

**Scientific
COMPUTING**

LIMS

Market Watch

2007

LABORATORY INFORMATION MANAGEMENT SYSTEMS MARKET WATCH REPORT

Executive Summary

October 2007

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INTRODUCTION AND METHODOLOGY

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Welcome to the *LIMS Market Watch 2007* report, an update of the 2005 landmark study of the use of laboratory information management systems (LIMS) in a broad cross-section of U.S. and international research labs.

The goal of this study was to provide a detailed look not only at how LIMS are being implemented, but also at what specific LIMS products are used (and in which types of labs they are being used), how satisfied labs are with their LIMS products and vendors, and what their future LIMS plans are.

LIMS Market Watch 2007 is a project developed and executed by *Scientific Computing* magazine, which created the questionnaire and guided the content of the study. Analysts from The Industry Measure (formerly TrendWatch Graphic Arts) coordinated the drafting of the report and assisted in data analysis.

Definition

Throughout this study, we use the term LIMS to refer to computer software that is used by laboratories to manage samples, instruments, users, standards, workflow, and other lab functions. The term laboratory information system (LIS) is also used to refer to similar software products, the primary difference being that LIMS products tend to be targeted toward environmental, research, or commercial scientific analysis, while LIS products are geared more toward clinical studies (such as hospital and other medical labs). While there is some overlap, for the sake of clarity, we use the term LIMS throughout this study.

How This Report Is Organized

As with the previous report, *LIMS Market Watch 2007* provides various levels of detail in the sections that follow.

Major Subject Areas

This report has been divided into five major sections, covering each of the following broad topics:

- LIMS Environment — This section details which industries and lab functions are represented in the survey sample.
- LIMS Implementation — This section covers many topics, such as how many labs use LIMS products, which products they use, how many users there are within the labs, how long labs have had their LIMS, and which hardware and software platforms are used.
- Researching and Purchasing a LIMS — This section details the factors that influenced labs in their choice of a LIMS product, as well as chronicling labs' experiences during the pre- and post-purchase and installation process.

- Service and Support — This section looks at how labs perceive the customer support services of their LIMS vendors.
- Validating and Implementing the LIMS — This section details the experiences labs have had in implementing their LIMS, as well as issues involving instrument interfacing.

Structure of Each Section

Within each of the above sections, the responses to specific questions are presented through a chart that visually illustrates the “all responses” data, giving readers an at-a-glance look at the data. In selected sections, “all responses” chart is followed by a set of tables that cross-tabulate and present the data in two ways:

- by industry
- by specific LIMS vendor

Each chart and table indicates the unweighted base of users from which the data was drawn. Not every cross-tabulation had a statistically projectable base, however. Cross-tabulations with small bases are indicated in each table and should be used with caution.

For the “Industry” cross-tabulations, we took the five biggest industry classifications cited by survey respondents. These were:

- Pharmaceutical labs (all)
- Biotechnology labs (all)
- Environmental testing labs
- Government labs
- Petrochemical labs

For the “Vendor” cross-tabulations, we used the seven most commonly cited vendors. These were:

- Applied Biosystems — SQL*LIMS
- LabVantage Solutions — Sapphire LIMS and LabVantage LIMS
- LabWare — LabWare
- Perkin Elmer — LABWORKS LIMS
- Quality Systems International (QSI) — WinLIMS and WinLIMS PC Client Family
- STARLIMS — STARLIMS
- Thermo Fisher Scientific — Nautilus LIMS, SampleManager LIMS, Watson LIMS, Galileo LIMS, Newton LIMS and LabManager LIMS

Other cross-tabulations would have yielded samples that were too small to make meaningful conclusions.

The charts and tables are accompanied by text commentary that highlights specific data points. There are many ways the data can be “sliced” and analyzed, and it’s difficult, if not impossible, to take into account all user requirements while preparing this report. Thus, the text highlights simply call out those areas where survey responses were higher (or lower) than average or where they were in other ways contrary to the prevailing trend — for example, a specific industry answering a particular question with greater (or lesser) frequency than other industries. Conclusions and implications are provided where appropriate.

