierarchical-based access via password and logging of all system interactions.

For a customer's specialized laboratory test equipment, OpreX LIMS V5 manages maintenance statuses to help ensure maximum equipment uptime and manages calibration records to eliminate deviations. In addition, OpreX LIMS V5 manages the validity of reagents to prevent the use of outdated compounds. The sample test planning function also helps facilitate stability studies required to determine product shelf life.

The ability to integrate LIMS with a plant information management system (PIMS) is particularly valuable for many customers. Prevalent in industries

like oil & gas and chemical, these systems collect the vast amount of data generated in process operations and present this as contextualized information, which can be accessed and visualized by the wider business. In plants that use the Yokogawa PIMS product, Exaquantum, LIMS integrates natively with PIMS to allow users to see both operations and laboratory information on the same screen. Yokogawa is one of the few suppliers that offers both LIMS and PIMS products.

According to the company, aside from technical features, in much the same way as Yokogawa approaches its flagship process automation business in oil & gas, chemical, etc., with LIMS, the emphasis is also very much based on building deep customer relationships and providing a high level of service and support throughout the lifecycle.

The OpreX LIMS V5 sales and implementation process involves close customer communication and coordination, with Yokogawa involved at all stages of the sales and installation and service lifecycle, from initial product presentation and demonstration through to proposal, system development, master data registration, on-site testing, and support and maintenance.

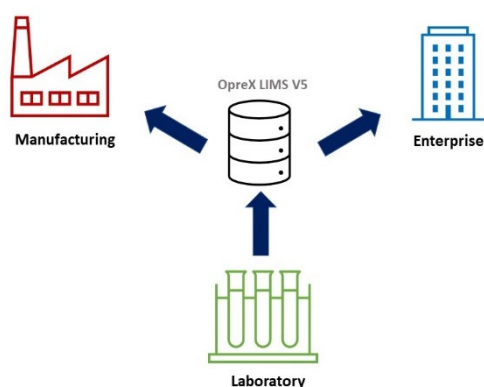
Yokogawa's domain expertise across the main LIMS markets and a deep reservoir of engineering skills enables the company to provide transfer of sector-specific LIMS best practices and services such as computer system validation (CSV). A documented process for assuring that a computer system does what it is designed to do, CSV is especially relevant in highly regulated industries like pharmaceutical and food & beverage. For example, the FDA 21 CFR Part 11 regulation on electronic records requires CSV to qualify for compliance.

Yokogawa's emphasis on aiding the customer through the sales-to-service lifecycle reflects a growing demand for technology suppliers to offer their customers both expertise and technology. Indeed, a reader survey featured in the December 2017 issue of industry publication *Lab Manager* revealed that service and support is the number one factor in a LIMS purchase decision.

Industrial Customers Reap Benefits

Customer experiences in Japan help illustrate the issues companies typically face before deploying a modern laboratory management information system and the benefits that can be realized by employing the technology.

Bushu Pharmaceuticals, a GMP certified contract manufacturing organization for pharmaceuticals and clinical samples, had previously relied largely on paper-based test forms and manual data entry practices. Recently, the welcome business uptick in manufacturing contract work resulted in overloaded lab staff and consequent increase in human errors in transcribing test results and entering data into spreadsheets, which necessitated remedial action, making the lab lead time even longer. OpreX LIMS V5 helped eliminate data errors and reduced the time to test results. The traceability afforded by the software also allows a level of audit readiness not possible in the pre-LIMS environment.



OpreX LIMS V5 Facilitates Sharing Quality Control Information to Enhance Manufacturing Operations and Business Decisions

Sumitomo Chemical faced similar problems, with onerous, non-value-added transcription work, a high volume of data errors, and long lead times for test results. Adopting OpreX LIMS V5 ameliorated all these problems. In addition, integration with the site's SAP system allows for easy and cost-effective sharing of quality control information throughout the organization, something not possible with the previous homegrown and rapidly obsolescing information management system for the laboratory.

At Otsuka Pharmaceutical, the OpreX LIMS V5 implementation enables the company to deploy a common set of operations' best practices across all its factories.

This Yokogawa customer says it especially appreciates the opportunity to get its laboratory staff engaged in more sophisticated activities than transcription and data entry, which are now handled by the software, and to have the opportunity to articulate ideas in a new spirit of innovation.

A large medical instrument company in Japan using in-house customized SAP QM to manage its laboratory information found that the costs of upgrading to a new corporate SAP version were prohibitive, leading it to look at best-of-breed LIMS solutions. Now, with OpreX LIMS V5, the company has a more cost-effective system for inspection work that also integrates to its SAP system to enable bidirectional information flows to improve both lab and manufacturing operations.

Going Global

With a strong client base and an acknowledged market leadership position in Japan, the next stage in Yokogawa's LIMS growth strategy is to focus on penetrating international markets. With 114 companies established across 62 countries in all major world regions, Yokogawa can leverage its global presence to drive the internationalization initiative.

As a well-established automation supplier to the process and hybrid industries, Yokogawa has a large installed base of control systems in the key industrial LIMS markets of chemical, food & beverage, oil & gas, and pharmaceutical & biotech. These existing customer relationships should help speed OpreX LIMS V5 adoption outside Japan.

Further, in many areas of the world, Yokogawa country offices are resourced with engineering staff as well as sales and service personnel. This means that, as in Japan, the company can be active in all stages of a LIMS project lifecycle. To supplement territories where in-country resources may not be so complete, Yokogawa is developing a channel partner ecosystem. The selected partners will provide consulting and other services to identify both explicit and implicit requirements in the earlier phases, as well as perform system installation and integration work.

Conclusions

Driven by factors including Asian economic and industrial growth, greater government regulation of industries, and increasing adherence to those regulations by companies anxious to enter global markets, the LIMS market is set to continue its expansion over the next several years. The efficiency gains and consistency of operations that LIMS brings to laboratories are readily apparent, making investment justification relatively straightforward.

As Yokogawa looks to take advantage of this expanding market and extend its position as a leading LIMS supplier in its home territory to other world regions, its large installed base of industrial customers, deep domain expertise in the main LIMS sectors, and an extensive network of global offices should all help ease market entry.

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