



OpreX™ Yokogawa achieves operational excellence by providing products, services, and solutions based on the OpreX comprehensive brand that cover everything from business management to operations.

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Represented by:

Printed in Japan, 001(CF) [Ed : 01/d]

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OpreX™ Asset Operations and Optimization

LIMS V5

Laboratory Information Management System



Laboratory Information Management System

OpreX™ LIMS V5

Laboratory Information Management System

Systematic approach for operational Quality Management

- ❖ Product Quality Improvement and Regulatory Compliance
- ❖ Efficiency and Standardization of Test Procedures
- ❖ Automated analysis and tests
- ❖ Overall performance improved through interface with other systems (ERP and MES)
- ❖ Compliance with PIC/S GMP Guide Annex11 and other requirements



- ❖ Support overall Laboratory work
- ❖ Proven over 25years at more than 160 sites
- ❖ Providing On-going Support



ALCOA Principles and Data Integrity

ALCOA Principle

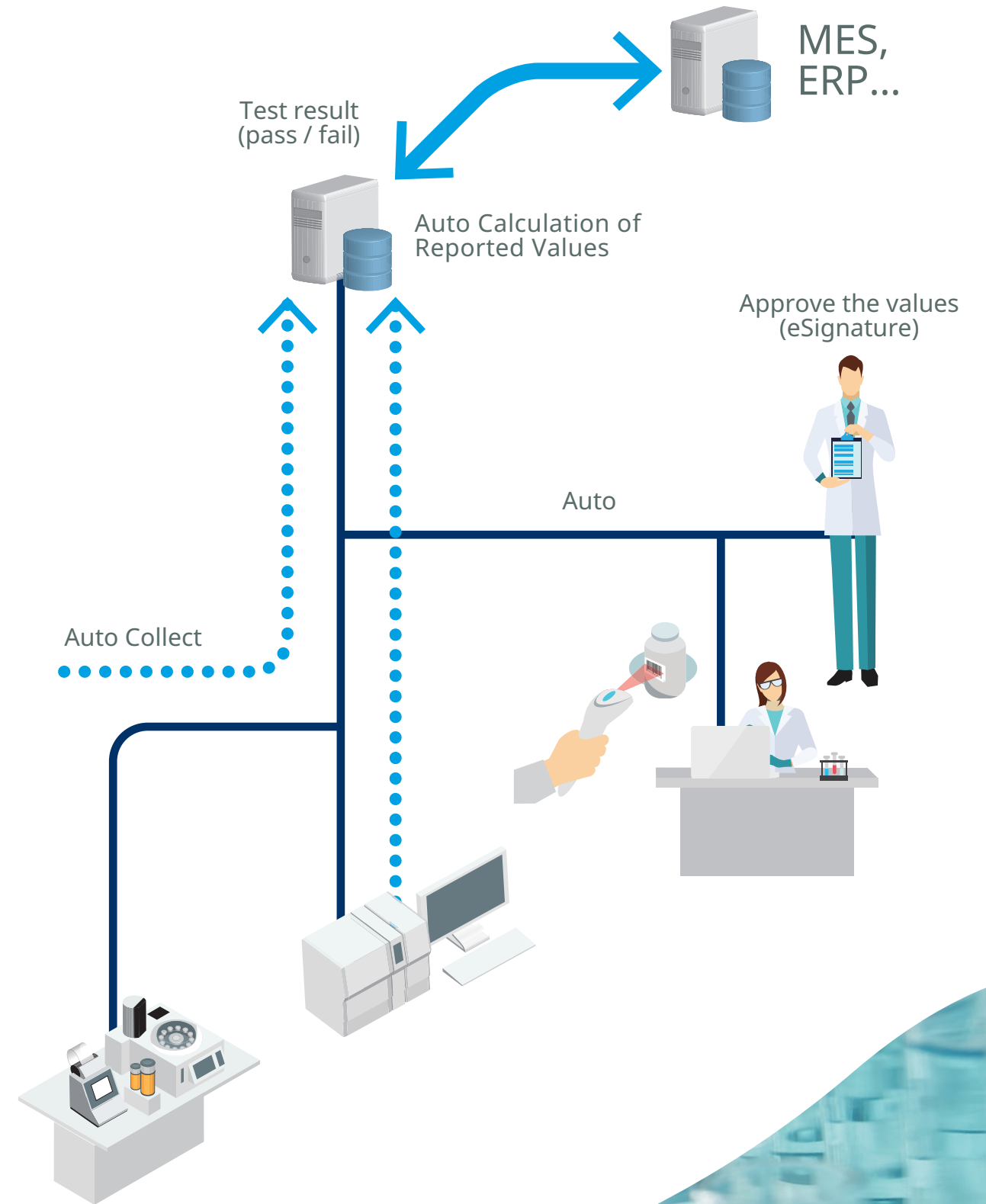
The complete data package from raw data generation (analyst, instrument, date) to reported values must be store

