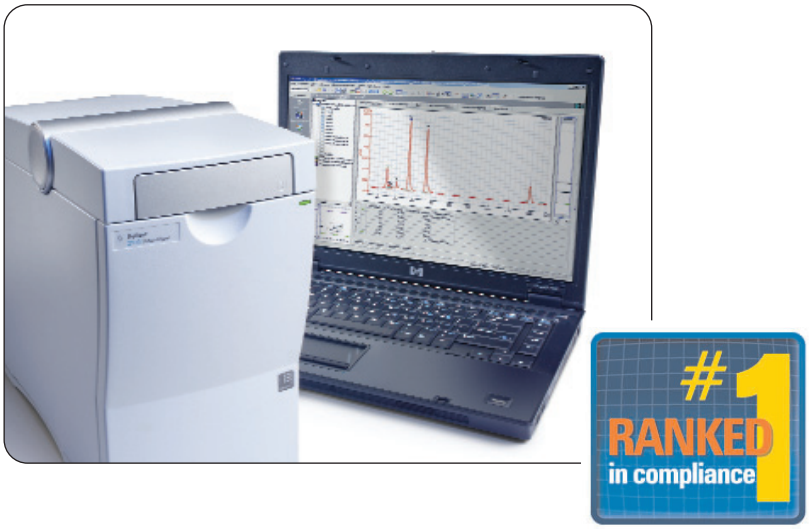
Agilent 2100 Bioanalyzer System

Compliance Solution



Feel safe in regulated environments

To achieve compliance, laboratory and production procedures have to be standardized, which is associated with extra costs and workload. To minimize this impact, the Agilent 2100 compliance solution provides a tool for reliable quality control. It supports the validation process from start to finish, regardless of whether you are analyzing nucleic acids, proteins or cells. The Agilent 2100 compliance solution addresses 21 CFR Part 11 requirements, provides tools for IQ (Installation Qualification) and OQ (Operational Qualification) and offers compliance services.

2100 Compliance Solution Components

- 2100 bioanalyzer
- Electrophoresis or cell fluorescence cartridge
- 2100 expert software
- 2100 security pack
- RNA, DNA, protein or cell assay kits
- Compliance services
- Design qualification documentation (including Declarations of Conformities)

Features

- **21 CFR Part 11 compliance** – All requirements regarding electronic records and electronic signatures are addressed, including data security, integrity and traceability.
- **Secured environment** – Nobody can acquire or access data without a dedi--cated user account and identification. All actions are tracked and documented with a clear, traceable audit trail and electronic signature.
- **User identification and roles** – Only users with valid user ID and password can log on, access and modify any electronic record. Users have distinct user names and passwords and specified roles. The software limits the functionality of the user, as defined by their role.
- **Workflow management** – The executable methods can include a predefined workflow, which defines who will be allowed to execute methods, perform peer reviews, and provide final approval. A predefined user must electronically sign every step in the review cycle or workflow level.
- **Compliance services** – Software and hardware IQ and OQ can be purchased at any time. A certified customer engineer will test and verify the functionality of the hardware and software, thereby qualifying the system.
- **High quality** – The 2100 bioanalyzer, the expert software and the kits were developed according to the quality process and life cycle followed by the Life Sciences and Chemical Analysis division of Agilent Technologies.

Agilent Technologies

Full Compliance

Design Qualification (DQ)
DQ defines the functional and operational specifications of the 2100 bioanalyzer system and ensures that it has all the necessary functions and performance criteria. Provided documents include *Declarations of system validation and conformity*.

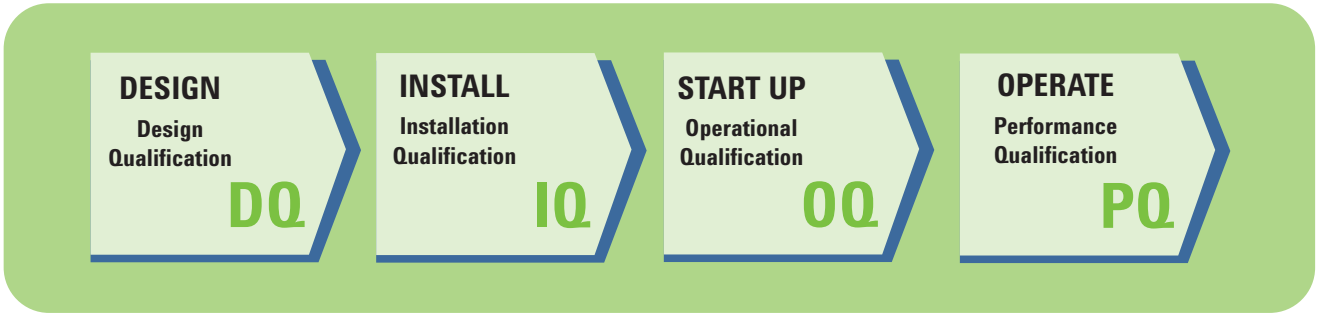
Installation Qualification (IQ)
IQ ensures that the 2100 bioanalyzer system is installed correctly from the moment the components are unpacked to the point the system is ready for operation – documenting the completeness of shipping, the operating environment, and the components of the system.

Operational Qualification (OQ)
Demonstrates that the 2100 bioanalyzer system will function according to its operational specifications in the selected environment. It verifies and documents the ability to meet specified performance criteria after installation. The complete system is comprehensively tested using established conditions.

Performance Qualification (OQ)
Standard Operating Procedures (SOPs) are developed by the customer for PQ.

Agilent supports your validation process
IQ and OQ are supported by the 2100 expert software in a dedicated validation context and are also available as services from Agilent Technologies.

- Agilent 2100 bioanalyzer hardware and/or software IQ (R1015A) and OQ (R1016A)



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