Survey Methodology

For this study, HTML e-mail invitations were sent in February 2007 to a list of 79,237 individuals representing a cross-section of laboratories from the Advantage Business Media Science Group magazine subscriber lists. In addition, an ad inviting LIMS users to take the survey was placed on the *Scientific Computing* Web site with a direct link to the survey site hosted by Wilson Research Group. A text invitation to take the survey was also posted on the LIMSList user group board. Seven hundred eighty-three respondents completed the survey.

Sample Profile

Section 1 below provides greater detail of the demographic breakdown of our survey sample. However, the top 10 industries represented by our survey are:

Industry	% of Respondents
Pharmaceuticals	24.9%
Government	7.2%
Biotechnology	7.1%
Petrochemical/oil & gas	6.9%
Environmental testing lab	6.0%
Test & research labs	5.3%
Organic chemicals	3.9%
Utilities	3.7%
Food and beverage	3.2%
Plastics	2.8%

The primary functions of the labs surveyed are:

Primary Function	% of Respondents
Analytical services	58.7%
Research and development	28.2%
Other	13.1%

LIMS Market Watch 2007 Team

Scientific Computing

Scientific Computing provides news and information about computer-based technology for scientists, engineers and other technical professionals. We deliver this vital information via print and electronic media, as well as research-based products. *Scientific Computing* is on the Web at www.ScientificComputing.com.

The Industry Measure

The Industry Measure (formerly TrendWatch Graphic Arts) publishes market trend and information reports and presentations, and conducts market/product strategy and proprietary research and consulting services. The Industry Measure's main products are surveys of the publishing, printing, creative, and Web design and development markets, as well as market sizing and forecasting tools. They are on the Web at www.theindustrymeasure.com.

Wilson Research Group

Wilson Research Group was established by Larry J. Wilson as an outgrowth of a long-standing commitment to improve products and services through research. The company's first clients were leading magazines in the computer and publishing industries. Clients now include a variety of national high-technology software, hardware, retail, publishing, and governmental organizations, but their prime focus continues to center on the software development and technology sector. Wilson Research Group conducts 40 to 60 studies a year and has surveyed millions of people. They are on the Web at www.wilsonresearch.com.

Laboratory Expertise Center

The Laboratory Expertise Center is a Georgia-based laboratory informatics consulting firm specializing in complex laboratory workflow analysis, system selection, informatics architecture design, system implementation, project management, and validation. They are on the Web at www.labexpertise.com.

For More Information

For questions or comments regarding this study, please contact *Scientific Computing* by phone 973-920-7199 or by e-mail at amy.onufrick@advantagemedia.com.