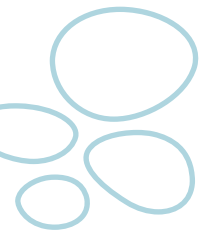


E-signature, the systematization of the record are effective to guarantee the reliability of the examination record from the apparatus measurement, raw data to a shipment judgment of (MES et al.)!

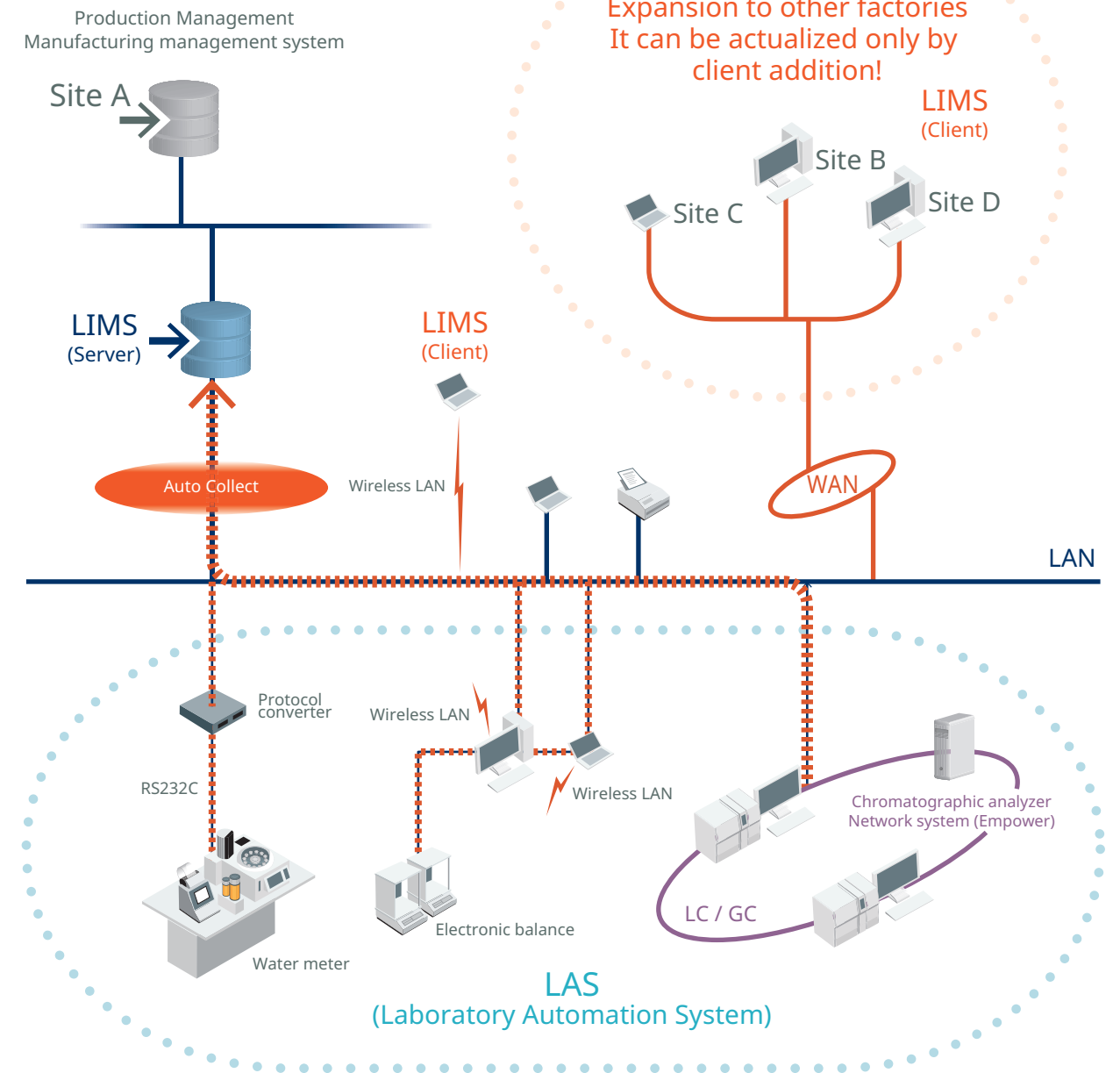
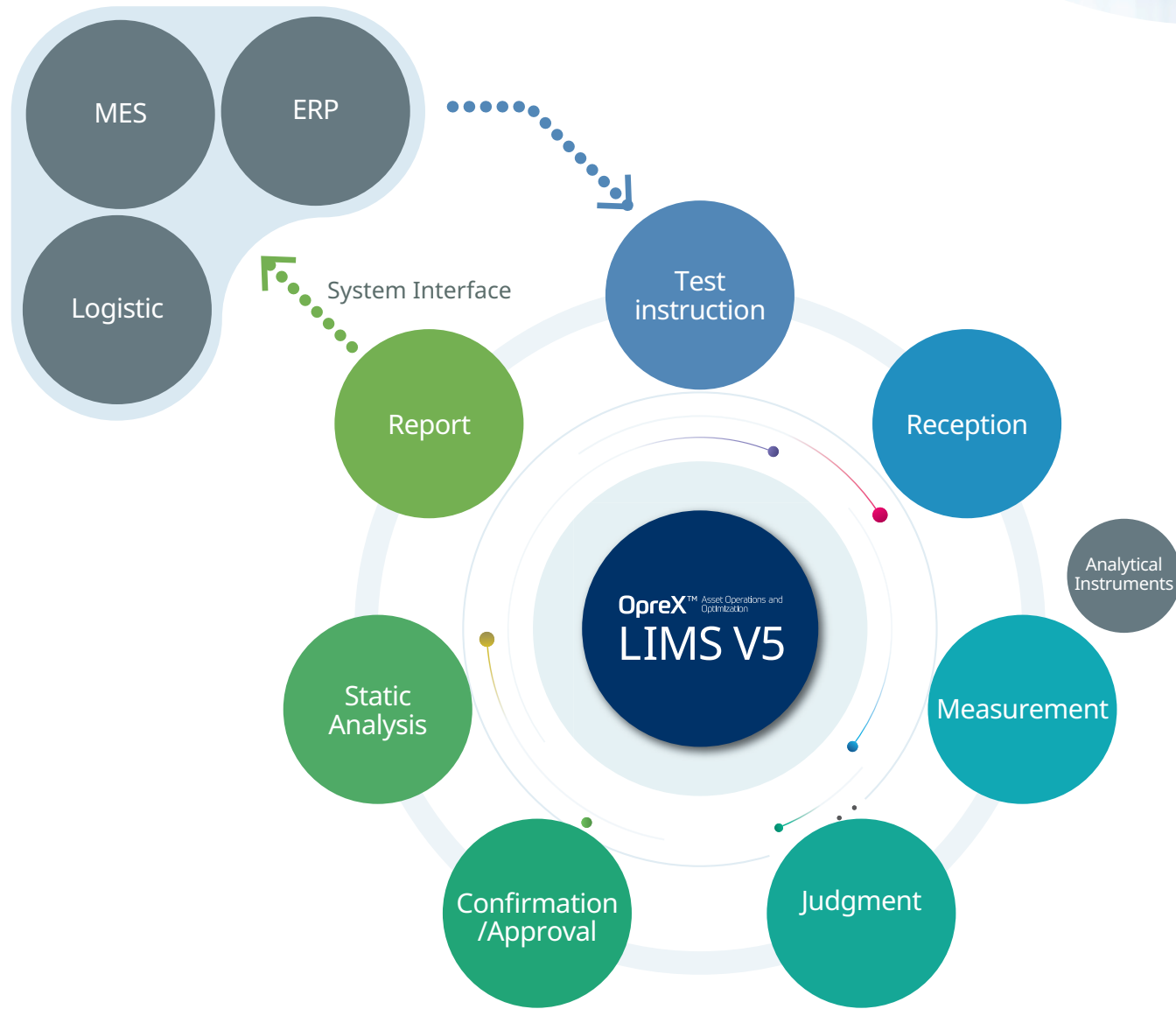
Introduction effect of OpreX LIMS

- > Submission of the test results
To avoid manipulation after judgement
- > Automatic calculation/judgement
To prevent human errors
- > eSignature for the final judgment
Identity verification
- > Electronic management of reagents and reference standards
Efficient Inventory Control
- > Electronic calibration records
Efficient instrument management
- > Traceability of steps performed
Audit trail



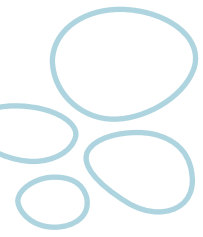


Basic business flow of OpreX LIMS



OpreX LIMS accelerates standardization of Quality Management by working seamlessly with other enterprise systems. Users can efficiently perform the tasks by leveraging laptops and tablet PCs.

