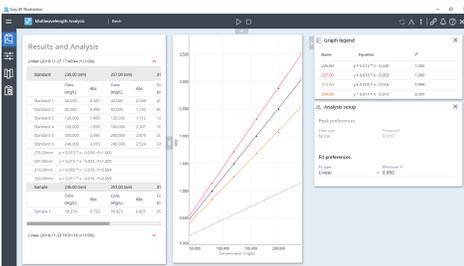




# Data Integrity Options for GMP Facilities

For the Agilent Cary 3500 UV-Vis Spectrophotometer

Agilent  
**OpenLab**



## Software to help meet global regulatory requirements

The Cary 3500 UV-Vis spectrophotometer is compatible with the Agilent OpenLab software suite of products. OpenLab provides technical controls to securely acquire and store data in laboratories that must comply with FDA 21 CFR Part 11, EU Annex 11, and similar regulations in other countries. These controls include:

### Access control and secure data

Extensive technical controls minimize the need for procedural controls, and prevent operators from deleting or manipulating data. Assign access privileges based on job function and data type so that the right people have the right access to the right information. Store and archive your data on a single system or from labs located on a single site, on multiple sites, and across the globe. Advanced disaster recovery tools are also included.

### Electronic signature workflows

E-signatures can be executed at multiple authority levels and signature order control can be enforced. E-signatures show the full name of the signer, as well as the date and time. Reasons for E-signatures can be predefined and are recorded with the E-signature. The reasons can be viewed either in the electronic record or on a printed version of it.

Cary UV Workstation provides seamless method setup and analysis capabilities. When combined with Agilent OpenLab, data integrity is assured with secure database storage for all electronic records.

## Advanced audit trail review

Secure, computer-generated, time-stamped audit trails automatically track all actions. Advanced tools for reviewing an audit trail include text or category searches and date and user name filters. It's also possible to document the audit trail review as part of the electronic record.

## Enhance operations

The Cary UV Workstation software includes a Help and Learning Center to help you get familiar with the software faster, reducing training time and costs. Simplified workflows mean setting only the parameters that matter, while data is quickly turned into meaningful results.

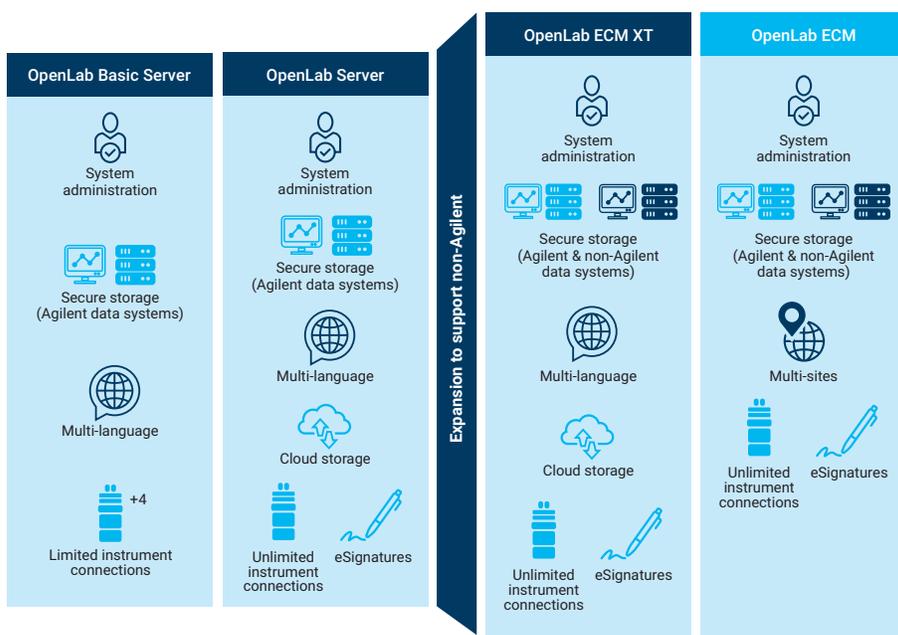
## Securing and managing Cary 3500 UV-Vis data with OpenLab

Agilent offers two configurations of Cary UV Workstation where data is stored in OpenLab:

- Data is stored and managed locally, on the PC attached to the Cary 3500
- Data is stored and managed centrally in one of the OpenLab options shown in the following diagram

## Other features of the Cary 3500

The design of the Cary 3500 has minimal moving parts and removes common sources of error in UV-Vis measurements, giving you greater confidence in your data.



An OpenLab solution can be tailored to suit the size of your organization.

Learn more.

[www.agilent.com/chem/networked-uv-vis](http://www.agilent.com/chem/networked-uv-vis)

DE57469904

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Published in the USA, August 23, 2022  
5994-0740EN

The Cary 3500 has:

- The ability to measure the full wavelength range, on eight cuvette positions, simultaneously
- Air cooled sample temperature control from 0 to 110 °C with no water, noise, or cables

You can increase productivity by measuring more samples, faster:

- Never miss critical information with a data collection rate of 250 points per second
- Simultaneously measure standards, samples, and controls, under the same conditions

The complete solution from Agilent:

- Meet pharmacopeia regulations with excellent instrument performance and inbuilt automated test suites
- Qualify and validate your system with Agilent's comprehensive portfolio of compliance services for both instrument software qualification and Computer System Validation (CSV)

## Further information

- [Agilent Cary 3500](#)
- [Agilent OpenLab Data Management Solutions](#)
- [White paper: Support for Part 11/Annex 11 Compliance with Cary 3500](#)
- [Pharmaceutical Analysis Using UV-Vis: Compliance with USP Chapter <857>, and European Pharmacopoeia \(Ph. Eur. Chapter 2.2.25\)](#)
- [Pharmaceutical Analysis using UV-Vis: Compliance with Supplement I to the Japanese Pharmacopoeia 17th Ed., Section 2.24](#)
- [Agilent Computer System Validation Services](#)