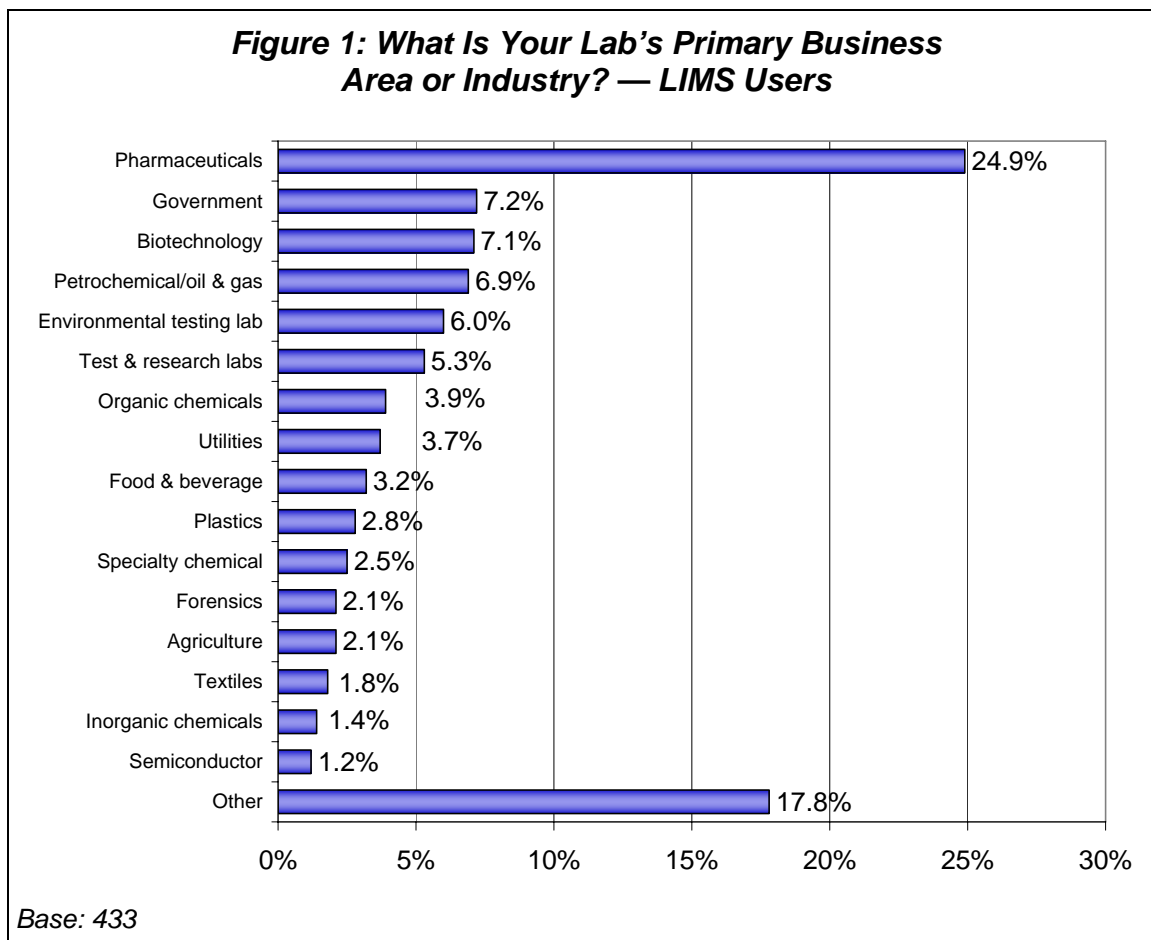
SECTION 1: LIMS ENVIRONMENT

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Primary Business/Industry

Figure 1 shows the top industries or businesses represented by all of the labs in our survey sample. One-fourth (24.9%) of the labs who filled out our survey are from the pharmaceutical industry, 7.2 percent are from government labs, 7.1 percent are from biotechnology labs, and 6.9 percent are from petrochemical labs.



Within the pharmaceutical industry, the labs responding to our survey break down as follows:

Pharmaceuticals	Total
Quality control	9.9%
Research & development	8.3%
Discovery	1.8%
Preclinical	1.6%
Clinical	1.4%
CRO	1.2%
Contract-manufacturing	0.7%

Within biotechnology, the labs responding to our survey break down as follows:

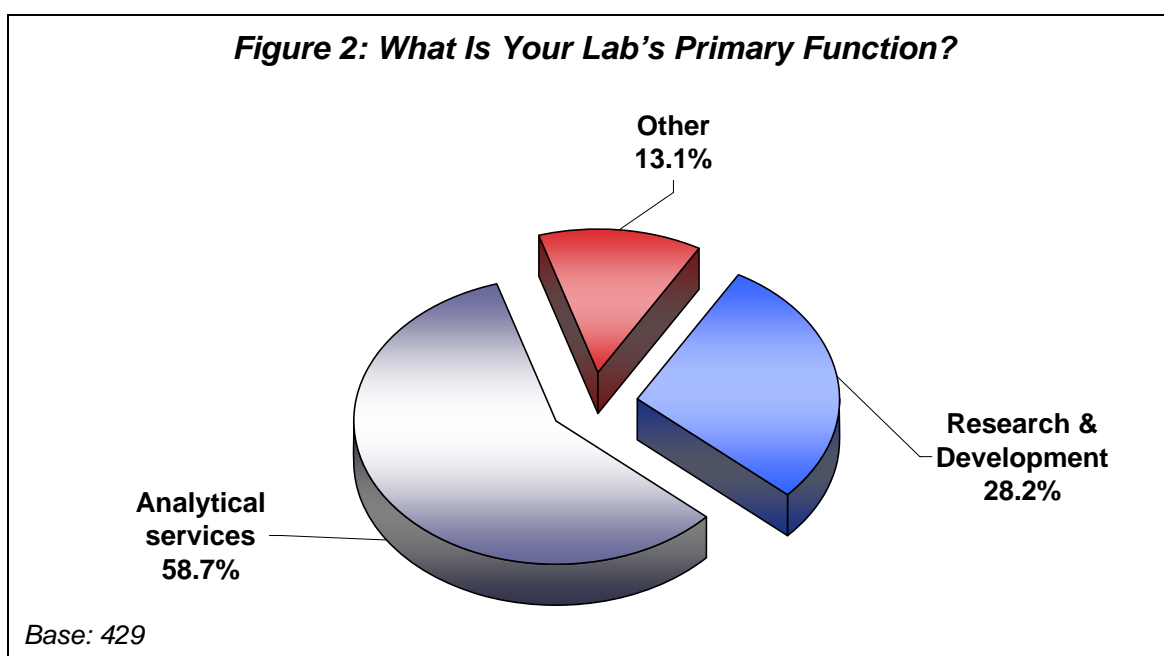
Biotechnology	Total
Genomics	2.5%
Proteomics	1.4%
Production	1.4%
Other	1.8%

Discovery respondents consider themselves to be ahead of the late R&D time point in the pharmaceutical continuum, and it is understandable that these respondents constitute a small percentage of LIMS users due to the amorphous nature of their work.

Lab's Primary Function

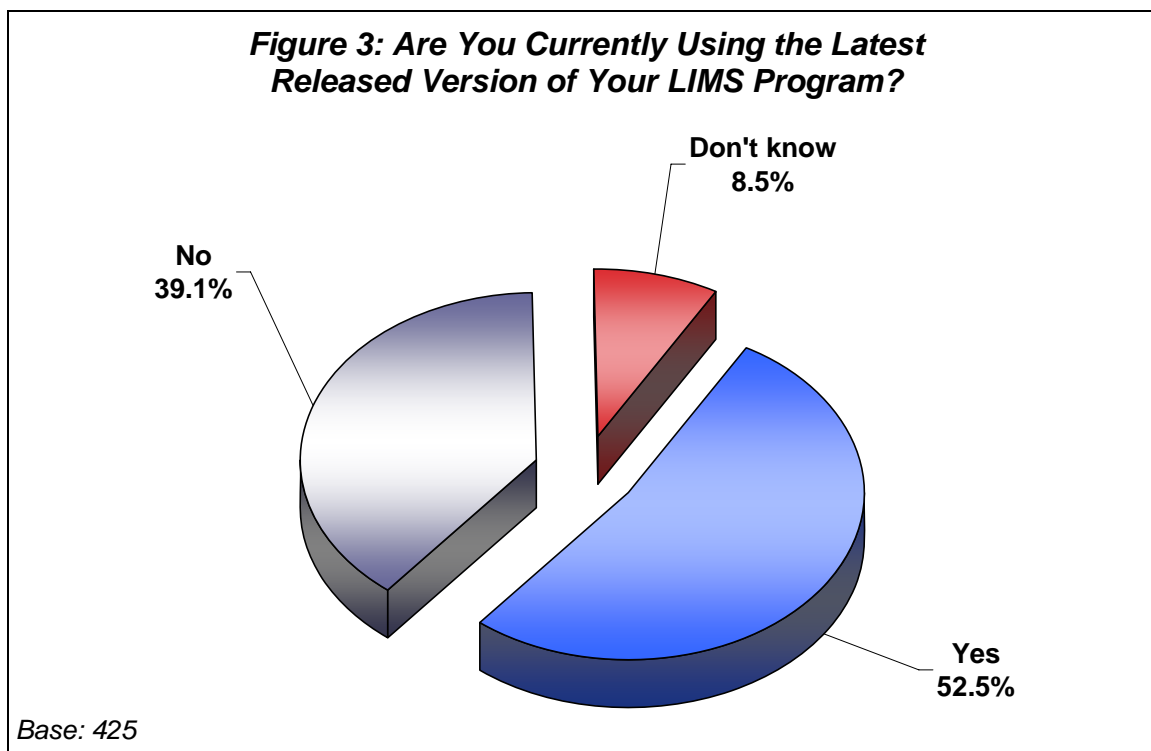
Figure 2 shows the breakdown of lab function for all labs. More than one-half (58.7%) of all labs provide analytical services, 28.2 percent perform research and development, and 13.1 percent selected "other." The most common write-in responses were:

