

# Preferences and Trends in Qualification Practices in Regulated Labs

Insights from a Global Compliance Services Survey



## Survey overview

In December 2021, marketing research company Cell Associates conducted an independent survey to the readers of LC/GC, the leading magazine of separation science.

The survey was developed to gather market research information about laboratory compliance services, including such topics as current regulatory trends and preferences regarding compliance services for analytical instruments and software validation. Over 475 responses were received and analyzed.

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**CrossLab**  
From Insight to Outcome

Have confidence in your data integrity program with Agilent CrossLab, the industry leader in instrument and software qualification and computer system validation services.

## Significant qualification survey findings

### Data Integrity

Remains the single greatest area of laboratory compliance concern. By switching to Agilent ACE for your analytical instrument qualification, your concerns will ease because ACE is designed to satisfy data integrity requirements such as ALCOA+<sup>1</sup>.

### Analytical Instrument Qualification, AIQ <1058>

After Data Integrity, AIQ was the next highest area of concern for laboratories. ACE is designed to be compliant with USP <1058> requirements. The Equipment Qualification Plans (EQPs) can be configured to align with your user requirements<sup>2</sup>.

### Simplification of AIQ

Was the largest single improvement people wanted to implement for AIQ. By harmonized qualification across multiple analytical technologies through Agilent ACE, you simplify your AIQ workload and audit preparation requirements.

### Paper vs Electronic Qualification

Only 37% of providers document qualification/calibration of instruments via fully electronic formats. The Equipment Qualification Plans (EQPs) and workflows used within ACE provide a paperless, fully electronic qualification solution.

### Expertise and Knowledge

Was the biggest single driver in choosing who performs instrument qualification. Contact Agilent and have one of our experienced compliance specialists discuss your qualification needs in detail, to see how we can help you<sup>3</sup>.

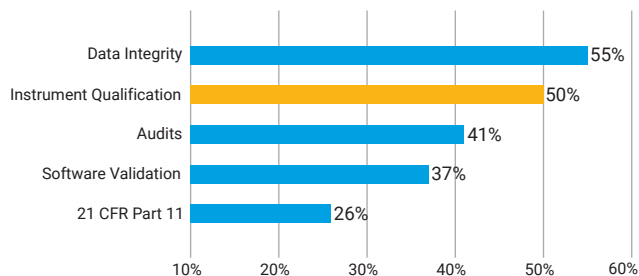
Agilent  
**CrossLab**  
Ranked #1 in  
Compliance  
Services  
Again Per independent surveys

 **Agilent**

## Results

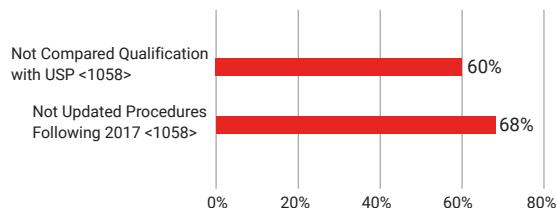
### Concerns about AIQ

When asked about areas of the lab. compliance that were of greatest concern, Instrument Qualification, was rated higher than audits, software validation, or 21 CFR Part 11 compliance (N=389).



### Alignment with USP <1058>

Labs were asked if they had compared their instrument qualification with <1058> on AIQ (2017) for gaps and changes, and if they had updated their qualification to align with it. The results help explain why instrument qualification is such a high area of concern – many labs may still be aligned to the 2008 version of <1058>.



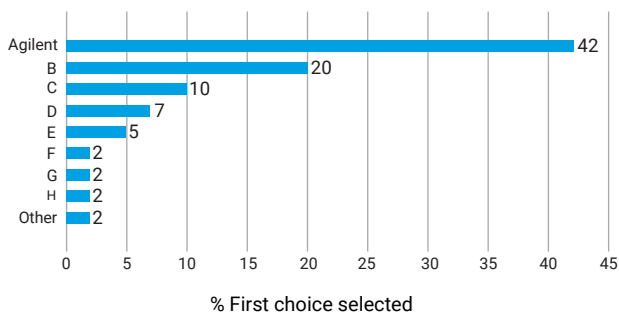
### Survey result conclusions

Survey respondents were asked which suppliers were considered leaders in instrument qualification and software validation services. In both service categories, **Agilent CrossLab Compliance Services** is clearly selected as 1<sup>st</sup> choice as a leader and trusted compliance service provider.

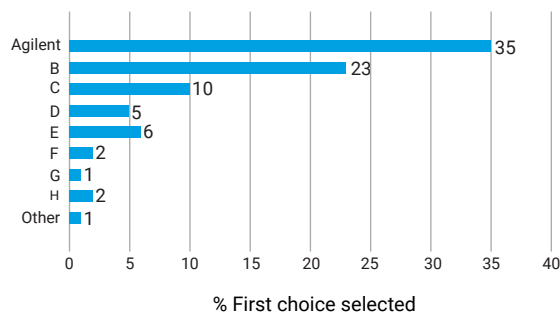
**For Instrument Qualification** – Agilent was rated more than double the % of the next service provider (42% vs 20%)

**For Software Validation** – Agilent was rated 50% higher than the value of the next service provider (35% vs 23%)

#### Leaders in Analytical Instrument Qualification



#### Leaders in Software Validation



### Survey Conclusions

Data integrity remains the top priority. The survey indicates significant interest in improving qualification and computer software validation compliance, with expertise and knowledge as key common drivers in choosing a service provider.

### Contact Agilent

To find out more about Agilent compliance and consultancy capabilities and how they can help you achieve your laboratory compliance goals, contact your local Agilent representative.

To know more about Agilent qualification services, please visit:

[www.agilent.com/chem/instrument-qualification](http://www.agilent.com/chem/instrument-qualification)

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### Reference

1. Agilent Network ACE, 5994-1660EN
2. Advantages of Agilent Qualification Documents, 5994-2147EN
3. Agilent Qualification Case Study, 5994-1754EN