# Ensure Compliance for Software Upgrades

## Stay current and compliant with Agilent software services


It's important to stay up-to-date with software in order to comply with current regulations and meet the data integrity expectations set forth by various regulatory agencies such as PIC/S[5], reliable laboratory systems which will support new technology adoption to improve laboratory workflow efficiency. Out-of-support operating systems and software applications can be vulnerable to cybersecurity attacks and data integrity risks.

Upgrading the operating system in a regulated lab involves a significant level of compliance risk. In most cases, the operating system and the scientific application software must be concurrently upgraded to ensure that the system operates properly. The software upgrade will be considered a "change" to the validated system, and the company's change control policy must be followed.

If an upgrade is implemented, it is critical to assess the impact of the change to understand the level of revalidation that will be required to maintain a compliant, validated state. An important step during a software upgrade is to perform software qualification.

### Software qualification

Agilent uses a proprietary software, the Agilent Automated Compliance Engine (ACE), to deliver qualification services to its customers. ACE meets all data integrity requirements of ALCOA+, and is USP <1058> compliant.

The new version of USP <1058> (2017) stresses the importance of software qualification in addition to instrument qualification. Software qualification demonstrates that the software has been installed correctly and is operating according to manufacturer specifications. Most software qualification will include thorough operational testing on any security and data management features to demonstrate that out-of-the-box functionality is compliant with 21 CFR Part 11 (electronic records and signatures). Software qualification is the foundation of a robust computer system validation (CSV) life cycle process.

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From Insight to Outcome

Partnering with Agilent can significantly reduce the cost and effort required to revalidate systems. Speak with an Agilent Computer System Validation Services expert today.

Learn more:
www.agilent.com/chem/computer-system-validation

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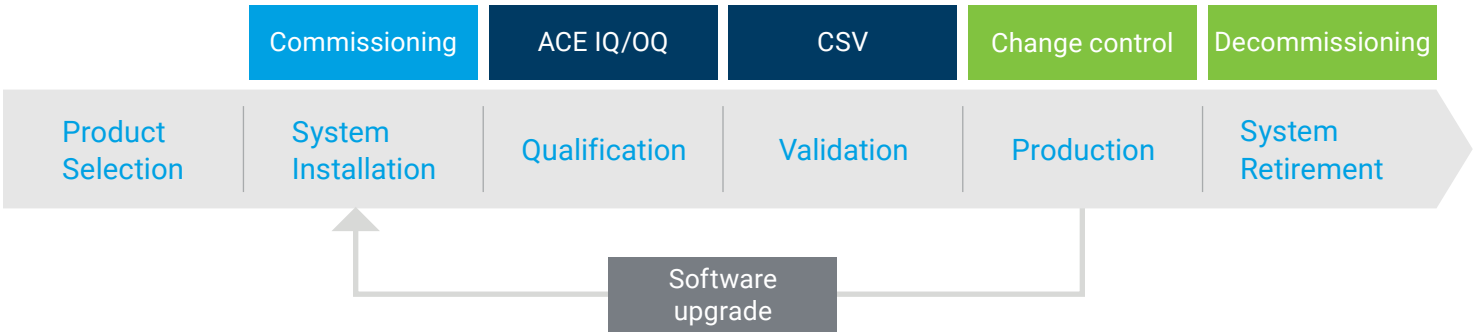
## Computer System Validation

The CSV process begins with a successful execution of ACE software IQ/OQ. CSV is a life cycle process that ensures that a computerized system (hardware, software, methods, and end users) meets the specific intended use and applicable regulatory requirements for the laboratory environment. User requirements and configuration specifications must be documented and tested during the validation process to ensure that the system can consistently and accurately produce results used for GxP processes. Agilent CSV starter kits and services are based on the universally accepted GAMP 5 model.

The following image illustrates the software upgrade life cycle.




## Benefits of partnering with Agilent Compliance Services

Software upgrades are important for maintaining vendor support, preventing cybersecurity and data integrity risks, and ensuring continuity of regulated workflows. Agilent software qualification and CSV products and services can help you achieve compliance throughout the upgrade process.

## Compliance services offered

- ACE software qualification—IQ/OQ
- CSV Services and Validation starter kits

Contact your local Agilent representative for more information about our software compliance services.

## References

1. Agilent Computer System Validation Services, Agilent Technologies, flyer, publication number, 5994-1753EN
   **Agilent Network ACE: How ACE satisfies ALCOA+ Data Integrity Requirements**
2. United States Pharmacopeia (USP) general chapter <1058>
3. GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems, 2nd Edition, ISPE, July 2022
4. 21 CFR Part 11, Electronic Records; Electronic Signatures, current revision
5. PIC/S Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments, July 2021

To know more, please visit:
**www.agilent.com/chem/csv**

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