- Quality control
- Clinical testing
- Medical lab/patient screening/testing



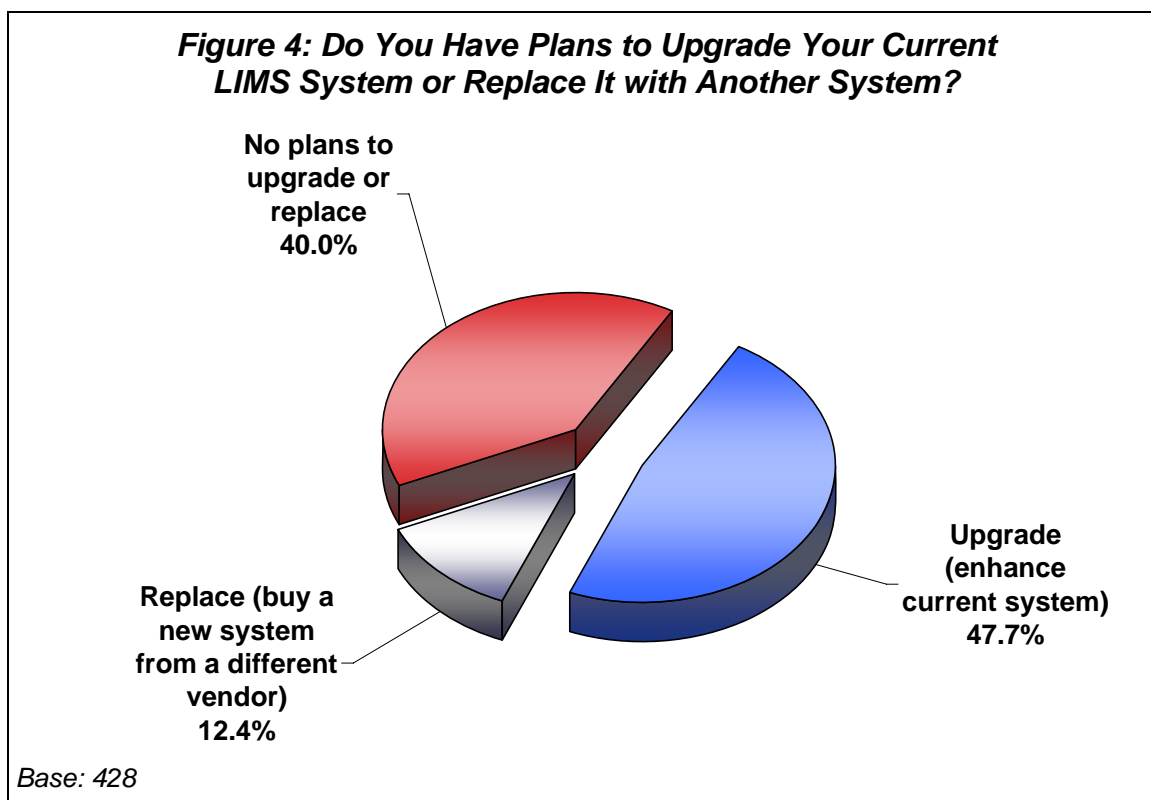
Latest LIMS Version

More than one-half (52.5%) of labs surveyed said they are currently using the latest version of their LIMS (see Figure 3).



As Figure 4 shows, 47.7 percent of labs surveyed said they had plans to upgrade their current LIMS, while 40.0 percent had no plans to upgrade. Twelve percent (12.4%) said they had plans to replace their current LIMS with one from a different vendor.

Bear in mind, however, that the tendency to upgrade is also a function of the number of minor and major revisions over time. Also, with the Applied Biosystems' SQL*LIMS product, the application is entirely dependent upon the Oracle database, and Oracle's upgrade pathways have a significant impact on SQL*LIMS. It is common for pharmaceutical companies to delay major version upgrades due to the validation cost associated with these upgrades.



