

FDA 21 CFR Part 11

To deal with these increasing challenges and to comply with rigorous FDA regulatory requirements: integrated and automated management system can certainly be of great help.

SoftExpert Excellence Suite is an integrated web-based management system designed to help you to fully meet 21 CFR PART 11 regulations.

With SoftExpert Excellence Suite organizations can easily and effortlessly:

- Achieve 21 CFR PART 11 compliancy quicker.
- Restrict access to electronic records to authorized users only.
- Control the access, distribution, and use of documentation for system operation and maintenance.
- Reduce the cost involved to comply with FDA regulations.
- Maintain the integrity of the process when taken offline.
- Ensure the authenticity, integrity, and confidentiality of electronic records.
- Retrieve computer-generated audit trails identifying an action, when it was performed, and by whom.
- Increase end user acceptance and productivity.
- Establish electronic signature unique to each user.
- Utilize pre-defined templates for reduction in human errors.
- Minimize costs by saving on consulting services.
- Obtain accurate up to the minute Status/Gap analysis.
- And much more ...

SoftExpert Excellence Suite provides organizational efficiency, process control, and flexibility to help simplify the tasks involved in managing data and information. It will also help your organization make better decisions in managing the content and process that drive your business.