Agaram Technologies

WHITE PAPER

21 CFR Part 11 Compliance for Analytical Instruments& SoftwareSystems

HOW CLOSER REGULATED LABS CAN GET TO COMPLIANCE?

Regulated laboratories use different types of instruments and software solutions. It is obvious that not all instruments or software will have features to enable the laboratory to comply with 21 CFR Part 11 or Eudralex annex 11. Also it may not be possible for certain instrument vendors to supply such software as their market share in the regulated industry may not be big enough to make the changes in their software

QUESTIONS YOU SHOULD ASK WHILE YOU PLAN FOR 21 CFR PART 11 COMPLIANCE

Q: Are there solutions out in the market that can help us in making our lab 21 CFR Part 11 compliant? What features should I look for making analytical instruments closer to compliance?

- ✓ A solution that can capture raw data and meta data generated by instruments
- ✓ A solution that is independent of the instrument manufacturer, model of instrument and software version
- ✓ A solution that has control over electronic records creation, deletion, editing with full audit trail of such events
- ✓ Non-proprietary format of storage of data for long term archival and retrieval, like pdf.

Q: We are supposed to be 21 CFR part 11/ Eudralex Annex 11 compliant lab. This means all our raw and meta-data have to be maintained and have to be linked to sample/batch test records?

A: A scientific data management system (SDMS) is the solution that will help you maintain raw and meta-data in a central repository. A SDMS integrated with a LIMS will provide accessibility to raw data through the LIMS for specific samples and tests. This will make the real difference in data accessibility.

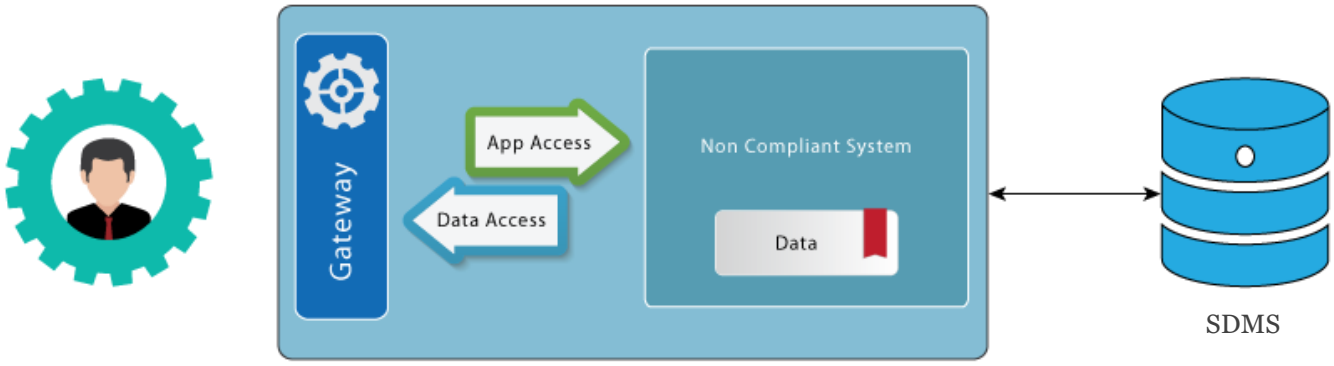
Q: We have a few instruments or software packages which do not have any user login or access controls nor control over the files generated by them. How can we make these system compliant?

A: Yes, it is possible to make such non-compliant systems to be bought under compliant environment. There are 2 major issues that need to be handled.

- ✓ Provide controlled access to the non-compliant instrument software or for that matter any software
- ✓ Make sure the raw and meta data generated by these systems are also managed in a controlled manner

“CFR GATEWAY” IS THE SOLUTION

- ✓ CFR Gateway is a unique tool when installed within windows OS acts like a gateway for windows applications.
- ✓ That is, it acts as the gateway through which other configured and accessible application can be used.
- ✓ Only authorized users can login to the gateway. Login/Logoff is audit trailed with date & time stamp
- ✓ Once users loginto the gateway, they can view only applications that they can use (configured non-compliant instrument software or any piece of software).
- ✓ They can easily run the non-compliant software from the gateway application launcher.
- ✓ While you run the software any files generated by the software is constantly monitored by Gateway. Those files are moved to the server automatically.
- ✓ User will not have direct access the folders/files in the local pc for deletion, editing, copy/paste. Application created or modified files will be moved to server with version control.
- ✓ System protects electronic records by giving access to authorized persons
- ✓ Data cannot be deleted. Application modified files are sent to server with versioning
- ✓ This brings the system under a controlled environment and makes the system compliant.



“We implemented LogiLab SDMS with“CFR Gateway”in our regulated lab. It is a great tool to make non-compliant instruments and software to become compliant. The system access is controlled and data access and protection is up to the mark that is necessary for 21 CFR Part 11 and Eudralex Annex 11 compliance”

Director of a Regulated Quality Control Laboratory