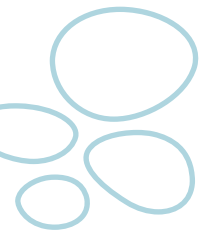
OpreX LIMS supports data sharing with other systems via corporate network. By linking inventory and manufacturing control information to quality information, you can maintain the finished product quality and increase productivity with greater efficiency.



Features

- 01 Intuitive and easy-to-use GUI
- 02 On-line Connection with Analytical Instruments
- 03 Easy connection with instruments
- 04 Automatic calculation and judgement based on the data transferred from the instruments
- 05 Quick snap shot of each lot for ease of management
- 06 Support flexible report formatting
- 07 Calculation not depend on other software
- 08 PIC/S GMP Guide Annex11 and Data Integrity compliant
- 09 Multi Language Support





Function

OpreX™LIMS offers the functions that can be used by various industries

- QC test management
- Stability test management
- Additional test management
- Multi-specimen Lot Management
- Interface with enterprise systems
- Inventory Management
- Worksheet
- Statistical Analysis
- Report generation
- Interfacing with analytical instruments
- Graph generation
- Ineterface with CDS
(Chromatography Data Management Systems)
- Calibration and Maintenance Management
- Reference standard and Reagent Management
- Interface with Waters Empower
- Data Protection
- Audit Trail



User

- Pharmaceutical
- Healthcare
- Bio/ Life Science
- Foods
- Chemical & Fine Chemical
- Oil and Gas & Chemical
- Environment
- Contracted research and analysis
- Material



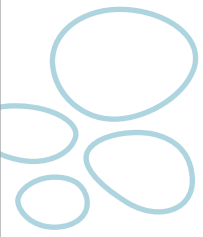
Key Features

Items	Features	Descriptions
Common	User definition screen (workflow)	
	Data search	
	Workflow function	
	Test requests	
Test related	Issuing test instruction and forms	Manual input
	Test data input	Automated data import from instrument
		Batch input
		Image capture
	Computing function (Estimated calculation)	
Additional test related	Data rounding	
	Automated specification judgment	
	Retest function	
	Additional test	
	Routine test planning	Plan registration/approval, Protocol request
Test support functions	Stability test function	Trend Graphs, Control Charts
	QC function	
	Reagent Management, Inventory Control	Expiration date management, reagent check-in, opening containers, expired reagents management, accountability log, inventory adjustment, approval of destruction
	Analyzer calibration management	Calibration schedule, Execution follow-up/Approval
	Connection with analytical instruments	Protocol converters, PC connection, via TCP/IP
Reporting	Shipment function	Release approval, CoA issuance
	Flexible report formatting	
System management	Master Data management	Master Data Maintenance(via screen)
		Master Data Load
		Master Data Version Management
		Supporting tools for batch registration
Security & Audit Trail		Password management
		Access Privilege Management
		Screen lock for idle timeout
		Saving Revision History
Interface with external systems	Receive from other systems	
	Send to other system	
Others	Multi Language support	
	Tablet PC support	
	Label printing	

Compliance Rules and Regulations

- * ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories
- * ANSI/NCSL Z 540.3-2013, Requirements for establishing the technical requirements of a Calibration Lab
- * 21CFR part11: Electronic records and electronic signatures (ERES)
- * 40CFR part3: CROSS-MEDIA ELECTRONIC REPORTING
- * Good Automated Laboratory Practices (GALP)





Usage Scenarios

- 01 Connecting analytical instruments**
Connect with various analytical instruments and automatically import analytical data
- 02 Additional test function**
Perform additional test in case test data is not reproducible (deviation)
- 03 Stability test function**
Perform long-term stability test
- 04 Audit Trail function**
Ensure Data Integrity by storing paper-based documents in an electronic form
- 05 Computing function, data rounding**
Aggregate and calculate automatically the data obtained
- 06 Flexible report formatting**
Creating a custom report template
- 07 Printing sample labels**
Flexible customization of various other functions at your fingertips

Various other functions can be customized freely!