



**SIEMENS**

# APOGEE Compliance Solution for FDA-Regulated Facilities

Safe, secure, efficient and compliant information management  
minimizes operating costs while protecting your value chain.

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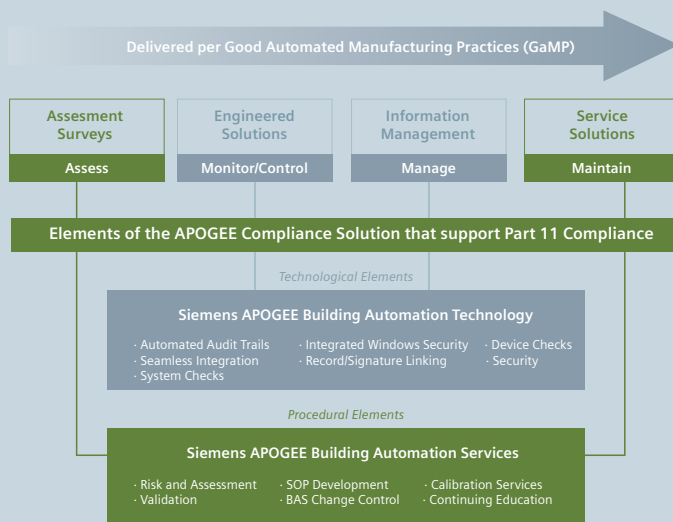
Siemens combines innovative technology and professional services to create the best total solution for compliance.

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

The APOGEE® 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 ensures that your facility meets cGMP requirements as well as current regulations governing electronic records and signatures.

- 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.

**Answers for infrastructure.**



The Siemens solution was designed to operate with its APOGEE Building Automation System from the ground up. So you get a completely integrated solution, supported and serviced by a single reliable source.

- 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.

### The APOGEE 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.

Combining innovative technology with professional services, we help you every step of the way with consulting, training, compliance analysis services and engineering support.

### 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

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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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