SECTION 2: VALIDATING AND IMPLEMENTING THE LIMS

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Validation

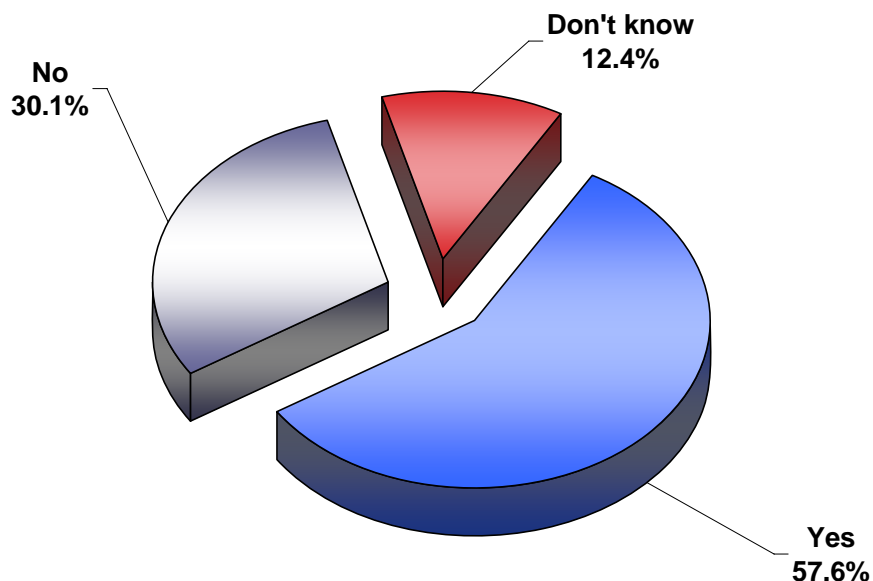
Validation is associated with FDA-regulated accounts, although elements of validation such as user requirements, functional and design specifications, and unit testing, make good sense in any software development life cycle (SDLC). However, in the FDA world, validation is ultimately a mandate to ensure consumer safety in the pharmaceutical and biotechnology worlds because the quality, uniformity, and purity of marketed drugs can make life and death differences to the consumer.

Beyond the basic constructs of a validation approach, the FDA does not dictate how to validate systems, nor do they dictate to what level of scrutiny systems must be validated. And, when customers are audited, the consistency of the audits is a function of the examiner performing the audit, as there is no cut-and-dry flowchart for auditors to follow.

