



SIEMENS

Ingenuity for life

Compliance Solution for FDA-Regulated Facilities

Minimize operational costs while maximizing
security, productivity, and compliance.

usa.siemens.com/lifescience

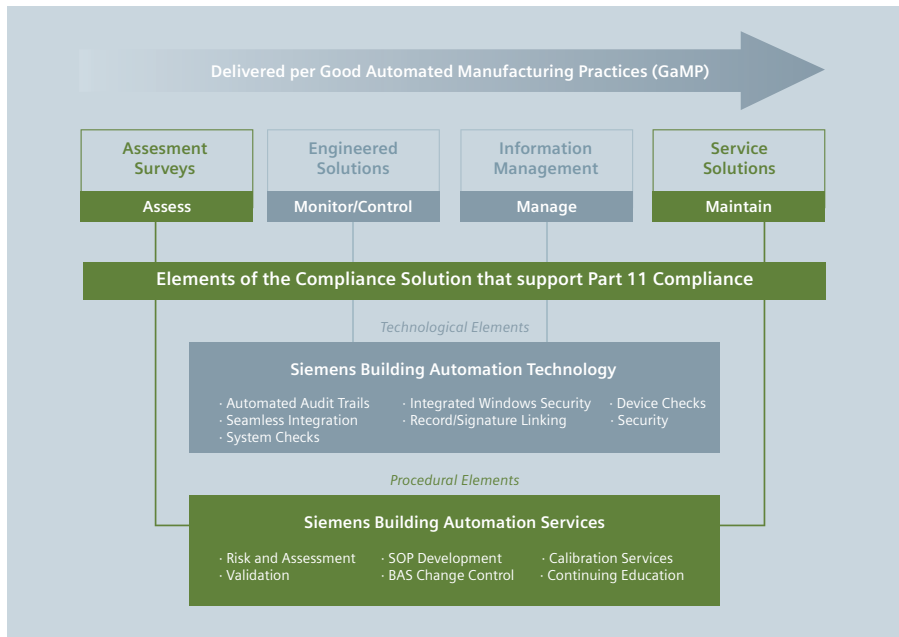
Delivering innovative building automation technology and professional services

Compliance Solution for FDA-Regulated Facilities provides end-to-end monitoring and control over facility conditions and data in your manufacturing operation, including data security, audit trails, record/signature linking, system/ device checks, ease of validation and integration with third-party systems. This supports your effort to comply with your facility cGMP requirements as well as current regulations governing electronic records and signatures. Siemens combines innovative technology and professional services to create the best total solution for compliance. Siemens services are designed to:

- Maintain a traceable, reliable and secure information management system that meets the requirements of 21 CFR Part 11.
- Meet 21 CFR Parts 210/211 (cGMP) requirements as applied to the Building Automation System.
- Establish a system based on the life cycle approach per GAMP 5 guidelines.
- Ensure the quality of environmental conditions in critical areas.
- Provide a safe and healthy work environment to minimize risk and liability.

Creating environments that care

The environments in which life science research, development, and storage are carried out have to meet some unique requirements – and they can make the difference between success and failure.



We help customers navigate the compliance process by bringing a thorough understanding of regulated facility operations, the BAS, and how 21 CFR Part 11 affects these processes.

- Improve staff productivity by developing a turn-key operation through integration of third-party systems and components.
- Minimize operational costs through monitoring and control of environmental, equipment and utility conditions.
- Provide a secure environment to protect staff, research integrity, product and processes.

Siemens Compliance Solution for FDA-Regulated Facilities

Structured around the APOGEE Building Automation System, our bundled compliance solution enables you to electronically capture building operation and environmental condition records – and their associated audit trails – in a secure format to achieve and maintain compliance with 21 CFR Part 11. The compliance solution was designed into the APOGEE Building Automation System from the ground up. So you get a complete solution, supported and serviced by a single reliable source.

About Siemens Smart Infrastructure for Life Science and Critical Environments

Siemens Smart Infrastructure brings innovations in smart building technologies to create environments that care for research labs and other life science environments. Our Intelligent Lab Infrastructure solutions further improve research and lab work experiences; lab efficiency; and safety for all staff, assets, and research.

Highlights

- Ensure safety, reliability and efficiency
- Automate and integrate critical systems
- Use single workstation for monitoring, controls and documentation
- Maximize energy efficiency and cost savings
- Help meet FDA regulations cost effectively
- Save valuable staff time

This document contains a general description of available technical options. Any specific solution(s) will be based on a client's particular requirements and will be addressed in the contract for the project.

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Smart Infrastructure

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