Agilent 2100 Bioanalyzer System Compliance Solution

Feel safe in regulated environments

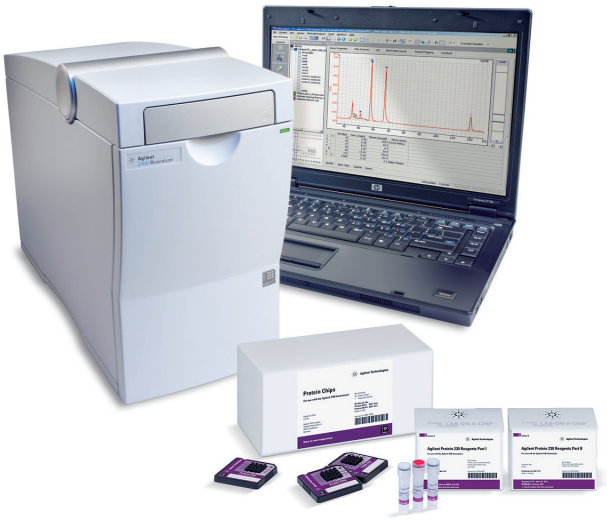
The Agilent 2100 Bioanalyzer compliance solution provides an integrated and reliable tool for quality control of nucleic acids and proteins. It supports the validation process from start to finish enabling users to run the Agilent 2100 Bioanalyzer system in regulated lab environments.

The Agilent 2100 Bioanalyzer compliance solution comprises the 2100 Bioanalyzer instrument, software, services, as well as application-specific consumables.

With Installation Qualification (IQ) and Operational Qualification (OQ) services, and 21 CFR Part 11 compliance, the Agilent 2100 Bioanalyzer system can easily be made compliant for the quality control and analysis of antibodies, protein pharmaceuticals and other biomolecules.

2100 Bioanalyzer system – an integrated compliance solution

- 2100 Bioanalyzer instrument and 2100 Expert software
- Electrophoresis or cell fluorescence cartridge
- RNA, DNA, protein or cell assay kits
- Design qualification documentation
- Compliance services (2100 Bioanalyzer Classic Edition IQ or OQ service)
- 2100 Security Pack license



Features

Reproducible results – System with prepackaged kits, standardized protocols and optimized assays.

High quality data – On-chip electrophoresis results in reliable digital data and provides objective information regarding concentration, size and integrity.

Compliance services – Software and hardware IQ and OQ can be purchased at any time. A certified engineer will test and verify the functionality of the hardware and software, thereby qualifying the system.

21 CFR Part 11 compliance – With the Security Pack add-on, all requirements for electronic records and electronic signatures are addressed, including data security, integrity and traceability.

Design qualification – Functional and operational specifications are defined by the declaration of conformity for the 2100 Bioanalyzer instrument and kits and the declaration of system validation for the Agilent 2100 Expert Security Pack software.

Accepted standard – Established for quality control of RNA, DNA and protein samples with citations in over 15,000 scientific papers.

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GLP/GMP Compliance

Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP) are guidelines to ensure minimal requirements are met for quality management or research facilities and/or manufacture of food and pharmaceutical products. These practices ensure uniformity, consistency, reliability, reproducibility, quality, and integrity of laboratory tests.

Validation process

The Agilent 2100 Bioanalyzer compliance solution supports the validation process from start to finish, regardless of whether you are analyzing nucleic acids, proteins or cells.

Design Qualification (DQ)
DQ defines the functional and operational specifications of the 2100 Bioanalyzer system and ensures that it has passed all performance criteria.

Documents provided:

- Declaration of System Validation for the 2100 Expert software
- Declaration of Conformity for 2100 Bioanalyzer instrument
- Declarations of Conformity for all assay kits

Installation Qualification (IQ)
IQ ensures that the Agilent 2100 Bioanalyzer instrument and the 2100 Expert software are installed correctly and all electrical connections are correct – 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. The correct installation of the software is checked in the verification context of the 2100 Expert software.

Operational Qualification (OQ)
OQ is performed to verify and document the 2100 Bioanalyzer system's ability to meet specified performance criteria ensuring basic accuracy of the system after it is installed in the selected environment. OQ should be performed after hardware or software updates, repair, or relocation and at regular intervals during routine use. Agilent recommends performing preventive maintenance prior to an OQ.

Performance Qualification (PQ)
PQ confirms that the system functions according to the needs of the application. The customer is responsible to develop Standard Operating Procedures (SOPs) for processing and analyses of their samples.