It can be concluded that the cost of LIMS validation is a matter of risk management in terms of the level of intensity to which the validation drills down. Companies that do not wish to assume much risk spend a great amount of time and budget on validation, sometimes 35 percent of the project budget. Many companies assume more risk, and utilize standard vendor operational qualification documents as templates for their own work. Some vendors even offer validation services, and whether this practice represents a conflict of interest is a matter of considerable debate in the world of compliance.

Figure 5 shows, 57.6 percent of all labs surveyed said that validation of their LIMS was required.

Figure 5: Was Validation of the LIMS Required?



Base: 429

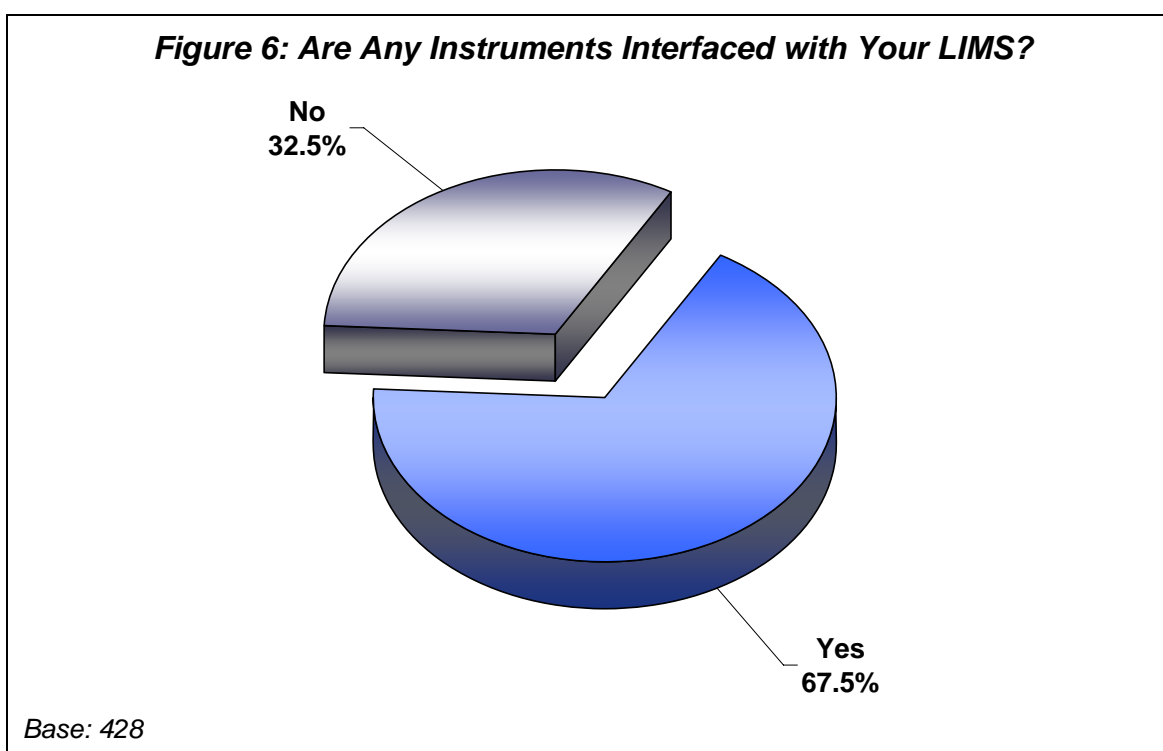
Instrument Interfacing

It is a common perception that instrument interfacing is a chief benefit of implementing a LIMS, because data transcription is a painstaking and error-prone task. Most LIMS sales personnel are asked to quote interfacing for every instrument with an electrical connection. However, when customers see the labor and cost involved, many downsize their expectations.

Some LIMS vendors rely on third-party instrument interfacing software, such as Labtronics' LIMSLink, and other vendors offer their own instrument interfacing software as part of their products. Many customers attend instrument interfacing classes offered by vendors to perform this work but, for complicated instrumentation such as auto-analyzers and other devices requiring bi-directional communication, the task is left to vendor or third-party professionals.

