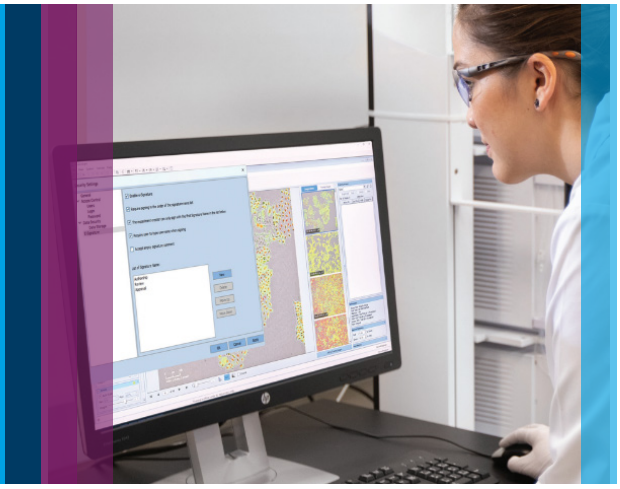
# Agilent xCELLigence RTCA eSight Compliance Software

## Support for 21 CFR Part 11 and Annex 11 Compliance



## Ensure regulatory compliance and data integrity

In today's regulated pharmaceutical and biotechnology environments, maintaining the authenticity, accuracy, and integrity of electronic records is not just best practice, but a compliance requirement. The latest Agilent xCELLigence RTCA eSight software, with full 21 CFR Part 11 and EU Annex 11 support, empowers your laboratory to meet the most stringent global regulatory standards for electronic records and electronic signatures, essential in GMP biopharmaceutical manufacturing.

With new and enhanced compliance features, all data and electronic records generated on Agilent xCELLigence RTCA eSight instruments are safeguarded to ensure they are trustworthy, authentic, and reliable. This includes:

- **Secure access controls:** restrict access to authorized users with unique logins, role-based permissions, and password protection.
- **Comprehensive audit trails:** automatically record who performed each action, what was changed, when and where it occurred, and why, ensuring full traceability for inspections.
- **Electronic signatures:** apply legally binding e-signatures that remain permanently linked to their respective records, complete with date, time, and purpose.
- **Data protection and retrieval:** store results in secure, access-controlled folders, with rapid retrieval in both human-readable and electronic formats.
- **Workflow integrity:** enforce procedural controls and operational sequences to maintain GMP manufacturing compliance.

By combining robust technical safeguards with your organization's procedural controls, the RTCA eSight software operates as a closed system designed for regulated environments. These capabilities help you not only meet but exceed the requirements for data integrity, traceability, and regulatory readiness, ensuring your laboratory is inspection-ready at any time.

**21 CFR Part 11 compliance license**: Purpose-built for regulated labs, this optional license adds secure access controls, audit trails, and electronic signatures, ensuring inspection-readiness and full traceability across GxP workflows.

| Software | |
|---|---|
| Part Numbers | Description |
| S2807-90095 | 21 CFR Part 11 compliance license (new) |

Contact your local Agilent representative to learn more about the complete compliance mapping, detailed requirements, and practical guidance for implementing 21 CFR Part 11 in your lab.

For more information, please visit **https://www.agilent.com/en/product/cell-analysis/real-time-cell-analysis/rtca-software/rtca-esight-software-921150**

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