Installation Qualification (IQ)		Operational Qualification (OQ)	
Hardware IQ	**Software IQ**	**Hardware OQ**	**Software OQ**
Confirm correct installation of the 2100 Bioanalyzer instrument.	Confirm correct installation of the 2100 Expert software.	Perform instrument validation tests.	Data calculation engine and software algorithm test.
Documentation of instrument details and system check.	Documentation of software details and integrity of installed software components.	Audit-ready documentation confirms 2100 Bioanalyzer system performs according to operational specifications.	Audit-ready documentation confirms 2100 Expert software performs according to operational specifications.
Certification to provide audit-ready documentation.	Certification to provide audit-ready documentation.		

Compliance services from Agilent

21 CFR Part 11 Compliance

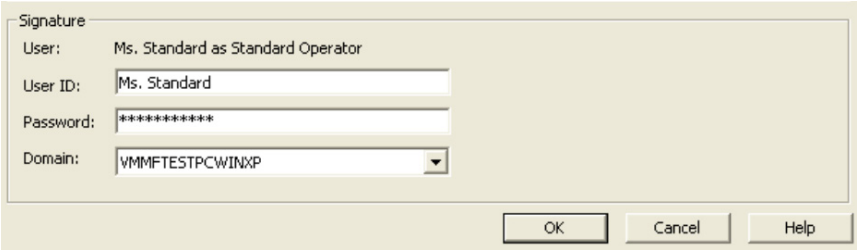
Full compliance requires the software to fulfill all guidelines in Title 21 CFR Part 11 defined by the US Food and Drug Administration (FDA) specifying the requirements for electronic recording. This code dictates particular FDA-regulated industries to implement controls for electronic documentation and data integrity – such as audit trails and electronic signatures – of software and systems involved in processing electronic data.

The Security Pack module (G2949CA) within the 2100 Expert software allows for operation in a fully secure environment and makes the 2100 Expert software fully compatible with 21 CFR Part 11.

- **Data integrity** – Data can only be modified or deleted by authorized users, all data files contain the raw data and the complete history.
- **Access control** – No one can acquire or access data without a proper user account and identification. Users are clearly identifiable with distinct user names and passwords. Only the 2100 administrator has access to the user and roles administration.
- **Electronic signature** – All activities such as creating or modifying data have to be confirmed by an electronic signature.
- **Audit trail** – All actions performed within the secured environment require an electronic signature and are tracked and documented with a clear, traceable audit trail and in logbooks.
- **Workflow management** – Customer developed methods detail the instrument, assay type, the users and the number of peer review cycles the data must go through before final approval or rejection.
- **Version control** – Even for a finalized method, the different versions of the workflow can be opened for review.

Operator	Permission
Standard Operator	Run methods
Advanced Operator	Develop and modify methods
2100 Administrator	Setup of users
Backup Operator	Archiving/de-archiving files
Validation Operator	Validation of system
2100 Unlock Operator	Unlock system after timing out

2100 Security Pack user roles



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Description	Timestamp	User Name	Setpoint	Operation	Old V...	New Value		Meaning
⊞ Modifications for file dearchiving								
⊞ Modifications for file archiving								
⊞ Applied result flagging rule								
⊞ Altered Chip Summary								
⊞ Smear Region modified								
⊟ Smear Region added								
Smear Region added	Jun-17-2014	Mr. Advanced	Region Color	Modified	0	16711680	6	Altered Analysis Set Points
Smear Region added	Jun-17-2014	Mr. Advanced	UseTimeValues	Modified	false	true	6	Altered Analysis Set Points
Smear Region added	Jun-17-2014	Mr. Advanced	Region End Size	Modified	0	6381.943	6	Altered Analysis Set Points
Smear Region added	Jun-17-2014	Mr. Advanced	Region Start Size	Modified	0	5063.425	6	Altered Analysis Set Points
Smear Region added	Jun-17-2014	Mr. Advanced	EndTime	Modified	-1	59.7967	6	Altered Analysis Set Points
Smear Region added	Jun-17-2014	Mr. Advanced	StartTime	Modified	-1	54.7967	6	Altered Analysis Set Points
Smear Region added	Jun-17-2014	Mr. Advanced	RegionName	Modified		Region 1	6	Altered Analysis Set Points
Smear Region added	Jun-17-2014	Mr. Advanced	Region ID	Modified	-1	1	6	Altered Analysis Set Points
Smear Region added	Jun-17-2014	Mr. Advanced	Regions	Item added			6	Altered Analysis Set Points
⊞ Altered Analysis Set Points								
⊞ Altered Chip Summary								
⊞ Altered Analysis Set Points								
⊞ Finalized workflow level								
⊞ Approved all samples								
⊞ Altered Chip Summary								
⊞ Started Chip Run								

All actions are listed in the audit trail of the software

Learn more
www.agilent.com/genomics/bioanalyzer

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