Last, chromatography is the most common instrument technology across many industries with 70.6 percent of respondents owning this technology, and LIMS vendors are keen to promote their ability to handle chromatographic data emanating from chromatography data systems (CDS) such as Agilent's ChemStation, Waters' Empower, or Dionex's Chromeleon. Some vendors have direct application programming interfaces (API) to link their LIMS to these CDS offerings, others rely on third-party software.

Slightly more than two-thirds (67.5%) of labs responding to our survey said they interface instruments with their LIMS, while 32.5 percent do not.

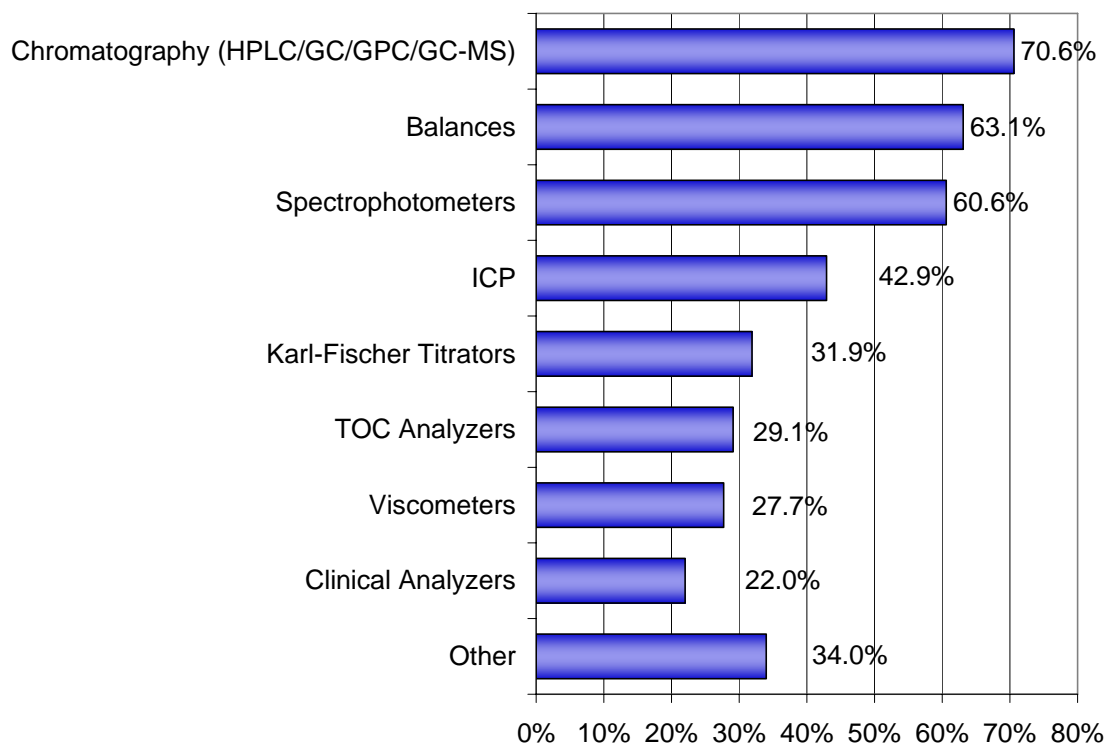


Instruments and Equipment Used

As for the specific types of instruments that are used in respondents' labs, 70.6 percent of all labs said they use chromatography equipment, 63.1 percent said they use balances, 60.6 percent said they use spectrophotometers. Thirty-four percent of respondents selected "other." Some common write-in responses were:

- mass spectrometers
- liquid handling systems
- particle size analysis equipment
- thermal analyzers
- pH meters, osmometers, etc.

Figure 7: What Types of Instruments Are Used in Your Lab?



Base: 282

Chromatography Data Systems

One-half (50.2%) of labs said that they interface chromatography data systems (CDS) with their LIMS.

