



Customer IT Responsibilities

Agilent Network ACE

Agilent Network automated compliance engine (ACE)— Essential IT support

Demands on pharmaceutical companies' IT resources can mean laboratory compliance projects compete with corporate projects for IT support. This document has been written to clarify IT requirements and responsibilities and explain the function of Network ACE to simplify implementation.

Agilent ACE – Explanation of ACE software function

Agilent offers a comprehensive set of compliance services for laboratory instruments and software. This includes **instrument qualification** (IQOQ, OQ, and RQ), software qualification, and maintenance contracts. These services are based on USP <1058> Analytical Instrument Qualification (AIQ) requirements,¹ are aligned with regulatory expectations, GAMP® 5,² and form the analytical foundation for data integrity within the laboratory.

The ACE software was developed by Agilent to enable electronic qualification workflow for HPLC, GC, and other complex laboratory systems.

ACE is a fully validated software tool, used to perform data processing, calculation, and reporting functions. Unprocessed OQ data is imported into ACE, which performs calculations on the data to satisfy tests defined in the Equipment Qualification Plan (EQP) and reports the results in the Equipment Qualification Report (EQR). ACE is a "Commercial off-the-shelf" (COTS) software and does not directly interact with your validated software systems.

Network ACE overview

To simplify implementation of ACE, Agilent enabled installation of **Network ACE** on customer sites. Network ACE enables data acquisition, transfer, processing, and reporting within the security of your network.

Use of the ACE software platform to deliver laboratory compliance services contributes toward Agilent consistently being recognized as the number 1 service provider for analytical instrument qualification in independent surveys.³



Benefits of Network ACE

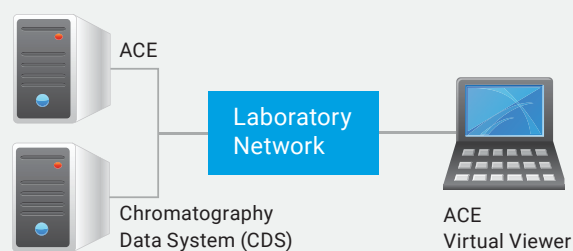
Network ACE delivers operational and compliance benefits over paper and Excel based qualification.

- Designed to satisfy ALCOA + data integrity requirements⁴
- Ensures direct electronic data transfer into ACE from the Chromatography Data System
- Provides secure end-to-end checksummed data traceability
- Qualification plans, reports, and all data is retained within your IT domain
- Safely move from Excel or paper-based protocols
- Simplify access and backup of qualification information by applying your existing IT policies, controls, and security



Network ACE – Implementation

Network ACE provides peace of mind to help laboratories comply with regulatory and data integrity requirements for laboratory instrument qualification. Designed to work with virtual environments such as Citrix™ and Remote Desktop Services, Network ACE supports cloud configurations.



Typical Network ACE installation diagram

Agilent responsibilities and deliverables



Agilent will provide:

- Network ACE Installation Software
- Support implementing Network ACE
- Support writing SOPs



An Agilent Engineer will:

- Install Network ACE
- Set up a secure data folder
- Perform Network ACE IQOQ



Other Documentation provided by Agilent:

- Site-prep checklist

Customer IT responsibilities

Components to be provided

- Required network infrastructure and operating system
- Operating system user administration
- Network user access (named engineer account)
- Internet connection for installation
- Additional support for Citrix™ or remote desktop services configuration
- Backup of ACE data (aligned with site policy)
- A customer representative should be available to the engineer while performing the installation

CDS access

- CDS log-in (named engineer account)
- CDS service project folder (segregated from GxP data)
- CDS service profile with ability to:
 - Create methods (for individual OQ test)
 - Create sequences (to run OQ/RQ tests)
 - Acquire data (to a pre-agreed service folder)
 - Export data

Network requirements

- 11121–11141 (across complete network for P2P NDA, internal for RDS/Citrix™ NDA)
- 137–138 (UDP), 139 (TCP), 445 (TCP). (Citrix™/remote desktop service)
- 443 (TCP)—Optional internet connection for online updates
- Compatible with cloud implementation requirements

Clarification of responsibilities

The information provided helps ensure alignment between Agilent qualification services and IT responsibilities by clarifying requirements. The ACE software platform follows a standard Agilent validation life cycle process within our global ISO accredited QMS. To find out more about Network ACE⁵ contact your local Agilent representative.

References

1. USP General Chapter <1058>, Analytical Instrument Qualification; 2. GAMP® 5, ISBN 1-931879-61-3, 2008;
3. Independent LC-GC Survey Data, [5994-5126EN](#); 4. Agilent Network ACE ALCOA+, [5994-1660EN](#); 5. [Agilent Network ACE Explanation Video](#)

www.agilent.com/chem/qualification

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